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### **COVID-19 and International Freedom of Movement: A Stranded Human Right?**

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### **Paid Donation: Reconciling Altruism and Compensation in Oocyte Transfer**

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## A Public Option for Employer Health Plans

Allison K. Hoffman, Howell E. Jackson, and Amy B. Monahan\*

Abstract:

Employer-based private health coverage—long the gold standard of health insurance—is in decline. Employers are increasingly unable to manage the escalating prices that consolidated health care systems can command. In response, over the past two decades, fewer employers are offering health benefits, and, when they do, they cabin their own spending through plans that shift more of the costs to employees to pay on their own. Employers are increasingly exasperated with their secondary role as health benefits companies. This changing picture offers an opportunity to rethink the role that employers play in designing and managing health plans, a role that is often described as an accident of history and that is an impediment to a better health care financing system. Major health reform ideas have tended largely to neglect the employer space (e.g., the Affordable Care Act) or to propose to displace it swiftly and in its entirety (e.g., Medicare for All).

This Article instead proposes a public option targeted at employers, which can both improve job-based health coverage and also build a foundation for a sounder health care financing system overall. In contrast to the more familiar public option proposal, which would offer government sponsored health insurance directly to individuals, our plan creates a public option for employers, who can select a public plan—based on Medicare and altered to meet the needs of working populations—instead of a private health plan for their employees.

We review the policy, regulatory, fiscal, and business arguments in favor of this form of public option, which we argue is less disruptive than a reform like Medicare for All but more impactful than an individual public option. Because employer take-up would be gradual and voluntary, our plan has lower fiscal costs

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\* Allison K. Hoffman is a Professor of Law at University of Pennsylvania Carey Law School, Howell E. Jackson is the James S. Reid, Jr., Professor of Law at Harvard Law School, and Amy B. Monahan is a Distinguished McKnight University Professor at University of Minnesota Law School. We are grateful for helpful comments and suggestions from the participants in the Federal Funding Issues Workshop, Harvard Law School Law & Economics Seminar and the Petrie-Flom Center panel (especially discussants Andrew Schwab and Judy Feder), and participants at faculty workshops at the University of Texas, University of Pennsylvania, USD Law, Saint Louis University School of Law, and Seton Hall Health Law Works in Progress Retreat (especially discussants Nicole Huberfeld and John Jacobi). For comments and conversations, we thank Matt Lawrence, Sherry Glied, the team at U.S. of Care, Mike Frakes, and our anonymous reviewers—one of whom, in particular, offered generous and detailed feedback. We received superb research assistance from Rachel Baker Mann, Anthony Sacco, Asher Trangle, and Hazel Bowen.

and should face less resistance from employees and vested interests than Medicare for All. Over time, if the plan meets employers' and employees' needs, more people would be covered by a public option, moving away from overreliance on private employer plans and toward something akin to Medicare for Many in a less politically, legally, and fiscally fraught way.

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## INTRODUCTION

When it comes to health policy in the United States, two opposing truths are evident. Fundamental change is needed, and fundamental change is impossible. Even a decade after the Patient Protection and Affordable Care Act (ACA) addressed some of the gaps in how Americans pay for health care, many people still struggle to afford care in a system that remains uncoordinated, inefficient, and inequitable. Perhaps the ACA's biggest accomplishment was to expand the Medicaid program, which provides medical care for lower-income individuals and families. The ACA's efforts to reform the private market, while remarkable politically, have had less impact. Most notably, these efforts were incremental and relatively small-scale. They did little to lay the groundwork in the United States for the longer-term structures needed to pay for health care more efficiently and equitably.

This Article sets out to build on existing policy proposals and offer a foundation for more productive and fundamental change in American health care financing—while being cautious not to proceed at a pace or in a direction that is fiscally irresponsible, politically fraught, or simply impractical. We propose giving employers the opportunity to provide health insurance coverage for their employees through a Medicare-based public health insurance option. Our proposal will disappoint those who would like to see a swift move to Medicare for All. Likewise, it entails more change than preferred by those who are used to, or profiting from, the current system. In other words, what we propose is probably not anyone's first choice. Yet, it offers transformative potential while avoiding unnecessary disruption, and the possibility of a consensus path forward on health care reform.

Recent health reform proposals suffer from being too disruptive or too limited in scope to warrant the political capital they demand. On the one hand, Medicare for All (MFA) would swiftly transform the current system. If designing from scratch today, this option that is closer to what exists in many peer nations would most certainly produce a lower cost system with better outcomes.<sup>1</sup> Yet, MFA dislocates a large number from existing coverage quickly and is demonized as antithetical to individual autonomy and free choice. It raises the specter of government overreach and evokes uncomfortable memories of President Obama's much-repeated assurance that under the ACA people who like their health care

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<sup>1</sup> Roosa Tikkanen & Melinda K. Abrams, *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?*, COMMONWEALTH FUND (Jan. 30, 2020), <https://www.commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019> (“The U.S. spends more on health care as a share of the economy—nearly twice as much as the average OECD country—yet has the lowest life expectancy and highest suicide rates among the 11 nations.”).

could keep it.<sup>2</sup>

The budgetary price tag for MFA is an equally substantial impediment. The cost of operating a fully implemented MFA program is estimated to run into the trillions of dollars, necessitating a substantial increase in federal taxes.<sup>3</sup> To be sure, comparative evidence suggests that a well-managed public health care financing system would reduce the overall health care spending in the United States.<sup>4</sup> Moreover, standard labor economics predicts that universal public coverage could help workers by reducing the share of their compensation consumed by ever-rising health care spending.<sup>5</sup> These defenses of MFA are, however, complicated and depend upon assumptions about market adjustments and economies of scale that are difficult to convey in academic seminars, much less presidential debates or Twitter feeds. For many, the specter of higher taxes for MFA drowns out all else.

On the other end of the spectrum are ideas for incremental expansion, building on the successes of the ACA. One example is adding a public option based on Medicare to the ACA Marketplaces, in theory to compete with private plans already offered.<sup>6</sup> It is targeted narrowly at those who purchase individual coverage—those who are not offered employer-based coverage and who are ineligible for Medicaid. In contrast to MFA, the main selling points of a public option are, first, that it retains a high degree of individual choice and, second, it has a relatively small fiscal footprint. But a public option for individuals would reach only a tiny fraction of the population.<sup>7</sup> This incremental reform would not

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<sup>2</sup> See Angie Drobnic Holan, *Lie of the Year: "If You Like Your Health Care Plan, You Can Keep It"*, POLITIFACT (Dec. 12, 2013), <https://www.politifact.com/article/2013/dec/12/lie-year-if-you-like-your-health-care-plan-keep-it/>.

<sup>3</sup> See *infra* Table One (estimating the net fiscal impact of Senators Sanders' and Warren's Medicare for All proposals at \$12.95 trillion and \$6.1 trillion, respectively).

<sup>4</sup> Tikkanen & Abrams, *supra* note 1.

<sup>5</sup> See, e.g., Lawrence H. Summers, *Some Simple Economics of Mandated Benefits*, 79 AM. ECON. REV. 177 (discussing the fungibility of compensation in cash and via benefits).

<sup>6</sup> During the 2019-2020 Democratic presidential primaries, Pete Buttigieg coined it "Medicare for all who want it." Scott Simon & Heidi Glenn, "*Just The Right Policy*": *Pete Buttigieg On His "Medicare For All Who Want It" Plan*, NPR (Nov. 8, 2019), <https://www.npr.org/2019/11/08/774716877/just-the-right-policy-pete-buttigieg-on-his-medicare-for-all-who-want-it-plan> (providing a video and summary of an interview with Pete Buttigieg regarding his health plan proposal during the 2019-2020 Democratic primaries); see also Letter from Frank Pallone, Jr., Chairman, H. Comm. on Energy & Com. & Patty Murray, Chair, S. Comm. on Health, Educ., Lab. & Pensions, to All Interested Persons (May 26, 2021), [https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Public%20Option.2021.5.26\\_FINAL.pdf](https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Public%20Option.2021.5.26_FINAL.pdf) (requesting information from stakeholders on potential public option legislation).

<sup>7</sup> According to a review of the most prominent health care reforms of Democratic presidential candidates updated in February 2020, the Biden public option proposal would have expanded coverage by only 15 to 20 million people. See COMM. FOR A RESPONSIBLE FED. BUDGET, PRIMARY CARE: ESTIMATING DEMOCRATIC CANDIDATES' HEALTH PLANS 2 (Feb. 26, 2020), <http://www.crfb.org/papers/primary-care-estimating-democratic-candidates-health-plans>.

address, and could deepen, structural problems in the system.<sup>8</sup> It is a layer of plaster spread gingerly across a crumbling wall. Even though some public option proposals engage to a limited degree with employer-sponsored plans, none has envisioned any significant movement away from our hefty reliance on job-based coverage.

Health policy experts in the United States have long lamented the centrality of employer-sponsored, or job-based, health insurance as an accident of history that has become increasingly engrained over time, due to its favorable treatment by the tax code and a series of other policy decisions.<sup>9</sup> Although having a connection between the workplace and health care is no global anomaly, the American way of tying health benefits to a job is unique and does not work well for many people, increasingly so. Employer-sponsored health insurance coverage has become less generous over time, leaving households vulnerable to unmanageable health care expenses, especially as this coverage comprises an increasing share of workers' total compensation.<sup>10</sup> And it has become a major stumbling block—we think the primary stumbling block—to more productive structural change, which is starkly needed now more than ever.

Our proposal has the potential to reverse the trend of creeping costs and less generous coverage by taking advantage of the government's ability to deliver lower prices for a large section of the health care market. The United States has the most expensive, inefficient, and inequitable health care system among its OECD peer nations.<sup>11</sup> We spend twice as much as the average OECD nation and get worse outcomes than most on critical metrics, like life expectancy, chronic disease burden, and avoidable death.<sup>12</sup> What most drives high health care spending is high prices (we use less care per capita than most other countries).<sup>13</sup> Prices are high because of a lack of governmental rate-setting, a financing system inefficiently fragmented into too many payers, and consolidation among providers, who in many geographies can name their reimbursement rates in negotiation with private payers, even the largest ones.<sup>14</sup> Public payers, like Medicare, in contrast, have more successfully controlled health care cost growth.

We all three believe that fixing how we pay for health care in the United States

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<sup>8</sup> See Allison K. Hoffman, *The Irony of Health Care's Public Option*, in *POLITICS, POLICY, AND PUBLIC OPTIONS* (Ganesh Sitaraman & Anne Alstott eds., 2021) (describing the limitations of an individual public option).

<sup>9</sup> See Timothy Jost, *Access to Health Insurance and Health Benefits*, in *OXFORD HANDBOOK OF U.S. HEALTH LAW* (I. Glenn Cohen, Allison K. Hoffman & William M. Sage eds., 2017).

<sup>10</sup> See *infra* Section I.C.

<sup>11</sup> Tikkanen & Abrams, *supra* note 1.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.* (showing lower rates of physician visits, similar hospitalization, but greater use of MRI scans per capita).

<sup>14</sup> See *infra* Section II.A.

must involve moving away from a primarily employer-based private financing system, and that such a shift needs to happen gradually given political and administrative realities. We think the best way to accomplish that gradual shift is to offer employers the opportunity to release themselves from the burden of designing and administering health care benefits for their employees through the creation of a different kind of public option that presents the opportunity for high-value coverage at a lower cost than the status quo.

In this Article, we make the case for a public option designed intentionally and primarily for employers as an alternative to private insurance plans for their employees. We propose that this employer public option build on Medicare because it offers good coverage, an excellent provider network, and the ability to rely on governmental price negotiations. It is not perfect, but it offers an excellent starting point. If workers like it, which we believe many would for reasons described below, it could warm people to the benefits of public coverage more broadly.<sup>15</sup>

If it works, gradually and organically, more employers—large and small—would opt in, eventually producing a less disjointed and expensive way of paying for health care. According to recent estimates, 158 million individuals had employer-sponsored health insurance as compared with 18.7 million with individual coverage and roughly 29.3 million uninsured (the remainder of the population already has public coverage).<sup>16</sup> In other words, three times more people have coverage through an employer than the sum of current individual market enrollees and the uninsured. Any effort to streamline the overall health care financing system must include this population. While our approach would not likely result in Medicare for All, an employer public option might deliver something like Medicare for Many More or Medicare for Most.

We present in this Article a basic concept for an employer-based public option. Arguments in favor are multi-faceted and compelling. First, it offers a coordinated way to test an expansion of public coverage to the working-age population. We advocate for focusing first on large employers to take advantage of these employers' relative expertise in health insurance and ability to support roll out and testing of the idea to a significant number of people.<sup>17</sup> If even just a handful

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15 An interesting question is whether people would understand this plan as public coverage, even if it is based on Medicare and administered by the government, if offered through the workplace. In addition, to the degree the employers are financing the coverage, as before, it is somewhat of a public-private partnership. Yet, since regulators design the benefits, set the prices, and pay the bills, it retains more public than private characteristic.

16 *Health Insurance Coverage of the Total Population*, KAISER FAM. FOUND., <https://www.kff.org/other/state-indicator/total-population/> (reporting 2019 data).

17 In 2020, over two-thirds of private sector employees worked for firms with more than 100 employees, with some 50.9% at firms with over one thousand employees, and a similar share of employees in these categories of firms had employer-sponsored insurance (ESI) coverage. These

of large employers chose to participate in a public option, it could provide valuable information about the benefits and costs savings possible from moving toward a national system of health care financing.<sup>18</sup> The experience gained through this transition—including understanding the number and type of employers that choose the public option—would offer compelling evidence on what might be the highest-value way to get employees health insurance, revealed through the voluntary, and hopefully educated, decisions made by employers with substantial expertise in choosing health care plans.

Employers also offer an efficient distribution channel to reach some of the remaining uninsured, especially lower-income uninsured. Recent surveys reveal that now, unlike before the ACA, the majority of uninsured people are employed either full-time or part-time.<sup>19</sup> Some of these workers, who are disproportionately low-income, are offered workplace coverage that they cannot afford and others are not offered it at all.<sup>20</sup> A public option for employers can be tailored to incentivize employers to extend coverage to previously excluded workers and can subsidize low-income workers' share of the costs of coverage.

An employer public option could offer an appealing alternative to private plans for employers, who are increasingly frustrated with administering private health benefits. There are good reasons to believe that many employers, both small and large, would not only choose to participate in a public option but would also help advocate for it, even if there may be some initial hurdles to overcome. Employers that choose to offer a group health plan in the current environment must manage health care costs that outpace inflation and must do so within a highly regulated and complex legal environment. Increasingly, they address cost increases by limiting the provider networks in their plans or by shifting more costs onto employees. The possibility for relief from this financial and regulatory morass

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estimates are derived from AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, U.S. DEP'T OF HEALTH & HUM. SERVS., MEDICAL EXPENDITURE PANEL SURVEY (2020) [hereinafter 2020 MEPS DATA]; see also KAISER FAM. FOUND., EMPLOYER HEALTH BENEFITS: 2020 ANNUAL SURVEY 11 (2020) [hereinafter KFF Employer Health Benefits 2020], <https://files.kff.org/attachment/Report-Employer-Health-Benefits-2020-Annual-Survey.pdf> (finding that most workers work for large firms that offer health benefits).

18 For example, if one focuses on just the top ten ESI programs as reported on Forms 5500 (the annual report filed by employee benefit plans with the Department of Labor) in 2018, covered individuals total more than 4.2 million. The largest reporting plan—Walmart Inc. Associates' Health and Welfare Plan—reports over 1.5 million employees covered. See FREEERISA, <https://freerisa.com> (last visited Mar. 11, 2022).

19 See *infra* text accompanying notes 125-127.

20 See Matthew Rae et al., *Long-Term Trends in Employer-Based Coverage*, PETERSON-KFF HEALTH SYSTEM TRACKER (Apr. 3, 2020), <https://www.healthsystemtracker.org/brief/long-term-trends-in-employer-based-coverage/> (showing that employer offer rates and employee take-up rates are both strongly correlated with household income level, with lower-income employees much less likely to be offered coverage by an employer and, even when offered coverage, much less likely to enroll in such coverage).

would motivate some employers to select a public option, so long as their employees were guaranteed high-quality coverage. And at employers where unions have had a role in shaping benefits in the past, they could be given a voice in whether and how to transition to a public option.

Our proposed public option is voluntary, not compelled, which helps with optics and politics. Employers would choose whether to participate, consistent with the choice a company faces today when it decides whether to ship its goods with the U.S. Postal System or Federal Express and whether to prioritize employee travel by Amtrak or airlines. Employers, especially large employers, are comparatively well-equipped to evaluate the relative value of health plans, while hopefully taking into account what their employees need. While a public option is usually touted on the grounds that private insurers “need real competition,”<sup>21</sup> competition works best when the consumers understand their choices. A mountain of evidence shows that individuals struggle to do so when making health insurance decisions.<sup>22</sup> Although not perfect, corporate human resources departments can better navigate these waters.

An employer public option also offers significant fiscal advantages. Current employer and employee contributions for employer-sponsored health insurance can be retained—in whole or part—to finance a significant share of this form of public option. Indeed, if the cost savings of Medicare over private coverage are preserved even in part, employers and employees should both come out ahead financially. Perhaps even more important, the need for higher taxes to support this transition will be dramatically lower than those required under other leading reform proposals, as payments made to the Medicare system for this kind of public option would be accounted for as a voluntary exchange transaction—technically an offsetting government collection—and not a tax and spending program. One disadvantage, as compared to Medicare for All or other all payer approaches, is that it would not lead to the same level of administrative simplification from the provider perspective.

No doubt, the political lift will still be herculean. Certain vested interests who have sunk health reform efforts in the past—most obviously private health insurance companies and providers—will resist an initiative of this sort. Medical providers, from hospitals to doctors to medical device and pharmaceutical companies, who gain great profit off the current system will fight against it, intuiting, correctly, that it would mean lower reimbursement rates than they currently enjoy from private health plans. Even labor unions who might support the idea on a blank slate could resist it if they saw the effort as threatening the loss

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21 Press Release, JoeBiden.com, Biden-Sanders Unity Task Force Recommendations 31 (July 8, 2020), <https://joebiden.com/wp-content/uploads/2020/08/UNITY-TASK-FORCE-RECOMMENDATIONS.pdf>.

22 See *infra* Section I.C.

of bargained-for health benefits. Any effort at national health care reform, regardless of the policy, will see resistance from these same groups, but a public option for employers offers transformative potential that makes it worth working through this resistance.

This Article is organized as follows. In Part I, we provide a brief overview of the U.S. health care finance system and the leading proposals for health reform. We then describe the current state of employer-provided coverage and its challenges. In Part II, we make the basic case for an employer public option and detail its key design features. We also consider in Part II the likelihood that employers will voluntarily choose to participate in such a public option. In Part III, we focus on the fiscal aspects of a public option for employers, comparing it to the widely publicized scoring estimates for prominent Medicare for All proposals as well as the more limited work that has been done on the budgetary scoring of other public option proposals. As explained in this section, the voluntary nature of a public option for employers has a dramatic impact on consequences of this proposal for the federal budget and elegantly internalizes the offsetting savings that employers and employees would enjoy by moving into the Medicare systems in this manner. We also offer in this section a brief analysis of why this kind of reform might be possible through a budget reconciliation bill that would only require a simple Senate majority.

## I. BACKGROUND ON U.S. HEALTH CARE FINANCE AND LEADING REFORM PROPOSALS

The United States is unique among nations when it comes to paying for health care, and not in a good way. Most OECD countries' systems for health care financing grew up in the early- to mid-twentieth century as medical care became more advanced and expensive.<sup>23</sup> In Europe, what emerged were public systems of health care finance in two forms, often characterized coarsely as Beveridge and Bismarckian systems.<sup>24</sup> The Beveridge approach was direct provision of health care by the government, as in England, where the government owns hospitals and employs medical professionals—aka “socialized medicine.” In Bismarckian systems, or social insurance, the government finances health care but the providers can be public or private. This is what traditional Medicare is in the United States. Even as countries developed variations on these themes, at their core, these systems embraced the idea that the government would take a central role in ensuring access to affordable health care for the entire population.

The United States charted a wholly different path, leading with private health

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<sup>23</sup> PAUL STARR, *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE: THE RISE OF A SOVEREIGN PROFESSION AND THE MAKING OF A VAST INDUSTRY* 237-40 (1982).

<sup>24</sup> See T.R. REID, *THE HEALING OF AMERICA* 16-27 (2009).

insurance and facilitated by hospitals. As medical care became both more effective and expensive, hospitals feared unpaid bills if they relied on patients to pay cash for service, or having to confirm the financial solvency of every patient prior to providing care.<sup>25</sup> In response, first hospitals and later cities created pre-paid health care funds, such as the one established by Baylor University Hospital in the 1920s, which guaranteed people access to medical care up to a certain level, with pre-payment.<sup>26</sup> These types of hospital service plans spread and eventually evolved into Blue Cross. Within a short period, Blue Shield followed, offering a similar a structure for monthly prepayment of fees for guaranteed access to outpatient, physician care.<sup>27</sup>

Through the mid-twentieth century, employers grew as a source of health coverage in the United States, coinciding with the moment that many other countries were doubling down on the government's role.<sup>28</sup> In the United States, several public policies fostered the growth of employer-sponsored insurance (ESI) coverage. A commonly told story is that the trend is due to wage controls during the war, prompting employers to compensate with benefits instead of cash wages, but the growth in employer health plans was relatively small in this period as compared to the years prior and after the war.<sup>29</sup> More consistent with the timing of a major upsurge in adoption of ESI were a 1945 federal rule that required employers to leave wartime health benefits in place, a 1949 federal rule allowing unions to bargain collectively for benefits, and most importantly a 1954 rule by the Internal Revenue Service excluding dollars spent on health benefits by employers and employees from taxation.<sup>30</sup> Because of this tax exemption, employer-provided health benefits are worth substantially more on an after-tax basis than an equivalent amount of cash compensation, creating a strong incentive for employers to offer such benefits. With all these factors, ESI and the centrality of private insurance took hold.

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25 STARR, *supra* note 23, at 295-96.

26 *Id.*

27 *Id.* Unlike the private health insurance of today, the Blues embraced some of the solidaristic characteristics that define systems elsewhere in the world, like charging all members of a community the same rate for membership regardless of their personal characteristics or health status.

28 In England, for example, during WWII the government built health infrastructure to deal with an unmet need for medical services and this infrastructure served as the beginning of the National Health Service, established at the end of the war. Donald W. Light, *Universal Health Care: Lessons From the British Experience*, 93 AM. J. PUB. HEALTH 25, 26 (2003).

29 David Blumenthal, *Employer-Sponsored Health Insurance in the United States—Origins and Implications*, 355 NEW ENG. J. MED. 82, 83 (2006).

30 *Id.*; see also Jost, *supra* note 9, at 157-58 (describing how the expansion of private health employer-based health insurance was driven by several policies following World War II, including a National Labor Relations Board clarification that “terms and conditions of employment” subject to bargaining include employee benefits and explicit recognition in the Internal Revenue Code that health benefits are not taxable).

The tax benefits associated with ESI continue to be an important driver of its primacy today, but other factors also contribute.<sup>31</sup> Before the ACA, markets for individually purchased health insurance functioned poorly, allowing employers to offer their employees a benefit they could not get elsewhere. Large employers also benefit from natural risk pooling and economies of scale that make their administrative costs lower than either individual or small group coverage (although still higher than Medicare).<sup>32</sup>

While the ACA significantly improved the availability and affordability of coverage on the individual market, ESI has continued to be the dominant source of private coverage. Today, nearly 60% of all nonelderly Americans have insurance through an employer,<sup>33</sup> with Medicare providing the primary source of coverage for the elderly and individuals with disabilities and Medicaid providing the primary source of coverage for certain low-income individuals. Across the entire U.S. population, 49.6% are covered by ESI, 5.9% by private individual market coverage, 19.8% by Medicaid, 14.2% by Medicare, and 1.4% through military coverage, with 9.2% remaining uninsured.<sup>34</sup>

Hundreds, or perhaps thousands, of proposals have promised to reform the dysfunctional health care financing system in the United States. Many of these, dating back decades, have questioned whether employers should continue to play a fundamental role in health coverage.<sup>35</sup> As context for our proposal, we mention two that have been most prominent in recent years—Medicare for All and an individual public option, the first of which abolishes the employer-based system and the latter of which leaves the employer-based system untouched. We describe why we believe that an employer public option provides an attractive path forward that avoids the downfalls of either extreme. Finally, we conclude this Part by focusing on the underappreciated challenges of employer-provided coverage and why what is often considered to be the highest-functioning piece of the U.S. health care system might, counterintuitively, be the best place to begin systemic reform.

### A. *Medicare for All*

At its passage in 1965, some believed Medicare would eventually become the

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31 For an overview of the many advantages of ESI, see David A. Hyman & Mark Hall, *Two Cheers for Employment-Based Health Insurance*, 2 YALE J. HEALTH POL'Y L. & ETHICS 23 (2001).

32 See *infra* text accompanying notes 90-92.

33 *Health Insurance Coverage of Nonelderly 0-64*, KAISER FAM. FOUND., <https://www.kff.org/other/state-indicator/nonelderly-0-64/> (last visited Aug. 6, 2021).

34 KAISER FAM. FOUND., *supra* note 16 (figures do not add up to 100% due to rounding).

35 See, e.g., INSTITUTE OF MEDICINE, EMPLOYMENT AND HEALTH BENEFITS: A CONNECTION AT RISK vii (Marilyn J. Field & Harold T. Shapiro eds., 1993) (“Unlike most National Research Council committees, however, this committee did not reach consensus on some central issues. For example, committee members could not agree on whether employment-based health benefits should be continued or abandoned . . .”).

health insurance program for all Americans.<sup>36</sup> Momentum in this direction slowed right away with the simultaneous passage of Medicaid, a program that insured what were considered the most vulnerable populations—children and pregnant women—and took the wind out of the sails of quick additional reforms that might have built on Medicare.<sup>37</sup>

Yet, the idea of building on Medicare has reemerged in various forms after a period of dormancy. With Senator Bernie Sanders in 2016 and a longer bench of proponents in the 2020 Democratic primaries, including Senators Elizabeth Warren and Kamala Harris, the idea of Medicare for All (MFA) gained momentum. Most proposals lacked concrete details, but the basic idea was similar. Candidates argued that we should replace the dysfunctional way that we pay for medical care in the United States with a more efficient and equitable model available to all, or most, people.

Senator Bernie Sanders advanced the “purest” version of this idea, a single-payer public health insurance program that would cover everyone with automatic enrollment. He introduced the plan as a Senate bill,<sup>38</sup> and it served as the basis of his health policy in his candidacy in the 2016 and 2020 Democratic primaries.<sup>39</sup> Following the 2016 election, more politicians began to follow in Senator Sanders’ footsteps. The Medicare for All Act of 2019 included fourteen co-sponsors, including prominent members such as Senators Harris, Leahy, Markey, and Warren.<sup>40</sup> Notable about Senator Sanders’ version of Medicare for All are its ideological commitments and truly universal and comprehensive nature, which for many made it more symbolic than realistic.<sup>41</sup> This proposal came with a hefty price tag—with estimates from think tanks or academics ranging from about \$25 trillion to \$35 trillion in increased federal government costs or outlays over the ten-year period following a Medicare for All enactment.<sup>42</sup> Yet, many experts estimated that

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36 THEODORE R. MARMOR, *POLITICS OF MEDICARE* 173 (2d ed. 2000).

37 *Id.* at 60.

38 For the most recent version, see Medicare for All Act of 2019, S. 1129, 116th Cong. (2019). The 2019 House version was sponsored by Representative Pramila Jayapal. Medicare for All Act of 2019, H.R. 1384, 116th Cong. (2019).

39 *Bernie Sanders on Healthcare*, FEELTHEBERN.ORG, <https://feelthebern.org/bernie-sanders-on-healthcare/> (last visited Mar. 5, 2020) (stating Medicare for All “[c]overs primary and preventive care, mental health care, reproductive care, vision, hearing and dental care, and prescription drugs, as well as long-term services for the disabled and elderly”).

40 S. 1129.

41 These commitments included universal coverage; a short four-year transition period after which every American would be automatically enrolled; comprehensive benefits that reached well beyond what Medicare covers today, including dental and vision benefits and long-term care; and no cost-sharing at the point of care, erasing the deductibles, copayments, co-insurance, and balance billing that vex and financially strain many Americans. *Id.*

42 COMMITTEE FOR A RESPONSIBLE FEDERAL BUDGET, *CHOICES FOR FINANCING MEDICARE FOR ALL 1* (Mar. 17, 2020), <http://www.crfb.org/papers/choices-financing-medicare-all>.

this plan that would leave no one uninsured or underinsured would result in little or no growth in total health care spending.<sup>43</sup> Nonetheless, as discussed further in Part III, because the federal government would pay a large part of the price tag through taxes, the fiscal case proved a major stumbling block.<sup>44</sup>

In response to concerns raised over an abrupt shift to Medicare for All, several 2020 Democratic presidential candidates, including Senators Sanders, Warren, and Harris, introduced “phase-in” plans on how to transition from the current system to MFA.<sup>45</sup> Perhaps most relevant now are the details—albeit few—of then-Senator Harris’ plan. After strong advocacy for MFA, Senator Harris pulled back slightly and acknowledged, rightly, that it is difficult to get from a deeply embedded employer-based health insurance system to Medicare for All. Thus, she proposed a ten-year transition period, during which people who wanted to buy into Medicare more quickly could do so.<sup>46</sup> Harris’ transition period included some structural components to lubricate more fundamental long-term transformation, including automatically enrolling all newborns and uninsured people into the Medicare program.<sup>47</sup> Senator Harris stood by the eventual goal of MFA: “At the end of the ten-year transition, every American will be a part of this new Medicare system.”<sup>48</sup> Even though delayed, this idea of governmentally imposed coverage generated significant opposition.

Some other proposals, like Medicare for America sponsored by Congresswomen Rosa DeLauro and Jan Schakowsky and informed by Jacob Hacker, also offer transition to public health insurance in a way that imagines possible reforms to the employer market.<sup>49</sup> This proposed legislation would fold

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43 See, e.g., Josh Katz et al., *Would ‘Medicare for All’ Save Billions or Cost Billions?*, N.Y. TIMES (Oct. 16, 2019).

44 Sanders proposed a variety of mechanisms for progressive financing, including increased taxes that also provided his opponents fodder for attack. *How Does Bernie Pay for His Major Plans?*, BERNIESANDERS.COM, <https://berniesanders.com/issues/how-does-bernie-pay-his-major-plans/> (last visited Dec. 23, 2020).

45 Elizabeth Warren, *My First Term Plan for Reducing Health Care Costs in America and Transitioning to Medicare for All*, ELIZABETHWARREN.COM, <https://elizabethwarren.com/plans/m4a-transition> (last visited Mar. 5, 2020) (detailing Warren’s plan for transitioning to Medicare for All, which included immediate and free coverage for children under age 18 and anyone earning under 200% of the federal poverty level).

46 Kamala Harris, *My Plan for Medicare for All*, MEDIUM (July 29, 2019), <https://medium.com/@KamalaHarris/my-plan-for-medicare-for-all-7730370dd421>. The Sanders and Warren transition plans also allowed this individual opt-in.

47 *Id.*

48 *Id.*

49 Medicare for America, H.R. 2452, 116th Cong. (2019). It would leave other programs, including the Veteran’s Health Care Services, Indian Health Service, and Federal Employees Health Benefits Program intact. There are other proposals that have offered opportunities for employer-buy in, but in very limited ways. For example, the Medicare-X Choice Act of 2019 sponsored by Senator Bennet and several co-sponsors makes a very limited effort to allow employers to enroll employees

those people currently insured by Medicare, Medicaid, and the ACA Marketplaces into a new public plan, and people in employer plans or employers could opt in as well. Eventually, it would subsume private coverage by enrolling all newborns at birth.<sup>50</sup> But before that point, individuals, even those who have access to ESI, can opt into the public plan and employers could enroll their entire employee pool in Medicare for America. It is this last feature, which in some ways seemed an afterthought of this proposal, that we focus on in our proposal and that we think is the right starting point for more fundamental, structural change.

### B. *Fixing the ACA with an Individual Public Option*

The public option has been described by its proponents as a public health insurance plan that would compete side-by-side with private plans. Presumably, if the public option offered a similar or better product for lower prices, people would choose it. Various pieces of recent proposed legislation have included a public option, including the majority of health insurance reform bills proposed in Congress in the 2019 session.<sup>51</sup>

What most defines the prominent public option plans is who makes the selection of the plan—the individual. These plans are built on individual choice and are sold as the epitome of autonomy. Pete Buttigieg promoted it on the

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in a public option. Medicare-X Choice Act of 2019, S. 981, 116th Cong. (2019). Public option plans have also been proposed at the state level, including some that would allow employer participation. Jaime S. King et al., *Are State Public Option Health Plans Worth It?*, 59 HARV. J. ON LEGIS. (forthcoming 2022) (manuscript at 15-16) (on file with authors) (noting that proposals in Massachusetts, Texas, Wisconsin, and Wyoming would allow employers to elect public option coverage).

<sup>50</sup> Sarah Kliff & Dylan Scott, *We Read 9 Democratic Plans for Expanding Health Care. Here's How They Work*, VOX (June 21, 2019), <https://www.vox.com/2018/12/13/18103087/medicare-for-all-explained-single-payer-health-care-sanders-jayapal> (“Medicare for America makes another policy decision that would erode employer-sponsored coverage: It automatically enrolls all newborns into the public program. That means a new generation of Americans likely won’t get coverage through their parents’ workplaces—and would assure the Medicare plan a constantly growing subscriber base.”).

<sup>51</sup> Choose Medicare Act, S. 1261, H.R. 2463, 116th Cong. (2019); Medicare for America, H.R. 2452, 116th Cong. (2019); CHOICE Act, S. 1033, H.R. 2085, 116th Cong. (2019) (seeking, with the co-sponsorship of Representative Jan Schakowsky and Senator Sheldon Whitehouse, to create a federal public plan option on the Affordable Care Act (ACA) marketplaces under existing procedures and rules); Medicare Buy-In and Health Care Stabilization Act of 2019, H.R. 1346, 116th Cong. (2019) (working to allow individuals age 50 and older to opt into Medicare, with the sponsorship of Representative Brian Higgins); State Public Option Act, S. 489, H.R. 1277, 116th Cong. (2019) (seeking, with the co-sponsorship of Senator Brian Schatz and Representative Ben Ray Lujan, to allow a state public option for Medicaid buy-in); Medicare at 50 Act, S. 470, 116th Cong. (2019) (seeking, with the sponsorship of Senator Debbie Stabenow, to allow individuals age 50 and older to opt into Medicare early); Keeping Health Insurance Affordable Act, S. 3, 116th Cong. (2019) (working to create a federal public option on ACA exchanges, with the sponsorship of Senator Ben Cardin).

campaign trail: “Medicare for all who want it.”<sup>52</sup> As Jacob Hacker suggested: “public plan choice gives Americans the opportunity to choose for themselves how they value the strengths and weaknesses of a public, Medicare-based plan and competing private health plans.”<sup>53</sup>

Although the policy details have evolved, the main contours remain similar among different plans. The public option is based on Medicare and is offered in the ACA exchanges, or marketplaces, where an individual, or in some cases a small business, could select it. Some versions of the public option, like the Sanders-Biden Unity Task Force recommendations, imagine that people who are offered employers plans could opt in too. These recommendations, similar to what Vice President Biden proposed on the campaign trail, offer the following:

Private insurers need real competition to ensure they have incentive to provide affordable, quality coverage to every American. To achieve that objective, we will give all Americans the choice to select a high-quality, affordable public option through the Affordable Care Act marketplace. The public option will provide at least one plan choice without deductibles, will be administered by the traditional Medicare program, not private companies, and will cover all primary care without any copayments and control costs for other treatments by negotiating prices with doctors and hospitals, just like Medicare does on behalf of older people. The lowest-income Americans not eligible for Medicaid will be automatically enrolled in the public option at no cost to them, although they may choose to opt out at any time. Everyone will be eligible to choose the public option or another Affordable Care Act marketplace plan, even those who currently get insurance through their employers, because Democrats believe working people shouldn’t be locked in to [sic] expensive or insufficient health care plans when better options are available.<sup>54</sup>

This idea would improve the status quo. It would fill gaps left by the ACA, especially in those states that have chosen not to expand Medicaid, which perversely left some of the poorest people uninsured when others earning just pennies more receive generous subsidies to buy private plans. Plus, in states where there are very few private insurers participating on the exchanges, the addition of

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<sup>52</sup> See Dylan Scott, *Pete Buttigieg’s Medicare-for-all-who-want-it Plan, Explained*, VOX (Sept. 19, 2019), <https://www.vox.com/2019/9/19/20872881/pete-buttigieg-2020-medicare-for-all>.

<sup>53</sup> JACOB S. HACKER, *THE CASE FOR PUBLIC PLAN CHOICE IN NATIONAL HEALTH REFORM 2* (2008).

<sup>54</sup> Press Release, *supra* note 21, at 31.

a public option might help keep premium prices in check.<sup>55</sup>

Yet, the problem with these proposals is that they will almost certainly fail to catalyze more fundamental change. It is unlikely that an individual public option—even in the best-case scenario—will reach very many people, which, in turn, limits its potential. As of now, only 6% of the non-elderly population (just under 20 million people) have individual market coverage.<sup>56</sup> In the unlikely case that every uninsured person were added to this market, it would grow to just under 50 million people.<sup>57</sup> By comparison, employer plans cover three times as many individuals as the best case coverage scenario for an individual public option—about 150 million currently with the potential to cover more with a well-designed employer public option.<sup>58</sup> If the goal of a public option is to drive systemic change, an employer public option is much better suited to the task than one available only to individuals.

Even more, these proposals all rely on individuals identifying that the public option is better for them than the private plans offered in their state and selecting it. A mountain of evidence makes clear that individuals struggle to figure out what health plan is best for them and are resistant to change plans once they select them.<sup>59</sup> Even those who understand health insurance well struggle to differentiate and select among health plans, which should be unsurprising when considering the nature of health plan choice.

At the most fundamental level, selecting among health insurance plans demands having preferences about things that most people have never experienced before. For example, to make a fully informed health insurance purchasing decision, individuals would need to evaluate their preferences for medical care they might eventually need but have no direct experience with—such as hospitalization or cancer care. Even more, in deciding how much to pay for health insurance, they must weigh the risk of ever needing such care against possible spending on other goods and services. Most people do not understand the basic features of health insurance plans that should shape their decisions—such as how

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55 See Jon R. Gabel et al., *Competition and Premium Costs in Single-Insurer Marketplaces: A Study of Five Rural States*, COMMONWEALTH FUND, (Mar. 6, 2018), <https://www.commonwealthfund.org/publications/issue-briefs/2018/mar/competition-and-premium-costs-single-insurer-marketplaces-study> (showing that decreases in the number of insurers in some states' Marketplaces led to relatively faster premium growth).

56 KAISER FAM. FOUND., *supra* note 33.

57 *Id.*

58 KAISER FAM. FOUND., *supra* note 16. An additional 26 million individuals are employed or have an employed family member, but either are not offered coverage through an employer, or are offered such coverage and decline it. Rae et al., *supra* note 20.

59 See Allison K. Hoffman, *The ACA's Choice Problem*, 45 J. HEALTH POL., POL'Y & L. 501, 504-06 (2020) (describing a selection of these studies); Allison K. Hoffman, *Health Care's Market Bureaucracy*, 66 UCLA L. REV. 1926, 1953-58 (2019) (citing studies showing the many ways in which people make poor health insurance choices, and why).

much a plan costs, cost-sharing features, and what benefits are covered.<sup>60</sup> Furthermore, choosing a health plan requires making calculations regarding deductibles, cost-sharing, and premiums that exceed many Americans' literacy and numeracy skills.<sup>61</sup> A volume of empirical work illuminates the many ways and reasons why individuals—regardless of education, income, or smarts—make poor choices among health plans.<sup>62</sup>

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60 Deborah W. Garnick et al., *How Well Do Americans Understand their Health Coverage*, 12 HEALTH AFFS. 204, 206 (1993) (finding that even though consumers largely understood whether their plans covered hospitalization or doctors' visits, they underreported that their plans covered services including mental health, alcohol and drug abuse treatment, or prescription drug and overreported that their plans covered long-term care); George Loewenstein et al., *Consumers' Misunderstanding of Health Insurance*, 32 J. HEALTH ECON. 850, 855 (2013) (noting that in a survey of insured adults, only 14% correctly answered four simple multiple-choice questions about cost-sharing features like a deductible or copayment).

61 Wendy Nelson et al., *Clinical Implications of Numeracy: Theory and Practice*, 35 ANN. BEHAV. MED. 261 (2008) (providing an overview of research on health numeracy and the clinical implications for patients); Ellen Peters & Irwin P. Levin, *Dissecting the Risky-Choice Framing Effect: Numeracy as an Individual-Difference Factor in Weighing Risky and Riskless Options*, 3 JUDGMENT & DECISION MAKING 435 (2008) (showing that lower levels of numeracy led to higher loss aversion). On health insurance literacy specifically, see, for example, ZSOFIA PARRAGH & DEANNA OKRENT, HEALTH LITERACY AND HEALTH INSURANCE LITERACY: DO CONSUMERS KNOW WHAT THEY ARE BUYING (Jan. 6, 2015), [http://www.allhealthpolicy.org/wp-content/uploads/2017/01/Health-Literacy-Toolkit\\_163.pdf](http://www.allhealthpolicy.org/wp-content/uploads/2017/01/Health-Literacy-Toolkit_163.pdf) (describing and summarizing studies on health insurance literacy).

62 The many studies showing these problems span different insurance marketplaces that have plan choices, including employer, ACA, and Medicare Part D. See, e.g., Jason Abaluck & Jonathan Gruber, *Heterogeneity in Choice Inconsistencies Among the Elderly: Evidence from Prescription Drug Plan Choice*, 101 AM. ECON. REV. 377, 379 (2011) (finding that 73% of Medicare Part D prescription drug program enrollees could have chosen a plan with lower premiums with no risk of spending more on prescription drugs over the course of the year); Vicki Fung et al., *Nearly One-Third of Enrollees in California's Individual Market Missed Opportunities to Receive Financial Assistance*, 36 HEALTH AFFS. 21 (2017) (describing that a significant share of ACA enrollees choose plans with the lowest monthly premiums but that make them ineligible for cost-sharing reductions to help pay for out-of-pocket costs, likely leading to more spending over the year for many of them); Florian Heiss et al., *Plan Selection in Medicare Part D: Evidence from Administrative Data*, 32 J. HEALTH ECON. 1325, 1377-78 (2013) (estimating that only about 10% of Medicare Part D enrollees choose the least-expensive plan option); Eric J. Johnson et al., *Can Consumers Make Affordable Care Affordable? The Value of Choice Architecture*, 8 PLOS ONE e81521 (showing in a simulated ACA model even odds that participants who passed a screening test for basic insurance literacy would select the better plan, and Wharton business school study participants got it wrong over one-quarter of the time); Anna D. Sinaiko & Richard A. Hirth, *Consumers, Health Insurance, and Dominated Choices*, 30 J. HEALTH ECON. 450, 453 (2011) (showing among enrollees in the University of Michigan's employee health plan, over one-third of workers selected a plan that was identical to another in every way except that it had a more restricted provider network, a plan known as a "dominated" plan because no one should choose such a plan in any circumstance). When measured more subjectively, people fail to buy plans that align with their own stated preferences or needs. See, e.g., Saurabh Bhargava et al., *The Costs of Poor Health (Plan Choices) & Prescriptions for Reform*, 3 BEHAV. SCI. & POL'Y 1, 7-8, 10 (2017) (simulating purchase on ACA exchanges to find that only one-third of respondents chose the cost-minimizing plan, based on their own anticipated medical care

The bottom line is that public option proposals focused on the individual market are unlikely to provide real movement towards more coherent and equitable health care financing. Even if the public option were widely taken up by currently uninsured individuals, it would reach only a small subset of the population, while leaving the larger inequitable and confusing patchwork in place. Competition in the individual health insurance market simply does not work as intended or predicted. Even if the public option were an obvious best alternative offered on the individual market, individuals would not necessarily select it. In turn, the public option would not exert competitive market pressure that some still predict and hope it might. All of these reasons suggest looking to another locus for a more meaningful public option: employers.

*C. Employer-Sponsored Coverage as an Attractive Starting Point for Reform*

Employers currently play a central role in providing health insurance, which at first blush makes targeting a public option and reforms at ESI seem potentially fraught. It is one of the higher quality parts of a health care financing system that has many more critical gaps to fix, including the fact that approximately 10% of the population under age 65 is still uninsured.<sup>63</sup> Yet, job-based coverage is currently in decline. As costs rise, fewer employers are offering coverage and many more are increasingly dissatisfied with the status quo. Moreover, even when ESI is offered, workers must pay a larger share of the costs, and policies have more restrictions, like limited provider networks. The declining value of ESI benefits leads some workers to decline coverage.

Even before the COVID-19 pandemic, the quality of job-based health insurance was diminishing and costs increasing. Fewer companies offer benefits today. In 2020, 56% of firms offered at least some employees health benefits, as compared to 66% two decades ago,<sup>64</sup> and the share of the nonelderly population covered fell eight percentage points from 1998 to 2018.<sup>65</sup> Low-income workers and their families are less likely to have job-based coverage, including only a quarter of full-time workers earning under the federal poverty level and under half of those workers earning between the poverty level and 250% of it.<sup>66</sup> Low-income workers are also much more likely to decline coverage, even when offered to them, increasingly so over the past 20 years, because their own contributions to that

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needs). The authors of this study estimated that if all people buying plans on the ACA exchanges had similar error rates as the study population, “the result would be roughly \$7.1 billion of excess spending each year, borne by a population with low to moderate incomes.” *Id.* at 10.

63 KAISER FAM. FOUND., *supra* note 33.

64 KAISER FAM. FOUND., EMPLOYER HEALTH BENEFITS: 2020 ANNUAL SURVEY 46 (2019). Note, the offer rates have remained steady for large firms but declined for all others. *Id.* at 47.

65 Rae et al., *supra* note 20.

66 *Id.*

coverage are unaffordable.<sup>67</sup>

In addition, without beginning to re-think employer-provided coverage, it is hard to imagine tackling fundamental issues such as cost containment and the provision of universal and equitable coverage. So, employers' strain under the weight of managing health care benefits and costs might provide an opportunity to shift away from job-based private plans and toward something better.

There are of course several reasons why employers might prefer to remain at the center of the U.S. health care financing system. Large employers generally view health benefits as an important part of their strategy to recruit and retain workers, a position that is generally supported by employee surveys.<sup>68</sup> Some employers use health benefits to try to maintain a healthy, and presumably productive, workforce, including wellness programs, gym membership, and health coaching for chronic or serious conditions.<sup>69</sup> These types of factors make the current structure sticky, but not unyielding to change, as we explore in the discussion in Section II.C of why employers might want change. There are also reasons to want to keep employers as part of the system, including as a good channel to test expansion of public coverage to a working-age population and, most importantly, to retain their current contributions toward health benefits, which we also explore in Section II.C. First, this Section offers a quick landscape of the employer market and its challenges to illuminate why we think targeting a public option here is beneficial.

### 1. *The Evolving Picture of the Employer Market and Growing Costs*

An estimated 158 million nonelderly individuals were enrolled in an employer plan in 2019 (49.6% of the total U.S. population).<sup>70</sup> Just over half of all private sector firms offer health insurance to some workers, but nearly all firms with more than 200 workers do so.<sup>71</sup> Seventy percent of workers covered by health insurance

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<sup>67</sup> *Id.*

<sup>68</sup> See, e.g., AMERICA'S HEALTH INSURANCE PLANS, THE VALUE OF EMPLOYER-PROVIDED COVERAGE (2018) (reporting results of employee survey where 71% reported satisfaction with their employer's health plan. Forty-six percent of surveyed employees stated that their employer's health plan played a role in recruiting them, and 56% reported that the health plan has an impact on the employee's choice to stay in their current job).

<sup>69</sup> See Jeffrey Pfeffer et al., *Employers' Role in Employee Health: Why They Do What They Do*, 62 J. OCCUPATIONAL & ENV'T MED. E601 (2020). But see Damon Jones et al., *What Do Workplace Wellness Programs Do? Evidence from the Illinois Workplace Wellness Study*, 134 Q.J. ECON 1747 (2019) (presenting the results of a randomized controlled trial of a workplace wellness program, which found that such programs neither lower medical costs nor improve health outcomes or worker productivity).

<sup>70</sup> KAISER FAM. FOUND., *supra* note 16.

<sup>71</sup> KFF Employer Health Benefits 2020, *supra* note 17, at 45.

are employed at large firms.<sup>72</sup>

Larger firms are more likely to offer better health insurance. Large firm plans tend to have higher total premiums, due to the generosity of benefits, but lower employee premium contributions, lower deductibles, lower out-of-pocket maximums, and lower copays, as compared to smaller firms.<sup>73</sup> Large firm plans generally offer several health plan options but they have only small differences among them with respect to the treatments and services covered.<sup>74</sup>

The cost of health benefits for employers has skyrocketed over the past two decades, far outpacing wage growth and inflation.<sup>75</sup> The average annual premiums in 2020 were \$7,470 for single coverage and \$21,342 for family coverage.<sup>76</sup> Employers have been paying more toward that coverage, with the average employer contribution for single coverage increasing 232% between 1999 and 2020, and for family coverage increasing by 271% during the same time period.<sup>77</sup> Employees have also faced significantly increased costs, with employee contributions for single coverage increasing by 291% between 1999 and 2020, and by 262% for family coverage.<sup>78</sup>

In addition to premiums, employees also face increasing out-of-pocket costs for medical care, in the form of deductibles, co-insurance, and co-pays. For example, in 2020, 57% of covered workers were in plans with an annual deductible of \$1,000 or more for single coverage, while 26% were in plans with an annual deductible of \$2,000 or more.<sup>79</sup> By contrast, just over ten years ago only 22% of covered workers were in plans with annual deductibles of \$1,000 or more, and only 7% were in plans with deductibles of \$2,000 or more.<sup>80</sup>

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<sup>72</sup> *Id.*, Figure M.6, at 25.

<sup>73</sup> *Id.* at 41.

<sup>74</sup> DEP'T OF LAB., SELECTED MEDICAL BENEFITS: A REPORT FROM THE DEPARTMENT OF LABOR TO THE DEPARTMENT OF HEALTH AND HUMAN SERVICES 5-36 (2011), <http://www.bls.gov/ncs/ebs/sp/selmedbensreport.pdf>.

<sup>75</sup> KFF Employer Health Benefits 2020, *supra* note 17, Figure 1.10, at 40, Figure 1.12, at 42.

<sup>76</sup> *Id.* at 7. Not surprisingly, firms with lower-wage workers have less generous benefits and greater worker contributions; for family coverage, these firms had an average family premium of \$19,332 in 2020, with workers contributions of \$7,226 (close to 40%).

<sup>77</sup> Percentage increase calculated by authors using data provided by *id.* at 83-84. The relevant employer contributions for single coverage were \$1,878 in 1999 and \$6,227 in 2020, while the figures were \$4,247 and \$15,754 for family coverage.

<sup>78</sup> *Id.* at 83-84. Today, employees are required to contribute on average 17% of the premium for single coverage and 27% of the premium for family coverage. *Id.* at 82. Rates of employer subsidization vary based on firm size, particularly for family coverage. Large firms require employees to pay on average 24% of the cost of family coverage, while small firms require employees to pay 35% of the cost. *Id.*

<sup>79</sup> *Id.* at 106.

<sup>80</sup> *Id.* at 109-10. When premiums and cost-sharing obligations are combined, employees on average pay 34% of total health care costs (21% premiums, 13% all other costs), up from 32% a decade earlier. Matthew Rae, Rebecca Copeland & Cynthia Cox, *Tracking the Rise in Premium*

Even as the cost of employer plans has increased, the breadth of provider networks offered by such plans is becoming more limited, meaning that beneficiaries might increasingly find their doctor or hospital to be out of network.<sup>81</sup> Most ESI plans have some limits on the network of providers someone can see, or charge more for seeing doctors out of network.<sup>82</sup> Shrinking provider networks will almost certainly continue since limiting networks is the most feasible mechanism under employers' control to try to manage prices paid for care.

The overhead costs for plans vary significantly, although they are difficult to estimate precisely because of the inconsistent and malleable ways that both private and public plans categorize various costs. The Congressional Budget Office (CBO) found that private fully insured health plans have, on average, overhead expenses equal to 15% of premiums,<sup>83</sup> significantly higher than the 2-5% administrative overhead for Medicare and Medicaid.<sup>84</sup> And it is not clear whether these estimates sufficiently account for the in-house resources devoted to health plan administration, as discussed below.

## 2. *The Administrative Costs and Challenges of Employer-Provided Health Coverage*

In addition to the significant premium expense of employer-provided health plans, there are also less obvious costs and risks associated with such coverage from the employer's perspective. In particular, offering a group health plan comes with significant plan design costs and challenges, compliance costs, and litigation risks. It is likely that at least some employers have become accustomed to these obligations and now have come to consider them among the costs of doing business. Yet, if offered the opportunity to relinquish them, we think many would

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*Contributions and Cost-Sharing for Families With Large Employer Coverage*, PETERSON-KFF: HEALTH SYSTEM TRACKER (Aug. 14, 2019), <https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/>. As for prescription drug costs, the same report found that large employers end up paying 88.9% of the cost. *Id.*

<sup>81</sup> KFF Employer Health Benefits 2020, *supra* note 17, Fig. 5.1, at 78.

<sup>82</sup> *Id.* at 77. Forty-seven percent of workers are in Preferred Provider Organizations (PPOs); 31% in a High Deductible Health Plan with Savings Option (HDHP/SO); 13% in Health Maintenance Organizations (HMOs); 8% in Point of Service (POS) plans; and 1% in conventional plans. The POS and conventional plans might compete on network, but all others have more network restrictions than Medicare does. Even among firms with 5000 workers or more, one-third consider their largest plan's provider network somewhat or very narrow. *Id.* at 205.

<sup>83</sup> CONGRESSIONAL BUDGET OFFICE, PRIVATE HEALTH INSURANCE PREMIUMS AND FEDERAL POLICY 27 (2016), [https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/51130-Health\\_Insurance\\_Premiums.pdf](https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/reports/51130-Health_Insurance_Premiums.pdf). Self-insured plans appear to have lower administrative expenses than fully insured plans, although there are no reliable measures of such amounts. *Id.* at 28.

<sup>84</sup> *Id.*

do so gladly.<sup>85</sup>

An employer that decides to offer a health plan to employees must begin by making various plan design decisions, such as eligibility terms, benefit design, cost-sharing structure, network breadth, and financing arrangement. For large employers, in-house benefits experts typically work with outside benefits consultants to make these decisions, while smaller employers may consult only an insurance broker.

Once these initial decisions are made, the employer must either purchase a group insurance policy or hire a third-party administrator (TPA) to administer the plan. That purchasing or hiring process is typically done through a request for proposals (RFP) that solicits bids from interested parties. In fact, it is not unusual for a large employer to issue multiple RFPs to cover not only traditional medical benefits, but also separate RFPs for the plan's prescription drug benefit, specialty drug benefit, wellness program, Consolidated Omnibus Budget Reconciliation Act (COBRA) administration, and data warehousing. Once bids are received, the employer must select a winner in each category and negotiate the final terms of the contracts.

If the employer wants to allow employees to pay for premiums on a pre-tax basis (as all should), the employer must establish a cafeteria plan under section 125 of the Internal Revenue Code to allow such contributions.<sup>86</sup> Many employers also choose to offer a health care flexible spending account under their cafeteria plan, which allows employees to pay out-of-pocket medical expenses on a pre-tax basis, which typically requires yet another vendor.

After the plan has been designed and agreements with vendors are in place, the employer must administer an open enrollment process,<sup>87</sup> informing eligible employees of their choices and allowing them to make an election within a specified window. Plus, they must establish technical processes to enroll the employee and family members in coverage and ensure the proper payroll deductions and plan contributions are made.

Following open enrollment, the plan must be administered on an ongoing basis. While the insurer or a third-party administrator is principally responsible for such administration, the tasks involved are significant. At a minimum, the insurer or TPA must process prior authorization requests, claims and appeals, and mid-

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<sup>85</sup> See, e.g., Pfeffer et al., *supra* note 69, at e604 (describing how even employers interested in employee health promotion offered employees high deductible health plans based on an apparent belief that such plans were “the only option”).

<sup>86</sup> See I.R.C. § 125(d). Without a cafeteria plan in place, an employee's share of health plan premiums must be paid with after-tax dollars (i.e., dollars that are taxable as wages and subject to both payroll and income taxes) rather than with tax-free dollars.

<sup>87</sup> An annual open enrollment process is required by the tax code provisions allowing pre-tax payment of premiums through a cafeteria plan. See Prop. Treas. Reg. § 1.125-2(a)(1), 72 Fed. Reg. 43938, 43955 (Aug. 6, 2007).

year changes in enrollment. The insurer or TPA is also responsible for negotiating and maintaining a provider network and, as a practical matter, must have a call center for both participant and provider inquiries.

a. Regulatory Burdens

Once the plan is up and running, employers are faced with myriad legal requirements. The Employee Retirement Income Security Act of 1974, as amended (ERISA) is the federal statute that governs nearly all employer-provided health plans, other than those sponsored by churches or governments.<sup>88</sup> Although ERISA was designed primarily with pension plans in mind,<sup>89</sup> it imposes significant reporting and disclosure and claims and appeals procedures on health plans.<sup>90</sup> ERISA also incorporates federal requirements that provide the right for individuals covered by an employer health plan to continue their coverage for a specific period of time if they have a qualifying loss of coverage (known as COBRA continuation coverage), as well as various nondiscrimination requirements included in the Health Insurance Portability and Accountability Act (HIPAA) and a small number of mandated benefits.<sup>91</sup>

In addition to ERISA, the federal tax code also regulates employer-provided health plans. The tax code contains the so-called employer mandate, which subjects large employers to a financial penalty if they fail to offer an affordable group health plan.<sup>92</sup> The calculation of the penalty is complicated, but it generally ranges from \$2,000 to \$3,000 per employee per year. There are regulations establishing when an employer is considered to offer a group health plan for these purposes, and when and to what extent that coverage is considered affordable for a particular employee.<sup>93</sup> The tax code also incorporates many of ERISA's

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<sup>88</sup> 29 U.S.C. § 1001. The exclusion for governmental and church plans is found in 29 U.S.C. § 1003(b).

<sup>89</sup> James A. Wooten, *"The Most Glorious Story of Failure in the Business": The Studebaker-Packer Corporation and the Origins of ERISA*, 49 BUFF. L. REV. 683, 735-36 (2001).

<sup>90</sup> See 29 U.S.C. §§ 1021-1025 (containing ERISA's reporting and disclosure requirements); 29 U.S.C. § 1133 (containing ERISA's claims and appeals procedures, which are further detailed in regulations promulgated at 29 C.F.R. § 2560.503-1 (2022)).

<sup>91</sup> See 29 U.S.C. § 1161 (providing Consolidated Omnibus Budget Reconciliation Act requirements); 29 U.S.C. §§ 1181-1184 (providing Health Insurance Portability and Accountability Act requirements). ERISA broadly preempts state laws that relate to employee benefit plans, other than those that regulate insurance, which creates an additional level of legal complexity that often results in litigation over what state laws are preempted and has produced an encyclopedic number of Supreme Court decisions. See 29 U.S.C. §1144 (a).

<sup>92</sup> I.R.C. § 4980H.

<sup>93</sup> Treas. Reg. § 54.4980H-5 (as amended in 2021); see also David Gamage, *Perverse Incentives Arising from the Tax Provision of Healthcare Reform: Why Further Reforms are Needed to Prevent Avoidable Costs to Low- and Moderate-Income Workers*, 65 TAX L. REV. 669 (2012) (detailing some of the labor market distortions that are likely to result from the ACA's tax

substantive group health plan requirements and the ACA's health insurance reforms (such as prohibitions on pre-existing condition exclusions and lifetime and annual limits) and subjects plans that do not comply with such requirements to a \$100 per day per affected individual excise tax.<sup>94</sup> In addition, as mentioned above, in order to allow participants to pay premiums on a pre-tax basis, the employer must adopt a cafeteria plan administered in accordance with IRS guidance. For example, the cafeteria plan regulations dictate when a married employee who is getting a divorce may change their health plan election from family coverage to single employee coverage, or may drop or add coverage altogether.<sup>95</sup> Similarly detailed rules apply to health care flexible spending accounts, which may only be offered through a cafeteria plan.<sup>96</sup>

Employers must also ensure compliance with several other federal laws that touch employer health plans, such as HIPAA's privacy rules, the Americans with Disability Act (ADA), and the Family Medical Leave Act (FMLA). For employees who are Medicare-eligible, the employer or plan administrator must navigate Medicare Secondary Payer rules, which determine how benefit payments are coordinated between the employer plan and Medicare.

Some employer plans, if financed through an insurance contract rather than self-insured, are also subject to state laws. Such laws regulate not only the insurance company itself (through mechanisms such as capital reserve requirements) but can also have an impact on substantive features of the group contract, such as mandated benefits or dispute resolution mechanisms. For plans that self-insure but purchase stop loss coverage, state law can regulate the stop loss policy.

While quantifying the economic costs of these administrative and regulatory requirements is difficult, it is important to understand that the 5-11% administrative expenses for large employer self-insured plans cited above<sup>97</sup> does not include or reflect these other costs.<sup>98</sup>

#### b. Claims Disputes and Litigation Risks

In addition to the upfront plan design costs and ongoing compliance costs, employers that sponsor a group health plan also face risks related to claims

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provisions).

94 I.R.C. § 4980D.

95 See Treas. Reg. § 1.125-4 (as amended in 2001).

96 See Prop. Treas. Reg. § 1.125-5, 72 Fed. Reg. 43938, 43957 (Aug. 6, 2007).

97 See *supra* text accompanying note 91.

98 See Alain C. Enthoven & Victor Fuchs, *Employment-Based Health Insurance: Past, Present, and Future*, 25 HEALTH AFFS. 1538, 1541 (2006) (noting that administrative costs do not "include the costs to employers to purchase and manage health care spending, including armies of consultants, benefits managers, and brokers").

disputes. Where a health plan denies a claim, the covered individual has the right to an internal appeal that is subject to detailed procedural requirements.<sup>99</sup> In addition, as part of ACA reforms, nearly all employer plans now must offer participants the ability to appeal claims that are denied on the basis of clinical or scientific judgment to an independent medical expert.<sup>100</sup> That independent review is conducted *de novo*, and is binding on the plan.<sup>101</sup> If those appeals are unsuccessful, the covered individual has the right to file suit under ERISA to challenge the claim denial.<sup>102</sup>

While the financial impact of these claims disputes may be relatively limited,<sup>103</sup> these lawsuits can have a profound impact on the relationship between employer and employee. A dispute between an employer and employee about potentially life-or-death issues can irreparably harm the employment relationship with the affected employee and can also damage morale within the broader employee community. The effects of such disputes can undermine the ability of an employer to rely on health benefits as a recruitment and retention tool.

In addition to lawsuits brought by employees, employers that sponsor health plans sometimes find themselves as plaintiffs in lawsuits *against* employees to enforce plan reimbursement clauses.<sup>104</sup> These clauses, common in employer health plans, require that covered individuals reimburse the plan for medical expenses if the plan paid for medical care and the employee later recovers against a third party in an action related to those medical expenses.<sup>105</sup> For example, if an employee is injured in a car accident and receives a related settlement or judgment from a third-party, the health plan has a right to be reimbursed for the amount it spent to provide medical care to the employee as a result of the car accident. As with denied claims

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99 29 C.F.R. § 2560.503-1 (2022).

100 Patient Protection and Affordable Care Act, Pub. L. No 111-148, § 2719, 124 Stat. 119, 887-88 (2010).

101 Treas. Reg. § 54.9815-2719(d)(2)(iii)(B)(5) (*de novo* review); (7)(v) (binding decision).

102 29 U.S.C. § 1132(a)(1)(B). While claims that proceed to litigation pose relatively low financial risk, independent external review carries greater risk for a plan. In litigation, a court reviews a plan's decision under the highly deferential "arbitrary and capricious" standard of review. In external review, a qualified expert reviews the claim *de novo*, but only claims that involve the exercise of clinical or scientific judgment are eligible for external review.

103 Punitive and extra-contractual damages are unavailable under ERISA, which limits recoveries in successful appeals of benefit denials to the cost of the service at issue and plaintiff's attorneys fees.

104 *See, e.g.,* U.S. Airways v. McCutchen, 569 U.S. 88 (2013) (suit by self-funded health plan to recover amounts paid for injured participant's medical care, where participant had received a settlement from a third party related to automobile accident that resulted in the need for medical care).

105 *Montanile v. Bd. of Trustees of Nat'l Elevator Industry Health Benefit Plan*, 577 U.S. 136, 136 (2016) ("Employee benefits plans regulated by [ERISA] often contain subrogation clauses requiring a plan participant to reimburse the plan for medical expenses if the participant later recovers money from a third party for his injuries.").

lawsuits, these reimbursement actions often damage the employer-employee relationship and have at times resulted in unfavorable media coverage of the employer.<sup>106</sup>

All told, designing and maintaining a group health plan is a significant and costly undertaking for large employers, over and above actual premium costs. While those efforts generally deliver a valued benefit, a public option that provides high value coverage without these burdens could prove very attractive to both employers and employees.

## II. OUR PROPOSAL: AN EMPLOYER PUBLIC HEALTH INSURANCE OPTION

In this Article, we propose a better way forward than either Medicare for All or an individual public option. This Article makes the case for a public option for employers, which would give employers a voluntary choice to offer Medicare-based public insurance coverage in lieu of traditional group coverage. We begin by making the basic case for an employer public option and then review key design features in greater detail. We conclude by examining the likelihood that the proposal would gain traction among employers and other stakeholders.

### A. *The Basic Case for an Employer Public Option*

If the paramount goal of health care reform is to move toward efficient and equitable coverage, then providing employers with the ability to offer employees coverage through a Medicare-based public insurance program presents a meaningful and politically plausible opportunity in that direction. Most employers, even those with a will to do so, will not be able to reverse the trend of cost increases in their plans. An employer public option can do so, offering immediate benefits for both employers and employees. At the same time, it can build the foundation for larger systemic reform by testing a meaningful expansion of public coverage.

#### 1. *Fixing Problems with Job-Based Health Coverage*

One of the key benefits of an employer public option is the ability to address the declining reach, value, and reliability of ESI. It provides a mechanism to decrease prices for care and plan administrative expenses, increase the number of workers and their families with health insurance coverage, and deliver subsidies to low- and moderate-income workers.

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106 See, e.g., Andrew Clark, *Wal-Mart Drops Bid to Sue Brain-Damaged Former Shelf-Stacker*, GUARDIAN (Apr. 2, 2008); Tara Parker-Pope, *Injured Woman Wins Wal-Mart Saga*, N.Y. TIMES (Apr. 4, 2008); Andrew Wolfson, *Walmart Changed Policy After Claiming an Injured Worker's Settlement Became a PR Nightmare*, LOUISVILLE COURIER J. (Apr. 5, 2018).

a. Addressing the Rising Cost of Private Job-Based Coverage

A key feature of an employer public option, and advantage over private coverage, is the ability of the government to negotiate down prices and still retain a large network of providers. Medicare prices are on average one-half that of private health insurance plans.<sup>107</sup> Over the past decade, Medicare has controlled per enrollee spending much better than private health insurance.<sup>108</sup> Health spending growth has far outpaced economic growth, ballooning from just under 7% of GDP in 1970 to nearly 20% now.<sup>109</sup> Even over the last decade, from 2008-2019, a period when the rate of spending has slowed, private health insurance cumulative growth in per enrollee spending is over 50%, as compared to half that rate (just over 26%) for Medicare.<sup>110</sup>

During this same period, health care providers—including hospitals and physicians—have merged and become increasingly consolidated.<sup>111</sup> As a result, in many areas of the country providers have been able to demand higher prices for care with little effective resistance from private insurers and employers against these demands.<sup>112</sup> Even when Amazon, Berkshire Hathaway, and JPMorgan Chase joined together to attempt to wield their collective power to improve employer-provided health care, they found that they lacked the market power to negotiate prices down.<sup>113</sup> Large insurers generally cannot and do not push back on providers in market-based negotiations. In some cases they lack the ability to do so in the face of provider consolidation, and, in others, they lack the incentive to find the edge of negotiations when they can pass price increases off onto employers (and eventually employees).<sup>114</sup> When insurers do push back, providers still often have the upper hand when they are critical to a local network, as in the case of “must-

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<sup>107</sup> Eric Lopez et al., *How Much More Than Medicare Do Private Insurers Pay? A Review of the Literature*, KAISER FAM. FOUND. (Apr. 15, 2020), <https://www.kff.org/medicare/issue-brief/how-much-more-than-medicare-do-private-insurers-pay-a-review-of-the-literature/>.

<sup>108</sup> Rabah Kamal et al., *How has U.S. Spending on Healthcare Changed Over Time?*, PETERSON-KFF: HEALTH SYSTEM TRACKER (Dec. 23, 2020), <https://www.healthsystemtracker.org/chart-collection/u-s-spending-healthcare-changed-time/>.

<sup>109</sup> *Id.*

<sup>110</sup> *Id.*

<sup>111</sup> *Examining the Impact of Health Care Consolidation: Hearing Before the Subcomm. on Oversight and Investigation of the H. Comm. on Energy and Commerce*, 115th Cong. 8-9 (2018) (statement of Martin Gaynor, E.J. Barone Univ. Professor of Econ. and Health Pol’y, Heinz College, Carnegie Mellon Univ.) [hereinafter Gaynor Statement].

<sup>112</sup> *Id.*

<sup>113</sup> Sebastian Herrera & David Benoit, *Why the Amazon, JPMorgan, Berkshire Venture Collapsed: ‘Health Care Was Too Big a Problem,’* WALL ST. J. (Jan. 7, 2021) (“Despite Amazon, JPMorgan and Berkshire’s collective size, they lacked scale to garner enough negotiating power with care providers.”).

<sup>114</sup> Gaynor Statement, *supra* note 111 at 9.

have” hospitals or large integrated networks of hospitals and physicians.<sup>115</sup>

Medicare, however, preserves a large, unrestricted network of providers despite lower reimbursement rates. It does so in part because of its scale, which translates to volume benefits to providers and makes it difficult for large providers and hospitals to refuse to accept Medicare patients. It also does so by paying rates that make Medicare reimbursement acceptable for many providers, and not just when subsidized by privately insured patients. Efficient hospitals were able, until recently, to break even based on Medicare reimbursement rates.<sup>116</sup>

A public option that uses Medicare’s rates as a starting point would substantially reduce prices paid for health care. In addition, a public option can provide benefits at lower administrative costs compared to current employer plans due to economies of scale and simplification. This means that even if beneficiaries used the same amount of care as they do today, the total cost would be considerably less.

A public option can achieve cost savings while preserving a large provider network by tying participation in Medicare to participation in the public option. It would be necessary to set rates carefully to ensure total reimbursement is sufficient for participating providers (we discuss further below this delicate task). For employers and employees, an employer public option thus offers the possibility of lower health care costs delivered by, in many cases, a less restricted network of providers than is available under the status quo.

Savings should, at least in theory, translate into wage growth and increased employment, since we know that rising health care costs have done the inverse.<sup>117</sup> Despite economic growth, wages have stagnated since the 1970s and many attribute that stagnation in part to health care cost growth that has well exceeded inflation.<sup>118</sup> Curbing health care cost growth through an employer public option

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115 See, e.g., Robert A Berenson et al., *Unchecked Provider Clout In California Foreshadows Challenges To Health Reform*, 29 HEALTH AFFS. 699, 702 (2010) (“‘Must-have’ hospitals, by definition, have market leverage over health plans, because plans cannot plausibly threaten to exclude them.”).

116 *Id.*

117 Katherine Baicker & Amitabh Chandra, *The Labor Market Effects of Rising Health Insurance Premiums*, 24 J. LAB. ECON. 609 (2006). There are no guarantees, of course, that cost savings will reach workers’ pockets, especially in industries where the balance of power between labor and employers has become lopsided. Eventually as Medicare covers more or most of the population, we would hope that workers experience an increase in wages, but these offsets are difficult to explain to the public and not guaranteed, which make the idea of Medicare for All more challenging politically. Some experts propose attempting to legislate the return of such savings into workers pockets, but guaranteeing they remain there in the long-run equilibrium would be difficult. See Emmanuel Saez & Gabriel Zucman, *We Can Afford Medicare For All*, POLITICO (Nov. 25, 2019), <https://www.politico.com/news/agenda/2019/11/25/agenda-can-we-afford-medicare-for-all-071560>.

118 Mark J. Warshawsky & Andrew G. Biggs, *Income Inequality and Risking Health-Care*

could help ameliorate wage stagnation.

b. Expanded Coverage, Especially for Low-Wage Workers

An employer public option also presents an opportunity to expand job-based coverage to the currently uninsured, through a combination of lowering premiums and incorporating ACA-style subsidies for low- and moderate-income households, many of whom are uninsured.

Assuming the plan delivers lower reimbursement rates and administrative expenses, the resulting lower premiums should result in more employees electing offered coverage.<sup>119</sup> There are currently 26 million employees who either are not offered coverage by their own firms or are offered and decline coverage.<sup>120</sup> In 2020, only 58.3% of employees at large firms enrolled in ESI.<sup>121</sup> Roughly 20% of employees were ineligible for ESI because of waiting periods or part-time or temporary work status.<sup>122</sup> Of those eligible for insurance, only 76% elected to purchase it.<sup>123</sup> Many of those declining to take up ESI offers likely did so because they obtained coverage elsewhere (under the health plan of another family member or through public programs like Medicaid), but some no doubt turned down the coverage because of the cost of their required contribution toward it.<sup>124</sup>

According to research by the Commonwealth Fund, the composition of uninsured Americans has shifted dramatically since 2010 so that a larger portion are now working uninsured.<sup>125</sup> Back when the ACA was enacted, 50% of working-age uninsured Americans were unemployed. By 2018, only 38% of the working-age uninsured were unemployed. Conversely, over 60% were employed. The share

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*Costs*, WALL ST. J. (Oct. 6, 2014), <https://www.wsj.com/articles/mark-warshawsky-and-andrew-biggs-income-inequality-and-rising-health-care-costs-1412568847>.

119 See, e.g., Philip F. Cooper & Jessica Vistnes, *Workers' Decision to Take-Up Offered Health Insurance Coverage: Assessing the Importance of Out-of-Pocket Premium Costs*, 41 MED. CARE III-35 (2003) (finding that reducing employee contributions for health insurance coverage will increase take-up rates).

120 KFF Employer Health Benefits 2020, *supra* note 17, at 58.

121 2020 MEPS DATA, *supra* note 17.

122 KFF Employer Health Benefits 2020, *supra* note 17, at 58.

123 *Id.*

124 See, e.g., David M. Cutler, *Employee Costs and the Decline in Health Insurance Coverage*, 6 F. FOR HEALTH ECON. & POL'Y 27 (2003) (illustrating the relationship between increased employee health insurance costs and a decline in employee enrollment in health insurance); Michael Chernew et al., *Increasing Health Insurance Costs and the Decline in Insurance Coverage*, 40 HEALTH SERVS. RSCH. 1021 (2005) (finding that more than half of the decline in health insurance coverage rates during the study period was attributable to an increase in health insurance premiums).

125 Munira Z. Gunja & Sarah R. Collins, *Who Are the Remaining Uninsured, and Why Do They Lack Coverage?*, COMMONWEALTH FUND 11 (Aug. 2019), [https://www.commonwealthfund.org/sites/default/files/2019-08/Gunja\\_who\\_are\\_remaining\\_uninsured\\_sb.pdf](https://www.commonwealthfund.org/sites/default/files/2019-08/Gunja_who_are_remaining_uninsured_sb.pdf).

of the uninsured who work full-time has increased from 30% in 2010 to 42% in 2018, while the share of those who work part-time stayed constant at 19% during this period. While more work needs to be done to understand exactly who are the working uninsured, the studies of Medicaid-eligible workers offer evidence of the labor attributes of low-wage workers without employer coverage. Nearly half of this population work at firms with more than 100 employees,<sup>126</sup> with heavy concentrations in the service sector and agriculture.<sup>127</sup>

In addition to bolstering affordability by reducing plan cost, it would be relatively straightforward to integrate ACA-style subsidies for low-wage workers into a government-administered public option. Under the current system, employees who are offered what the ACA has defined as affordable and adequate employer coverage are ineligible for the premium tax credits that are available to subsidize individual coverage on its Marketplace, even if their employer coverage is less affordable than subsidized individual coverage.<sup>128</sup> An employer public option offers an attractive mechanism to equalize subsidies between employer and individual coverage, likely increasing the take up of job-based coverage by low-wage and part-time workers. This approach, which we detail further in the next part, could improve the equity of health coverage among workers, regardless of income or work hours.

### c. Addressing Churn and Portability

An employer public option, particularly if widely adopted, could also help address other problems caused by relying on employers for health benefits, such as churn between employer-provided coverage and Medicaid, and the care disruptions that often occur when individuals switch employment or lose jobs. Rather than falling out of private insurance coverage as they do today, workers covered by a public option could more easily and seamlessly retain their health care coverage if they become unemployed or move between jobs.

For example, if an employer public option were offered alongside an individual public option, an individual who loses employer-provided coverage could seamlessly switch to individual coverage at subsidized rates, if applicable. Similarly, an employer public option could be designed to allow low-income individuals to retain their employer-provided coverage even when their income

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126 THE KAISER COMMISSION ON MEDICAID AND THE UNINSURED, KAISER FAM. FOUND., ARE UNINSURED ADULTS WHO COULD GAIN MEDICAID COVERAGE WORKING? 2 (Feb. 2015), <http://files.kff.org/attachment/fact-sheet-are-uninsured-adults-who-could-gain-medicaid-coverage-working>.

127 *Id.*; Jennifer Tolbert, *What Issues Will Uninsured People Face with Testing and Treatment for COVID-19?*, KAISER FAM. FOUND. (Mar. 16, 2020), <https://www.kff.org/uninsured/fact-sheet/what-issues-will-uninsured-people-face-with-testing-and-treatment-for-covid-19/>.

128 See *infra* Section II.B.6, for more details on subsidy design.

dips to Medicaid-eligibility levels. And if enough employers decide to participate, over time, workers can change jobs while retaining the same health plan and providers, which would reduce job lock, the tendency to stay in a job to retain health benefits. A well-structured employer public option would thus reduce costs and inefficiencies that inevitably occur when individuals must switch coverage when changing jobs. We discuss all of these points in greater detail below.

## 2. *Ability to Test Transition to a Single-Payer System*

One of the most significant benefits offered by an employer public option is the ability to enroll a large number of younger participants into a public Medicare-based plan to test the transition toward a single-payer system.<sup>129</sup> If just a small number of major employers elected to participate, hundreds of thousands of households would transition to the public option, providing a meaningful opportunity to test the feasibility of expanding to more populations over time. It would also allow refinement in cooperation with sophisticated private industry partners. If several major employers make the leap and it works, it might persuade others that the benefits of their siloed private plans are not worth maintaining.

Importantly, it would provide regulators access to data needed for large-scale reforms. Right now, most of the data on employer health plans, including on utilization, is not transparent. Through an employer public option, regulators could have access to that data, which would help inform fine tuning the public option and also broader analyses and reforms that require understanding and tracking health care use over time.

## 3. *Fiscal and Political Advantages*

In Part III below, we describe in detail the fiscal benefits of this approach to expanding public coverage to a working-age population. A major stumbling block to expanding public coverage is typically the need for new taxes to offset the loss of employer contributions and most ideas, including Medicare for All, do not offer a straightforward way to retain those contributions.

In contrast, because an employer public option does not fully dislodge benefits from the workplace, it is easier to retain current employer and employee contributions. These contributions would, in turn, finance a significant share of the cost of public coverage especially considering the cost saving that would result from shifting from private plan reimbursement rates to ones based on Medicare

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129 LINDA J. BLUMBERG ET AL., ESTIMATING THE IMPACT OF A PUBLIC OPTION OR CAPPING PROVIDER PAYMENT RATES viii–ix (Mar. 2020), <https://www.urban.org/sites/default/files/2020/03/23/estimating-the-impact-of-a-public-option-or-capping-provider-payment-rates.pdf>.

rates. As a result, the amount that would need to be financed through new taxes would be significantly lower than under other reform proposals.

### *B. Design Features of an Employer Public Option*

For an employer public option to be successful—both in terms of providing valuable coverage to employees and facilitating structural reform—it must be carefully designed to appeal to employers and employees on dimensions like covered benefits and provider network while also controlling costs. The design details will, of course, determine political feasibility and whether employers, especially large employers, will trade current private coverage for a public alternative.

This Section explores the key design features that will be necessary to navigate carefully. Although we do not intend to solve these details perfectly here, we mention several that we think are the most important and explain their significance. We also describe how we would approach these design choices, recognizing that some readers might have different preferences, but proceeding under the assumption that there is value in setting forth a concrete proposal. As explained below, aspects of our proposal would work better if implemented alongside an individual public option sold through ACA exchanges, but one could also envision the proposal as providing a public option exclusively for employers.

#### *1. Voluntary Employer Adoption*

Critically, there would be no mandatory change in employer health care plans, which has been a political stumbling block for Medicare for All. Participation would be entirely voluntary on the part of employers and would be subject to the same labor market pressures that currently inform their health plan decision-making. Large employers are among the most sophisticated health finance decision-makers in our current system and would hopefully smartly assess the benefits of the public option over their private plans.<sup>130</sup>

Many individuals would be more receptive to a public option if selected and offered by their employers than if imposed on them by the government—although we do not want to imply that it would be completely smooth sailing since some

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130 Of course, employers do not always get it right. Some of the best research illuminating how employees make poor choices was made possible by their employers offering what are called “dominated” health plans. These plans are worse than an alternative option for all possible enrollees in all possible scenarios. No employee should choose such plans and no wise employer should have it on the menu of options. One of the most well-known of these studies was conducted at University of Michigan, which one might think would have a sophisticated HR department. Sinaiko & Hirth, *supra* note 62. But compared to individuals navigating options, many employers, especially large ones, should be able to identify a public option that is better than what they offer privately.

workers who currently have several private plan options might lose that menu if their employer pivots to the public option. Employees are much more likely to resist a plan change that they do not understand, and health plans are notoriously difficult for individuals to understand. Employers could manage the transition from their current offering(s) to the public option by communicating the most salient benefits, such as broad provider networks and lower costs, to employees. They could offer explanations of common coverage situations and a comparison to their current employer plan options.

Making employer adoption voluntary is critical for two reasons. First, it insulates the approach from the charge of government overreach. Employers will only adopt a public option plan if they conclude that it is in their best interest and, hopefully, in the best interest of their employees. Second, a public option for employers structured in this way would reduce the budgetary impact of expanding public coverage, as compared with either Medicare for All or even leading public options programs focused on individuals. We review the budgetary treatment of a public option for employers in Part III, but, for current purposes, it is sufficient to note that, from a fiscal perspective, a voluntary public option for employers has considerable advantages over other approaches.

## 2. *Target Market*

Focusing initially on firms with over one thousand employees would enable a smooth roll-out to a large number of people in a more streamlined way. It would also allow partnering with a handful of large employers to test and refine the idea to demonstrate effectiveness and to refine policy details in the initial years of implementation, before attempting more widespread implementation.

Roughly 62.4 million or 50.9% of all private sector employees in the United States are located in these larger firms.<sup>131</sup> Approximately twelve thousand firms have more than one thousand employees, an average of roughly six thousand employees per firm.<sup>132</sup> By way of contrast, according to census data from 2017, there are nearly six million U.S. firms with fewer than fifty employees and more than five million of these have fewer than twenty employees, making it much

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<sup>131</sup> See 2020 MEPS DATA, *supra* note 17.

<sup>132</sup> The MEPS data cited in the preceding footnotes reports on establishments rather than firms, but BLS data indicates that the number of large firms is on the order of the twelve thousand figure cited in the text. See U.S. BUREAU OF LABOR STATISTICS, DISTRIBUTION OF PRIVATE SECTOR FIRMS BY SIZE CLASS, [https://www.bls.gov/web/cewbd/table\\_g.txt](https://www.bls.gov/web/cewbd/table_g.txt). These figures are substantially consistent with more comprehensive Census Department data for 2017, which reports on both firms and establishments. See U.S. CENSUS BUREAU, 2017 SUSB ANNUAL DATA TABLES BY ESTABLISHMENT INDUSTRY (Mar. 2020), <https://www.census.gov/data/tables/2017/econ/susb/2017-susb-annual.html>.

harder to roll out to a significant number of people through smaller firms.<sup>133</sup>

Another advantage of focusing on larger employers is that nearly all these firms already offer health insurance to their employees, likely making them more receptive to a solution that could improve upon their status quo. Importantly, these firms already have the health insurance expertise to make informed decisions in this area, through their own human resources staff and outside benefit consultants.<sup>134</sup> To the extent that an employer public option offers a strong value proposition, large employers should be well equipped to recognize it.

### 3. *Exclusivity Requirements*

We suggest requiring employers to opt either to retain their private plan(s) or to move all employees to the public option exclusively. Although it would be possible to do otherwise and offer the public option side-by-side with private plan options, it would significantly diminish many of the benefits of our proposal.

Exclusivity would maximize equity and reduce concerns that employers might encourage, explicitly or implicitly, employees with greater medical needs to choose the public option.<sup>135</sup> An exclusivity requirement would in turn lessen the need for experience-based pricing and similar safeguards to counteract such sorting.

Exclusivity is necessary for achieving the cost savings, noted above, as well as reduced employer responsibility for managing and arranging health benefits. If some employees opted for a public plan and others for private, administrative costs and internal hassles might in fact increase.

Even though employers and employees, especially at large firms, are used to a menu of options, there is no evidence that employees choose among health plan options effectively and in a way that feels meaningful. In fact, there is much evidence to the contrary: that people agonize over and dislike making health plan choices and that they often fail to make good choices, as discussed above.<sup>136</sup>

Some studies have looked specifically at decision-making among options of workplace coverage. One showed that over one-third of all workers in the University of Michigan employee plan enrolled in a plan that was identical to another option in every way, except that it had a more restricted provider

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133 U.S. CENSUS BUREAU, *supra* note 132.

134 Employers would likely continue to rely on benefits consultants and brokers and so any policy targeting this market must account for how to involve these parties effectively in shaping plan choices.

135 Amy Monahan & Daniel Schwarcz, *Will Employers Undermine Health Care Reform by Dumping Sick Employees?*, 97 VA. L. REV. 125, 181-88 (2011) (describing the financial incentives employers have to encourage high-cost employees to seek coverage outside of the employer's group health plan).

136 See *supra* notes 60-63 and accompanying text.

network.<sup>137</sup> Another study of a large U.S. firm similarly found that a majority of employees chose a “dominated” option, which was otherwise identical to a higher-deductible option (in terms of benefits, provider network, administrator, etc.) but would cost them more at every level of possible health care use, and which resulted in 24% excess employee spending on premiums.<sup>138</sup> Lower-income employees were more likely to select dominated plans.<sup>139</sup> Allowing employers to offer the public option on a menu would simply redouble the problems with individual-level health plan decision-making.

An exclusivity requirement instead offers an opportunity to rewrite the script that choice of health plan is so valuable, a script penned by the insurance industry.<sup>140</sup> When pressed, people care more about access to providers they know and trust than access to choice of health plans.<sup>141</sup> Consumers appear to have conflated provider choice with health plan choice, or used health plan choice to proxy provider choice.<sup>142</sup> Since the public option would deliver a wide provider network, more so than many of today’s private plan options, it will likely maximize choice on the dimension that people genuinely value. Over time, the notion that having choices among various health plans is important will likely dissipate.

Some employers—especially larger employers—do, however, regard the ability to provide gold-plated health care plans as an important tool in attracting top talent. Unions, as well, may object to a strict exclusivity requirement as reducing the potential dimensions of negotiation for collective bargaining agreements. One way to meet these concerns would be to require employers to

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137 Sinaiko & Hirth, *supra* note 6262, at 453.

138 Saurabh Bhargava et al., *Choose to Lose: Health Plan Choices From a Menu With Dominated Options*, 132 Q.J. ECON. 1319, 1321-22 (2017) (studying an employer where employees can “build” their own plans by choosing four cost sharing elements—deductible, copayment, coinsurance, and out-of-pocket maximum—for plans that otherwise are identical in terms of, for example, covered benefits, provider network, and plan administrator). To illustrate a dominated plan, for employees to lower their deductible from \$1000 to \$750, they had to play \$528 more in premiums per year, spending \$278 more than they would in any scenario under the \$1000 deductible plan. *But cf.* Benjamin R. Handel, *Adverse Selection and Inertia in Health Insurance Markets: When Nudging Hurts*, 103 AM. ECON. REV. 2643 (2013) (showing that in one employer setting, correcting inertia that leaves people in dominated plans exacerbates adverse selection and leads to an overall welfare reduction).

139 Bhargava et al., *supra* note 138, at 1322.

140 Wendell Potter, *How the Health Insurance Industry (and I) Invented the “Choice” Talking Point*, N.Y. TIMES (Jan. 14, 2020), <https://www.nytimes.com/2020/01/14/opinion/healthcare-choice-democratic-debate.html>.

141 See DAVID BETTS ET AL., DELOITTE, WHAT MATTERS MOST TO THE HEALTH CARE CONSUMER 3 (2016), <https://www2.deloitte.com/content/dam/Deloitte/us/Documents/life-sciences-health-care/us-lshc-cx-survey-pov-provider-paper.pdf> (explaining that what consumers most want is “to be known and understood in order to get a personalized health care experience”).

142 See *id.*

adopt the public option as an exclusive base health care plan for all employees,<sup>143</sup> but allow supplemental policies with more extensive benefits for all or some of their workforce, including, for example, those covered by collective bargaining agreements. Doing so would reduce some of the simplification offered by the public option, but, importantly, it would still mean considerable cost savings over the status quo.

#### 4. *Benefits and Cost-Sharing*

An employer public option needs to offer benefits that are roughly comparable to current large employer plan benefits, recognizing that plan details, of course, vary across such employers. Current Medicare coverage would have to be modified for a working population and could be simplified as well. If rolled out in legislation that also creates a public option for the individual markets, the two programs should be aligned, both as a matter of equity and to facilitate transitions between the two forms of public option when people face changing employment status.<sup>144</sup>

A public option for employers should, at a minimum, cover the treatments and services typically covered by large employer plans.<sup>145</sup> This will mean augmenting Medicare in some ways already contemplated, like vision and dental benefits, and in others that become more obvious when thinking about covering younger workers and their families, including children. Another wrinkle is how to handle prescription drug coverage, which is an optional, private add on for Medicare enrollees through Medicare Part D, a program that is currently under fire for questionable administrative structures and high prices. Drug benefits would need to be included as part of the employer public option, ideally without requiring enrollees to select among private plans. But if building on Part D, the addition of a new population might offer the right moment to establish price regulation in the program.

Cost-sharing should be determined under the same principles. Medicare's complicated cost-sharing provisions that result in many enrollees purchasing supplemental coverage should not serve as the guide for the employer public option in the same way that it would not for an individual public option (and

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143 For current purposes, we leave to the side questions about how to define the boundaries of an employer in the case of affiliate firms or those organized as conglomerates engaged in substantially different lines of business.

144 As discussed below, this alignment is especially important for gig economy workers who repeatedly transition between traditional employment and self-employment. See Section II.B.8, *infra*.

145 For an overview of the benefits typically offered by large employer plans, see DEP'T OF LABOR, *supra* note 74 (while it can be difficult to determine the precise contours of coverage under employer plans, most cover a broad range of medical services with substantial differences only in a few areas).

perhaps should be revisited for Medicare as well in the future). And cost-sharing design would have a different framework for the employer public option since many people would enroll in family plans, unlike in Medicare.

Cost-sharing has at least two different components. The first is the overall level of cost-sharing within a plan, referred to as the plan's actuarial value. A plan's actuarial value represents the percentage of covered expenses paid by the plan for an average population. At firms with 500 or more employees, the average health plan actuarial value is 86%.<sup>146</sup>

The second component is the cost-sharing design, which refers to how cost-sharing requirements are allocated among particular types of care or points of service. For example, will there be an annual deductible, which enrollees must pay first before insurance pays, or just copayments and co-insurance so that they pay a share of costs as they go along? Will copayments for a specialist be higher than those for a general practitioner? Will treatments with a higher value be subject to lower cost-sharing requirements than those of lower value? Mapping these features to an employer plan benchmark is more difficult than overall actuarial value because there is significant variation among plans.

While mirroring the amount of cost-sharing in the large employer market may be necessary to generate employer participation, the public option could attempt to alleviate some of the burden employees have borne with recent increases in cost-sharing requirements.<sup>147</sup> This shift might help build early employee support for the plan. The public option may also present an opportunity to simplify cost-sharing design based on the growing research that most people do not understand or act according to the complex financial incentives embedded in their plans complicated cost-sharing structures.<sup>148</sup> It might be unrealistic to expect an employer public

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146 ACTUARIAL RSCH. CORP., FINAL REPORT: ANALYSIS OF ACTUARIAL VALUES AND PLAN FUNDING USING PLANS FROM THE NATIONAL COMPENSATION SURVEY 9 (2017), <https://www.dol.gov/sites/dolgov/files/ebsa/researchers/analysis/health-and-welfare/analysis-of-actuarial-values-and-plan-funding-using-plans-from-the-national-compensation-survey.pdf>; see also Jon R. Gabel et al., *More Than Half of Individual Health Plans Offer Coverage that Falls Short of What Can Be Sold Through Exchanges as of 2014*, 31 HEALTH AFFS. 1339, 1342 (2012) (finding that 23.9% of employer plans had actuarial values that exceeded 90%).

147 As health care costs have outpaced inflation over the past several decades, many employers have managed this increase by moving employees onto high deductible health plans where they pay a higher share of medical care costs. From 2005 to 2020, the share of large firms offering a high-deductible health plan increased from 8% to 67% and the number of enrollees in such plans increased from 3% in 2006 to 33% in 2020. KFF Employer Health Benefits 2020, *supra* note 17, at 133 Fig. 8.2, 135 Fig. 8.4.

148 See, e.g., Michael Chernew et al., *Are Health Care Services Shoppable? Evidence from the Consumption of Lower Limb MRI Scans* (Nat'l Bureau of Econ. Rsch., Working Paper No. 24869, 2019), [https://www.nber.org/system/files/working\\_papers/w24869/w24869.pdf](https://www.nber.org/system/files/working_papers/w24869/w24869.pdf); Mary E. Reed et al., *In Consumer-Directed Health Plans, A Majority of Patients were Unaware of Free or Low-Cost Preventive Care*, 31 HEALTH AFFS. 2641 (2012) (finding that a majority of enrollees were unaware that the deductible did not apply to certain high-value care, such as preventive office visits, medical

option to be as generous as some of the best employer plans are today, but individual employers could choose to fill in the gaps through supplemental coverage or by increasing wages.

### 5. *Pricing and Financing of the Employer Public Option*

The public option would retain employer contributions—in part or whole—to finance benefits, but there are various ways that these contributions could be designed. The simplest way would be to set a *minimum* flat per employee contribution for participating employers, for example, 70% of the total cost of community-rated coverage, based on the average cost of covering workers and their families in the plan. Employers could pay a larger share of costs, if they want. Employees would contribute whatever amount employers do not. The downside with this simplified approach is that it could decrease current employer contribution shares if employers who are currently paying a larger share default to this minimum level. That said, if total plan costs decrease, employees' actual costs might not increase even if their share does.

An alternate, although more complicated approach, is to require employers to maintain the share of premiums they currently cover, at least for some period, possibly gradually moving to an employer minimum contribution requirement. Employers offering ESI for the first time could be required to pay a minimum flat contribution percentage from the start.

Although it is possible to use experience-based pricing—that is, pricing that varies by employer group based on its employees' recent medical care costs—doing so would cut squarely against coverage and equity goals. Experience-based pricing is consistent with current practices as most large employers (83.8%) self-insure their health care coverage and thus pay more when plan members use more care,<sup>149</sup> and fully-insured policies for large employers are generally experience rated.<sup>150</sup> But if one goal of an employer public option is to encourage employers to cover lower-wage workers, who will disproportionately have more costly health care needs, experience-rating would undermine that goal.<sup>151</sup> It is also unlikely that

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tests, and screenings).

149 See 2020 MEPS DATA, *supra* note 17 (derived from Table I.A.2.a).

150 Questions of experience rating interact with those addressed just below on whether employers must move all employees over to a public option, or are allowed to offer other plans as well. If the latter, experience rating may be advisable to combat employer sorting among plan choices. Among small employers, most only offer one plan, which eliminates concerns of employee sorting if that plan becomes the public option. Only 20.9% of employers with fewer than 50 employees have two or more plans in 2020. See 2020 MEPS DATA, *supra* note 17 (derived from Table I.A.2.d). On the other hand, a very high percentage—88.2%—of employers with more than one thousand employees offer two or more health care plans. *Id.*

151 For employers with low-income and less-healthy workforces, experience-based pricing could disincentivize selecting an employer public option. In this context, pricing that is blind to

a community-rated employer public option would deter employers with a healthier-than-average employee population because the savings from lower prices and administrative costs would likely offset any cross-subsidization of less-healthy employer groups.

Regardless of the pricing method, it would be important to limit the growth of employers' costs over time. Since they will no longer have the tools in hand to limit their own spending through reduced benefits, increased cost sharing, or smaller networks, employers would need a guarantee that spending will not skyrocket once they opt in. Such guarantees are relatively low risk since, as noted above, Medicare has done much better than private coverage in controlling health care cost growth over time.

#### 6. *Incorporating ACA Subsidies*

To maximize enrollment of low-income workers, ACA subsidies could be rolled into the employer public option coverage. While adding to fiscal costs, this feature might contribute substantially to the number of workers covered, especially among those who currently decline enrollment in ESI for financial reasons or whom employers predict would do so and thus exclude from coverage.<sup>152</sup>

The ACA addressed the unaffordability of privately financed coverage in two ways, through premium tax credits and cost-sharing subsidies. Premium costs for individual insurance policies purchased on ACA exchanges are subsidized for individuals with household income between 100% and 400% of the federal poverty level through refundable tax credits. These subsidies cover the difference between a specified percentage of household income and the cost of the “benchmark plan” available to the individual, on a sliding scale.<sup>153</sup> Individuals who are offered

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employee health status could be seen as a positive rather than a negative because employees in greater need of medical care and less able to afford it will gain access. Cf. Deborah Stone, *Beyond Moral Hazard: Insurance as Moral Opportunity*, in *EMBRACING RISK: THE CHANGING CULTURE OF INSURANCE AND RESPONSIBILITY* 52 (Tom Baker & Jonathan Simon eds., 2002) (describing how increased use of medical care with insurance might indeed be a good thing since it could mean that people who previously needed care but did not receive it are able to do so without insurance). It might give employers with a less healthy workforce more chance to operate without shouldering an excessive share of health care costs of American workers. It might mean those workers get better benefits than they would otherwise. And it might mean that lower-paid workers are able to get better health care without seeing their wages stagnate. Plus, it might make sense that part of the cost of keeping higher-risk workforces healthy should be cross-subsidized.

<sup>152</sup> As ineligible workers are typically lower-paid, many employers may have rationally concluded that many of these individuals would not wish to participate in an employer-sponsored health care plan. But this calculation might change if ACA-style subsidies were available.

<sup>153</sup> I.R.C. § 36B. The benchmark plan is the second lowest-cost silver level plan available to the individual. § 36B(b)(3)(B). For example, an individual with household income equal to 150% of the federal poverty level would receive a credit equal to the difference between 4.12% of household income and the cost of the benchmark plan, while an individual with household income of 375% of

employer coverage that is considered affordable and adequate by the ACA are not, however, eligible for these subsidies. In effect this means that people offered coverage through work are rarely eligible for subsidies.

Even worse, the definition of what is “affordable” coverage under the ACA puts many families at a sharp disadvantage when a member of the family is offered coverage at work. The ACA provides that employer coverage is “affordable” when an employee’s required contribution is less than 9.78% of household income,<sup>154</sup> and adequate if the actuarial value of the plan is at least 60%. Regulations, however, base the affordability calculation solely on the required contribution for employee-only coverage, even if the employee desires family coverage.<sup>155</sup> For example, assume an employee is married with two minor children and has household income of \$65,500 per year. Her employer offers her health insurance where the required contribution for employee-only coverage is \$5,000, while the contribution for family coverage is \$10,000. Because the contribution for employee-only coverage is equal to 7.6% of the employee’s household income, the ACA deems that coverage affordable, even though family coverage would cost 15.3% of household income. Because the family is deemed to have “affordable” employer coverage under this test, no one in the family may receive a premium tax credit on the individual market. If this same family had not been offered employer coverage at all, they would have been eligible for a tax credit that would allow them to purchase subsidized silver-level coverage for the entire family with a household required contribution of \$5,456 annually.<sup>156</sup> As this example known as the “family glitch” illustrates, under the current system, individuals can be made *worse off* by being offered employer-provided coverage because it causes them to lose premium subsidies that would otherwise be available to them based on their income level.

The second ACA mechanism to address the problem of unaffordability is cost-sharing subsidies that lower the out-of-pocket costs of receiving care once insured. These cost-sharing subsidies are available to individuals with household income between 100% and 250% of the federal poverty level, but only if they purchase

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federal poverty receives a credit equal to the difference between 9.78% of income and the cost of the benchmark plan. *See* Rev. Proc. 2019-29, 2019-32 I.R.B. 620.

154 The statute sets affordability at 9.5% of income, subject to future annual adjustments based on growth in income and growth in premiums. For 2020, affordability is set at 9.78% of income. Rev. Proc. 2019-29, 2019-32 I.R.B. 620. Note that this calculation does not account for the part of health care costs that the employer funds. So with a typical 70/30 employer/employee split, affordability is measured only with respect to the 30% employee contribution.

155 Treas. Reg. § 1.36B-2(c)(3)(v)(A)(1) (as amended in 2020).

156 This amount was calculated using an income of \$65,500 for a family of four, which is equal to 250% of the federal poverty level for 2021, and a resulting premium tax credit equal to the difference between the cost of silver coverage and 8.33% of income.

silver-level coverage on an exchange.<sup>157</sup> As with the premium tax credits just described, these subsidies are unavailable to low- and moderate-income individuals who are offered affordable and adequate coverage by an employer. Because of this limitation on eligibility, low- and moderate-income individuals again may be made financially worse off by an offer of employer-provided coverage. The cost-sharing subsidies require insurers to lower out-of-pocket maximums<sup>158</sup> and increase the percentage of covered expenses on average paid by the insurer from the 70% generally required for silver-level coverage to at least 73% and in some cases as high as 94%. The threshold for “adequate” employer coverage, by contrast, requires the plan to pay, on average, only 60% of covered expenses. It is therefore possible that a low-income employee offered coverage by an employer could both pay more in health insurance premiums and receive much less generous coverage than would be available if the employer offered no coverage at all.

These problems need to be fixed regardless, but an employer public option might offer a more elegant and equitable solution. Most proposals attempt to fix this incongruity for low-income workers by removing the firewall between employer and individual coverage and allowing workers to receive subsidies on the ACA Marketplaces, even if their employer offers them adequate and affordable coverage.<sup>159</sup> The problem with this approach is that low-income workers and their families may end up in lesser Marketplace health plans than their higher income peers, given that the average large employer plan is more generous than even “gold” level exchange coverage.<sup>160</sup> An employer public option, however, presents an attractive mechanism to help address the shortcomings and distortions present in these two affordability tools by doing the opposite: weaving the ACA subsidies

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<sup>157</sup> These cost-sharing subsidies are complicated because they require the insurer to reduce cost sharing to increase the actuarial value of the plan from 70% to between 73% and 94% for the individual, depending on income. It is up to the insurer how to adjust deductibles, coinsurance, and copays to hit the required actuarial values for the various income tiers.

<sup>158</sup> Individual Marketplace plans can have an out-of-pocket maximum no higher than \$8,550 for individual coverage in 2021. Out-of-pocket maximums for those eligible for cost-sharing reductions can be no higher than \$2,850 to \$6,800 for an individual. Similar reductions apply to family level coverage.

<sup>159</sup> Vice President Biden has proposed this type of universal subsidy availability, in addition to other changes to subsidy amounts and income limits. Cynthia Cox et al., *Affordability in the ACA Marketplace Under a Proposal Like Joe Biden’s Health Plan*, KAISER FAM. FOUND. (2020), <https://www.kff.org/health-reform/issue-brief/affordability-in-the-aca-marketplace-under-a-proposal-like-joe-bidens-health-plan/>. In addition, Biden would allow workers with an offer of job-based coverage to enroll in Marketplace plans with subsidies if that would be a better deal. Under current law, employees qualify for Marketplace subsidies only if their employer’s plan is deemed unaffordable or does not satisfy minimum coverage requirements.

<sup>160</sup> The average actuarial value of a health plan offered by firms with 500 or more employees is 86%, compared with gold-level coverage, which has an actuarial value of 80%. See ACTUARIAL RSCH. CORP., *supra* note 146.

into job-based coverage.

Specifically, the public option could incorporate premium subsidies that are consistent with those offered on the individual market and could vary cost-sharing schedules by household income.<sup>161</sup> For example, the public option might specify that individuals with income at or below 150% of federal poverty pay a \$5 copay for an office visit, moderate income enrollees pay \$15, and everyone else pays \$25. While cost-sharing subsidies are relatively straightforward to apply to job-based coverage, premium subsidies are less so, and are worth a bit more discussion. There are many possible subsidy designs that could be implemented in conjunction with an employer public option, but we envision an approach that smooths subsidy design between the employer public option and individually purchased coverage, while providing employers with a simplified method of satisfying the existing employer mandate.

Imagine the public option specified, for example, a 70% minimum required employer contribution percentage for all coverage tiers (employee-only, employee plus spouse, and family coverage).<sup>162</sup> To prevent distortion between individual and employer market subsidies, we assume the same subsidy amount and structure would be available to employer public option participants as those in the individual market. If premium subsidies continue to be based on the percentage of household income a family is required to pay for health insurance, public option administrators could gather household income information from the IRS and inform the employer of the required employee contribution amounts. That would ensure that each eligible employee's payroll deduction reflects no more than their subsidized cost of public option coverage.<sup>163</sup>

If the employer's contribution to coverage is enough that the full federal subsidies are not needed to reduce the employee's share, any excess could subsidize part of the employer's share as well, to create additional incentives for employers to extend coverage to their low-income employees. As with the current

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161 One complexity is that employers would only have data on worker income and subsidies are based on household income so, as with the ACA subsidies, the public option administrators would need to have access to tax data on household income.

162 As mentioned earlier, there may be value in allowing employers currently providing employer sponsored insurance to transition from current cost sharing arrangements to the fixed percentages assumed in the text. For simplicity, the example given above assumes uniform cost-sharing arrangements.

163 One potential downside of this approach is that a participating employer could theoretically gain information about an employee's household income by referencing the employee's required employee contribution for public option coverage. While we acknowledge that some employees may be uncomfortable with their employer gaining access to such information, we believe the benefits of advanced subsidy calculation outweigh the downsides, given how critical cash flow can be to the subsidized population. For example, if employees could only receive their premium subsidy upon filing their tax return for the year, many eligible individuals might decline to enroll in coverage because they could not afford to pay the unsubsidized price upfront.

individual market subsidies, final subsidy amounts could be reconciled when an employee files his or her tax return for the year. Finally, because the current employer mandate is based on whether the employer offers full-time employees affordable coverage, employers participating in the public option could be deemed to satisfy the employer mandate without having to engage in any complicated calculations.<sup>164</sup>

Addressing the current shortcomings of the ACA's affordability tools through an employer public option has advantages over addressing them through either an individual public option or the current employer-based system. As noted above, providing subsidies through an employer public option promotes more equitable coverage among lower and higher earning workers. Moving the subsidies into an employer public option, rather than moving employees into the ACA Marketplaces, also enables low-income workers to benefit from both employer subsidies and ACA subsidies. In effect, many would get no-cost coverage with the combination of the two. It also places less burden on low-income individuals who, if pushed into ACA Marketplaces, must learn of individual market subsidies and decide if they are better off with those subsidies and an ACA plan versus employer subsidies and an ESI plan. Harnessing the ability of employers, particularly large employers, to educate employees, facilitate enrollment, and subsidize coverage offers distinct advantages over solutions that rely on individual initiative.

It is even less plausible to address the current shortcomings through existing employer plans. Doing so would be difficult for a host of reasons, including the lack of standardization among employer plans and the need to have a sophisticated interface between employers and the government to advance premium tax credits. How would the government determine the correct level of subsidy, for example, if employer plans can differ fundamentally in their coverage terms and generosity? While income-based cost-sharing could perhaps be implemented within the current employer system, doing so would involve significant duplication of effort across thousands of plans.

To be clear, our proposed solutions do not address the universe of distortions and inequities caused by the current tax treatment of health benefits and medical expenses. While there are many, the best known and most expensive is the tax preference for employer-provided coverage, which is one of our largest tax expenditures, resulting in an estimated \$179.2 billion of forgone revenue in fiscal year 2021.<sup>165</sup> Because this subsidy takes the form of an exclusion from otherwise

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164 While deeming the employer mandate satisfied is a straightforward regulatory simplification where the employer allows all employees to elect the public option, a more nuanced approach might be warranted where only certain employee segments are able to participate.

165 JOINT COMMITTEE ON TAXATION, ESTIMATE OF FEDERAL TAX EXPENDITURES FOR FISCAL YEARS 2020-2024, at 33 (2020). By comparison, the cost of current exchange-based subsidies for health insurance is estimated to be 55.1 billion in fiscal year 2020. *Id.*

taxable income, the amount of the subsidy varies with an individual's marginal tax rate, with the result that those in the highest tax brackets receive a larger subsidy in absolute dollars (a structure commonly referred to in the tax literature as an "upside-down" subsidy), although lower income employees might receive a larger subsidy as a share of income. Although we do not propose to take on this long-standing and long-criticized tax benefit as part of our public option proposal, we note that rationalizing premium tax credits and cost-sharing subsidies between the employer and individual markets would at least help offset the upside-down nature of other tax benefits for employer-provided coverage.<sup>166</sup>

### 7. *Network and Reimbursement Rates*

A singular advantage the public option could have over existing employer plans is the ability to offer a broad, unrestricted provider network. Most hospitals and many doctors accept reimbursement from Medicare, which means that someone who has a public option based on Medicare—so long as provider participation is tied to Medicare participation—would have a broad choice of providers. Even though many employer plans have relatively broad networks, it is possible that as employers continue to work to control health care spending, more may turn to narrow networks, as the ACA individual plans have done. Even compared to the current baseline in employer plans, a shift to a public option will increase provider choice for many employees.

In the short term, however, some people may lose access to a provider who participates in their private plan but not in Medicare. Over time, if more large employers selected the public option, more and more providers would be compelled to accept it for reimbursement, but that tipping point could take time.

A major political and technocratic question is whether the public option is based on traditional, public Medicare, which has an open network, or Medicare Advantage, Medicare plans operated by private insurers that have more narrow networks. While basing a public option on Medicare Advantage would be more appealing to the insurance industry because it would guarantee them a more substantive role, and greater excuse for retaining profits, enrollees might be worse off, certainly in terms of network and in other regards as well.<sup>167</sup> Since evidence

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166 The employer public option might feasibly offer an opportunity to scale back the tax exclusion for employer-provided coverage, if desired. For example, particularly if the public option is expected to lower premiums significantly, Congress could specify that premiums for the public option are ineligible for pre-tax payment while, at the same time, adding ACA-style premium subsidies for low- and moderate-income enrollees to address affordability for the population most in need. With such a change, the public option could begin a shift away from a highly criticized tax policy. That said, the political opposition to such a move might prove insurmountable.

167 *See, e.g.,* DANIEL R. LEVINSON, INSPECTOR GEN., MEDICARE ADVANTAGE APPEAL OUTCOMES AND AUDIT FINDINGS RAISE CONCERNS ABOUT SERVICE AND PAYMENT DENIALS 7 (Sept.

has not yet suggested a strong benefit of privately administered Medicare plans after several decades of testing and because insurers can command a larger share of program budget, we think it is better policy to build the employer public option on traditional Medicare.

One of the most complicated aspects of this proposal is how to set reimbursement rates to preserve this wide provider network and in cases where adequacy can be a particular problem, like behavioral health, to grow it. Although we do not begin to solve this aspect here, we note why we think it is feasible to move to a system with reimbursement based on and closer to Medicare rates than to private insurance rates—although necessarily somewhat higher than current Medicare rates. As noted above, providers participate in large numbers in the Medicare program both because of the volume benefits and because evidence suggests that Medicare rates were, until recently, sufficient that efficient hospitals could profit based on them.<sup>168</sup> In recent years, the rates have dipped slightly below break-even, but would require very little upward adjustment to enable profitability.<sup>169</sup> Reimbursement rates could be marked up considerably over current Medicare rates to ensure adequate provider participation, while still offering cost savings as compared to current private reimbursement rates.

Over time, and as more employers adopt a public option, rates could be adjusted to ensure continued provider participation, especially by providers who are important to the large employer market. While a relatively modest transfer of employer-sponsored plan enrollment over to a public option with rates close to current Medicare reimbursement rates would not have a significant impact on hospital revenues, more substantial movements of coverage would. With such revenue decreases, plan design would have to account for what levels of decreases are manageable operationally and, perhaps more important, politically. Employer-based public option plans could have a formula for reimbursement increases over time as the market share of those plans increased. Given existing inefficiencies, margins should not be fully equalized, but finding the right level of reimbursement that will maintain provider supply and still trim overall spending will be one of the

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2018), <https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf> (“High overturn rates of appealed denials, and widespread and persistent CMS audit findings about inappropriate denials, raise concerns that some Medicare Advantage beneficiaries and providers were denied services and payments that should have been provided”); AMANDA STARC, WHO BENEFITS FROM MEDICARE ADVANTAGE? (2014), <https://repository.upenn.edu/cgi/viewcontent.cgi?article=1019&context=pennwhartonppi> (describing limited networks). The Unity Task Force has proposed an individual public option based on traditional Medicare, not Medicare Advantage, but the space between what is on the page in that proposal and what is feasible in Congress might prove formidable. Press Release, JoeBiden.com, Biden-Sanders Unity Task Force Recommendations 31 (July 2020), <https://joebiden.com/wp-content/uploads/2020/08/UNITY-TASK-FORCE-RECOMMENDATIONS.pdf>.

<sup>168</sup> Lopez et al., *supra* note 107.

<sup>169</sup> *Id.*

hardest aspects of this or any rate-based reform.

#### 8. *Designing for Portability and Integrating with Medicaid*

An employer public option could be designed to address two common challenges with job-based benefits: coverage disruptions that result from job change or job loss, and churn between employer-provided coverage and Medicaid.

Medicaid expansion, enacted by the ACA, was intended to provide universal coverage to families at or below 138% of the federal poverty level.<sup>170</sup> In those states that have elected to participate in the Medicaid expansion, the coverage is typically provided at very low or no cost to participants. Because eligibility to participate is tied to household income, many individuals churn between Medicaid eligibility and employer coverage, even within a single year, as wages and hours fluctuate. This churn is not only inefficient but has been shown to result in significant care disruptions.<sup>171</sup>

An employer public option could improve continuity of coverage for low-income workers who currently churn between Medicaid and employer-provided coverage by specifying that the public option qualifies as Medicaid expansion coverage. If a worker's projected income falls below 138% of federal poverty, the individual and the employer would cease contributing to the cost of coverage, with the Medicaid program paying the full premium for the public option instead, enabling continuity of coverage through the employer plan. One complexity would be that while most of the Medicaid funding for the expansion population is federal and thus easy to transfer to the public option, a small share is state-funded and will require a mechanism to redirect state dollars. This accounting challenge is similar to the clawback that drew state Medicaid dollars into Medicare when the initiation of Medicare Part D drug coverage alleviated state Medicaid programs of significant drug spending responsibility for people eligible for both Medicare and

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<sup>170</sup> States, however, are not obligated to participate in this Medicaid expansion, and currently fourteen states leave this population uncovered. This expanded Medicaid coverage under the ACA is almost entirely funded by the federal government with very limited out of pocket expense for beneficiaries.

<sup>171</sup> One study estimated that as many as half of adults with income below 200% of federal poverty will move between Medicaid and individual market subsidies in a given year, Benjamin D. Sommers & Sara Rosenbaum, *Issues in Health Reform: How Changes in Eligibility May Move Millions Back and Forth Between Medicaid and Insurance Exchanges*, 30 HEALTH AFFS. 228 (2011), while a more recent study found that, in states that had expanded Medicaid, 13.7% of individuals with Medicaid coverage faced a coverage disruption over the course of a year, Anna L. Goldman & Benjamin D. Sommers, *Among Low-Income Adults Enrolled in Medicaid, Churning Decreased After the Affordable Care Act*, 39 HEALTH AFFS. 85 (2020). In states that had not expanded Medicaid, 23.8% of Medicaid recipients faced disruption. Churning is obviously inefficient, but it has also been shown to result in delayed medical care, lower utilization of preventive care, fewer prescription refills, and increased emergency department visits. *Id.*

Medicaid.

As with premium tax credits and cost-sharing subsidies, addressing Medicaid churn through an employer public option provides a solution that private employer plans could not, because we could not, without further regulation, ensure that private employer plans offer the benefits and cost-sharing structures that would be appropriate for a Medicaid expansion population.

With respect to the second issue of care disruptions caused by job loss or changes, the employer public option again provides some unique solutions. The easiest scenario is for an employee who leaves one employer that has selected the public option for another that has also done so. This would be the ideal seamless transition between jobs with no change in benefits or network. What is less obvious is how to manage continuous coverage for individuals who leave a job and remain unemployed or begin work in one of the increasing number of gig-economy jobs without coverage. Ideally, an individual public option would be implemented alongside the employer public option, and they would offer identical or nearly identical coverage and networks. If that were the case, someone losing coverage through the employer public option could shift to the individual market public option, with relevant subsidies, and not face any care disruptions. The ability to move from employer coverage to nearly identical individual coverage at subsidized rates would offer a substantial improvement over the current system, which often results in dramatic shifts in coverage and providers for affected individuals, not to mention the sheer difficulty of navigating the relevant choices following a loss of job-based coverage.

### 9. *Regulatory Relief*

While employers play an important role in providing health insurance coverage to 154 million Americans,<sup>172</sup> the current system demands that employers navigate complex legal requirements and make significant financial and health policy decisions, as described above. An employer public option offers the possibility of greatly simplifying their role.

A key feature of a public option for employers should be to shift from the employer to the public option nearly all administrative tasks and legal responsibilities. To accomplish this simplified employer experience, ERISA should be amended to provide that employer participation in the public option does not create an employee benefit plan for purposes of ERISA, thereby relieving employers of all ERISA obligations with respect to public option participation. Once an employer elects to participate in the public option, its main responsibilities should be limited to facilitating employee enrollment, processing payroll

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<sup>172</sup> KAISER FAM. FOUND., *supra* note 16.

contributions, and transmitting enrollment information to the public option. The public option would be responsible for reporting and disclosure, claims administration and appeals, and pursuit of reimbursement claims.

### C. *Potential Interest in an Employer Public Option*

Large employers may have some reservations about abandoning private coverage that is generous and highly valued by employees. Small employers would in many ways be a more obvious target for public option participation, given their well-known struggles to offer quality coverage at a competitive cost.<sup>173</sup> That said, there is reason to believe that some large employers might welcome the opportunity to relinquish the burden of running a mini health care operation with escalating costs, if there were a good enough alternative.

It is difficult to predict how employers of any size are likely to react to the availability of a public option, but it seems as if interest may be brewing.<sup>174</sup> One survey found that 64% of employers would consider a simplified health plan design rather than the custom solutions created by many large firms, suggesting that a public option may appeal to those craving simplicity.<sup>175</sup> Another survey, conducted of companies mostly with one thousand or more employees, reported that 34% indicated a Medicare public option could be a helpful reform, even if a majority were resistant to Medicare for All.<sup>176</sup> In a recent survey of corporate executives by the Kaiser Family Foundation and Purchaser Business Group on Health, 87% said they believe the cost of providing private health insurance to workers will become unsustainable in the next 5-10 years.<sup>177</sup> Over 80% responded that a stronger government role in providing coverage and containing costs would

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173 See G. EDWARD MILLER & PATRICIA KEENAN, TRENDS IN HEALTH INSURANCE AT PRIVATE EMPLOYERS, 2008-2020 (2021), [https://meps.ahrq.gov/data\\_files/publications/st536/stat536.pdf](https://meps.ahrq.gov/data_files/publications/st536/stat536.pdf).

174 See, e.g., Phil Galewitz, *Why Some CEOs Figure 'Medicare for All' is Good for Business*, KAISER HEALTH NEWS (June 7, 2019), <https://khn.org/news/a-large-employer-frames-the-medicare-for-all-debate/>; Susannah Luthi, *Why Employers Are Flirting with the Public Option*, POLITICO (Feb. 8, 2020, 8:17 AM), <https://www.politico.com/news/2020/02/08/employers-health-care-public-option-112380>.

175 JEFFREY C. MCGUINNESS, AMERICAN HEALTH POLICY INSTITUTE, CHANGING ATTITUDES AMONG LARGE EMPLOYERS TOWARDS HEALTH CARE DELIVERY 9 (2017), [http://www.americanhealthpolicy.org/Content/documents/resources/Employer\\_Attitudes\\_Towards\\_HC\\_Delivery.pdf](http://www.americanhealthpolicy.org/Content/documents/resources/Employer_Attitudes_Towards_HC_Delivery.pdf).

176 *Pulse of the Purchaser: Views on Affordability and Health Reforms*, NAT'L ALL. HEALTHCARE PURCHASER COALS., <https://www.nationalalliancehealth.org/www/resources-new/pulse-of-the-purchaser> (last updated Feb. 2020).

177 GARY CLAXTON ET AL., HOW CORPORATE EXECUTIVES VIEW RISING HEALTH CARE COSTS AND THE ROLE OF GOVERNMENT 7 (Apr. 2021), <https://www.pbgh.org/wp-content/uploads/2021/04/9704-How-Corporate-Executives-View-Rising-Health-Care-Costs-and-the-Role-of-Government-v2.pdf>.

be better for their business and their employees.<sup>178</sup> Finally, recent polling by Data for Progress suggests a majority of likely voters supports an employer public option, which could influence employer receptivity.<sup>179</sup>

While these polls do not precisely measure employer receptivity to our proposal, conceptually they suggest that even large employers might be inclined to consider a public option, especially with the right policy design and incentives. Over the past several decades as health care cost growth has exceeded inflation and legal compliance costs have increased, managing a health plan has become increasingly burdensome. Many large employers have had to redesign plans several times to deal with these costs increases, shuffling cost increases onto employees in the form of larger cost sharing, which can strain relationships with employees.

As illustration of employer frustration with the status quo, some of the largest employers—Amazon, Berkshire Hathaway, and JPMorgan Chase—joined forces in early 2018 to create a new venture, Haven Healthcare, to attempt to fundamentally restructure how their collective employees get health care. They recruited Atul Gawande, a leading voice on health care innovation to run Haven.<sup>180</sup> Then, after a short period in this role, Gawande stepped back in May 2020, and the chief operating officer stepped down after nine months, suggesting some hurdles.<sup>181</sup> In January 2021, the whole enterprise folded.<sup>182</sup> Likewise, Walmart created Care Clinics for its employees that it is now rolling out to the broader public, whose impact remains to be seen.<sup>183</sup> Employers increasingly want better health care options than the status quo, and most will struggle to invent it themselves.

If only a few large employers were to move their employees into a public option, it could create a cascading effect. The top twenty largest employers in 2018, including Walmart, Amazon, UPS, Kroger, and Home Depot, alone employed on the order of ten million people.<sup>184</sup> If even just a few of them were to

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178 *Id.*

179 ETHAN WINTER & JACOB S. HACKER, DATA FOR PROGRESS, VOTERS SUPPORT A PUBLIC OPTION FOR HEALTH INSURANCE 8 (Oct. 2020), <https://filesforprogress.org/memos/a-public-option-for-health-insurance.pdf>.

180 Atul Gawande, *A Message from Our Chairman*, HAVEN HEALTH CARE, <https://havenhealthcare.com/> (last visited Dec. 23, 2020).

181 Alia Paavola, *Haven Sees Exodus of Execs: 8 Things to Know*, BECKER'S HOSP. REV. (Aug. 6, 2020), <https://www.beckershospitalreview.com/hospital-management-administration/haven-sees-exodus-of-execs-8-things-to-know.html>.

182 Sebastian Herrera & Kimberly Chin, *Amazon, Berkshire Hathaway, JPMorgan End Health-Care Venture Haven*, WALL ST. J. (Jan. 4, 2021), <https://www.wsj.com/articles/amazon-berkshire-hathaway-jpmorgan-end-health-care-venture-haven-11609784367>.

183 Elise Reuter, *Walmart Divulges Plans for 'Healthcare Supercenters'*, MEDCITYNEWS (June 28, 2020), <https://medcitynews.com/2020/06/walmart-divulges-plans-for-healthcare-supercenters/>.

184 *List of Largest United States-Based Employers Globally*,

offer public coverage for employees and their dependents, the number of enrollees would add up quickly and would generate a strong incentive for regulators to focus attention on getting programmatic details right, in partnership with the early adopters who would be able to help shape the program.

A public option program could be designed with additional incentives to encourage large businesses to be early adopters to counterbalance inertial effects. For example, as discussed in Part II, participating employers would need to contribute to financing the public option. There could be lower contribution rates for employers who opt-in during the initial years, increasing every year thereafter up to a maximum amount.

Businesses that have not selected the public option might worry that the public plan with provider reimbursement closer to Medicare rates would translate into cost shifting onto them, where providers charge higher prices to those private plans. Such practices are possible, at least in some regions where providers have outsized bargaining power and seek to recapture any lost revenue when some share of their patient population shifts to a lower-reimbursing public option.<sup>185</sup> While this might cause employer opposition initially, it might also lead to the ultimate success of an employer public option as increasing numbers of employers decide the public option offers the best mechanism for controlling costs.

The ACA likewise offers some reason to be circumspect about enthusiasm for plans to displace existing private employer coverage. As we saw with the small business health options program (SHOP) established by the ACA, rollout needs to be carefully managed to avoid early disasters, particularly of a technological nature. While SHOP held theoretical appeal—designed to offer a convenient method for small employers to shop for coverage and to offer a variety of coverage choices to employees—it fell far short in practice. Very few small employers chose to use the SHOP exchanges in the early years, with SHOP enrolling less than one percent of the small group market in its official launch in 2016.<sup>186</sup> Today, SHOP exchanges barely exist.<sup>187</sup> While many factors contributed to the general failure of

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[https://en.wikipedia.org/wiki/List\\_of\\_largest\\_United\\_States%E2%80%93based\\_employers\\_globally](https://en.wikipedia.org/wiki/List_of_largest_United_States%E2%80%93based_employers_globally) (last visited Mar. 11, 2022).

<sup>185</sup> See James Robinson, *Hospitals Respond to Medicare Payment Shortfalls by Both Shifting Costs and Cutting Them, Based on Market Concentration*, 30 HEALTH AFFS. 1265 (2011).

<sup>186</sup> U.S. GOV'T ACCOUNTABILITY OFF., GAO-19-306, *Private Health Insurance: Enrollment Remains Concentrated Among Few Issuers, Including in Exchanges* 30 (2019).

<sup>187</sup> In 2017, CMS announced that effective January 1, 2018, the federal government would no longer handle small business health options program (SHOP) functions for states that chose not to operate their own SHOP exchanges. Timothy Jost, *CMS Announces Plans to Effectively End the SHOP Exchange*, HEALTH AFFS. BLOG (May 15, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170515.060112/full/>; *SHOP Marketplace Enrollment as of January 2017*, CMS (May 15, 2017), <https://www.cms.gov/CCIIO/Resources/Data-Resources/Downloads/SHOP-Marketplace-Enrollment-Data.pdf>. As of 2021, only ten states and the District of Columbia maintain any type of SHOP platform. See Louise Norris, *Can Small Businesses*

SHOP, early technical problems and broker opposition were key elements.<sup>188</sup>

Small employers may, based in part on the failure of SHOP, have little trust in federal solutions to health care. Yet if large employers were to get on board first with successful results, small employers might follow. Small employers have more reason than large employers to want to outsource health benefits and have more explicitly voiced their preference to do so through a public option.<sup>189</sup> Perhaps the key takeaway of the SHOP experience is that any employer public option—regardless of where it is offered—must roll out smoothly and strategically to overcome inertia and other barriers.

We also know from previous health care reform efforts that the support or opposition of insurers can be critical.<sup>190</sup> Efforts to create a public option in Connecticut were defeated in part because of opposition by Cigna and Aetna, two of the state’s top employers and the state’s largest insurance companies.<sup>191</sup> Yet, if a federal public option focused on the largest employers, insurance opposition might be easier to manage. Most of the largest employers self-insure,<sup>192</sup> which reduces the role for insurance companies to that of a third-party administrator. While insurers are paid a per capita monthly fee for such administrative work, it is typically a less profitable sector than insurance, which allows the insurer to keep at least a certain percentage of “experience gains.”<sup>193</sup> That said, providing

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*Use the ACA’s Health Insurance Marketplaces (Exchanges)?*, HEALTHINSURANCE.ORG (June 1, 2021), <https://www.healthinsurance.org/faqs/ive-heard-a-lot-about-health-insurance-exchanges-but-what-are-shop-exchanges/#yeararound>.

188 LINDA J. BLUMBERG & SHANNA RIFKIN, EARLY 2014 STAKEHOLDER EXPERIENCES WITH SMALL-BUSINESS MARKETPLACES IN EIGHT STATES 3, 6 (2014), <https://www.urban.org/sites/default/files/publication/22851/413204-Early-Stakeholder-Experiences-with-Small-Business-Marketplaces-in-Eight-States.PDF>; see also RHETT BUTTLE ET AL., SMALL-BUSINESS OWNERS’ VIEWS ON HEALTH COVERAGE AND COSTS 4 (2019) (69% reporting they rely on a broker to choose a health plan); Marshall Allen, *Insurers Hand Out Cash and Gifts to Sway Brokers Who Sell Employer Health Plans*, NPR (Feb. 20, 2019, 5:01 AM), <https://www.npr.org/sections/health-shots/2019/02/20/694719998/insurers-hand-out-cash-and-gifts-to-sway-brokers-who-sell-employer-health-plans> (detailing the significant financial incentives available to brokers who help small employers select group health coverage outside of SHOP exchanges).

189 See, e.g., Press Release, Hunter Railey, Colo. Dir. for Small Bus. Majority, New Report on Public Option Opens the Door for More Healthcare Choices for Colorado Small Businesses (Nov. 15, 2019), <https://smallbusinessmajority.org/press-release/new-report-public-option-opens-door-more-healthcare-choices-colorado-small-businesses> (small business majority in Colorado voicing support for public option based on Medicare).

190 Shefali Luthra, *Insurers Sank Connecticut’s ‘Public Option.’ Would a National Version Survive?*, KAISER HEALTH NEWS (Mar. 4, 2020), <https://khn.org/news/connecticut-public-option-battle-insurers-pushback-federal-health-care-reform/>.

191 *Id.*

192 KFF Health Benefits 2020, *supra* note 17, at 161. Ninety-two percent of firms with 1000 or more workers self-insure. *Id.* at 162, Fig. 10.2.

193 While there is almost no publicly available information on the relative profitability of

administrative services for self-insured plans is a core part of most health insurers' business. Insurer opposition to an employer public option might be lessened to the extent that a public option retains an explicit role for private insurers as administrators, although it would be naïve to expect insurers to embrace an idea that would eventually erode much of their business and profits. Likewise, many providers will resist the idea since it will, by definition, mean a decrease in revenue for them.<sup>194</sup> Already opposition is brewing to efforts to replace job-based health benefits, as evinced by a July 30, 2021, letter from all Republican members of the House Energy and Commerce Committee to Health and Human Services Secretary Xavier Becerra and Labor Secretary Marty Walsh emphasizing the "critical importance of employer-sponsored health insurance."<sup>195</sup>

Some large employers, however, may support the idea and get behind it politically. Labor unions may support an employer-based public option at greater levels than Medicare for All. During the leadup to the ACA, major labor unions publicly supported the inclusion of an individual public option.<sup>196</sup> With respect to Medicare for All, some unions support it on the basis that it would allow unions to focus more intently on other bargaining issues such as wages. Other unions oppose it because they do not want to give up their bargained-for health benefits, when more generous than Medicare.<sup>197</sup>

A key advantage of a public option for employers is that it allows union plans to stay in place, consistent with President Biden's campaign promise: "If you have a generous union-backed plan and you have given up union wages to get that plan,

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insured lines of business compared to administrative-only contracts, basic economic principles would suggest that insurers could charge a risk premium for taking on the uncertainty of medical expenses in a fully insured arrangement. Some support for this position can be seen in health insurers' security filings. *See, e.g.*, CVS HEALTH CORP. ANNUAL REPORT (FORM 10-K) 31 (Feb. 18, 2020) ("Our Insured Health Care Benefits products that involve greater potential risk generally tend to be more profitable than our [administrative services contract] products").

194 It may be possible, however, to win over some providers with the administrative simplification that a widely adopted employer public option could bring. *See* Sandeep Jauhar, *The Crushing Burden of Healthcare Microregulation*, WALL ST. J. (Apr. 28, 2021) (describing physician dissatisfaction with the administrative burdens created by multiple payors).

195 Letter from Comm. on Educ. and Lab., U.S. H.R., to Xavier Becerra, Sec'y of Health and Hum. Servs. and Martin Walsh, Sec'y of Lab. (July 30, 2021), [https://republicans-edlabor.house.gov/uploadedfiles/esi\\_letter\\_-\\_final.pdf](https://republicans-edlabor.house.gov/uploadedfiles/esi_letter_-_final.pdf).

196 Helen A. Halpin & Peter Harbage, *The Origins and Demise of the Public Option*, 29 HEALTH AFFS. 1117, 1121 (2010).

197 Amanda Becker, *Democrats' Medicare for All Must Consider Union-Won Plans*: AFL-CIO, REUTERS (Aug. 29, 2019), <https://www.reuters.com/article/us-usa-election-healthcare/democrats-medicare-for-all-plans-must-consider-union-negotiated-health-plans-afl-cio-chief-idUSKCN1VJ268>; Ian Kullgren & Alice Miranda Ollstein, *Labor's Civil War Over 'Medicare for All' Threatens its 2020 Clout*, POLITICO (Feb. 18, 2020); Matt Pearce, *Candidates' Talk of 'Medicare for All' Makes Some Unions Nervous. Here's Why*, LA TIMES (Dec. 23, 2019), <https://www.latimes.com/politics/story/2019-12-23/why-some-unions-are-nervous-about-medicare-for-all>.

you can keep it.”<sup>198</sup> Indeed, if health benefits are subject to a collective bargaining agreement, they would remain unchanged under this proposal. The decision of an employer to offer the public option to union employees would be subject to future bargaining upon expiration of the current labor agreement and could easily accommodate differing union preferences in a way that Medicare for All could not. For example, transition to an employer public option could be tailored in a way to preserve bargained-for benefits as supplemental coverage, or translate them into increased wages, and unions could be given a role in deciding whether to shift to the public option at all. This flexibility may allow greater union support for an employer public option than for other reform proposals under serious consideration. A coalition of large employers and some unions in favor could go a long way politically, although, as with any major health reform, it would still be a substantial effort to overcome opposition.

### III. FISCAL IMPLICATIONS: SCORING AN EMPLOYER PUBLIC OPTION

We turn now to the fiscal implications of an employer public option. From this perspective, the employer public option has a much smaller footprint than MFA, while still catalyzing structural improvement to health care financing. We start with a short primer on the basic principles of federal budgeting for exchange transactions as opposed to direct government spending. We next show how those principles have been applied to the scoring of Medicare for All proposals as well as some of the more prominent public options. We then describe how an employer public option would likely be scored, contrasting that approach with other leading health reform plans. Finally, we conclude by examining the likelihood that an employer public option could be established through budget reconciliation.

#### A. *A Short Primer on Federal Budgeting for Exchange Transactions*

Our current system for accounting for the federal budget was established in the President’s Commission on Budget Concepts in 1967.<sup>199</sup> One of the controversial budgetary issues of the day was how the federal budget should account for the many instances in which governmental entities interacted with the general public through market-like transactions, ranging from concession stands at the Smithsonian Museum to operations at national parks where visitors paid an entrance fees, from flood insurance to land leasing programs, where members of the public chose to make payments to government entities in exchange for goods

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<sup>198</sup> Becker, *supra* note 197.

<sup>199</sup> See MICHELLE RODGERS & DAN SULLIVAN, HARV. L. SCHOOL, RECONSIDERING THE PRESIDENT’S COMMISSION ON BUDGET CONCEPTS OF 1967 (2006), [https://scholar.harvard.edu/files/briefingpapers/files/30\\_-\\_rodgers\\_sullivan\\_-\\_reconsidering\\_the\\_presidents\\_commission\\_on\\_budget\\_concepts\\_of\\_1967.pdf](https://scholar.harvard.edu/files/briefingpapers/files/30_-_rodgers_sullivan_-_reconsidering_the_presidents_commission_on_budget_concepts_of_1967.pdf).

or services. Since all involved payment to a government entity, would all of those receipts be considered comparable to federal taxes and therefore included in government revenues for purposes of budgetary aggregates or should receipts of this sort be treated differently for the purposes of the federal budget? To address these questions, the Commission's report included a chapter on "Offsetting Receipts Against Expenditures" and specified:

For purposes of summary budget totals, receipts from activities which are essentially governmental in character, involving regulation or compulsion, should be reported as receipts. But receipts associated with activities which are operated as business-type enterprises, or which are market-oriented in character, should be included as offsets to expenditures to which they relate.<sup>200</sup>

As the report explained, when dealing with "enterprise-type" government activities, net cost to the government—that is, expenditures less offsetting receipts—is the relevant measure of public support and thus inclusion in budgetary aggregates. And as long as the underlying transactions were voluntary in nature and subject to market discipline, incorporating gross revenues and receipts into budgetary aggregates would give "an exaggerated view of the Government's role in the economy."<sup>201</sup> In recognition that the overall size of the operation of government enterprises remains a topic of public interest, the Commission proposed that the appropriate approach was to include supplemental information on total revenues and expenditures in supporting budgetary documents, but to include only net expenditures into budgetary aggregates, such as total government revenues and spending.

The approach laid out in 1967 remains the practice today. In the Analytical Perspectives section of Office and Management and Budget's FY2021 budget documents, the budget office invoked the work of the President's Commission and offered a similar justification for this aspect of budgetary practice:

Most of the funds collected through offsetting collections and offsetting receipts from the public arise from business-like transactions with the public. Unlike governmental receipts, which are derived from the Government's exercise of its sovereign power, these offsetting collections and offsetting receipts arise primarily from voluntary payments from the public for goods or services provided by the Government. They are classified as

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200 See REPORT OF THE PRESIDENT'S COMMISSION ON BUDGET CONCEPTS 65 (1967), [https://budgetcounsel.files.wordpress.com/2016/10/report\\_of\\_the\\_presidents\\_commission\\_on\\_budget\\_concepts.pdf](https://budgetcounsel.files.wordpress.com/2016/10/report_of_the_presidents_commission_on_budget_concepts.pdf).

201 *Id.* at 64.

offsets to outlays for the cost of producing the goods or services for sale, rather than as governmental receipts. These activities include the sale of postage stamps, land, timber, and electricity; charging fees for services provided to the public (e.g., admission to National parks); *and collecting premiums for healthcare benefits (e.g., Medicare Parts B and D)*. As described above, treating offsetting collections and offsetting receipts as offsets to outlays ensures the budgetary totals represent governmental rather than market activity.<sup>202</sup>

As this excerpt helpfully notes, premiums for Medicare programs are one enumerated example of offsets in the current federal budget, as are comparable charges for federal flood insurance and a host of other market-based transactions with government entities.<sup>203</sup> Although these premiums reflect private payments to government entities, they are not counted as government revenues or taxes in budgetary aggregates.<sup>204</sup> This approach accurately makes these programs look less expensive as a fiscal matter: were the CBO to score a public option for employers for purposes of estimating its impact on the federal deficit or spending aggregates, employer contributions and the costs they cover would not be included, making legislative passage far more likely.

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202 Off. of Mgmt. & Budget, *Chapter 0: Offsetting Collections and Offsetting Receipts*, in ANALYTICAL PERSPECTIVES 97 (2021), [http://www.whitehouse.gov/wp-content/uploads/2021/05/ap\\_9\\_offsetting\\_fy22.pdf](http://www.whitehouse.gov/wp-content/uploads/2021/05/ap_9_offsetting_fy22.pdf) (emphasis added).

203 Reliance on voluntarily paid premiums to cover a good portion of for what become Medicare Part B along with its budgetary implications was a crucial step in the passage of the original Medicare legislation back in 1965. See THEODORE R. MARMOR, *THE POLITICS OF MEDICARE 2* (1973); Julian E. Zelizer, *How Medicare Was Made*, NEW YORKER (Feb. 15, 2015), <https://www.newyorker.com/news/news-desk/medicare-made>. See generally Eric M. Patashnik & Julian E. Zelizer, *Paying for Medicare: Benefits, Budgets, and Wilbur Mills's Policy Legacy*, 26 J. HEALTH POL., POL'Y & L. 7 (2001) (chronicling the political compromises that led the funding mechanisms included in the original Medicare legislation).

204 One additional refinement with respect to offsetting payments is their relationship to the law of appropriations. Here, there are two basic approaches: offsetting collections and offsetting receipts, and the distinction is important in terms of whether the payment generates “budget authority” on the part of the receiving entity. The former produces additional budget authority and thus funds received as offsetting collections is available for expenditure without further legislative action. As the Government Accountability Office has explained, “Generally, offsetting collections are collections resulting from business-type or market-oriented activities, such as the sale of goods or services to the public . . .” See U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-464SP, PRINCIPLES OF FEDERAL APPROPRIATIONS LAW 2-6 (4th ed. 2016). While the classification of offsets as either collections or receipts is a matter that would ordinarily be specified in enabling legislation, the more common practice for insurance premiums would be to denominate such payments as offsetting collections and would thereby produce new budget authority to finance expenditures.

*B. An Overview of Scoring Estimates for Leading Reform Proposals*

Public debates over the cost of leading reform ideas illustrate how these scoring conventions play out in practice and were detrimental to MFA proposals. Table One below reproduces a chart from a Committee for Responsible Federal Budget publication comparing the costs of health care plans for candidates in the Democratic presidential primaries of 2020.<sup>205</sup> The table focuses on the central estimates for four different plans from the 2019-2020 primaries: then-Vice President Biden’s and then-Mayor Pete Buttigieg’s public option plans and two MFA plans, Senator Sanders’ and Senator Warren’s. The chart breaks down effects into four components: increased federal costs for expanded and improved coverage, assumed savings from programmatic changes, direct offsets (from tax feedback effects and direct taxes), and indirect offsets from tax and spending adjustments in other areas. It presents the ten-year fiscal impacts of the four proposals.

Central Estimates of the Ten-Year Fiscal Impact of Candidates' Health Proposals				
Proposals	Biden	Buttigieg	Sanders	Warren
Health Care Coverage Expansion	-\$1.7 trillion	-\$1.6 trillion	-\$29.0 trillion	-\$29.0 trillion
Long-Term Care Coverage Expansion	-\$0.35 trillion	-\$0.5 trillion	-\$4.5 trillion	-\$4.5 trillion
Maintenance of Effort Payments	N/A	N/A	\$3.1 trillion	\$3.1 trillion
Other Spending Increases	-\$0.2 trillion	-\$0.75 trillion	-\$0.2 trillion	-\$1.35 trillion
<b>Subtotal</b>	<b>-\$2.25 trillion</b>	<b>-\$2.85 trillion</b>	<b>-\$30.6 trillion</b>	<b>-\$31.75 trillion</b>
Prescription Drug Savings	\$0.4 trillion	\$0.75 trillion	\$1.7 trillion	\$1.7 trillion
Other Health Savings	\$0.05 trillion	\$0.45 trillion	N/A	\$2.5 trillion
Cap Health Cost Growth	N/A	N/A	N/A	\$0.5 trillion
<b>Subtotal</b>	<b>\$0.45 trillion</b>	<b>\$1.2 trillion</b>	<b>\$1.7 trillion</b>	<b>\$4.7 trillion</b>
Tax Feedback/Other Health Revenue	\$0.35 trillion	\$0.4 trillion	\$3.0 trillion	\$1.5 trillion
Employer Contributions/Taxes	N/A	N/A	\$5.2 trillion	\$12.7 trillion
Worker Contributions/Taxes	N/A	N/A	\$4.0 trillion	N/A
<b>Subtotal</b>	<b>\$0.35 trillion</b>	<b>\$0.4 trillion</b>	<b>\$12.2 trillion</b>	<b>\$14.2 trillion</b>
Individual Income Tax Increases	\$0.1 trillion	N/A	\$1.1 trillion	N/A
Capital and Wealth Tax Increases	\$0.55 trillion	N/A	\$1.55 trillion	\$1.5 trillion
Business Tax Increase	N/A	\$1.7 trillion	\$1.2 trillion	\$2.75 trillion
Other Taxes and Spending Cuts	N/A	N/A	N/A	\$2.5 trillion
<b>Subtotal</b>	<b>\$0.65 trillion</b>	<b>\$1.7 trillion</b>	<b>\$3.75 trillion</b>	<b>\$6.75 trillion</b>
<b>Net Fiscal Impact</b>	<b>-\$800 billion</b>	<b>\$450 billion</b>	<b>-\$12.95 trillion</b>	<b>-\$6.1 trillion</b>

*Negative numbers add to the debt. Estimates rounded to nearest \$100 billion for larger policies and \$50 billion for smaller policies.*

Table One: Central Estimates of the Ten-Year Fiscal Impact of Candidates’ Health Proposals

205 COMM. FOR A RESPONSIBLE FED. BUDGET, PRIMARY CARE: ESTIMATING DEMOCRATIC CANDIDATES’ HEALTH PLANS 2 (Feb. 26, 2020), <https://www.crfb.org/papers/primary-care-estimating-democratic-candidates-health-plans>.

Table One illustrates the different fiscal presentations of the two different kinds of health care reform. Due to their mandatory nature, the Sanders and Warren proposals reflect substantial new revenues in the form of employer and worker contributions along with substantial additional tax increases, generating between \$15 and over \$20 trillion in new revenues over the ten-year window (but still adding substantially to the federal deficit). The Biden and Buttigieg plans had a much smaller fiscal footprint, and not just because they are less ambitious programs. The scoring for neither of these proposals includes the amount of premium payments that individuals would pay toward premiums for the public option, consistent with the treatment described above of offsetting collections in market-based transactions with government entities. To be sure, both the Biden and Buttigieg plans entailed additional federal expenditures to expand coverage (reflecting subsidies and tax credits), but they do not reflect the entire cost of health care coverage for individuals who choose to participate in the public option on a voluntary basis. While these differences may sound technical in nature, the very large amount of new taxes required to finance the Sanders and Warren MFA proposals proved to be a significant impediment in public debates over the course of the Democratic primaries and are likely to continue to act as serious impediments to passage of such proposals.

### *C. Designing an Employer Public Option with Budget Scoring in Mind*

So with this background in mind, how should an employer public option be designed to capture current employer and employee contributions as offsets to expenditures and to more accurately reflect the net costs to the federal government? First and foremost, the public option program should be voluntary in nature and designed to compete with private employer plans, as discussed above. Contributions should be made directly to the public option plan, from both employers and employees, as is currently the case with private health insurance plans. Structuring these payments as voluntary premiums instead of as new taxes on employers who opt into the public option and on their employees is critical. For budgetary purposes, taxes would be mandatory and considered government revenues rather than offsetting collections and therefore included into budgetary aggregates.<sup>206</sup>

The precise budgetary impact of an employer public option will depend on numerous design choices discussed in detail in Part II: reimbursement rates for

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<sup>206</sup> Several public option proposals that envision mandatory employer payments to cover employees who opt out of employer ESI and into a public option offered through an ACA exchange would also run the risk of being denominated government revenues as opposed to offsetting collections.

medical care, the quality of the benefits provided as well as out-of-pocket charges, and the amount and design of any subsidies.<sup>207</sup> The amount of out-of-pocket spending would also have a fiscal impact since higher levels will reduce total premium costs.<sup>208</sup>

It is beyond the scope of this Article to offer a complete assessment of the budgetary impact of the system of subsidies outlined in Part II. Clearly there would be a direct budgetary impact as the federal government would be expanding the scope of ACA subsidies beyond policies purchased on Exchanges. In addition, the availability of these subsidies as well as the integration of Medicaid coverage into employer-sponsored plans would reduce the costs of employer-provided insurance (especially for lower income workers), but it would also increase the level of tax expenditures for employer-sponsored health insurance as more low-income workers are covered by it.<sup>209</sup> Finally, in calculating the overall cost of the program, CBO scorekeepers would need to assess the extent to which Medicaid costs for lower-income workers would be offset by reductions in ACA-style subsidies otherwise directed to public option coverage. So the details of producing a complete score for our proposal would be complicated, but the key point is that the overall impact of the proposal on budgetary aggregates—both total revenues and total spending—would be significantly lower than a mandatory program affecting a similar number of individuals, because voluntary paid premiums for both employers and employees would offset outlays for health care for covered employees and their families.

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207 Another potentially important consideration is the extent to which a public option for employers might have an impact on the number of Medicare-eligible employees who choose to stay on their employer-sponsored plans. Movement of significant numbers of elderly away from Medicare could reduce revenues for that program, but replacing it with, most likely, greater revenues for the public option, as combined employer and employee contributions to the public option would likely be greater than Medicare premiums. But the effects would need to be considered in a comprehensive scoring exercise. Another wrinkle is that some Medicare-eligible workers now choose to stay on employer plans rather than opt into Medicare. If their employer plan became a Medicare-based public option, and if the cost of Medicare were less to them than the public option, more people might opt for Medicare, causing quicker depletion of the Trust Fund.

208 To the extent that public option plans retain some degree of out-of-pocket expense for workers and dependents, flexible spending accounts offered under an employer's cafeteria plan could continue to be used to allow for the payment of these out-of-pocket expenses with pre-tax dollars. A separate question might arise if employees participating in an employer-based public option were to purchase Medigap-style supplement plans. The need for such plans would depend on the features of the public option. Medigap premiums cannot generally be paid with pretax dollars. You can deduct them, but only to the extent they, along with any other medical expenses, exceed 10% of annual income. *See* I.R.C. § 213.

209 Furthermore, the approach we describe would likely expand the number of individuals receiving Medicaid benefits (albeit primarily those already eligible for those benefits but currently lacking the wherewithal to claim their entitlements).

#### *D. Using Reconciliation to Enact an Employer Public Option*

While this Article is primarily focused on sketching out a new approach to health care reform, questions understandably may arise in some readers' minds as to the political viability of our proposal, especially given the closely divided composition of the current U.S. Senate. That concern necessarily poses the question whether legislation implementing a public option for employers—or even a simple public option for individuals—could be structured to comply with budget reconciliation procedures and hence avoid the Senate's current filibuster requirements. In truth, a definitive answer to this question would ultimately come from the Senate Parliamentarian, but we believe a public option for employers could be structured to be eligible for inclusion in a reconciliation bill.

The chief impediment to inclusion of legislation in reconciliation bills is the Byrd Rule.<sup>210</sup> A number of the Byrd Rule's limitations are inapplicable, such as the prohibition on changes in social security, or relatively easy to meet through advanced planning, such as the requirement that the legislation not fall outside of the jurisdiction of the submitting committee or does not match the specifications of the authorizing budget resolution. In addition, the budgetary effects of the public option would need to be anticipated in the budget resolution issuing reconciliation instructions. There are, however, several elements of the Byrd Rule that could present challenges.

First is the Byrd Rule's prohibition on provisions in a reconciliation bill that do not “produce a change in outlays or revenue, including changes in outlays and revenues brought about by changes in the terms and conditions under which outlays are made or revenues are required to be collected.”<sup>211</sup> To meet this requirement, the public option for employers would need to be crafted, in the first instance, as an expansion of the traditional Medicare program to cover a new group of participants on terms that would be competitive in the employer sponsored market. A provision of this sort would clearly increase federal outlays. As a second step, the legislation could authorize the Centers for Medicare and Medicaid Services (or some other governmental entity) to establish a premium schedule for employer and employee contributions to cover the costs of the public option. As discussed elsewhere, these fees would not be denominated revenues in budgetary aggregates, but they would reduce federal outlays as they would offset the costs of the programs. Again, this approach would seem to meet the Byrd Rule's requirements of directly affecting (that is, decreasing) federal spending. Finally, to

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210 See CONG. RSCH. SERV., RL30862, THE BUDGET RECONCILIATION PROCESS: THE SENATE'S “BYRD RULE” (2021) (including a short history of the Byrd Rule and its applications over the years).

211 Congressional Budget Act of 1974 § 313(b)(1)(A), 2 U.S.C. § 644 (adopted in substantially its current form in the Budget Enforcement Act of 1990, Pub. L. No. 101-595, § 13214, 104 Stat. 1388-621, 1388-621 to -622 (Nov. 5, 1990)).

the extent that ACA subsidies or some variant thereon were included in a public option, that expansion would also seem to fall squarely within the permissible limits of reconciliation bills as it directly increases in federal spending in the same manner as the creation of a new tax expenditures.

To be sure, drafters would need to be careful not to include in any reconciliation bill additional provisions with budgetary effects that are “merely incidental to non-budgetary components.”<sup>212</sup> For this reason, there could be advantages of hewing as closely as possible to the existing Medicare program with delegated rulemaking authority to CMS to adopt programmatic adjustments, along the lines discussed elsewhere in this article, in order to make the public option a viable alternative to employer sponsored health insurance. Many reconciliation bills in the past—including both the Affordable Care Act and Trump era tax reform legislation—have included such delegated authority and the purpose of such delegation would be to fix “the terms and conditions under which outlays are made,” that would seem to protect them from challenges that they were merely incidental to budgetary effects. In a similar vein, CMS should also be authorized to determine the extent to which employers adopting a public option would be relieved of regulatory burdens under other federal provisions, such as ERISA. This authorization should again be justified under the Byrd Rule on the grounds that it determines the terms and conditions under which outlays are made, as the terms of the public option for employers would be different (and quite likely infeasible) were the programs subject to conflicting federal statutory requirements.

A final issue under the Byrd Rule would be whether the employer public option increased the projected federal deficit beyond the current budget window, presumably but not necessarily ten years, which would need to be addressed in order to survive points of order in the Senate.<sup>213</sup> The application of this requirement would ultimately turn on scoring decisions by the Congressional Budget Office. While it is conceivable that labor market effects of this public option would increase employment growth and tax revenues beyond ten years and have other positive budgetary effects related to increase competition in the private sector, one should probably assume that over the ten-year window, the public option would increase the projected deficit, particularly if ACA style subsidies were included. To address these issues, proponents could explore pay-for options that would be expected to offset outlays in the outyears, either related to health care reform or in other areas, including tax increases. An alternative response would be to include a sunset provision—as has often been done with tax legislation passed through

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212 § 313(b)(1)(D).

213 Here the relevant subsection of the Byrd Rule reads: “a provision shall be considered to be extraneous if it increases, or would increase, net outlays, or if it decreases, or would decrease, revenues during a fiscal year after the fiscal years covered by such reconciliation bill or reconciliation resolution.” § 313(b)(1)(E).

reconciliation—in the final year of the budget window. While arguably diminishing the attractiveness of the program for employers contemplating adoption, a sunset in this case might be justified to the extent the public option for employers is seen as an experimental measure, which over the coming decade will either prove itself to be a productive step forward or not.

## CONCLUSION

Our system of job-based coverage leads to variability in access to medical care among workers and inefficiently asks each employer also to be a health benefits company and manage the impossible task of escalating health care prices. It no longer makes sense to preserve this system, and this Article offers a smooth transition to something better for workers and companies.

We have proposed a novel employer public option that could ameliorate problems facing employer-sponsored health insurance and build a foundation for a more efficient and equitable health care financing system. Health financing reform is for good reason a highly contested issue. It is no exaggeration to say it is life or death, since it shapes who can afford life-improving and sustaining access to medical care. Simultaneously, it is also a big dollar concern for many invested parties, who may or may not want changes to the status quo. These concerns demand cautious and slow adjustments. Yet, moving responsibly should not preclude making fundamental changes when needed.

We think an employer public option offers a responsible and politically plausible means to begin to make necessary fundamental changes in job-based health coverage. In contrast, Medicare for All moves all Americans onto a publicly financed system but, while effective in addressing many of the shortcomings of the U.S. system, does so in a highly disruptive way that cements political opposition. On the other hand, the more politically palatable individual public option may help improve coverage at the margins, but such an approach has limited ability to improve the health care financing system. Our proposal attempts to find a middle ground, by allowing employers to lead the movement toward public coverage to the extent they find doing so to be in their interests and their employees' interests. This voluntary mechanism could lessen political opposition to change and also improve budget scoring and fiscal impact. Most importantly, an employer public option offers a means to address inequities in coverage among today's workers and serve as a genuine test of the viability of a broader system of public coverage in the future.

# **COVID-19 and International Freedom of Movement: A Stranded Human Right?**

**Fernando Dias Simões\***

Abstract:

Despite the lack of evidence that travel restrictions are effective, governments confronted with an infectious disease outbreak, especially one involving a poorly understood pathogen, often seek to restrict movement—both internally and across their borders. In response to COVID-19, most countries imposed a ban on foreign travelers, with some States even closing borders to their own nationals and residents or prohibiting them from leaving. While border control is a legitimate prerogative that States can use to assess the health condition of travelers, broader travel restrictions are more complex and raise intricate legal questions. This Article focuses on a specific category of travel restrictions: travel bans. Such measures are blanket prohibitions against crossing international borders applied to all or particular individuals, regardless of their health status. The lawfulness of travel bans depends on several elements. First, one needs to examine the applicable legal framework: the International Health Regulations and human rights treaties. Determining whether travel bans are lawful also depends on a second element: the status of travelers, namely, whether they qualify as nationals, residents, or something else. While all people have the right to leave any country and return to their country, there is no human right to enter a foreign state. After reviewing the legal framework and (available) information on travel bans implemented in response to COVID-19, this Article questions whether the pertinent requirements were respected and examines a few of the more clear-cut cases where travel bans breached the rules and principles that should govern international mobility.

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## INTRODUCTION

The outbreak of the virus, now known as COVID-19, was reported by Chinese authorities to the World Health Organization (WHO) on the last day of 2019.<sup>1</sup> Based on the information available at the time, WHO advised “against the application of any travel or trade restrictions on China.”<sup>2</sup> On January 30, 2020, the organization declared the novel coronavirus a “Public Health Emergency of International Concern” (PHEIC).<sup>3</sup> The Emergency Committee stated that it did “not recommend any travel or trade restriction based on the current information available.”<sup>4</sup> Tedros Ghebreyesus, WHO’s Director-General, reiterated: “[T]here is no reason for measures that unnecessarily interfere with international travel and trade. WHO doesn’t recommend limiting trade and movement.”<sup>5</sup> These recommendations were in line with the purpose and scope of the 2005 International Health Regulations (IHR)<sup>6</sup> and the nature of temporary recommendations.<sup>7</sup>

Historically, governments confronted with a pandemic have engaged in a “knee-jerk” reaction of imposing travel restrictions.<sup>8</sup> Such reactions were taken to

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1 *COVID-19—China*, WORLD HEALTH ORG. (Jan. 5, 2020), <https://www.who.int/emergencies/disease-outbreak-news/item/2020-DON229>.

2 *Id.*

3 *Statement on the Second Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Novel Coronavirus (2019-nCoV)*, WORLD HEALTH ORG. (Jan. 30, 2020), [https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-\(2019-ncov\)](https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)) [hereinafter *Statement on the Second Meeting of the International Health Regulations (2005)*]. A PHEIC is “an extraordinary event which is determined . . . (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.” International Health Regulations, WORLD HEALTH ORG. art. 1(1) (2005) [hereinafter IHR]; see also *id.* at art. 12 (determination of a PHEIC).

4 *Statement on the Second Meeting of the International Health Regulations (2005)*, *supra* note 3.

5 *WHO Director-General’s Statement on IHR Emergency Committee on Novel Coronavirus (2019-nCoV)*, WORLD HEALTH ORG. (Jan. 30, 2020), [https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ih-er-emergency-committee-on-novel-coronavirus-\(2019-ncov\)](https://www.who.int/dg/speeches/detail/who-director-general-s-statement-on-ih-er-emergency-committee-on-novel-coronavirus-(2019-ncov)).

6 IHR, *supra* note 3, at art. 2 (“[T]o prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.”).

7 *Id.* at art. 1(1) (“[N]on-binding advice issued by WHO under Article 15 for application on a time-limited, risk-specific basis, in response to a public health emergency of international concern, to prevent or reduce the international spread of disease and minimize interference with international traffic.”).

8 Lawrence O. Gostin, *Pandemic Influenza: Public Health Preparedness for the Next Global Health Emergency*, 32 J. L. MED. & ETHICS 565, 569 (2004); D. Hagen, *Case Study 1: Port Health and International Health Regulations*, in INTRODUCTION TO PANDEMIC INFLUENZA 194 (Jonathan Van-Tam & Chloe Sellwood eds., 2009). Michael Kenwick & Beth Simmons, *Pandemic Response as Border Politics*, 74 Int’l Org. E36, E37 (2020) (“Hardening international borders in the face of perceived health threats is historically states’ first (and sometimes only) move.”).

unprecedented levels in response to COVID-19. According to WHO, 194 countries adopted some form of travel restriction, with 143 closing their borders.<sup>9</sup> In April 2020, around 90% of the world population lived in countries with restrictions on non-citizens and non-residents, and roughly 39% lived in countries with borders closed to everyone.<sup>10</sup> Many countries prohibited the entry of citizens or recent travelers from the most affected areas.<sup>11</sup> Others went farther and imposed an absolute ban on incoming travelers, including their own citizens,<sup>12</sup> or prohibited them from leaving.<sup>13</sup> As conditions improved, some countries gradually lifted or

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9 WHO, *Weekly Update on COVID-19, 8-15 April 2020*, WORLD HEALTH ORG. 5 (May 7, 2020), <https://www.who.int/publications/m/item/weekly-update-on-covid-19---15-april-2020>.

10 Phillip Connor, *More than Nine-in-Ten People Worldwide Live in Countries with Travel Restrictions amid COVID-19*, PEW RSCH. CTR. (Apr. 1, 2020), <https://www.pewresearch.org/fact-tank/2020/04/01/more-than-nine-in-ten-people-worldwide-live-in-countries-with-travel-restrictions-amid-covid-19>.

11 For a useful roadmap of the maze of travel restrictions implemented worldwide, see COVID-19 TRAVEL RESTRICTIONS DATABASE, <https://restrictions.info>.

12 See, e.g., *Ecuador Closes Borders to Foreign Travelers due to Coronavirus*, REUTERS (Mar. 15, 2020) <https://www.reuters.com/article/health-coronavirus-ecuador-idUSL8N2B70XK> (Ecuador, giving residents and nationals two days to return); U.S. Embassy in Trinidad & Tobago, *Closure of Trinidad and Tobago Borders Midnight March 22, 2020*, U.S. EMBASSY (Mar. 21, 2020), <https://tt.usembassy.gov/health-alert-u-s-embassy-port-of-spain-trinidad-and-tobago-march-21-2020> (Trinidad and Tobago); *Buhari Directs Closure of Air, Land Borders for 4 Weeks*, VANGUARD (Mar. 26, 2020), <https://www.vanguardngr.com/2020/03/breaking-buhari-directs-closure-of-air-land-borders-for-4-weeks> (Nigeria); *Belize is Now on War Footing; PM Barrow Announces Closure of Borders to Nationals*, BREAKING BELIZE NEWS (Apr. 3, 2020), <https://www.breakingbelize.com/news/2020/04/03/belize-is-now-on-war-footing-pm-barrow-announces-closure-of-borders-to-national> (Belize); Adriaan Alsema, *Colombia Closes Land and Sea Borders after Restricting Air Travel*, COLOM. REPS. (Mar. 16, 2020), <https://colombiareports.com/colombia-closes-land-and-sea-borders-after-restricting-air-travel> (Colombia, allowing only restricted air travel); *Suriname: Vice President Announces Nationwide Entry and Exit Ban March 13*, GARDAWORLD (Mar. 14, 2020), <https://www.garda.com/crisis24/news-alerts/322751/suriname-vice-president-announces-nationwide-entry-and-exit-ban-march-13-update-1> (Suriname); *Morocco to Start Reopening Borders After Strict Lockdown*, ASSOCIATED PRESS (July 9, 2020), <https://www.voanews.com/covid-19-pandemic/morocco-start-reopening-borders-after-strict-lockdown> (Morocco); Angela Burns, *British Virgin Islands Closes Borders to All Travelers Effective Midnight*, VIRGIN IS. CONSORTIUM (Mar. 22, 2020), <https://viconsortium.com/vi-coronavirus/virgin-islands-british-virgin-islands-closes-borders-to-all-travelers-effective-midnight> (British Virgin Islands); *COVID-19: Gambia, Senegal to Close Border for 21 Days*, ANADOLU AGENCY (Mar. 23, 2020), <https://www.aa.com.tr/en/africa/covid-19-gambia-senegal-to-close-border-for-21-days/1776298> (Gambia and Senegal).

13 In addition to Colombia, Suriname, Morocco, Gambia, and the British Virgin Islands, see *supra* note 12, additional countries or territories imposed an exit ban. See Hazlin Hassan, *Malaysia Bans Travel Abroad, Shuts Schools and Businesses over Coronavirus Spread; Lockdown till March 31*, STRAITS TIMES (Mar. 17, 2020), <https://www.straitstimes.com/asia/se-asia/malaysia-to-impose-lockdown-from-wednesday-to-march-31> (Malaysia); BBC News, *Covid: Australia to end ban on citizens leaving country*, BBC NEWS (Oct. 27, 2021), <https://www.bbc.com/news/world-australia-59058945> (Australia); *Kazakhstan, Uzbekistan Close Borders after First Coronavirus Cases*, REUTERS (Mar. 15, 2020), <https://www.reuters.com/article/us-health-coronavirus-kazakhstan-emergen-idUSKBN2120EX> (Uzbekistan and Kazakhstan); *Dominican Republic Closing Borders for*

alleviated restrictions.<sup>14</sup>

Travel contributes significantly to the propagation of infectious diseases,<sup>15</sup> especially air travel.<sup>16</sup> However, contrary to common perception, scientific studies have consistently demonstrated that travel restrictions have not been effective in significantly preventing the spread of infectious diseases, at most delaying the peak of past pandemics by a few days to weeks.<sup>17</sup> By merely delaying the initial spread of the disease, such measures fail to considerably reduce transmissions if not combined with infection prevention and control measures.<sup>18</sup> In addition, travel restrictions may create significant harm as they have disastrous economic effects, particularly for developing countries;<sup>19</sup> hamper the flow of medical supplies and

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15 *Days in Coronavirus Measure*, CARIBBEAN J. (Mar. 2, 2020), <https://www.caribjournal.com/2020/03/18/dominican-republic-closing-borders-15-days> (Dominican Republic); Rasidah Bakar, *No Plans to Reopen Brunei Borders in August*, SCOOP (July 18, 2020), <https://thescoop.co/2020/07/18/no-plans-to-reopen-brunei-borders-in-august> (Brunei); Giff Johnson, *FSM, Marshall Islands Step up Coronavirus Travel Bans*, RADIO N.Z. (Feb. 3, 2020), <https://www.rnz.co.nz/international/pacific-news/408617/fsm-marshall-islands-step-up-coronavirus-travel-bans> (Federated States of Micronesia).

14 See, e.g., Lauren Egan & Monica Alba, *Biden Administration to Lift Travel Restrictions on 8 African Nations*, CNBC (Dec. 24, 2021), <https://www.cnn.com/2021/12/24/biden-administration-to-lift-travel-restrictions-on-8-african-nations.html>; *Singapore Lifts Travel Ban for 10 African Countries*, CHANNEL NEWS ASIA (Dec. 27, 2021), <https://www.channelnewsasia.com/singapore/covid-19-omicron-singapore-lift-travel-ban-10-africa-countries-2402061>; Ido Efrati & Shira Kadari-Ovadia, *Israel Lifts All COVID Travel Bans Made Irrelevant by Omicron, Eases School Restrictions*, HAARETZ (Jan. 6, 2022), <https://www.haaretz.com/israel-news/israel-to-lift-covid-travel-restrictions-on-all-countries-from-midnight-1.10519925>.

15 Mary Wilson, *Travel and the Emergence of Infectious Diseases*, 1 EMERGING INFECTIOUS DISEASES 39 (1995); Douglas MacPherson & Brian Gushulak, *Human Mobility and Population Health: New Approaches in a Globalizing World*, 44 PERSPS. BIOLOGY & MED. 390 (2001).

16 Rebecca Grais, Hugh Ellis & Gregory Glass, *Assessing the Impact of Airline Travel on the Geographic Spread of Pandemic Influenza*, 18 EUR. J. EPIDEMIOLOGY 1065 (2003); Aidan Findlater & Isaac Bogoch, *Human Mobility and the Global Spread of Infectious Diseases: A Focus on Air Travel*, 34 TRENDS PARASITOLOGY 772 (2018).

17 Joshua Epstein et al., *Controlling Pandemic Flu: The Value of International Air Travel Restrictions*, 5 PLoS ONE 1 (2007); Paolo Bajardi et al., *Human Mobility Networks, Travel Restrictions, and the Global Spread of 2009 H1N1 Pandemic* 6 PLoS ONE e16591 (2011); Ana Mateus et al., *Effectiveness of Travel Restrictions in the Rapid Containment of Human Influenza: A Systematic Review* 92 BULL. WORLD HEALTH ORG. 868 (2014); Nicole Errett, Lauren Sauer & Lainie Rutkow, *An Integrative Review of the Limited Evidence on International Travel Bans as an Emerging Infectious Disease Disaster Control Measure*, 18 J. EMERGENCY MGMT. 7 (2020); Asami Anzai et al., *Assessing the Impact of Reduced Travel on Exportation Dynamics of Novel Coronavirus Infection (COVID-19)* 9(2) J. CLINICAL MED. 601 (2020).

18 Matteo Chinazzi et al., *The Effect of Travel Restrictions on the Spread of the 2019 Novel Coronavirus (COVID-19) Outbreak* 368 SCIENCE 395 (2020).

19 See ECONOMICS IN THE TIME OF COVID-19 (Richard Baldwin & Beatrice di Mauro eds., 2020).

health workers;<sup>20</sup> infringe upon the rights of migrants and refugees;<sup>21</sup> and deprive countries of migrant workers.<sup>22</sup>

A sharp reduction in international mobility is expected, given that individuals voluntarily refrain from traveling during an epidemic.<sup>23</sup> However, travel restrictions also send a powerful signal to businesses, namely airlines, who react by canceling flights, thus imposing de facto travel restrictions that compound the problem. The IHR, however, only apply to States Parties and do not impose any standards of behavior on private actors.<sup>24</sup>

Travel restrictions were particularly cruel for migrants. Many were dismissed from their jobs and became unable to support themselves or return “home.”<sup>25</sup> Several countries chartered flights to bring them back.<sup>26</sup> Most flights were reserved for nationals, revealing a nationality-based approach to public health. As demonstrated earlier, these “rescue missions” ironically might have resulted in the importation of the virus if not coupled with proper control measures.<sup>27</sup> Those without a golden ticket had to scramble for a seat in the remaining regular flights, often to no avail. The “global village,” normally within the reach of a few flights, turned into an archipelago of inaccessible islands.

Like other epidemics or pandemics, COVID-19 is a threat to both human

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20 Jennifer Nuzzo et al., *Travel Bans Will Increase the Damage Wrought by Ebola*, 12 BIOSECURITY & BIOTERRORISM: BIODEFENSE STRATEGY, PRAC. & SCI. 306 (2014); Chiara Poletto et al., *Assessing the Impact of Travel Restrictions on International Spread of the 2014 West African Ebola Epidemic*, 19 EUROSURVEILLANCE 1, 2 (2014).

21 Deisy Ventura, *The Impact of International Health Crises on the Rights of Migrants*, 23 INT'L J. ON HUM. RTS. 61 (2016); Elise Mercier & Sean Rehaag, *The Right to Seek Asylum in Canada (During a Global Pandemic)*, 57 OSGOODE HALL L.J. 705 (2020).

22 Julia Gelatt, *Immigrant Workers: Vital to the U.S. COVID-19 Response, Disproportionately Vulnerable*, MIGRATION POL'Y INST. (Mar. 2020), [https://www.immigrationresearch.org/system/files/COVID-19-EssentialWorkers-FS\\_Final.pdf](https://www.immigrationresearch.org/system/files/COVID-19-EssentialWorkers-FS_Final.pdf).

23 Hagen, *supra* note 8, at 194; Timothy Russell et al., *Effect of Internationally Imported Cases on Internal Spread of COVID-19: A Mathematical Modelling Study*, 6 LANCET PUB. HEALTH e12, e15 (2021) (“International travel has decreased greatly since the COVID-19 pandemic began because of travel restrictions, but also owing to individual self-exclusion due to fear of infection and reduced business and tourism opportunities.”).

24 Lawrence Gostin, Mary DeBartolo & Eric Friedman, *The International Health Regulations 10 Years on: The Governing Framework for Global Health Security*, 386 LANCET 2222, 2225 (2015).

25 See Lorenzo Guadagno, *Migrants and the COVID-19 Pandemic: An Initial Analysis*, INT'L ORG. FOR MIGRATION 1, 9-10 (2020), <https://publications.iom.int/books/mrs-no-60-migrants-and-covid-19-pandemic-initial-analysis>; *From the Field: COVID-19 Restrictions Leave Migrant Workers Stranded*, UNITED NATIONS (June 13, 2020), <https://news.un.org/en/story/2020/06/1066092>.

26 See, e.g., *Overview of Repatriation Flights*, EUR. COMM'N (Dec. 7, 2020), [https://ec.europa.eu/info/files/overview-repatriation-flights\\_en](https://ec.europa.eu/info/files/overview-repatriation-flights_en); Michael Goldstein, *U.S. State Department Brings Home Over 85,000 Americans in Coronavirus Crisis*, FORBES (Apr. 10, 2020), <https://www.forbes.com/sites/michaelgoldstein/2020/04/10/us-state-department-brings-home-more-than-50000-americans-in-coronavirus-crisis/#40c87d865d93>.

27 Khan Sharun et al., *International Travel During the COVID-19 Pandemic: Implications and Risks Associated with ‘Travel Bubbles,’* 27 J. TRAVEL MED. 1 (2020).

health and human rights.<sup>28</sup> There are inextricable connections between these two spheres. Under human rights law, States must protect public health by fighting to contain the pandemic.<sup>29</sup> However, they also have a duty to protect other fundamental human rights. The pandemic endangers almost all human rights.<sup>30</sup> Governmental measures such as compulsory quarantine and travel restrictions may violate individual rights.<sup>31</sup> The rights to bodily integrity, to privacy, to be free from inhumane or degrading treatment, to be free from discrimination, and to freedom of movement are particularly vulnerable.<sup>32</sup>

Freedom of movement has significant economic, political, and legal dimensions. This right has received some scholarly attention in connection with certain topics such as the rights of migrants<sup>33</sup> and the right to obtain a passport,<sup>34</sup>

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28 Alessandra Spadaro, *COVID-19: Testing the Limits of Human Rights*, 11 EUR. J. RISK REGUL. 317, 317-18 (2020); Karima Bennouna, “*Lest We Should Sleep*”: *COVID-19 and Human Rights*, 114 AM. J. INT’L L. 666 (2020).

29 Article 12(1) of the International Covenant on Economic, Social and Cultural Rights provides that “States Parties . . . recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” Off. of the High Comm’r for Hum. Rts., *International Covenant on Economic, Social and Cultural Rights*, UNITED NATIONS (Jan. 3, 1976), <https://www.ohchr.org/en/professionalinterest/pages/cescr.aspx>. Article 12(2)(c) adds that “[t]he steps to be taken by the States Parties to . . . achieve the full realization of this right shall include those necessary for . . . [t]he prevention, treatment and control of epidemic, endemic, occupational and other diseases.” *Id.*

30 Bennouna, *supra* note 28, at 666, 669.

31 See Larry Gostin & Ben Berkman, *Isolation, Quarantine, Border Control and Social-Distancing Measures*, in ADDRESSING ETHICAL ISSUES IN PANDEMIC INFLUENZA PLANNING: DISCUSSION PAPERS 29, 34 (2008); Christian Enemark, *Is Pandemic Flu a Security Threat?*, 51 SURVIVAL 191, 200-01 (2009); Belinda Bennett, *Travel in a Small World: SARS, Globalization and Public Health Laws*, in GLOBALIZATION AND HEALTH: CHALLENGES FOR HEALTH LAW AND BIOETHICS 1, 5 (Belinda Bennett & George F. Tomossy eds., 2006).

32 Gostin & Berkman, *supra* note 31, at 35; Wendy Parmet, *Public Health & Social Control: Implications for Human Rights*, INT’L COUNCIL ON HUM. RTS. POL’Y 2 (2009), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1546654](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1546654); Brigit Toebes, *Human Rights and Public Health: Towards a Balanced Relationship*, 19 INT’L J. HUM. RTS. 488, 496 (2015); *Update and Summary Guide to the Report: Advancing the Right to Health—The Vital Role of Law*, WORLD HEALTH ORG. 29 (2018), [https://www.who.int/healthsystems/topics/health-law/ARH-Summary-Guide\\_Final\\_online\\_version.pdf](https://www.who.int/healthsystems/topics/health-law/ARH-Summary-Guide_Final_online_version.pdf).

33 See, e.g., Colin Harvey & Robert Barnidge, *Human Rights, Free Movement, and the Right to Leave in International Law*, 19 INT’L J. REFUGEE L. 1 (2007); Eric Retter, *You Can Check out Any Time You Like, But We Might Not Let You Leave: Cuba’s Travel Policy in the Wake of Signing the International Covenant on Civil and Political Rights*, 23 EMORY INT’L L. REV. 651 (2010); Dmitry Kochenov, *The Right to Leave Any Country Including Your Own in International Law*, 28 CONN. J. INT’L L. 43 (2012).

34 See, e.g., Daniel Turack, *Freedom of Movement and the Travel Document*, 4 CAL. W. INT’L L. J. 8 (1973); Paul Lansing, *Freedom to Travel: Is the Issuance of a Passport an Individual Right or a Governmental Prerogative*, 11 DENVER J. INT’L L & POL’Y 15 (1981); Paul Scott, *Passports, the Right to Travel, and National Security in the Commonwealth*, 69 INT’L & COMPAR. L.Q. 365 (2020).

but mainly from a domestic law perspective.<sup>35</sup> In the context of epidemics and pandemics, this right has mostly been examined vis-à-vis another well-known limitation to individual freedom: quarantine.<sup>36</sup> However, what is missing is a thorough analysis of how travel restrictions limit some of the facets of (international) freedom of movement that are safeguarded by human rights treaties. This right has been suppressed in the global response to COVID-19. In particular, the pandemic accentuated the need to devote greater consideration to the individual's right to return to his or her own country, a matter mostly neglected in the literature thus far.<sup>37</sup>

This Article contributes to that discussion by questioning the lawfulness of certain travel restrictions implemented during the COVID-19 pandemic. The legal limitations to international freedom of movement during this period are absolutely unparalleled in human history.<sup>38</sup> Several authors have argued that travel restrictions breach international law.<sup>39</sup> The IHR enable WHO to recommend States Parties to refuse entry of suspect and affected persons and refuse entry of unaffected persons to affected areas,<sup>40</sup> but they do not mention the closure of borders.<sup>41</sup> Travel restrictions are generally not supported by scientific evidence,

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35 See, e.g., Allan Vestal, *Freedom of Movement*, 41 IOWA L. REV. 6 (1995); Jeanne Woods, *Travel That Talks: Toward First Amendment Protection for Freedom of Movement*, 65 GEO. WASH. L. REV. 106, 109 (1996); J. Nicholas Murosko, *Communicable Diseases and the Right to Re-Enter the United States*, 24 WM. & MARY BILL RTS. J. 913, 920 (2016).

36 See, e.g., Kathleen Choi, *A Journey of a Thousand Leagues: From Quarantine to International Health Regulations and Beyond*, 29 U. PA. J. INT'L L. 989, 1006 (2008); Gregory Campbell, *Global H1N1 Pandemic, Quarantine Law, and the Due Process Conflict*, 12 SAN DIEGO INT'L L. J. 497, 504 (2011); Courtney Maccarone, *Crossing Borders: A TRIPs-Like Treaty on Quarantines and Human Rights*, 36 BROOK. J. INT'L L. 781, 788 (2011); Erin Pauley, *Human Rights in the Midst of Quarantine*, 13 LOY. U. CHI. INT'L L. REV. 71, 77 (2016).

37 Frédéric Mégret, *Homeward Bound? Global Mobility and the Role of the State of Nationality During the Pandemic*, 114 AJIL UNBOUND 322, 323 (2020).

38 Lawrence Gostin, Roojin Habibi & Benjamin Meier, *Has Global Health Law Risen to Meet the COVID-19 Challenge? Revisiting the International Health Regulations to Prepare for Future Threats*, 48 J. L., MED & ETHICS 376, 379 (2020); Kelley Lee et al., *Global Coordination on Cross-Border Travel and Trade Measures Crucial to COVID-19 Response*, 395 LANCET 1593, 1594 (2020).

39 Roojin Habibi et al., *Do Not Violate the International Health Regulations During the COVID-19 Outbreak*, 396 LANCET 664, 665 (2020); Benjamin Meier, Roojin Habibi & Y. Tony Yang, *Travel Restrictions Violate International Law*, 367 SCIENCE 1436 (2020); Weijun Yu & Jessica Keralis, *Controlling COVID-19: The Folly of International Travel Restrictions*, HEALTH & HUM. RTS. J. (Apr. 6, 2020), <https://www.hhrjournal.org/2020/04/controlling-covid-19-the-folly-of-international-travel-restrictions>.

40 IHR, *supra* note 3, at art. 18(1).

41 Robert Steffen, *Influenza in Travelers: Epidemiology, Risk, Prevention, and Control Issues*, 12 CURRENT INFECTIOUS DISEASE REP. 181, 182 (2010); Sarah Goldfarb, *The Phase-Out and Sunset of Travel Restrictions in the International Health Regulations*, 41 BROOK. J. INT'L L. 781, 803 (2016). According to Adam Ferhani and Simon Rushton, "[t]he IHR's overall orientation is firmly against the imposition of border restrictions." Adam Ferhani & Simon Rushton, *The International Health Regulations, COVID-19, and Bordering Practices: Who Gets in, What Gets out, and Who Gets*

and even if they were, more effective alternatives could have been adopted with less restrictive effects, including procedures recommended by WHO.<sup>42</sup> Other authors adopt a more nuanced approach, stressing the unprecedented nature of the pandemic and the need to contemplate multiple factors when evaluating the scientific justification and proportionality of measures.<sup>43</sup>

This split in scholarship echoes previous disagreements over the legality under international law of measures adopted during epidemic outbreaks. While some have asserted that travel restrictions constitute a violation of human rights, namely freedom of movement,<sup>44</sup> others contend that such measures do not violate the right to freedom of movement because countries have the right to decide who may enter their borders.<sup>45</sup>

It would be a Herculean task to scrutinize every single measure implemented around the world that, in one way or another, constrained international mobility. While border control is a legitimate prerogative that States can use to prevent the entry of infected individuals or those suspected of carrying the virus, broader travel restrictions are more complex and raise intricate legal questions.<sup>46</sup> This work focuses on a specific category of travel restrictions: travel bans, specifically, “entry bans” and “exit bans” (referred to collectively in this Article as “travel bans”).<sup>47</sup> These measures are a blanket prohibition applied to all or certain individuals who

*Rescued?*, 41 CONTEMP. SEC. POL’Y 458, 459-60 (2020).

42 Habibi et al., *supra* note 39, at 664; Meier, Habibi & Yang, *supra* note 39, at 1436.

43 Barbara von Tigerstrom & Kumanan Wilson, *COVID-19 Travel Restrictions and the International Health Regulations (2005)*, 5 BMJ GLOB. HEALTH 1, 2-3 (2020); Barbara von Tigerstrom, Sam Halabi & Kumanan Wilson, *The International Health Regulations (2005) and the Re-Establishment of International Travel Amidst the COVID-19 Pandemic*, 27 J. TRAVEL MED. 1, at 2 (2020).

44 Gostin & Berkman, *supra* note 31, at 53; LARRY GOSTIN & ZITA LAZARRINI, HUMAN RIGHTS AND PUBLIC HEALTH IN THE AIDS PANDEMIC 87-88 (1997); Lawrence Gostin, Ronald Bayer & Amy Fairchild, *Ethical and Legal Challenges Posed by Severe Acute Respiratory Syndrome: Implications for the Control of Severe Infectious Disease Threats*, 290 J. AM. MED. ASS’N 3229, 3235 (2003).

45 DAVID FIDLER, INTERNATIONAL LAW AND INFECTIOUS DISEASES 205 (1999); *see also* Andrés Miklós, *Public Health and the Rights of States*, 2 PUB. HEALTH ETHICS 158, 161-62 (2009). These statements, naturally, were of a general nature and not made in response to COVID-19.

46 Vincent Chetail, *Crisis Without Borders: What Does International Law Say About Border Closure in the Context of Covid-19?*, 2 FRONTIERS IN POL. SCI. 1, 2 (2020); Daniel Thym, *Travel Bans in Europe: A Legal Appraisal (Part I)*, EU IMMIGRATION & ASYLUM L. & POL’Y (Mar. 18, 2020), <http://eumigrationlawblog.eu/travel-bans-in-europe-a-legal-appraisal-part-i>.

47 *Travel Ban*, CAMBRIDGE DICTIONARY, <https://dictionary.cambridge.org/dictionary/english/travel-ban> (“[T]ravel ban: a law preventing people from travelling somewhere, especially preventing a particular person or group from entering a particular country . . .”). Other measures that can be qualified as travel restrictions include entry bans for citizens of or recent travelers to affected areas; bans on the entry of tourists, business travelers, new immigrants, and refugees; medical checks, presentation of a health certificate, registration for the purpose of contract tracing, mandatory quarantine upon arrival, and travel conditioned on the existence of a “valid reason.” Many of these measures raise distinct legal questions and therefore are not be addressed in this piece.

cross international borders, regardless of their health status.

Over the last year, “social distancing” and “physical distancing” became household expressions and quotidian obligations, raising a host of legal and ethical queries:

Physical distancing raises profound questions of culture, faith, and family. Coming together affords comfort during times of crisis. At the same time, physical distancing affects rights, including liberty, privacy, and freedoms of speech, religion, and assembly. How are the fundamental values of health and human rights balanced in times of crisis? Although there is no clear answer, there are guideposts: adopt rigorous scientific standards based on the best available evidence, make decisions transparently and fairly, and adopt the least restrictive measures needed to protect the public’s health.<sup>48</sup>

This Article submits that travel bans constitute the utmost form of physical distancing and inquires into whether they fall within those (elusive) guideposts. The validity of such measures depends on several elements. First, one needs to examine the applicable legal framework—the IHR and human rights treaties—and the standards they contain. As discussed in Part I, both sets of rules protect international mobility, but with different goals and scopes of application. The IHR acknowledge the link between controlling the global spread of disease and human rights protection, prescribing that its provisions be implemented “with full respect for the dignity, human rights and fundamental freedoms of persons.”<sup>49</sup> On the other hand, like the IHR, human rights treaties recognize that in some cases, it may be necessary to constrain the freedom of movement of individuals to protect other interests such as public health.

Determining whether travel bans are lawful also depends on a second element: the traveler’s status. Thus, Part I also examines the rights bestowed upon individuals depending on whether they qualify as nationals, residents, or something else. After reviewing the relevant legal framework and (available) information on how travel bans were applied, Parts II and III question whether the pertinent requirements and principles were respected. While these measures seem like an intuitive way to “curb the spread,” reality is much more complicated.

A judgment on whether travel bans comply with international law may sound premature. These measures are often decided in a context of significant scientific

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<sup>48</sup> Lawrence Gostin & Lindsay Wiley, *Governmental Public Health Powers During the COVID-19 Pandemic: Stay-at-Home Orders, Business Closures, and Travel Restrictions*, 323 J. AM. MED. ASS’N 2137, 2138 (2020).

<sup>49</sup> IHR, *supra* note 3, at art. 3(1).

uncertainty.<sup>50</sup> Gathering, processing, and validating reliable scientific information takes time, a scarce resource.<sup>51</sup> Governments are under pressure to act rapidly without having complete information about the appropriate public health measures to adopt, especially in the case of an unknown disease.<sup>52</sup> When they turn to scientists, they may be confronted with “dueling experts” who advocate contradicting courses of action.<sup>53</sup> In the context of urgency and scientific uncertainty about the dangerousness and magnitude of the pandemic, governments may implement travel bans to avoid accusations, including from political quarters,<sup>54</sup> of “doing nothing” to prevent the spread of the virus.<sup>55</sup> The public pressure to “do something” may be compounded as rumors and misinformation float on the press and social media,<sup>56</sup> leading to what has been termed an “infodemic.”<sup>57</sup> Governments also face a form of peer pressure: as other countries implement travel bans, they feel compelled to do the same.<sup>58</sup> Closing borders allows States to demonstrate authority<sup>59</sup> and convey to their citizens a message that the situation is “under control.”<sup>60</sup>

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50 Jonathan Suk, *Sound Science and the New International Health Regulations*, 1 GLOB. HEALTH GOVERNANCE 1, 2 (2007); Terry Carney & Belinda Bennett, *Governance, Rights and Pandemics: Science, Public Health or Individual Rights?*, in ETHICS AND SECURITY ASPECTS OF INFECTIOUS DISEASE CONTROL: INTERDISCIPLINARY PERSPECTIVES 201 (Michael Selgelid ed., 2012).

51 Frederick Burkle, *Global Health Security Demands a Strong International Health Regulations Treaty and Leadership from a Highly Resourced World Health Organization*, 9 DISASTER MED. & PUB. HEALTH PREPAREDNESS 568, 570 (2015).

52 Johan Giesecke, *Prevention, not Panic—Epidemics and Trade Sanctions*, 356 LANCET 588 (2000).

53 DAVID FAIRMAN ET AL., NEGOTIATING PUBLIC HEALTH IN A GLOBALIZED WORLD: GLOBAL HEALTH DIPLOMACY IN ACTION 30 (2012).

54 Catherine Worsnop, *Domestic Politics and the WHO’s International Health Regulations: Explaining the Use of Trade and Travel Barriers During Disease Outbreaks*, 12 REV. INT’L ORGS. 365, 371 n.7 (2017); SARA E. DAVIES, ADAM KAMRADT-SCOTT & SIMON RUSHTON, DISEASE DIPLOMACY: INTERNATIONAL NORMS AND GLOBAL HEALTH SECURITY 120 (2015).

55 Worsnop, *supra* note 54, at 373; Adam Kamradt-Scott et al., *WHO Tracking Mechanism for IHR Additional Health Measures*, 392 LANCET 2251 (2018); Lee et al., *supra* note 38, at 1594.

56 Adaobi Duru, *Narratives of Death: Systemic Determinants of the Coverage of a Public Health Emergency of International Concern*, 15 GLOB. MEDIA & COMM’NS 215 (2019); Giuseppe Ippolito et al., *Toning Down the 2019-nCoV Media Hype—and Restoring Hope*, 8 LANCET RESPIRATORY MED. 230 (2010).

57 Gabriel Leung & Kathy Leung, *Crowdsourcing Data to Mitigate Epidemics*, 2 LANCET DIGIT. HEALTH e156 (2020).

58 Ria Vaidya et al., *Travel Restrictions and Infectious Disease Outbreaks*, 27 J. TRAVEL MED. 1 (2020). According to Mara Pillinger, “[t]he fact that China [implemented] travel restrictions on its own citizens—and WHO [did] not [challenge] those restrictions—[made] it difficult to convince policymakers in other countries not [to] follow suit.” Mara Pillinger, *Virus Travel Bans Are Inevitable But Ineffective*, FOREIGN POL’Y (Feb. 23, 2020), <https://foreignpolicy.com/2020/02/23/virus-travel-bans-are-inevitable-but-in-effective>.

59 Kenwick & Simmons, *supra* note 8, at 3, 7, 9; Tine Hanrieder, *Priorities, Partners, Politics: The WHO’s Mandate Beyond the Crisis*, 26 GLOB. GOVERNANCE 534, at 535-36 (2020).

60 Derek Lutterbeck, *The COVID-19 Pandemic and Territoriality: Some Initial Reflections*, in

There is still much we do not know about COVID-19, so it might seem advisable to reserve judgment. Still, there are important lessons to draw from this pandemic, as it will almost certainly not be the last. A committee is already reviewing the functioning of the IHR during the COVID-19 response, and one of the key topics under discussion is the implementation of travel restrictions.<sup>61</sup> International travelers may be carriers of infection, raising important questions that need to be addressed by international law. As underlined by one author, “[d]isease has been the unwelcome traveling companion of international commerce.”<sup>62</sup> While international travelers are an important piece in the puzzle of the fight against infectious diseases, they should not be turned into scapegoats and shoulder an unreasonable burden. The tension between international mobility and human health protection is not new, and COVID-19 is just one reminder of the need for governments to adopt justified, calibrated measures. Some measures adopted in the name of public health seem difficult, if not impossible, to justify. This Article examines a few more clear-cut cases where travel bans breached the rules and principles governing international mobility.

## I. THE LEGAL FRAMEWORK ON INTERNATIONAL MOBILITY

Cross-border mobility is regulated by two international legal frameworks: the IHR and human rights treaties. Part I examines each in turn and explains how they should shape the behavior of States during a pandemic.

### A. *The IHR*

The history of international cooperation to tackle infectious diseases spans 170 years.<sup>63</sup> The IHR, last revised in 2005, are the only international legal instrument in the field<sup>64</sup> and have almost universal membership (196 States Parties).<sup>65</sup> The goal remains the same: to protect people from infectious diseases

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MEDITERRANEAN ACADEMY OF DIPLOMACY, TOWARDS A POST PANDEMIC EURO-MEDITERRANEAN STRATEGY 36, 41 (Stephen Calleya ed., 2020), [https://www.um.edu.mt/\\_data/assets/pdf\\_file/0005/448655/Towardsapostpandemic-euro-med.pdf](https://www.um.edu.mt/_data/assets/pdf_file/0005/448655/Towardsapostpandemic-euro-med.pdf).

61 See *Strengthening Preparedness for Health Emergencies: Implementation of the International Health Regulations (2005): Interim Progress Report of the Review Committee on the Functioning of the International Health Regulations (2005) During the COVID-19 Response*, WORLD HEALTH ORG. (Jan. 12, 2021), <https://reliefweb.int/report/world/strengthening-preparedness-health-emergencies-implementation-international-health>.

62 Allyn Taylor, *Global Health Law: International Law and Public Health Policy*, in 3 INTERNATIONAL ENCYCLOPEDIA OF PUBLIC HEALTH 268 (2d ed. 2017).

63 See David Fidler, *From International Sanitary Conventions to Global Health Security: The New International Health Regulations*, 4 CHINESE J. INT'L L. 325 (2005).

64 Jennifer Ruger, *Normative Foundations of Global Health Law*, 96 GEO. L.J. 423, 434-35 (2008).

65 See *States Parties to the International Health Regulations (2005)*, WORLD HEALTH ORG.,

while minimizing interference with international trade and travel. To achieve this purpose, the IHR mandate that WHO issue temporary recommendations to States Parties on when and how to respond to transnational health threats.<sup>66</sup> Recommendations should take into account, inter alia, scientific principles, and available scientific evidence and information. Importantly, WHO's Director-General shall consider "health measures that, on the basis of a risk assessment appropriate to the circumstances, are not more restrictive of international traffic and trade and are not more intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection."<sup>67</sup> Through these statements, WHO seeks to exercise authority in the epidemiological field.<sup>68</sup> Admittedly described within the IHR as "non-binding advice,"<sup>69</sup> recommendations lay down a benchmark allowing for a comparison of measures adopted by States with the actions recommended by WHO.<sup>70</sup>

### 1. WHO's Recommendations

After declaring COVID-19 a PHEIC, WHO made several statements to guide States Parties' responses to the unfolding public health crisis. In early February 2020, WHO issued a "Strategic Preparedness and Response Plan" where the organization adopted a nuanced approach towards the suitability of travel restrictions:

Evidence has shown that restricting the movement of people and goods during public health emergencies may be ineffective, and may interrupt vital aid and technical support, disrupt businesses,

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<http://www.emro.who.int/health-topics/international-health-regulations/index.html>. The IHR entered into force on 15 June 2007. *Id.*

66 IHR, *supra* note 3, at art. 15.

67 *Id.* at art. 17.

68 Armin von Bogdandy & Pedro Villarreal, *Critical Features of International Authority in Pandemic Response: The WHO in the COVID-19 Crisis, Human Rights and the Changing World Order*, MAX PLANCK INST. 14 (2020), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3600058](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3600058); Lawrence Gostin, *A Proposal for a Framework Convention on Global Health*, 10 J. INT'L ECON. L. 989, 998 (2007). On the "epistemic authority" of WHO, see Jan Klabbers, *The Normative Gap in International Organizations Law: The Case of the World Health Organization* 16 INT'L ORGS. L. REV. 272 (2019).

69 IHR, *supra* note 3, at art. 1.

70 Benjamin Meier, Dabney Evans & Alexandra Phelan, *Rights-Based Approaches to Preventing, Detecting, and Responding to Infectious Disease*, in *INFECTIOUS DISEASES IN THE NEW MILLENNIUM: LEGAL AND ETHICAL CHALLENGES* 217, 243 (Mark Eccleston-Turner & Iain Brassington eds., 2020). According to Gian Burci, "IHR-based temporary recommendations constitute a reliable reference and a kind of default normative guidance in the absence of diverging national considerations." Gian Burci, *The Legal Response to Pandemics: The Strengths and Weaknesses of the International Health Regulations*, 11 J. INT'L HUMANITARIAN LEGAL STUD. 204, 216 (2020).

and have a negative impact on the economies of affected countries and their trading partners. However, in certain specific circumstances, such as uncertainty about the severity of a disease and its transmissibility, measures that restrict the movement of people may prove temporarily useful at the beginning of an outbreak to allow time to implement preparedness activities, and to limit the international spread of potentially highly infectious cases. In such situations, countries should perform risk and cost-benefit analyses before implementing such restrictions, to assess whether the benefits outweigh the drawbacks.<sup>71</sup>

A few days later, WHO made additional remarks on the subject, again sounding relatively favorable to the adoption of travel restrictions:

Evidence on travel measures that significantly interfere with international traffic for more than 24 hours shows that such measures may have a public health rationale at the beginning of the containment phase of an outbreak, as they may allow affected countries to implement sustained response measures, and non-affected countries to gain time to initiate and implement effective preparedness measures. Such restrictions, however, need to be short in duration, proportionate to the public health risks, and be reconsidered regularly as the situation evolves.<sup>72</sup>

Later that month, WHO updated its recommendations and reiterated its position:

WHO continues to advise against the application of travel or trade restrictions to countries experiencing COVID-19 outbreaks.

In general, evidence shows that restricting the movement of people and goods during public health emergencies is ineffective in most situations and may divert resources from other interventions. Furthermore, restrictions may interrupt needed aid and technical support, may disrupt businesses, and may have negative social and economic effects on the affected countries.

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<sup>71</sup> *2019 Novel Coronavirus (2019-nCoV): Strategic Preparedness and Response Plan*, WORLD HEALTH ORG. 10 (Feb. 4, 2020), <https://www.who.int/publications/i/item/strategic-preparedness-and-response-plan-for-the-new-coronavirus>.

<sup>72</sup> *Key Considerations for Repatriation and Quarantine of Travellers in Relation to the Outbreak of Novel Coronavirus 2019-nCoV*, WORLD HEALTH ORG. (Feb. 11, 2020), <https://www.who.int/news-room/articles-detail/key-considerations-for-repatriation-and-quarantine-of-travellers-in-relation-to-the-outbreak-of-novel-coronavirus-2019-ncov>.

However, in certain circumstances, measures that restrict the movement of people may prove temporarily useful, such as in settings with few international connections and limited response capacities.

Travel measures that significantly interfere with international traffic may only be justified at the beginning of an outbreak, as they may allow countries to gain time, even if only a few days, to rapidly implement effective preparedness measures. Such restrictions must be based on a careful risk assessment, be proportionate to the public health risk, be short in duration, and be reconsidered regularly as the situation evolves.

Travel bans to affected areas or denial of entry to passengers coming from affected areas are usually not effective in preventing the importation of cases but may have a significant economic and social impact. Since WHO declaration of a public health emergency of international concern in relation to COVID-19, and as of 27 February, 38 countries have reported to WHO additional health measures that significantly interfere with international traffic in relation to travel to and from China or other countries, ranging from denial of entry of passengers, visa restrictions or quarantine for returning travellers. Several countries that denied entry of travellers or who have suspended the flights to and from China or other affected countries, are now reporting cases of COVID-19.<sup>73</sup>

In April 2020, WHO updated its COVID-19 strategy, shifting its stance for the first time. It stated that one of the global strategic objectives was for countries to “[s]uppress community transmission through context-appropriate infection prevention and control measures, population-level physical distancing measures, and *appropriate and proportionate restrictions on non-essential domestic and international travel.*”<sup>74</sup> It also added:

In countries and/or subnational regions in which community transmission has become established, or that are at risk of entering this phase of an epidemic, authorities must immediately adopt and

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<sup>73</sup> Updated WHO Recommendations for International Traffic in Relation to COVID-19 Outbreak, WORLD HEALTH ORG. (Feb. 29, 2020), <https://www.who.int/news-room/articles-detail/updated-who-recommendations-for-international-traffic-in-relation-to-covid-19-outbreak>.

<sup>74</sup> COVID-19 Strategy Update, WORLD HEALTH ORG. (Apr. 14, 2020), <https://www.who.int/publications/i/item/covid-19-strategy-update---14-april-2020> (emphasis added).

adapt population-level distancing measures and movement restrictions in addition to other public health and health system measures to reduce exposure and suppress transmission, including . . . [m]easures to reduce the risk of importation or reintroduction of the virus from high-transmission areas, such as *limits on national and international travel . . .*<sup>75</sup>

In early May 2020, WHO recommended that States Parties “[i]mplement appropriate travel measures with consideration of their public health benefits, including entry and exit screening, education of travelers on responsible travel behaviour, case finding, contact tracing, isolation, and quarantine, by incorporating evidence on the potential role of pre-symptomatic and asymptomatic transmission.”<sup>76</sup> Again, WHO recommended that States “not implement trade restrictions beyond those considered to be of public health importance in accordance with relevant international agreements” and “[c]ontinue to provide appropriate public health rationale to WHO for additional health measures in accordance with [the] IHR.”<sup>77</sup>

In October 2020, WHO recommended that States Parties only introduce travel restrictions with clear, justified limits. Specifically, WHO recommended that State Parties “[r]egularly re-consider measures applied to international travel in compliance with Article 43 of the IHR (2005) and continue to provide information and rationales to WHO on measures that significantly interfere with international traffic” and “[e]nsure that measures affecting international traffic (including targeted use of diagnostics and quarantine) are risk-based, evidence-based, coherent, proportionate and time-limited.”<sup>78</sup>

Finally, in its latest public statement specifically addressing international travel, in mid-January 2021, WHO again recommended that States:

[i]mplement coordinated, time-limited, risk-based, and evidence-based approaches for health measures in relation to international traffic in line with WHO guidance and IHR provisions. Careful

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<sup>75</sup> *Id.* (emphasis added).

<sup>76</sup> *Statement on the Third Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Outbreak of Coronavirus Disease (COVID-19)*, WORLD HEALTH ORG. (May 1, 2020), [https://www.who.int/news/item/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-\(covid-19\)](https://www.who.int/news/item/01-05-2020-statement-on-the-third-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-coronavirus-disease-(covid-19)).

<sup>77</sup> *Id.*

<sup>78</sup> *Statement on the Fifth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic*, WORLD HEALTH ORG. (Oct. 30, 2020), [https://www.who.int/news/item/30-10-2020-statement-on-the-fifth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/30-10-2020-statement-on-the-fifth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic).

consideration should be given to when and if travel bans should or should not be used as tools to reduce spread. Such decisions should be based on the best available evidence.<sup>79</sup>

In addition, States were asked to “[s]hare information with WHO on the effects of health measures in minimizing transmission of SARS-CoV-2 during international travel to inform WHO’s development of evidence-based guidance.”<sup>80</sup> Temporary recommendations offer guidance to States based on WHO’s “assessment of risk to human health, risk of international spread of disease and of risk of interference with international travel.”<sup>81</sup> Still, that assessment is not peremptory, as Article 43 of the IHR allows States Parties to go beyond WHO’s recommendations:

1. These Regulations shall not preclude States Parties from implementing health measures, in accordance with their relevant national law and obligations under international law, in response to specific public health risks or public health emergencies of international concern, which:
  - a. achieve the same or greater level of health protection than WHO recommendations; or
  - b. are otherwise prohibited under Article 25, Article 26, paragraphs 1 and 2 of Article 28, Article 30, paragraph 1(c) of Article 31 and Article 33,

provided such measures are otherwise consistent with these Regulations.<sup>82</sup>

There is, however, an important caveat: additional health measures “shall not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.”<sup>83</sup>

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<sup>79</sup> *Statement on the Sixth Meeting of the International Health Regulations (2005) Emergency Committee Regarding the Coronavirus Disease (COVID-19) Pandemic*, WORLD HEALTH ORG. (Jan. 15, 2021), [https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-\(2005\)-emergency-committee-regarding-the-coronavirus-disease-\(covid-19\)-pandemic](https://www.who.int/news/item/15-01-2021-statement-on-the-sixth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic).

<sup>80</sup> *Id.*

<sup>81</sup> *What Are the International Health Regulations?*, WORLD HEALTH ORG. (Dec. 19, 2019), <https://www.who.int/news-room/q-a-detail/emergencies-international-health-regulations-and-emergency-committees>.

<sup>82</sup> IHR, *supra* note 3, at art. 43(1).

<sup>83</sup> *Id.*

Under the same provision, a decision to implement additional health measures shall be based upon the following elements: “(a) scientific principles; (b) available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information including from WHO and other relevant intergovernmental organizations and international bodies; and (c) any available specific guidance or advice from WHO.”<sup>84</sup> If such measures “significantly interfere with international traffic,” the State Party “shall provide to WHO the public health rationale and relevant scientific information for it.”<sup>85</sup> Importantly, the following measures are generally considered as “significant interference”: “refusal of entry or departure of international travellers, baggage, cargo, containers, conveyances, goods, and the like, or their delay, for more than 24 hours.”<sup>86</sup> WHO assesses these additional health measures and may request the State to reconsider their application.<sup>87</sup> States must also report measures to WHO within 48 hours of implementation, together with their health rationale, unless a temporary or standing recommendation already covers the measures.<sup>88</sup> States should review measures within three months, taking into account WHO's advice and the criteria set forth in Article 43(2).<sup>89</sup>

## 2. States' Non-Compliance

States Parties to the IHR decided almost universally to disregard WHO's recommendations not to implement travel restrictions.<sup>90</sup> At the early stage of the pandemic, WHO was chastised by some for giving such counsel.<sup>91</sup> The imposition of travel restrictions in response to an epidemic outbreak is not a novelty—rather, it has become the rule.<sup>92</sup> In addition, countries frequently breach their obligations

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<sup>84</sup> *Id.* at art. 43(2).

<sup>85</sup> *Id.* at art. 43(3).

<sup>86</sup> *Id.*

<sup>87</sup> *Id.* at art. 43(4).

<sup>88</sup> *Id.* at art. 43(5).

<sup>89</sup> *Id.* at art. 43(6).

<sup>90</sup> According to Burci, a “weakness of the IHR 2005, in dramatic display since the declaration of the COVID-19 PHEIC, is the failure or refusal of many states to follow WHO's temporary recommendations, in particular with regard to disruptive international measures such as border closures, travel restrictions and trade limitations.” Burci, *supra* note 70, at 213.

<sup>91</sup> See Amanda Watts & Veronica Stracqualursi, *WHO Defends Coronavirus Response after Trump Criticism*, CNN (Apr. 8, 2020), <https://edition.cnn.com/2020/04/08/politics/who-responds-trump-claims-coronavirus/index.html>.

<sup>92</sup> Lawrence Gostin, *Influenza A(H1N1) and Pandemic Preparedness Under the Rule of International Law* 301 J. Am. Med. Ass'n 2376, 2377-78 (2009); Lawrence Gostin, *Our Shared Vulnerability to Dangerous Pathogens*, 25 MED. L. REV. 185, 191 (2017); Morenike Folayan & Brandon Brown, *Ebola and the Limited Effectiveness of Travel Restrictions*, 9 DISASTER MED. & PUB. HEALTH PREPAREDNESS 92 (2015); Wendy Rhymer & Rick Speare, *Countries' Response to WHO's Travel Recommendations During the 2013-2016 Ebola Outbreak*, 95 BULL. WORLD HEALTH

to report additional measures to WHO<sup>93</sup> and to explain their scientific and public health rationale.<sup>94</sup> This lack of compliance with reporting obligations was also pervasive during the COVID-19 pandemic. While practically all countries adopted some form of travel restriction, by the end of February 2020, only thirty-eight countries had reported such measures to WHO.<sup>95</sup> It seems evident that many such measures went unreported.<sup>96</sup>

COVID-19 seems to be the latest episode in a saga of “pathological”<sup>97</sup> or even “epidemic”<sup>98</sup> non-compliance with the IHR. The root of the problem is the lack of enforceability of the duties imposed on States Parties.<sup>99</sup> As acknowledged recently by the Chair of the Review Committee on the Functioning of the International Health Regulations (2005), the IHR “lack . . . teeth.”<sup>100</sup> WHO has historically favored the formulation of recommendations over the imposition of binding obligations. There is no compliance mechanism to monitor and review the conduct

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ORG. 10, 13 (2017); ADAM KAMRADT-SCOTT, *MANAGING GLOBAL HEALTH SECURITY: THE WORLD HEALTH ORGANIZATION AND DISEASE OUTBREAK CONTROL* 145 (2015); Adam Kamradt-Scott, *The International Health Regulations (2005): Strengthening Their Effective Implementation and Utilisation*, 16 INT'L ORGS. L. REV. 242, 252 (2019).

93 *Strengthening Response to Pandemics and Other Public-Health Emergencies: Report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza (H1N1) 2009*, WORLD HEALTH ORG. 62, 80-81 (2011), [https://www.who.int/ihr/publications/RC\\_report/en](https://www.who.int/ihr/publications/RC_report/en); David Fidler, *Epic Failure of Ebola and Global Health Security*, 21 BROWN J. WORLD AFFS. 179, 189 (2015); Trygve Ottersen, Steven Hoffman & Gaëlle Groux, *Ebola Again Shows the International Health Regulations are Broken: What Can Be Done Differently to Prepare for the Next Epidemic?*, 42 AM. J. L. & MED. 356, 377 (2016).

94 *Report of the Ebola Interim Assessment Panel*, WORLD HEALTH ORG. 12 (2015), <https://www.who.int/csr/resources/publications/ebola/report-by-panel.pdf>; Ottersen, Hoffman & Groux, *supra* note 93, at 377; Tsung-Ling Lee, *Making International Health Regulations Work: Lessons from the 2014 Ebola Outbreak*, 49 VAND. J. TRANSNAT'L L. 931, 965 (2016).

95 WORLD HEALTH ORG., *supra* note 73. Subsequent updates by WHO are silent on whether the organization received more reports from States Parties.

96 Von Tigerstrom & Wilson, *supra* note 43, at 2; von Bogdandy & Villarreal, *supra* note 68, at 16.

97 Andrea Spagnolo, *(Non) Compliance with the International Health Regulations of the WHO from the Perspective of the Law of International Responsibility*, 18 GLOB. JURIST 1 (2018).

98 David Heymann et al., *Global Health Security: The Wider Lessons from the West African Ebola Virus Disease Epidemic* 385 LANCET 1884, 1888 (2015).

99 Ali Tejpar & Steven Hoffman, *Canada's Violation of International Law during the 2014-16 Ebola Outbreak*, 54 CANADIAN Y.B. INT'L L. 366, 370 (2016); Kumanan Wilson, John Brownstein & David Fidler, *Strengthening the International Health Regulations: Lessons from the H1N1 Pandemic*, 25 HEALTH POL'Y & PLANNING 505, 507 (2010); Ottersen, Hoffman & Groux, *supra* note 93, at 378-79; Robert Frau, *Law as an Antidote: Assessing the Potential of International Health Law Based on the Ebola-Outbreak 2014*, 7 GOETTINGEN J. INT'L L. 261, at 287-88 (2016).

100 *Statement to the 148th Executive Board by the Chair of the Review Committee on the Functioning of the International Health Regulations (2005) During the COVID-19 Response*, WORLD HEALTH ORG. (Jan. 19, 2021), [https://www.who.int/news/item/19-01-2021-statement-to-the-148th-executive-board-by-the-chair-of-the-review-committee-on-the-functioning-of-the-international-health-regulations-\(2005\)-during-the-covid-19-response](https://www.who.int/news/item/19-01-2021-statement-to-the-148th-executive-board-by-the-chair-of-the-review-committee-on-the-functioning-of-the-international-health-regulations-(2005)-during-the-covid-19-response).

of States Parties,<sup>101</sup> and no consequences follow from breaching the regulations.<sup>102</sup> As a result, States Parties have little incentive to fulfill their duties<sup>103</sup>, and non-compliance pays off.<sup>104</sup>

Despite being an international legal instrument, the IHR resemble a soft law document,<sup>105</sup> with compliance based on persuasion.<sup>106</sup> While it is hoped that reporting obligations “nudge” States to comply with temporary recommendations,<sup>107</sup> this “soft” diplomatic approach has not been assertive enough. In addition, breaches of the IHR are not met with firm reactions from

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101 Fidler, *supra* note 63, at 390. The Review Committee notes:

The lack of a robust compliance evaluation and accountability mechanism was identified during the interviews as reducing incentives for adequate preparedness and cooperation under the Regulations and as deterring timely notifications of events and public health information. Such criticism was raised in particular with regard to the adoption of additional health measures in view of their transboundary social and economic consequences. A robust system of compliance evaluation built into the Regulations was cited during the interviews as a potential approach to strengthening the overall framework of the Regulations and its credibility as a legal instrument; such an approach could include consideration of a universal peer review mechanism.

WORLD HEALTH ORG., *supra* note 61, at ¶ 12. While Article 56(5) of the IHR (“settlement of disputes”) provides that disputes between WHO and one or more States Parties concerning the interpretation or application of the regulations shall be submitted to the Health Assembly, this is not a fully-fledged, structured review mechanism. One may also question whether this avenue could be used to review the fulfillment of obligations contained in Article 43 of the IHR. Be it as it may, this mechanism has never been used. Ruger, *supra* note 64, at 437; Allyn Taylor et al., *Solidarity in the Wake of COVID-19: Reimagining the International Health Regulations*, 396 LANCET 82, 83 (2020).

102 WORLD HEALTH ORG., *supra* note 93, at 13; Joseph Dute, *World Health Organization—Revision of the International Health Regulations*, 12 EUR. J. HEALTH L. 269, 271 (2005); Wilson, Brownstein & Fidler, *supra* note 99, at 507; JEREMY YAUDE, BIOPOLITICAL SURVEILLANCE AND PUBLIC HEALTH IN INTERNATIONAL POLITICS 166 (2010); Colin McInnes, *WHO’s Next? Changing Authority in Global Health Governance After Ebola* 91 INT’L AFFS. 1299, 1314-15 (2015); Brigit Toebes, Lisa Forman & Giulio Bartolini, *Toward Human Rights-Consistent Responses to Health Emergencies: What Is the Overlap between Core Right to Health Obligations and Core International Health Regulation Capacities?*, 22 HEALTH & HUM. RTS. J. 99, 102 (2020).

103 David Bishop, *Lessons from SARS: Why the WHO Must Provide Greater Economic Incentives for Countries to Comply with International Health Regulations*, 36 GEO. J. INT’L L. 1173, 1193 (2005); Lee, *supra* note 94, at 965; Lauren Asher, *Confronting Disease in a Global Arena*, 9 CARDOZO J. INT’L COMPAR. L. 135, 151 (2001).

104 Lee, *supra* note 94, at 965; Jennifer Nuzzo & Gigi Gronvall, *Global Health Security: Closing the Gaps in Responding to Infectious Disease Emergencies*, 4 GLOB. HEALTH GOVERNANCE 1, 10 (2011); Catherine Worsnop, *Provoking Barriers: The 2014 Ebola Outbreak and Unintended Consequences of WHO’s Power to Declare a Public Health Emergency*, 11 GLOB. HEALTH GOVERNANCE 7, 20 (2017).

105 David Fidler, *The Role of International Law in the Control of Emerging Infectious Diseases*, 95 BULL. DE L’INSTITUT PASTEUR 57, 63-64 (1997).

106 David Fidler, *Return of the Fourth Horseman: Emerging Infectious Diseases and International Law*, 81 MINN. L. REV. 771, 849 (1997).

107 Frau, *supra* note 99, at 237.

WHO.<sup>108</sup> The organization is normally careful not to antagonize members about the measures they adopt,<sup>109</sup> and the same happened in the context of COVID-19.<sup>110</sup> Several authors have suggested that it be more proactive and emphatic in requesting States Parties to justify their measures.<sup>111</sup> While WHO has the power to “name and shame” violating States, this tool has not been deployed.<sup>112</sup> In practice, the regulations are too restrained in regulating when and how States Parties can adopt additional health measures. The focus seems to be on engaging States in multilateral cooperation without impinging upon their sovereignty.<sup>113</sup>

These problems are well known within WHO. Several months into the pandemic, the Chair of the Review Committee on the Functioning of the International Health Regulations (2005) acknowledged that “[t]he role of WHO in relation to travel recommendations as well as incentives for States Parties to comply with their obligations related to travel measures need to be further examined.”<sup>114</sup> The Committee is considering the introduction of new tools to monitor and evaluate compliance with the IHR, namely a peer-review mechanism similar to the Universal Periodic Review used by the Human Rights Council.<sup>115</sup> This proposal is currently being pilot tested under the “Universal Health and Preparedness Review,” an initiative launched in November 2020.<sup>116</sup>

The weakness of the IHR in achieving their stated purpose is deeply associated with the use of non-binding recommendations. In the end, they are “a guide more than a legal mandate.”<sup>117</sup> While the value of “soft law” standards should not be

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108 Stefania Negri, *Communicable Disease Control*, in RESEARCH HANDBOOK ON GLOBAL HEALTH LAW 265, 299 (2018).

109 Antoine Puyvallée & Sonja Kittelsen, “Disease Knows No Borders”: *Pandemics and the Politics of Global Health Security*, in PANDEMICS, PUBLICS, AND POLITICS: STAGING RESPONSES TO PUBLIC HEALTH CRISES 59, 66 (Kristian Bjørkdahl & Benedicte Carlsen eds., 2019).

110 Lee et al., *supra* note 38, at 1593.

111 Gostin, DeBartolo & Friedman, *supra* note 24, at 2225; Wilson, Brownstein & Fidler, *supra* note 99, at 508; *see also* WORLD HEALTH ORG., *supra* note 93, at 113.

112 Adam Kamradt-Scott, *WHO’s to Blame? The World Health Organization and the 2014 Ebola Outbreak in West Africa*, 37 THIRD WORLD Q. 401, 411 (2016).

113 Goldfarb, *supra* note 41, at 808.

114 *Statement to the Resumed 73rd World Health Assembly by the Chair of the Review Committee on the Functioning of the International Health Regulations (2005) During the COVID-19 Response*, WORLD HEALTH ORG. (Nov. 9, 2020), <https://www.who.int/news/item/09-11-2020-statement-73rd-wha-chair-of-the-review-committee-IHR-covid-19>.

115 *Id.*; WORLD HEALTH ORG., *supra* note 100; *see also* WORLD HEALTH ORG., *supra* note 61, at ¶ 18.

116 *See WHO Director-General’s Opening Remarks at 148th Session of the Executive Board*, WORLD HEALTH ORG. (Jan. 18, 2021), <https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-148th-session-of-the-executive-board>.

117 James Hodge, Jr., *Global Legal Triage in Response to the 2009 H1N1 Outbreak*, 11 Minn. J. L. Sci. & Tech. 599, 608 (2010).

downplayed,<sup>118</sup> as non-binding duties may also hold some sway over States,<sup>119</sup> the universal refusal by States Parties to follow WHO's advice raises red flags about the regime's effectiveness in coordinating responses to international health crises.

### B. Human Rights Law

International mobility is protected with much more intensity and detail by human rights law, where it is framed as the right to freedom of movement. This right is linked to the notion of individual self-determination.<sup>120</sup> Based on natural law, international law theoreticians have long asserted the existence of a *jus intergens*: a human right to travel.<sup>121</sup> But this idea has only been formally recognized recently. The right was first enshrined in the Universal Declaration of Human Rights of 1948, which states:

1. Everyone has the right to freedom of movement and residence within the borders of each State.
2. Everyone has the right to leave any country, including his own, and to return to his country.<sup>122</sup>

While the first paragraph refers to the domestic dimension, the second describes the cross-border facet of freedom of movement. The right to transnational mobility is charted broadly, encompassing different groups—from tourists to migrants, refugees to stateless persons.<sup>123</sup>

Freedom of movement, both within and across borders, is also protected by the International Covenant on Civil and Political Rights (ICCPR), Article 12 of which proclaims:

1. Everyone lawfully within the territory of a State shall,

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118 Lawrence Gostin et al., *Towards a Framework Convention on Global Health*, 91 BULL. WORLD HEALTH ORG. 790, 792 (2013).

119 Burkle, *supra* note 51, at 571.

120 Harvey & Barnidge, *supra* note 33, at 2.

121 Siegfried Wiessner, *Blessed Be the Ties That Bind: The Nexus Between Nationality and Territory*, 56 MISS. L.J. 447, 457 (1986).

122 *Universal Declaration of Human Rights*, UNITED NATIONS at art. 13, <https://www.un.org/en/universal-declaration-human-rights>. See Atle Grahl-Madsen, *Article 13, in THE UNIVERSAL DECLARATION OF HUMAN RIGHTS: A COMMENTARY* 203 (Asbjørn Eide et al. eds., 1993) (commenting on Article 13). The Universal Declaration of Human Rights does not have binding force but is normally acknowledged as customary international law. See Hurst Hannum, *The Status of the Universal Declaration of Human Rights in National and International Law* 25 GA. J. INT'L & COMPAR. L. 287, 323 (1998); see also Ilias Bantekas & Lutz Oette, INT'L HUM. RTS. L. & PRAC. 62 (2013) (describing the legal consequence of a rule of customary international law).

123 Ved Nanda, *The Right to Movement and Travel Abroad: Some Observations on the U.N. Deliberations*, 1 DENVER J. INT'L L. & POL'Y 109, 113 (1971).

within that territory, have the right to liberty of movement and freedom to choose his residence.

2. Everyone shall be free to leave any country, including his own.

...

4. No one shall be arbitrarily deprived of the right to enter his own country.<sup>124</sup>

The right to freedom of movement is also enshrined in many universal<sup>125</sup> and regional<sup>126</sup> human rights treaties, which argue in favor of the right being part of general international law.<sup>127</sup> The reference to freedom of movement as a human right is also well established in doctrinal writings.<sup>128</sup> This freedom has been

124 Off. of the High Comm'r for Hum. Rts., *International Covenant on Civil and Political Rights*, UNITED NATIONS at art. 12 (Mar. 23, 1976), <https://www.ohchr.org/en/professionalinterest/pages/ccpr.aspx> [hereinafter ICCPR]. See generally Stig Jagerskiold, *The Freedom of Movement*, in THE INTERNATIONAL BILL OF RIGHTS: THE COVENANT ON CIVIL AND POLITICAL RIGHTS 166, 166-82 (Louis Henkin ed., 1981) (describing Article 12). The Covenant, in force since 1976, is "probably the most important human rights treaty in the world." SARAH JOSEPH & MELISSA CASTAN, THE INTERNATIONAL COVENANT ON CIVIL AND POLITICAL RIGHTS: CASES, MATERIALS, AND COMMENTARY 3 (3d ed. 2013).

125 Among universal instruments, see Off. of the High Comm'r for Hum. Rts., *International Convention on the Elimination of All Forms of Racial Discrimination*, UNITED NATIONS at art. 5(d)(ii) (Jan. 4, 1969), <https://www.ohchr.org/EN/ProfessionalInterest/Pages/CERD.aspx>; Off. of the High Comm'r for Hum. Rts., *Convention on the Rights of the Child*, UNITED NATIONS at art. 10(2) (Sept. 2, 1990), <https://www.ohchr.org/en/professionalinterest/pages/crc.aspx> [hereinafter *Convention on the Rights of the Child*]; Off. of the High Comm'r for Hum. Rts., *International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families*, UNITED NATIONS at art. 8 (Dec. 18, 1990), <https://www.ohchr.org/EN/ProfessionalInterest/Pages/CMW.aspx> [hereinafter *International Convention on the Protection of the Rights of All Migrant Workers*].

126 Among regional instruments, see *Protocol No. 4 to the Convention for the Protection of Human Rights and Fundamental Freedoms*, COUNCIL OF EUR. at art. 2 (Sept. 16, 1963), [https://www.echr.coe.int/Documents/Library\\_Collection\\_P4postP11\\_ETS046E\\_ENG.pdf](https://www.echr.coe.int/Documents/Library_Collection_P4postP11_ETS046E_ENG.pdf); *European Social Charter*, COUNCIL OF EUR. at art. 18(4) (May 3, 1996), <https://rm.coe.int/168007cf93>; *American Convention on Human Rights*, INTER-AM. COMM'N ON HUM. RTS. at art. 22 (Nov. 22, 1969), <https://www.cidh.oas.org/basicos/english/basic3.american%20convention.htm>; *African Charter on Human and Peoples' Rights*, AFR. COMM'N ON HUM. & PEOPLES' RTS. at art. 12 (Oct. 21, 1986), <https://www.achpr.org/legalinstruments/detail?id=49>; *Arab Charter on Human Rights*, art. 27 (Mohammed Amin Al-Midani & Mathilde Cabanettes trans.), [http://www.eods.eu/library/LAS\\_Arab%20Charter%20on%20Human%20Rights\\_2004\\_EN.pdf](http://www.eods.eu/library/LAS_Arab%20Charter%20on%20Human%20Rights_2004_EN.pdf).

127 Francesca De Vittor, *Nationality and Freedom of Movement*, in THE CHANGING ROLE OF NATIONALITY IN INTERNATIONAL LAW 96 (Serena Forlati & Alessandra Annoni eds., 2013).

128 See, e.g., Rosalyn Higgins, *The Right in International Law of an Individual to Enter, Stay in and Leave a Country*, 49 INT'L AFFS. 341 (1973); Jane McAdam, *An Intellectual History of Freedom of Movement in International Law: The Right to Leave as a Personal Liberty*, 12 MELBOURNE J. INT'L L. 27 (2011). Some authors phrase it as a "right to travel." See, e.g., Nanda,

depicted as a “basic”<sup>129</sup> human right and “the first and most fundamental of man’s liberties.”<sup>130</sup>

On its cross-border dimension, freedom of movement is composed of two interdependent rights: the right to leave and the right to return.<sup>131</sup> The two facets are closely interrelated, but they satisfy different needs or aspirations. Individuals may want to leave their country for tourism, to migrate, or to seek refuge, whereas people going in the opposite direction normally wish to return “home.”<sup>132</sup>

### 1. *Right to Leave*

General Comment No. 27, issued by the Human Rights Committee in 1999,<sup>133</sup> sheds light on the scope of the right to leave:

Freedom to leave the territory of a State may not be made dependent on any specific purpose or on the period of time the individual chooses to stay outside the country. Thus travelling abroad is covered, as well as departure for permanent emigration. Likewise, the right of the individual to determine the State of destination is part of the legal guarantee. As the scope of [A]rticle 12, paragraph 2, is not restricted to persons lawfully within the territory of a State, an alien being legally expelled from the country is likewise entitled to elect the State of destination, subject to the agreement of that State.<sup>134</sup>

All individuals benefit from the right to leave, whether they are citizens,

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*supra* note 123, at 109; Turack, *supra* note 34, at 8; Richard Sobel, *The Right to Travel and Privacy: Intersecting Fundamental Freedoms*, 30 J. MARSHALL J. INFO. TECH. & PRIV. L. 639 (2014); Scott, *supra* note 34. One author talks about a “right to move.” Tamás Foldesi, *The Right to Move and Its Achilles’ Heel, the Right to Asylum*, 8 CONN. J. INT’L L. 289 (1993).

129 Francis Gabor, *Reflections on the Freedom of Movement in Light of the Dismantled Iron Curtain*, 65 TUL. L. REV. 849, 850 (1991); Satvinder Juss, *Free Movement and the World Order* 16 INT’L J. REFUGEE L. 289, 290 (2004); Christian Enemark, *Ebola, Disease-Control, and the Security Council: From Securitization to Securing Circulation*, 2 J. GLOB. SEC. STUD. 137, 140 (2017).

130 MAURICE CRANSTON, WHAT ARE HUMAN RIGHTS? 31 (1973).

131 Vincent Chetail, *Freedom of Movement and Transnational Migrations: A Human Rights Perspective*, in *MIGRATION AND INTERNATIONAL LEGAL NORMS* 47, 54, 57 (T. Alexander Aleinikoff & Vincent Chetail eds., 2003); De Vittor, *supra* note 127, at 97.

132 Kathleen Lawand, *The Right to Return of Palestinians in International Law*, 8 INT’L J. REFUGEE L. 532, 540 (1996).

133 *General Comment No. 27: Article 12 (Freedom of Movement)*, HUM. RTS. COMM., <https://www.refworld.org/docid/45139c394.html>. The General Comment can be said to constitute “persuasive authority on the freedom of movement provision of the ICCPR.” Jessica Leal, *Stateless with Nowhere to Go: A Proposal for Revision of the Right of Return According to the International Covenant on Civil and Political Rights*, 46 GEO. WASH. INT’L L. REV. 677, 687 (2014).

134 HUM. RTS. COMM., *supra* note 133, at ¶ 8.

residents, or foreigners, even if they are in the country illegally.<sup>135</sup> The right covers temporary visits as well as permanent leave for emigration purposes.<sup>136</sup>

## 2. *Right to Return*

The personal scope of application of the right to return is narrower. General Comment 27 starts by noting that “[t]he right of a person to enter his or her own country recognizes the special relationship of a person to that country.”<sup>137</sup> The Human Rights Committee emphasizes:

The wording of [A]rticle 12, paragraph 4, does not distinguish between nationals and aliens (“no one”). Thus, the persons entitled to exercise this right can be identified only by interpreting the meaning of the phrase “his own country.” The scope of “his own country” is broader than the “country of his nationality.” It is not limited to nationality in a formal sense, that is, nationality acquired at birth or by conferral; it embraces, at the very least, an individual who, because of his or her special ties to or claims in relation to a given country, cannot be considered to be a mere alien. Since other factors may in certain circumstances result in the establishment of close and enduring connections between a person and a country, States parties should include in their reports information on the rights of permanent residents to return to their country of residence.<sup>138</sup>

The ICCPR only gives the right of entry into a country to persons who “have a strong attachment to that country,” for example, its nationals and residents.<sup>139</sup> In the words of one author, it is “innate in human nature to yearn to be back home.”<sup>140</sup> This “natural desire for a base or a homeland” has been said to demonstrate the rational association of freedom of movement with the right to a nationality.<sup>141</sup> In this sense, the right to return is closely connected with the concept of nationality.<sup>142</sup>

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135 JOSEPH & CASTAN, *supra* note 124, at 400; Chetail, *supra* note 131, at 54.

136 *Id.*

137 HUM. RTS. COMM., *supra* note 133, at ¶ 19.

138 *Id.* at ¶ 20.

139 See Andraž Zidar, *WHO International Health Regulations and Human Rights: from Allusions to Inclusion*, 19 INT’L J. HUM. RTS. 505, 515 (2015).

140 D. Nseroko, *The Right to Return Home*, 21 INDIAN J. INT’L L. 335, 336 (1981).

141 Maurice Cranston, *The Political and Philosophical Aspects of the Right to Leave and to Return*, in THE RIGHT TO LEAVE AND TO RETURN: PAPERS AND RECOMMENDATIONS OF THE INTERNATIONAL COLLOQUIUM HELD IN UPPSALA, SWEDEN, 19-20 JUNE 1972 at 21, 28 (Karel Vasak & Sidney Liskofsky eds., 1976).

142 Higgins, *supra* note 128, at 342; Lawand, *supra* note 132, at 540.

However, because the covenant employs broad language (“his own country”), without restricting this scenario to a nationality link, it is frequently argued that the provision also covers categories such as long-term (or permanent) residents.<sup>143</sup>

### 3. *No Right to Enter a Foreign Country*

Importantly, human rights treaties do not guarantee an unfettered right to access a country other than one’s own. In other words, there is no human right to enter a foreign state.<sup>144</sup> States have the sovereign power to decide matters concerning their territory and population, including border security and migration policies.<sup>145</sup> The Human Rights Committee confirmed this in 1986, stating that “[t]he [ICCPR] does not recognize the right of aliens to enter or reside in the territory of a State [P]arty. It is in principle a matter for the State to decide who it will admit to its territory.”<sup>146</sup>

### 4. *Limitations and Derogations*

Naturally, freedom of movement is not an absolute right and may be subject to restrictions based on the need to pursue and protect other public values.<sup>147</sup> Human rights treaties typically include two mechanisms that can interfere with human rights: limitations and derogations. The possibility of imposing limitations results from the acknowledgment that most human rights are not absolute and must be weighed against collective interests.<sup>148</sup> Limitations should not affect the “core of the right,”<sup>149</sup> striking a balance between the protection of individual and

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143 Chetail, *supra* note 131, at 57; Jeremie Bracka, *Past the Point of No-Return? The Palestinian Right of Return in International Human Rights Law*, 6 MELBOURNE J. INT’L L. 272, 298-300 (2005); *see also* HUM. RTS. COMM., *supra* note 133, at ¶ 20 (“The language of [A]rticle 12, paragraph 4, moreover, permits a broader interpretation that might embrace other categories of long-term residents, including but not limited to stateless persons arbitrarily deprived of the right to acquire the nationality of the country of such residence.”). In principle it is up to the individual to prove that the State in question is “his own country.” *See* THE LAW AND PRACTICE OF EXPULSION AND EXCLUSION FROM THE UNITED KINGDOM 47-48 (Eric Fripp ed., 2015).

144 Karl Doehring, *Aliens, Admission*, in ENCYCLOPEDIA OF PUBLIC INTERNATIONAL LAW 11, 12 (1985); Chetail, *supra* note 131, at 57; De Vittor, *supra* note 127, at 96; Higgins, *supra* note 128, at 344.

145 De Vittor, *supra* note 127, at 96, 103.

146 *General Comment No. 15: The Position of Aliens Under the Covenant*, HUM. RTS. COMM. ¶ 5, <https://www.refworld.org/pdfid/45139acfc.pdf>.

147 In the words of Sir Hersch Lauterpacht, “[i]t is axiomatic that the natural rights of the individual find a necessary limit in the natural rights of other persons.” Hersch Lauterpacht, INTERNATIONAL LAW AND HUMAN RIGHTS 366 (1st ed. 1968) (1950).

148 Dominic McGoldrick, *The Interface Between Public Emergency Powers and International Law*, 2 INT’L J. CONST. L. 380, 383 (2004).

149 Toebes, *supra* note 32, at 497.

community interests.<sup>150</sup> Derogations, on the other hand, result in the complete suspension of the right.<sup>151</sup> While the first mechanism compresses the protection of some human rights, the second temporarily interrupts their enjoyment.<sup>152</sup>

Specifically apropos limitations to freedom of movement, Article 12(3) of the covenant provides:

The above-mentioned rights shall not be subject to any restrictions except those which are provided by law, are necessary to protect national security, public order (ordre public), public health or morals or the rights and freedoms of others, and are consistent with the other rights recognized in the present Covenant.<sup>153</sup>

The “above-mentioned” rights are domestic freedom of movement and the right to leave. While the ICCPR seems to establish a strong presumption in favor of freedom of movement,<sup>154</sup> balancing individual rights with other societal imperatives may still be necessary. A serious threat to public health may qualify as one such case. In fact, it may be necessary to constrain the freedom of individuals if that is necessary to avoid or mitigate potential damages for other persons and the broader community.<sup>155</sup> In the case of an epidemic, limitations may be grounded on the need to protect both “public health” and “the rights and freedoms of others.”

General Comment No. 27 offers specific parameters on the permissible limitations of the right to freedom of movement. The General Comment starts by affirming that “[l]iberty of movement is an indispensable condition for the free development of a person” that “interacts with several other rights enshrined in the

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<sup>150</sup> Spadaro, *supra* note 28, at 320.

<sup>151</sup> Toebe, *supra* note 32, at 496; Spadaro, *supra* note 28, at 321.

<sup>152</sup> Zidar, *supra* note 139, at 507.

<sup>153</sup> ICCPR, *supra* note 124, at art. 12(3). Other human rights treaties also allow for the restriction of the right to freedom of movement when necessary to protect other interests, including public health. See *Convention on the Rights of the Child*, *supra* note 125, at art. 10(2); *International Convention on the Protection of the Rights of All Migrant Workers*, *supra* note 125, at art. 8(1); *Protocol No. 4 to the Convention for the Protection of Human Rights and Fundamental Freedoms*, *supra* note 126, at art. 2(3); *American Convention on Human Rights*, *supra* note 126, at art. 22(3); *African Charter on Human and Peoples’ Rights*, *supra* note 126, at art. 12(2). The Universal Declaration of Human Rights makes no reference to public health as a ground for limitations: “In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.” *Universal Declaration of Human Rights*, *supra* note 122, at art. 29(2).

<sup>154</sup> See HURST HANNUM, *THE RIGHT TO LEAVE AND RETURN IN INTERNATIONAL LAW AND PRACTICE* 21 (1987).

<sup>155</sup> Enemark, *supra* note 31, at 201; Meier, Evans & Phelan, *supra* note 70, at 227.

Covenant.”<sup>156</sup> Importantly, the Human Rights Committee added:

The permissible limitations which may be imposed on the rights protected under [A]rticle 12 must not nullify the principle of liberty of movement, and are governed by the requirement of necessity provided for in [A]rticle 12, paragraph 3, and by the need for consistency with the other rights recognized in the Covenant.<sup>157</sup>

If States decide to impose limits to freedom of movement, they need to ensure that such interventions conform to human rights. The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights (“Siracusa Principles”) offer useful guidance in this regard.<sup>158</sup> This set of soft law rules was drawn up by a group of thirty-one experts in international law and is “widely recognized as a legal standard for measuring the validity of limitations on human rights.”<sup>159</sup> The Principles establish several requirements for limitations to be lawful:

Whenever a limitation is required in the terms of the Covenant to be “necessary,” this term implies that the limitation:

- a. is based on one of the grounds justifying limitations recognized by the relevant article of the Covenant;
- b. responds to a pressing public or social need;
- c. pursues a legitimate aim; and

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<sup>156</sup> *General Comment No. 27: Article 12 (Freedom of Movement)*, *supra* note 133, at ¶ 1. One author has even claimed that “[t]he right to travel is the basis of all other rights, since they depend upon freedom of movement.” Darren O’Byrne, *On Passports and Border Controls*, 28 ANNALS TOURISM RSCH. 399, 413 (2001).

<sup>157</sup> *General Comment No. 27: Article 12 (Freedom of Movement)*, *supra* note 133, at ¶ 2.

<sup>158</sup> *Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights*, INT’L COMM’N JURISTS (Apr. 1985), <https://www.icj.org/wp-content/uploads/1984/07/Siracusa-principles-ICCPR-legal-submission-1985-eng.pdf> [hereinafter *Siracusa Principles*].

<sup>159</sup> Lawrence Gostin & Benjamin Berkman, *Pandemic Influenza: Ethics, Law, and the Public’s Health*, 59 ADMIN. L. REV. 121, 146 (2007). The Principles are “[n]on-binding but authoritative.” Roojin Habibi et al., *The Stellenbosch Consensus on Legal National Responses to Public Health Risks: Clarifying Article 43 of the International Health Regulations*, INT’L ORGS. L. REV. 1, 53 (2020) [hereinafter *Stellenbosch Consensus*].

d. is proportionate to that aim.<sup>160</sup>

Proportionality is key to this balancing test, involving “a delicate equation evaluating the importance of the social aim, the importance of the right guaranteed, and the degree of encroachment.”<sup>161</sup> The Siracusa Principles also contain a provision specifically dealing with limitations of rights for public health reasons, stating:

Public health may be invoked as a ground for limiting certain rights in order to allow a state to take measures dealing with a serious threat to the health of the population or individual members of the population. These measures must be specifically aimed at preventing disease or injury or providing care for the sick and injured.<sup>162</sup>

Instead of being limited, the human right to freedom of movement may be derogated. Indeed, a public health crisis of exceptional severity may be invoked as a reason to derogate from human rights. There is a continuum between the two types of measures, and states should only resort to derogations when limitations are insufficient.<sup>163</sup> Derogations require a more demanding assessment of the seriousness of the threat to public interests and its implications in protecting other human rights.<sup>164</sup>

Derogation clauses operate as an escape valve, allowing States to suspend some human rights obligations in extreme scenarios.<sup>165</sup> Article 4 of the ICCPR permits the derogation of otherwise legally protected rights as long as several requirements are met:

1. In time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations

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160 *Siracusa Principles*, *supra* note 158, at ¶ 10.

161 Frédéric Mégret, *Nature of Obligations*, in INTERNATIONAL HUMAN RIGHTS LAW 96, 112 (Daniel Moeckli, Sangeeta Shah & Sandesh Sivakumaran eds., 2014).

162 *Siracusa Principles*, *supra* note 158, at ¶ 25.

163 Spadaro, *supra* note 28, at 321-322; McGoldrick, *supra* note 148, at 384.

164 Zidar, *supra* note 139, at 507.

165 Emilie Hafner-Burton, Laurence Helfer & Christopher Fariss, *Emergency and Escape: Explaining Derogations from Human Rights Treaties*, 65 INT'L ORG. 673, 674 (2011); Gentian Zyberi, *Some Reflections on Countering the Covid-19 Pandemic: Moving from Emergency to the “New Normal” Without Trampling on Human Rights?*, INT'L L. OBSERVER (Dec. 15, 2020), <https://internationallawobserver.eu/some-reflections-on-countering-the-covid-19-pandemic-moving-from-emergency-to-the-new-normal-without-trampling-on-human-rights>.

under the present Covenant to the extent strictly required by the exigencies of the situation, provided that such measures are not inconsistent with their other obligations under international law and do not involve discrimination solely on the ground of race, colour, sex, language, religion or social origin.

2. No derogation from [A]rticles 6, 7, 8 (paragraphs 1 and 2), 11, 15, 16, and 18 may be made under this provision.<sup>166</sup>

Article 4(1) of the ICCPR requires a “public emergency which threatens the life of the nation” for rights to be derogated.<sup>167</sup> The concept of “public emergency” is very broad and includes public health emergencies, as long as it meets all other criteria—that is, that it represents “a direct, exceptional and actual or imminent threat to the life of the nation.”<sup>168</sup> When is this the case? In the words of the Human Rights Committee, “[n]ot every disturbance or catastrophe qualifies as a public emergency which threatens the life of the nation.”<sup>169</sup> And it adds:

If States purport to invoke the right to derogate from the Covenant during, for instance, a natural catastrophe, a mass demonstration including instances of violence, or a major industrial accident, they must be able to justify not only that such a situation constitutes a threat to the life of the nation, but also that all their measures derogating from the Covenant are strictly required by the exigencies of the situation. In the opinion of the Committee, the possibility of restricting certain Covenant rights under the terms of, for instance, freedom of movement ([A]rticle 12) or freedom of assembly ([A]rticle 21) is generally sufficient during such situations and no derogation from the provisions in question

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<sup>166</sup> ICCPR, *supra* note 124, at art. 4.

<sup>167</sup> *Id.*

<sup>168</sup> Zidar, *supra* note 139, at 508.

<sup>169</sup> *General Comment No. 29: Derogations During a State of Emergency*, HUM. RTS. COMM. ¶ 2, <https://www.refworld.org/docid/453883fd1f.html>. According to the Siracusa Principles, “[a] state party may take measures derogating from its obligations under the International Covenant on Civil and Political Rights pursuant to Article 4 . . . only when faced with a situation of exceptional and actual or imminent danger which threatens the life of the nation. A threat to the life of the nation is one that: (a) affects the whole of the population and either the whole or part of the territory of the state; and (b) threatens the physical integrity of the population, the political independence or the territorial integrity of the state or the existence or basic functioning of institutions indispensable to ensure and protect the rights recognized in the Covenant.” *Siracusa Principles*, *supra* note 158, at ¶ 39.

would be justified by the exigencies of the situation.<sup>170</sup>

Even though the Committee does not expressly refer to the case of pandemics, its considerations seem to apply in such instances.<sup>171</sup> The concept of PHEIC, as defined in the IHR, is particularly helpful in this regard: “[A]n extraordinary event which is determined, as provided in these Regulations: (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.”<sup>172</sup> According to WHO, “[t]his definition implies a situation that: is serious, unusual or unexpected; carries implications for public health beyond the affected State’s national border; and may require immediate international action.”<sup>173</sup> Thus, a PHEIC may amount to a public emergency for states under Article 4 of the ICCPR.<sup>174</sup>

Due to its severe impact—yet to be fully determined—the COVID-19 pandemic is likely one of those circumstances where the “life of the nation is at stake,” and so the derogation of certain human rights may be justified.<sup>175</sup> There are, however, important safeguards and requirements to the derogation of human rights, which are based on the principles of legality and the rule of law.<sup>176</sup> As stated in the Siracusa Principles, derogation “is not exercised in a legal vacuum. It is authorized by law, and as such, it is subject to several legal principles of general application.”<sup>177</sup> The Principles also add that provisions allowing for certain derogations in a public emergency are to be interpreted restrictively.<sup>178</sup>

It should be noted that the right to return is not bound by the restrictions contained in Article 12(3) of the ICCPR, based on the need to protect national security, public order (*ordre public*), public health or morals, or the rights and freedoms of others, as it is not one of the “above-mentioned rights.”<sup>179</sup> Article

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170 *General Comment No. 29: Derogations During a State of Emergency*, *supra* note 169, at ¶ 5.

171 Spadaro, *supra* note 28, at 321.

172 IHR, *supra* note 3, at art. 1(1).

173 *IHR Procedures Concerning Public Health Emergencies of International Concern (PHEIC)*, WORLD HEALTH ORG., [https://www.who.int/ihr/revised\\_annex2\\_guidance.pdf](https://www.who.int/ihr/revised_annex2_guidance.pdf).

174 Zidar, *supra* note 139, at 508.

175 Spadaro, *supra* note 28, at 322; Altea Rossi, *COVID-19: The ‘Fine Balance’ under Human Rights Law*, GENEVA CTR. FOR SEC. POL’Y (Apr. 17, 2020), <https://www.gesp.ch/global-insights/covid-19-fine-balance-under-human-rights-law>; Audrey Lebret, *COVID-19 Pandemic and Derogation to Human Rights*, 7 J.L. & BIOSCIENCES 1, 5 (2020).

176 *General Comment No. 29: Derogations During a State of Emergency*, *supra* note 169, at ¶ 16.

177 *Siracusa Principles*, *supra* note 158, at ¶ 61.

178 *Id.* at ¶ 63.

179 Barbara von Tigerstrom, *The Revised International Health Regulations and Restraint of National Health Measures*, 13 HEALTH L.J. 35, 64 n.147 (2005); Bracka, *supra* note 143, at 305; Leal, *supra* note 133, at 683; John Quigley, *Displaced Palestinians and a Right of Return*, 39 HARV. INT’L L.J. 171, 201-02 (1998); Eric Richardson & Colleen Devine, *Emergencies End Eventually*:

12(4) only states that “[n]o one shall be arbitrarily deprived of the right to enter his own country.” The Human Rights Committee clarifies:

In no case may a person be arbitrarily deprived of the right to enter his or her own country. The reference to the concept of arbitrariness in this context is intended to emphasise that it applies to all State action, legislative, administrative and judicial; it guarantees that even interference provided for by law should be in accordance with the provisions, aims and objectives of the Covenant and should be, in any event, reasonable in the particular circumstances. The Committee considers that there are few, if any, circumstances in which deprivation of the right to enter one’s own country could be reasonable.<sup>180</sup>

The right to return (just like the right to leave) may be derogated as long as the requirements set in Article 4(1) of the ICCPR are met. The assessment of whether the circumstances require derogation from a certain right is subject to the principle of strict proportionality. According to General Comment No. 29:

A fundamental requirement for any measures derogating from the Covenant, as set forth in [A]rticle 4, paragraph 1, is that such measures are limited to the extent strictly required by the exigencies of the situation. This requirement relates to the duration, geographical coverage[,] and material scope of the state of emergency and any measures of derogation resorted to because of the emergency. Derogation from some Covenant obligations in emergency situations is clearly distinct from restrictions or limitations allowed even in normal times under several provisions of the Covenant. Nevertheless, the obligation to limit any derogations to those strictly required by the exigencies of the situation reflects the principle of proportionality which is common to derogation and limitation powers. Moreover, the mere fact that a permissible derogation from a specific provision may, of itself, be justified by the exigencies of the situation does not obviate the

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*How to Better Analyze Human Rights Restrictions Sparked by the COVID-19 Pandemic Under the International Covenant on Civil and Political Rights*, MICH. J. INT’L L. 1, 29 (2021).

<sup>180</sup> *General Comment No. 27: Article 12 (Freedom of Movement)*, *supra* note 133, at ¶ 21. Still, the term “arbitrarily” may imply some limits to the exercise of the right. Chetail, *supra* note 131, at 58; Jagerskiold, *supra* note 124, at 181. States’ practice remains relatively sparse with regard to the concrete standards for assessing arbitrariness. Chetail, *supra* note 131, at 58. Moreover, all of the other international instruments do not refer to the term “arbitrarily” and guarantee an unrestricted right to return. *Id.*

requirement that specific measures taken pursuant to the derogation must also be shown to be required by the exigencies of the situation. In practice, this will ensure that no provision of the Covenant, however validly derogated from will be entirely inapplicable to the behaviour of a State [P]arty. When considering States parties' reports the Committee has expressed its concern over insufficient attention being paid to the principle of proportionality.<sup>181</sup>

The Siracusa Principles offer valuable guidance when designing and implementing derogatory measures:

51. The severity, duration, and geographic scope of any derogation measure shall be such only as are strictly necessary to deal with the threat to the life of the nation and are proportionate to its nature and extent.
52. The competent national authorities shall be under a duty to assess individually the necessity of any derogation measure taken or proposed to deal with the specific dangers posed by the emergency.
53. A measure is not strictly required by the exigencies of the situation where ordinary measures permissible under the specific limitations clauses of the Covenant would be adequate to deal with the threat to the life of the nation.
54. The principle of strict necessity shall be applied in an objective manner. Each measure shall be directed to an actual, clear, present, or imminent danger and may not be imposed merely because of an apprehension of potential danger.
55. The national constitution and laws governing states of emergency shall provide for prompt and periodic independent review by the legislature of the necessity for derogation measures.
56. Effective remedies shall be available to persons claiming that derogation measures affecting them are not strictly

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181 *General Comment No. 29: Derogations During a State of Emergency*, *supra* note 169, at ¶ 4.

required by the exigencies of the situation.

57. In determining whether derogation measures are strictly required by the exigencies of the situation the judgment of the national authorities cannot be accepted as conclusive.<sup>182</sup>

The ICCPR makes clear that freedom of movement may be limited or even suppressed for public health reasons. To be lawful, limitations and derogations need to comply with the safeguards and requirements contained in the ICCPR, on which the Siracusa Principles meticulously shed light. Derogations are particularly dangerous moments for human rights protection and should invite close scrutiny. According to the Principles, derogation is “an authorized and limited prerogative in order to respond adequately to a threat to the life of the nation” that the derogating state has the burden of justifying under the law.<sup>183</sup> A proclamation of a public emergency, and the imposition of derogations, should be made in good faith; otherwise, it qualifies as a violation of international law.<sup>184</sup>

This Article does not question the good faith of states confronted with a “once in a century pandemic.”<sup>185</sup> While some governments have likened the pandemic to a war, the lawfulness of limitations and derogations should not be automatically assumed. This assessment should be based on respect for the conditions and requirements laid down in the ICCPR. Part II applies the canons of legality, necessity, proportionality, and non-discrimination to travel bans so as to determine whether they comply with international law.

## II. THE (UN)LAWFULNESS OF TRAVEL BANS

As described in Part I, both the IHR and the ICCPR recognize that in some situations, it may be necessary to constrain the (international) freedom of movement of individuals to protect public health. The fact that WHO never recommended (at least explicitly) the implementation of travel bans does not automatically render these measures illegal under the IHR so long as the requirements of Article 43 are respected. When implementing additional health measures, states should bear in mind the important connections between the IHR and human rights, namely, the fact that such measures may result in the introduction of limitation to or of derogations from the human right to freedom of

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182 *Siracusa Principles*, *supra* note 158, at ¶¶ 51-57.

183 *Id.* at ¶ 64.

184 *Id.* at ¶ 62.

185 Bill Gates, *Responding to Covid-19—A Once-in-a-Century Pandemic?*, 382 *NEW ENG. J. MED.* 1677 (2020).

movement.<sup>186</sup>

References to human rights principles, including the “protection of the human rights of persons and travelers,” were explicitly incorporated in the IHR for the first time in 2005.<sup>187</sup> The basic principles are stated as follows:

1. The implementation of these Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons.
2. The implementation of these Regulations shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization.
3. The implementation of these Regulations shall be guided by the goal of their universal application for the protection of all people of the world from the international spread of disease.
4. States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so, they should uphold the purpose of these Regulations.<sup>188</sup>

The inclusion of these provisions made human rights rules and principles part and parcel of the accurate interpretation and implementation of the IHR.<sup>189</sup> The new references were seen as a welcome addition,<sup>190</sup> revealing WHO’s willingness to exert its influence on matters of human rights<sup>191</sup> and its “new normative discourse” on global health.<sup>192</sup>

These provisions integrate human rights treaties into the construal and operation of the regulations, imposing on States the obligation to ensure that they

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186 *Stellenbosch Consensus*, *supra* note 159, at 46.

187 IHR, *supra* note 3, foreword.

188 *Id.* at art. 3. Pursuant to Article 32 of the regulations, “[i]n implementing health measures under these Regulations, States Parties shall treat travellers with respect for their dignity, human rights and fundamental freedoms and minimize any discomfort or distress associated with such measures . . . .” *Id.* at art. 32; *see also id.* at art. 23 (health measures on arrival and departure).

189 David Fidler & Lawrence Gostin, *The New International Health Regulations: An Historic Development for International Law and Public Health*, 34 J.L. MED. & ETHICS 85, 87 (2006).

190 *Id.*; Michael Baker & David Fidler, *Global Public Health Surveillance Under the New International Health Regulations*, 12 EMERGING INFECTIOUS DISEASES 1058, 1058 (2006).

191 Lawrence Gostin, *Meeting Basic Survival Needs of the World’s Least Healthy People: Toward a Framework Convention on Global Health*, 96 GEO. L.J. 331, 378 (2008).

192 David Fidler, *Architecture Amidst Anarchy: Global Health’s Quest for Governance*, 1 GLOB. HEALTH 1, 12 (2007).

comply with both legal frameworks. The same connection between human rights treaties and the IHR is made in the Siracusa Principles, which provide that when limiting certain rights on public health grounds, “[d]ue regard shall be had to the international health regulations of the World Health Organization.”<sup>193</sup> As underlined by Negri, “[s]uch a reference to the IHR is particularly noteworthy because it stresses that in times of public health emergency national authorities have to comply with both the Regulations and human rights treaties, and that they are called to ensure consistency and coordination between the obligations stemming therefrom.”<sup>194</sup>

The connection between the IHR and human rights treaties also stems from Article 57(1) of the IHR, under which “States Parties recognize that the IHR and other relevant international agreements should be interpreted so as to be compatible. The provisions of the IHR shall not affect the rights and obligations of any State Party deriving from other international agreements.”<sup>195</sup> This reinforces the central role of human rights law in guiding the interpretation of additional health measures under Article 43 of the IHR.<sup>196</sup> As recognized by WHO, “[i]n emergency situations, the enjoyment of individual human rights and civil liberties may have to be limited in the public interest. However, efforts to protect individual rights should be part of any policy.”<sup>197</sup> Specifically discussing the different measures that may restrict the freedom of movement, WHO stated:

These measures can often play an important role in controlling infectious disease outbreaks, and in these circumstances, their use is justified by the ethical value of protecting community well-being. However, the effectiveness of these measures should not be assumed; in fact, under some epidemiological circumstances, they may contribute little or nothing to outbreak control efforts, and may even be counterproductive if they engender a backlash that leads to resistance to other control measures. Moreover, all such

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193 *Siracusa Principles*, *supra* note 158, at ¶ 26.

194 Negri, *supra* note 108, at 289-90.

195 IHR, *supra* note 3, at art. 57(1).

196 *Stellenbosch Consensus*, *supra* note 159, at 45-46; *see also id.* at 67 (“It is clear the IHR was conceived to be closely intertwined with international human rights law and international trade law. With respect to human rights law, Article 43 sets limitations to additional health measures by deferring to the rights contained in the UDHR, ICCPR and other international and regional human rights treaties. This symbiosis suggests that in cases where an additional health measure may curtail the rights and freedoms of individuals, states should at minimum apply the principles of legitimacy, necessity and proportionality to guide them in understanding the limited circumstances under which they may legally deviate from their human rights obligations.”)

197 *Ethical Considerations in Developing a Public Health Response to Pandemic Influenza*, WORLD HEALTH ORG. 3 (2007), [https://www.who.int/csr/resources/publications/WHO\\_CDS\\_EPR\\_GIP\\_2007\\_2c.pdf](https://www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2c.pdf).

measures impose a significant burden on individuals and communities, including direct limitations of fundamental human rights, particularly the rights to freedom of movement and peaceful assembly.<sup>198</sup>

WHO acknowledges that human rights rules and principles “provide the framework for evaluating the ethical acceptability of public health measures that limit individual freedom, just as human rights provide the foundation for other pandemic-related policies.”<sup>199</sup> Measures that limit individual rights and civil liberties must be necessary, reasonable, proportional, equitable, non-discriminatory, and comply with national and international laws.<sup>200</sup> Thus, to conform to both the IHR and international human rights treaties, travel bans must cumulatively satisfy all of these (demanding) standards.

### A. *Legal Basis*

The first requirement is that governmental measures have a legal basis.<sup>201</sup> With respect to limitations, Article 12(3) of the ICCPR invokes the principle of legality when it states that “[t]he above-mentioned rights shall not be subject to any restrictions except those which are provided by law.”<sup>202</sup> The Human Rights Committee stated:

The law itself has to establish the conditions under which the rights may be limited. State reports should therefore specify the legal norms upon which restrictions are founded. Restrictions which are not provided for in the law or are not in conformity with the requirements of [A]rticle 12, paragraph 3, would violate the rights guaranteed by paragraphs 1 and 2.<sup>203</sup>

It further added:

In adopting laws providing for restrictions permitted by [A]rticle 12, paragraph 3, States should always be guided by the principle that the restrictions must not impair the essence of the right . . . ; the relation between right and restriction, between norm and

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198 *Guidance for Managing Ethical Issues in Infectious Disease Outbreaks*, WORLD HEALTH ORG. 25 (2016), <https://apps.who.int/iris/handle/10665/250580>.

199 WORLD HEALTH ORG., *supra* note 197, at 9.

200 *Id.* at 3.

201 *General Comment No. 27: Article 12 (Freedom of Movement)*, *supra* note 133, at ¶ 11.

202 ICCPR, *supra* note 124, at art. 12(3). *General Comment No. 27: Article 12 (Freedom of Movement)*, *supra* note 133, at ¶ 11 (“To be permissible, restrictions must be provided by law . . .”).

203 *General Comment No. 27: Article 12 (Freedom of Movement)*, *supra* note 133, at ¶ 12.

exception, must not be reversed. The laws authorising the application of restrictions should use precise criteria and may not confer unfettered discretion on those charged with their execution.<sup>204</sup>

In this regard, the Siracusa Principles stipulate:

15. No limitation on the exercise of human rights shall be made unless provided for by national law of general application which is consistent with the Covenant and is in force at the time the limitation is applied.
16. Laws imposing limitations on the exercise of human rights shall not be arbitrary or unreasonable.
17. Legal rules limiting the exercise of human rights shall be clear and accessible to everyone.<sup>205</sup>

As for derogations, Article 4 of the ICCPR states that the existence of a public emergency that threatens the life of the nation shall be officially proclaimed.<sup>206</sup> The State must immediately inform the other States Parties, through the intermediary of the Secretary-General of the United Nations, of the provisions from which it has derogated and of the reasons by which it was actuated. A further communication shall be made, through the same intermediary, on the date on which it terminates such derogation.<sup>207</sup> The COVID-19 pandemic prompted a frantic legislative response.<sup>208</sup> While some countries implemented measures pursuant to laws already in place, others passed specific statutes for that purpose.<sup>209</sup> There are obvious

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204 *Id.* at ¶ 13.

205 *Siracusa Principles*, *supra* note 158, at ¶¶ 15-17.

206 ICCPR, *supra* note 124, at art. 4(1). Similarly, Article 42 of the Siracusa Principles states that “[a] state party derogating from its obligations under the Covenant shall make an official proclamation of the existence of a public emergency threatening the life of the nation.” *Siracusa Principles*, *supra* note 158, at art. 42.

207 ICCPR, *supra* note 124, at art. 4(3); *see also General Comment No. 29: Derogations During a State of Emergency*, *supra* note 169, ¶ 17; *Siracusa Principles*, *supra* note 158, at arts. 44, 49.

208 See Ronan Cormacain, *Keeping Covid-19 Emergency Legislation Socially Distant from Ordinary Legislation: Principles for the Structure of Emergency Legislation*, 8 *THEORY & PRAC. OF LEGIS.* 245 (2020).

209 Bård Andreassen et al., *COVID-19: Human Rights Trade-offs, Challenges and Policy Responses*, NORWEGIAN CTR. FOR HUM. RTS. 16 (2020), <https://www.jus.uio.no/smr/english/research/publications/occasional-papers/oc-13-20.pdf>. Article 43 of the Siracusa Principles provides that “[p]rocedures under national law for the proclamation of a state of emergency shall be prescribed in advance of the emergency.” *Siracusa Principles*, *supra* note 158, at art. 43.

dangers to legislating in the context of a crisis,<sup>210</sup> namely that the use of emergency powers results in draconian measures by the executive.<sup>211</sup>

*B. (Public Health) Necessity*

The second fundamental tenet is that restrictive measures comply with the necessity test.

With respect to limitations of human rights, General Comment No. 27 provides: “To be permissible, restrictions must be . . . necessary in a democratic society for the protection of these purposes [protect national security, public order (ordre public), public health or morals and the rights and freedoms of others] . . . .”<sup>212</sup> The Human Rights Committee further added: “Article 12, paragraph 3, clearly indicates that it is not sufficient that the restrictions serve the permissible purposes; they must also be necessary to protect them.”<sup>213</sup>

The Siracusa Principles define “necessary” as follows:

Whenever a limitation is required in the terms of the Covenant to be “necessary,” this term implies that the limitation:

- a. is based on one of the grounds justifying limitations recognized by the relevant article of the Covenant;
- b. responds to a pressing public or social need;
- c. pursues a legitimate aim; and
- d. is proportionate to that aim.<sup>214</sup>

Any assessment as to the necessity of a limitation shall be made on objective considerations.

Turning to derogations, the ICCPR provides, quite laconically, that States invoking the existence of a “public emergency which threatens the life of the nation” must also submit the reasons for their decision to derogate from their obligations and justify the need to introduce specific measures.<sup>215</sup> The Siracusa

210 Robyn Martin et al., *Pandemic Influenza Control in Europe and the Constraints Resulting from Incoherent Public Health Laws*, 10 BMC PUB. HEALTH 532 (2010).

211 Cormacain, *supra* note 208, at 251.

212 *General Comment No. 27: Article 12 (Freedom of Movement)*, *supra* note 133, at ¶ 11.

213 *Id.* at ¶ 14.

214 *Siracusa Principles*, *supra* note 158, at ¶ 10.

215 ICCPR, *supra* note 124, at art. 4(3); *see also General Comment No. 29: Derogations During a State of Emergency*, *supra* note 169, at ¶ 5.

Principles are very useful in this regard, as they elaborate with great detail on the contents of the notification:

45. The notification shall contain sufficient information to permit the states parties to exercise their rights and discharge their obligations under the Covenant. In particular it shall contain:
  - (a) the provisions of the Covenant from which it has derogated;
  - (b) a copy of the proclamation of emergency, together with the constitutional provisions, legislation, or decrees governing the state of emergency in order to assist the states parties to appreciate the scope of the derogation;
  - (c) the effective date of the imposition of the state of emergency and the period for which it has been proclaimed;
  - (d) an explanation of the reasons which actuated the government's decision to derogate, including a brief description of the factual circumstances leading up to the proclamation of the state of emergency; and
  - (e) a brief description of the anticipated effect of the derogation measures on the rights recognized by the Covenant, including copies of decrees derogating from these rights issued prior to the notification.
46. States parties may require that further information necessary to enable them to carry out their role under the Covenant be provided through the intermediary of the Secretary-General.
47. A state party which fails to make an immediate notification in due form of its derogation is in breach of its obligations to other states parties and may be deprived of the defenses otherwise available to it in procedures under the Covenant.<sup>216</sup>

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<sup>216</sup> *Siracusa Principles*, *supra* note 158, at ¶¶ 45-47.

States Parties to the ICCPR can only derogate from their obligations under the covenant “to the extent strictly required by the exigencies of the situation.”<sup>217</sup> According to the Siracusa Principles, this principle of “strict necessity” requires that each measure “be directed to an actual, clear, present, or imminent danger and . . . not . . . imposed merely because of an apprehension of potential danger.”<sup>218</sup> WHO speaks, in this regard, of “public health necessity.”<sup>219</sup> By requiring that States Parties base their decisions on scientific evidence and information, Article 43(2) of the IHR requires the demonstration that additional health measures are necessary to protect public health.<sup>220</sup> Measures need to “respond to a pressing public and social need” and have the purpose of “preventing and controlling the spread of communicable diseases.”<sup>221</sup> Assessing whether certain measures are strictly necessary—and therefore valid and legitimate—depends on the best available scientific evidence.<sup>222</sup> In this regard, WHO states:

Decisions to impose restrictions on freedom of movement should be grounded on the best available evidence about the outbreak pathogen, as determined in consultation with national and international public health officials. No such interventions should be implemented unless there is a reasonable basis to expect they will significantly reduce disease transmission. The rationale for relying on these measures should be made explicit, and the appropriateness of any restrictions should be continuously re-evaluated in light of emerging scientific information about the outbreak. If the original rationale for imposing a restriction no longer applies, the restriction should be lifted without delay.<sup>223</sup>

In deciding whether to implement additional health measures, States Parties shall<sup>224</sup> base their determinations upon scientific principles;<sup>225</sup> available scientific evidence of a risk to human health, or where such evidence is insufficient, the available information including from WHO and other relevant intergovernmental organizations and international bodies,<sup>226</sup> and any available specific guidance or

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217 ICCPR, *supra* note 124, at art. 4(1).

218 *Siracusa Principles*, *supra* note 158, at ¶ 54.

219 WORLD HEALTH ORG., *supra* note 32, at 29.

220 *Stellenbosch Consensus*, *supra* note 159, at 53; Fidler, *supra* note 63, at 382.

221 Negri, *supra* note 108, at 290.

222 Enemark, *supra* note 31, at 201; Negri, *supra* note 108, at 290.

223 WORLD HEALTH ORG., *supra* note 198, at 25-26.

224 The use of the word “shall” denotes the mandatory nature of this duty. *Stellenbosch Consensus*, *supra* note 159, at 22.

225 IHR, *supra* note 3, at art. 43(2)a.

226 *Id.* at art. 43(2)b.

advice from WHO.<sup>227</sup>

Temporary recommendations issued by WHO play a central role in determining whether a certain measure is strictly necessary. They clearly qualify as one of the elements that, according to the IHR, shall be the base of the decision to implement additional health measures (“any available specific guidance or advice from WHO”).<sup>228</sup> WHO’s recommendations are a central element in determining the relevant scientific evidence.<sup>229</sup> They are based on scientific principles<sup>230</sup> and available scientific evidence<sup>231</sup> and information.<sup>232</sup>

WHO issued several recommendations and statements specific to COVID-19. Consistent with its position in previous PHEICs, WHO never explicitly recommended the implementation of travel restrictions, much less of travel bans.<sup>233</sup> It is true that WHO’s official position somewhat evolved over time. While the first statement was unequivocally against the implementation of any travel restrictions,<sup>234</sup> later pronouncements added ambivalent and flexible language, denoting that such measures could be adopted in some circumstances.<sup>235</sup> This shift towards a more nuanced approach may have been influenced by the almost universal non-compliance with the original recommendations,<sup>236</sup> with WHO seeking to strike a more flexible and conciliatory tone.

The effectiveness of temporary recommendations depends on States

227 *Id.* at art. 43(2)c.

228 IHR, *supra* note 3, at art. 43(2)c. See *Stellenbosch Consensus*, *supra* note 159, at 26.

229 Von Bogdandy & Villarreal, *supra* note 68, at 21.

230 IHR, *supra* note 3, at art. 1(1) (“[S]cientific principles’ means the accepted fundamental laws and facts of nature known through the methods of science . . .”).

231 IHR, *supra* note 3, at art. 1(1) (“[S]cientific evidence’ means information furnishing a level of proof based on the established and accepted methods of science . . .”).

232 IHR, *supra* note 3, at art. 17(c).

233 Before COVID-19, five events were declared a PHEIC under the IHR (2005): the 2009 H1N1 influenza pandemic, Ebola (2013-2015 and 2018-2020), poliomyelitis (2014 to present), and Zika (2016). See Annelies Wilder-Smith & Sarah Osman, *Public Health Emergencies of International Concern: A Historic Overview*, 27 J. TRAVEL MED. 1 (2020). According to Burci, “the Secretariat and the public health expertise represented in the emergency committees share a bias against general travel and trade restrictions as ineffective and counterproductive; recommendations in previous PHEICs focus on responsible behaviour by travelers or exit screenings at international airports.” Burci, *supra* note 70, at 214. Another author states: “The WHO’s sceptical attitude towards travel restrictions is to some extent built into its remit, which is based on the International Health Regulations . . .” Ruud Koopmans, *A Virus that Knows No Borders? Exposure to and Restrictions of International Travel and the Global Diffusion of COVID-19*, WZB 1, 2 (2020), <https://www.econstor.eu/handle/10419/225533>.

234 WORLD HEALTH ORG., *Statement on the Second Meeting of the International Health Regulations (2005)*, *supra* note 3.

235 See sources cited *supra* notes 71-73; see also Raymond Yiu, Chin-Pang Yiu & Veronica Li, *Evaluating the WHO’s Framing and Crisis Management Strategy During the Early Stage of COVID-19 Outbreak*, POL’Y DESIGN & PRAC. 1, at 7 (2020); Burci, *supra* note 70, at 215.

236 Von Bogdandy & Villarreal, *supra* note 68, at 16.

perceiving them as credible.<sup>237</sup> The almost universal non-compliance with WHO's recommendations may have to do with the fact that the statement was too terse and not accompanied by a clear, detailed justification that could assuage States Parties' fears and anxieties.<sup>238</sup> This may have given States the impression that such advice was incorrect and something bolder was needed.<sup>239</sup> Still, if States Parties had doubts about the effectiveness of the measures recommended by WHO, they could have approached the organization requesting further advice.<sup>240</sup>

One author has argued that by sending a clear message about the seriousness of the outbreak, the declaration of a PHEIC serves as a signal to some states to overreact.<sup>241</sup> Still, a decision on such grave matters cannot be made in the spur of the moment—States Parties have the duty to justify their decision. The system follows the “basic logic . . . of comply or explain—a known instrument of global governance.”<sup>242</sup> Thus, even if one considers that the “available specific guidance or advice” from WHO did not rule out travel bans entirely, States Parties also had to “base”<sup>243</sup> their determination upon scientific principles and available scientific evidence of a risk to human health, or where such evidence was insufficient, the available information including from WHO and other relevant intergovernmental organizations and international bodies.<sup>244</sup>

Decisions on additional health measures need to be evidence-based; that is, they must be “generated by the ‘methods of science’” and stand the test of scientific judgment.<sup>245</sup> The duty to base additional health measures upon scientific principles

237 Gian Burci, *The Outbreak of COVID 19 Coronavirus: Are the International Health Regulations Fit for Purpose?*, EJIL:TALK! (Feb. 27, 2020), <https://www.ejiltalk.org/the-outbreak-of-covid-19-coronavirus-are-the-international-health-regulations-fit-for-purpose/>; Burci, *supra* note 70, at 214-215; Von Tigerstrom, Halabi & Wilson, *supra* note 43, at 3.

238 Burci, *supra* note 70, at 215.

239 Eskild Petersen et al., *COVID-19 Travel Restrictions and the International Health Regulations—Call for an Open Debate on Easing of Travel Restrictions*, 94 INT'L J. INFECTIOUS DISEASES 88, 89 (2020); von Tigerstrom & Wilson, *supra* note 43, at 1; Nick Wilson, Lucy Barnard & Michael Baker, *Rationale for Border Control Interventions and Options to Prevent or Delay the Arrival of Covid-19 in New Zealand: Final Commissioned Report for the New Zealand Ministry of Health* 1, 3 (2020), [https://www.health.govt.nz/system/files/documents/publications/final\\_report\\_for\\_moh\\_-\\_border\\_control\\_options\\_for\\_nz\\_final.pdf](https://www.health.govt.nz/system/files/documents/publications/final_report_for_moh_-_border_control_options_for_nz_final.pdf) (“WHO advice on travel restrictions is very general and does not address the needs of islands or consider very severe pandemics.”).

240 IHR, *supra* note 3, at arts. 13(3), (6).

241 Worsnop, *supra* note 104, at 12, 20-21.

242 Von Bogdandy & Villarreal, *supra* note 68, at 15.

243 According to the *Stellenbosch Consensus*, the use of the word “base” “suggests that states have some margin of appreciation in how they render their determination of an additional health measure . . . .” *Stellenbosch Consensus*, *supra* note 159, at 22.

244 As noted in the *Stellenbosch Consensus*, “[t]he use of ‘and’ rather than ‘or’ in paragraph 2 signals that the sources of information listed in paragraphs 2(a) to 2(c) must be cumulatively present when states are determining whether to apply additional health measures.” *Stellenbosch Consensus*, *supra* note 159, at 22.

245 *Stellenbosch Consensus*, *supra* note 159, at 23-24.

and available evidence parallels similar requirements in the agreements of the World Trade Organization (WTO), namely the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).<sup>246</sup> Therefore, decisions issued by WTO panels and the Appellate Body may be useful interpretive tools when examining Article 43 of the IHR.<sup>247</sup> Drawing on the rich jurisprudence of the WTO, the Stellenbosch Consensus formulates the following rules:

First, before implementing additional health measures, states must consider whether there is a rational relationship between the measure being implemented and the scientific principles and available scientific evidence cited to support them. Second, scientific evidence may be derived from minority or non-dominant scientific experts, but the evidence must represent more than just an opinion and must consist of a bona fide scientific risk assessment exercise. Third, in determining whether a measure is necessary to achieve a stated objective, the measure must contribute substantially to the objective. Alternatives will be deemed as “reasonably available” if they practically serve the level of health protection chosen by a state and are not simply alternatives “in theory.”<sup>248</sup>

Science is the key metric in determining the necessity of additional health measures.<sup>249</sup> Governments should defer to epidemiologists’ judgment concerning settled science, that is, in matters where a scientific consensus has been

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246 Fidler & Gostin, *supra* note 189, at 91; Fidler, *supra* note 63, at 382. See The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), WORLD TRADE ORG. at art. 2(2), [https://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm) (“Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.”); *id.* at art. 51(1) (“Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.”).

247 *Stellenbosch Consensus*, *supra* note 159, at 45-46; *id.* at 59-60 (“Even if not an authoritative source of interpretation, case law from the WTO may provide invaluable insight or logic, and it certainly qualifies as a supplementary means of interpretation . . . since WTO case law constitutes an authoritative expression of the obligations in force for WTO member . . .”). Caroline Foster, *Justified Border Closures Do Not Violate the International Health Regulations 2005*, EJIL:TALK! (June 11, 2020), <https://www.ejiltalk.org/justified-border-closures-do-not-violate-the-international-health-regulations-2005> (“Together the IHR and the SPS Agreement form the leading international instruments on health-based border closures, whether to persons or to goods. Helpful insights into how the IHR may function in relation to border closures can be gained by reading the IHR in the light of the SPS Agreement.”).

248 *Stellenbosch Consensus*, *supra* note 159, at 59-60.

249 Fidler, *supra* note 93, at 184.

consolidated. However, governmental decisions about what measures to implement during a pandemic outbreak and when to implement them are often made in a context of scientific uncertainty.<sup>250</sup> This is especially so when the nature and dangerousness of the disease are unknown: the decision-making process is clouded by interrogations about the incubation period, mode of transmission, fatality rate, etc.<sup>251</sup> In these circumstances, the degree of deference owed to epidemiologists is lower due to the absence of a reliable scientific consensus.<sup>252</sup> Some authors argue that COVID-19 is one such case, that is, that a scientific consensus has not yet been formed concerning the best course of action.<sup>253</sup> The urgency in findings answers to the coronavirus even changed the way science is done.<sup>254</sup>

Governments have to decide based on incomplete, tentative information, not mature scientific evidence.<sup>255</sup> In such a trying and uncertain context, it is only fair to concede a certain measure of deference to States' decisions about what measures they deem necessary<sup>256</sup> instead of immediately assuming that such choices are unsubstantiated.<sup>257</sup> According to Foster, the SPS Agreement provides useful guidance in this regard as it gives States greater regulatory freedom in situations

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250 Gostin, *supra* note 8, at 571; Gostin & Berkman, *supra* note 159, at 147; Weituo Zhang & Bi-yun Qian, *Making Decisions to Mitigate COVID-19 with Limited Knowledge*, LANCET INFECTIOUS DISEASES 1 (Apr. 7, 2020); Lee et al., *supra* note 38, at 1594.

251 DAVIES, KAMRADT-SCOTT & RUSHTON, *supra* note 54, at 120-122; Suk, *supra* note 50, at 2; Kenwick & Simmons, *supra* note 8, at 3.

252 Neil Levy & Julian Savulescu, *Epistemic Responsibility in the Face of a Pandemic*, 7 J. L. & BIOSCIENCES 1, 2 (2020).

253 *Id.* at 7. *Id.* ("For those decision-makers who must settle policy, [COVID-19] is a perfect epistemic storm."); see also Foster, *supra* note 247.

254 Ed Yong, *How Science Beat the Virus. And What it Lost in the Process*, ATLANTIC (Dec. 14, 2020), <https://www.theatlantic.com/magazine/archive/2021/01/science-covid-19-manhattan-project/617262>.

255 The rush in finding answers may even compromise the credibility of research outcomes, with some scholarly papers being withdrawn after their fragilities had been exposed. See John Ioannidis, *Coronavirus Disease 2019: The Harms of Exaggerated Information and Non-Evidence-Based Measures*, 50 EUR. J. CLINICAL INVESTIGATION 1 (2020).

256 Antonio Coco & Talita de Souza Dias, *Prevent, Respond, Cooperate: States' Due Diligence Duties Vis-à-Vis the COVID-19 Pandemic*, 11 J. INT'L HUMANITARIAN LEGAL STUD. 218, 220 (2020); Joan Hartman, *Derogation from Human Rights Treaties in Public Emergencies—A Critique of Implementation by the European Commission and Court of Human Rights and the Human Rights Committee of the United Nations*, 22 HARV. INT'L L.J. 1, 2 (1981); see also Evan Criddle, *Protecting Human Rights During Emergencies: Delegation, Derogation, and Deference*, in NETHERLANDS YEARBOOK OF INTERNATIONAL LAW (Evan Criddle ed., 2014). More generally, see Andrew Legg, *THE MARGIN OF APPRECIATION IN INTERNATIONAL HUMAN RIGHTS LAW: DEFERENCE AND PROPORTIONALITY* (2012).

257 Cindy Nelson, *An Unnecessary Sacrifice: Restrictions on the Right of Freedom of Movement in an Effort to Establish an Effective Global AIDS Policy*, 13 DICK. J. INT'L L. 177, 184 (1994); von Tigerstrom & Wilson, *supra* note 43, at 2; von Bogdandy & Villarreal, *supra* note 68, at 16.

of scientific uncertainty than the IHR.<sup>258</sup>

This context of doubt may also increase the relevance of the precautionary principle, frequently invoked in situations of scientific uncertainty, namely in the field of environmental policymaking.<sup>259</sup> Without offering a technical delineation of the concept,<sup>260</sup> the European Commission stated that it is applicable in “those specific circumstances where scientific evidence is insufficient, inconclusive[,] or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the chosen level of protection.”<sup>261</sup> Even if not expressly named, the principle has implicitly steered some public measures deployed in the context of pandemics,<sup>262</sup> for instance, justifying the implementation of lockdowns during COVID-19.<sup>263</sup> It has been argued that the same approach can be taken regarding travel bans.<sup>264</sup>

The IHR acknowledge that in some cases, available scientific evidence is insufficient. In such situations, governments may instead refer to the available information from WHO and other relevant intergovernmental organizations and international bodies.<sup>265</sup> However, the regulations do not clarify what level of scientific evidence or information qualifies as sufficient.<sup>266</sup> According to the Stellenbosch Consensus, additional measures may not be based on evidence (because it is not available) but cannot be totally unscientific: “[A] process of risk assessment is not merely a formality; states can err on the side of caution during

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258 Foster, *supra* note 247.

259 Lawrence Gostin & James Hodge Jr., *U.S. Emergency Legal Responses to Novel Coronavirus: Balancing Public Health and Civil Liberties*, 323 J. AM. MED. ASS’N 1131, 1132 (2020). See, e.g., JACQUELINE PEEL, *THE PRECAUTIONARY PRINCIPLE IN PRACTICE: ENVIRONMENTAL DECISION-MAKING AND SCIENTIFIC UNCERTAINTY* (2005); BIODIVERSITY AND THE PRECAUTIONARY PRINCIPLE: RISK AND UNCERTAINTY IN CONSERVATION AND SUSTAINABLE USE (Rosie Cooney & Barney Dickson ed., 2005).

260 See JOAKIM ZANDER, *THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE IN PRACTICE: COMPARATIVE DIMENSIONS* 26-31 (2010) (discussing several attempts at a definition).

261 *Communication from the Commission on the Precautionary Principle*, EUR. COMM’N (Feb. 2, 2000), <https://op.europa.eu/en/publication-detail/-/publication/21676661-a79f-4153-b984-aeb28f07c80a/language-en>.

262 Gostin, Bayer & Fairchild, *supra* note 44, at 3232.

263 Levy & Savulescu, *supra* note 252, at 9.

264 Foster, *supra* note 247.

265 IHR, *supra* note 3, at art. 43(2)b. As noted in the *Stellenbosch Consensus*, the word “competent” is used in the French version of the IHR instead of the French equivalent for “relevant.” Because the two concepts do not have interchangeable meanings, it is preferable to favor the term “competent,” that is, to understand this provision as referring to international organizations or bodies that have the mandate and ability (such as the scientific expertise and technical resources) to issue such information. *Stellenbosch Consensus*, *supra* note 159, at 24-25 (offering a list of organizations that may be considered competent for the purposes of this provision).

266 *Stellenbosch Consensus*, *supra* note 159, at 24.

risk assessment, but the exercise of risk assessment itself . . . must be undertaken and must withstand scientific scrutiny.”<sup>267</sup> The authors of the Consensus conclude:

At minimum, there should be a rational and proportional connection between the legitimate aim that the additional health measure is seeking to address and the scientific evidence underpinning the decision to implement the health measure. Such scientific evidence need not be the monolithic view or opinion of all scientists but must withstand scientific scrutiny in the discipline of public health.<sup>268</sup>

The crux of the question is thus the following: is there a rational connection between travel bans and the reduction of contagion? Infectious diseases need to move to propagate.<sup>269</sup> Hence, common sense seems to dictate that if you prevent people from moving, you reduce the mobility of the virus and thereby the spread of the contagion. However, the epidemiological reality is not so black and white.

New Zealand, one of the countries that implemented strict travel restrictions, presented several public health rationales that may apply during the initial stages of the pandemic (nicknamed “keep it out” and “stamp it out” phases):

1. Opportunity to better understand the nature of the pandemic and its health impact to assess a proportionate response. This particularly applies to novel agents where key characteristics are unknown (far more rapid decisions will be possible for well characterised infectious agents)
2. Opportunity to decide whether a combination of border controls may be sufficient to entirely exclude a pandemic from a country or region
3. Opportunity to push the period of maximum transmission into a season with less respiratory pathogen transmission . . .
4. Opportunity to improve organisation of healthcare services to maximise effectiveness and ensure infection control
5. Opportunity to build trust with health authorities and better prepare the population psychologically, including for severe

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<sup>267</sup> *Id.* at 67.

<sup>268</sup> *Id.* at 24.

<sup>269</sup> Tim Cresswell, *Valuing Mobility in a Post COVID-19 World*, 16 *MOBILITIES* 1, 5 (2020).

outcomes and potentially for difficult rationing decisions

6. Opportunity for development, production, and distribution of vaccine
7. Opportunity for evolutionary processes to reduce severity of a novel infectious agent<sup>270</sup>

Travel restrictions and outright entry bans may be effective when the rate of transmission inside the country is still very low.<sup>271</sup> However, if local numbers are already at a high level, travel bans become less effective.<sup>272</sup> The particular circumstances of the case should be considered, namely the rate of local transmission, the rate of transmission in source countries, and the number of travelers entering the respective country.<sup>273</sup> These measures may work better, for instance, in the context of island nations.<sup>274</sup>

While states enjoy some margin of appreciation to adjust measures to their particular context, travel bans and other measures must be in line with the public health considerations that underpin the IHR.<sup>275</sup> If the contagion is already spreading locally, how can one claim that travel bans “contribute substantially” to their stated objective?<sup>276</sup> And if the purpose of entry bans is to “keep the disease out,” what is the health rationale of exit bans? These measures seem hard to justify when border closure is normally perceived as a way to “keep the ill out.” Were countries that adopted exit bans doing it out of altruism for other States and their populations?

WHO recently stated that public health measures may reduce risk but not achieve a “zero risk,” arguing that a “risk-based approach to international travel is needed.”<sup>277</sup> The problem is that entry bans treat travelers as a risk that cannot be

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270 Wilson, Barnard & Baker, *supra* note 239, at 4.

271 Lindsay Wiley, *Public Health Law and Science in the Community Mitigation Strategy for Covid-19*, J. L. & BIOSCIENCES 1, 6 (2020); Russell et al., *supra* note 23, at e13; Koopmans, *supra* note 233, at 74.

272 Russell et al., *supra* note 23, at e13. The United States of America, for example, closed its borders to travelers from the European Union even though its infection rate was higher. See Lutterbeck, *supra* note 60, at 39.

273 Russell et al., *supra* note 23, at e13-e14, e19.

274 Matt Boyd et al., *Protecting an Island Nation from Extreme Pandemic Threats: Proof-of-Concept Around Border Closure as an Intervention*, 12 PLoS ONE 1, 10 (2017).

275 Stellenbosch Consensus, *supra* note 159, at 23.

276 *Id.* at 67; von Tigerstrom & Wilson, *supra* note 43, at 2 (“Any type of restriction that targets specific countries becomes increasingly difficult to justify once other countries begin reporting similar or larger numbers of cases.”).

277 *Considerations for Implementing a Risk-based Approach to International Travel in the Context of COVID-19*, WORLD HEALTH ORG. 1 (Dec. 16, 2020), <https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based-international-travel-2020.1>.

tolerated. Again, citing WHO, “[i]nternational travellers should not be categorized as suspected COVID-19 cases.”<sup>278</sup>

### C. Proportionality

The necessity test is closely associated with an element of proportionality. On limitations, General Comment No. 27 states<sup>279</sup>:

14. Restrictive measures must conform to the principle of proportionality; they must be appropriate to achieve their protective function; they must be the least intrusive instrument amongst those which might achieve the desired result; and they must be proportionate to the interest to be protected.
15. The principle of proportionality has to be respected not only in the law that frames the restrictions, but also by the administrative and judicial authorities in applying the law. States should ensure that any proceedings relating to the exercise or restriction of these rights are expeditious and that reasons for the application of restrictive measures are provided.
16. States have often failed to show that the application of their laws restricting the rights enshrined in [A]rticle 12, paragraphs 1 and 2, are in conformity with all requirements referred to in [A]rticle 12, paragraph 3. The application of restrictions in any individual case must be based on clear legal grounds and meet the test of necessity and the requirements of proportionality.

According to the Siracusa Principles, “[i]n applying a limitation, a state shall use no more restrictive means than are required for the achievement of the purpose of the limitation.”<sup>280</sup> In addition, when limiting certain rights on public health grounds, “[d]ue regard shall be had to the international health regulations of the World Health Organization.”<sup>281</sup> Again, WHO’s recommendations are an important parameter to consider when conducting the proportionality test.<sup>282</sup>

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<sup>278</sup> *Id.* at 5.

<sup>279</sup> *General Comment No. 27: Article 12 (Freedom of Movement)*, *supra* note 133, ¶¶ 14-15.

<sup>280</sup> *Siracusa Principles*, *supra* note 158, at ¶ 11.

<sup>281</sup> *Id.* at ¶ 26.

<sup>282</sup> Von Bogdandy & Villarreal, *supra* note 68, at 17.

Regarding derogations from the ICCPR, such derogations are also subject to a requirement of proportionality. In its statement on ICCPR derogations related to COVID-19, the Human Rights Committee highlighted that any derogating measure should be strictly necessary and proportional.<sup>283</sup> In line with the ICCPR's preference for limitations over derogations,<sup>284</sup> the Committee also made the following recommendations:

Where possible, and in view of the need to protect the life and health of others, States parties should replace COVID-19-related measures that prohibit activities relevant to the enjoyment of rights under the Covenant with less restrictive measures that allow such activities to be conducted, while subjecting them as necessary to public health requirements, such as physical distancing;

States parties should not derogate from Covenant rights or rely on a derogation made when they are able to attain their public health or other public policy objectives by invoking the possibility to restrict certain rights.<sup>285</sup>

Turning to the IHR, they also recognize the principle of proportionality in Article 43(1). Article 43(1) requires that additional health measures “not be more restrictive of international traffic and not more invasive or intrusive to persons than reasonably available alternatives that would achieve the appropriate level of health protection.”<sup>286</sup> Again, the IHR are aligned with the logic of international human rights law and the SPS Agreement: all these instruments require that the implemented measures not be more restrictive than reasonably available alternatives.<sup>287</sup>

Apropos the principle of proportionality, WHO states that “governments should ensure there is a reasonable fit between the coercive measures imposed and the public health benefit they seek to achieve” and that “specific measures taken

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283 *Statement on Derogations from the Covenant in Connection with the COVID-19 Pandemic*, HUM. RTS. COMM. ¶ 2, b (Apr. 30, 2020), <https://www.ohchr.org/Documents/HRBodies/CCPR/COVIDstatementEN.pdf>.

284 *General Comment No. 29: Derogations During a State of Emergency*, *supra* note 169, at ¶ 5 (“In the opinion of the Committee, the possibility of restricting certain Covenant rights under the terms of, for instance, freedom of movement ([A]rt. 12) or freedom of assembly ([A]rt. 21) is generally sufficient during such situations and no derogation from the provisions in question would be justified by the exigencies of the situation.”).

285 HUM. RTS. COMM., *supra* note 283, at ¶ 2, b, c.

286 *Stellenbosch Consensus*, *supra* note 159, at 53.

287 Fidler, *supra* note 63, at 383.

must be appropriate to prevent or reduce the threat.”<sup>288</sup> Specifically regarding restrictions to freedom of movement, WHO adds:

Any restrictions on freedom of movement should be designed and implemented in a manner that imposes the fewest constraints reasonably possible. Greater restrictions should be imposed only when there are strong grounds to believe that less restrictive measures are unlikely to achieve important public health goals. For example, requests for voluntary cooperation are generally preferable to public health mandates enforced by law or military authorities.<sup>289</sup>

Saying that additional health measures should be proportional means that they must be calibrated to the risk posed. In the words of a leading expert:

Interventions should be the least restrictive alternative necessary to prevent or ameliorate the health threat. Requiring the least restrictive/intrusive alternative represents a means to impose limits on state interventions consistent with the traditions of privacy, freedom of association, and individual liberties. The standard does not require officials to utilize less-than-optimal interventions. However, they must choose the least intrusive alternative that can best achieve the health objective.<sup>290</sup>

This begs the question of whether there were reasonably available alternatives to travel bans that would achieve the appropriate level of health protection. An alternative is “reasonably available” when it achieves in practice the same level of health protection aimed by a State.<sup>291</sup> When choosing which measures to adopt, States will naturally compare the costs of different available measures. Just because a measure is cheap to implement (or, to put it differently, that alternatives are costlier) does not mean it is effective—and thus justified.<sup>292</sup> Naturally, the specific context and capacity of countries to deal with the pandemic may be a factor to consider.<sup>293</sup>

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288 WORLD HEALTH ORG., *supra* note 32, at 29.

289 WORLD HEALTH ORG., *supra* note 198, at 26.

290 Gostin, *supra* note 8, at 572.

291 *Stellenbosch Consensus*, *supra* note 159, at 67 (drawing on the WTO case law).

292 WORLD HEALTH ORG., *supra* note 1988, at 26; *see also* Gostin, *supra* note 8, at 570.

According to the Siracusa Principles, “[e]conomic difficulties *per se* cannot justify derogation measures.” *Siracusa Principles*, *supra* note 158, at ¶ 41.

293 Von Tigerstrom & Wilson, *supra* note 43, at 2; Jaya Ramji-Nogales & Iris Goldner Lang, *Freedom of Movement, Migration, and Borders*, 19 J. HUM. RTS. 593, at 598 (2020), <https://www.tandfonline.com/doi/full/10.1080/14754835.2020.1830045>

The goal of the IHR is to achieve an appropriate level of protection against the pandemic with minimum interference with international travel. How to operationalize this requirement is not clear, nor is the definition of an “appropriate” level of protection.<sup>294</sup> Asymptomatic individuals are a major concern as they reveal no symptoms and therefore may go undiagnosed by health surveillance systems.<sup>295</sup> Travel bans are imposed blindly, especially once reliable tests are available, and seem to presume that every international traveler is an asymptomatic carrier of the disease when, statistically, that is not the case. Regardless of whether the individual indeed represents “actual, clear, present, or imminent danger” to public health (to borrow from the language of the Siracusa Principles),<sup>296</sup> his freedom of movement is suppressed. As argued by one author, “restrictions should be applied only to people suffering from the disease, or likely carriers, and not to regions or nations as a whole.”<sup>297</sup>

Caution recommends that risks be minimized. Ensuring that cautionary measures are proportionate is especially difficult in an emergency situation.<sup>298</sup> Still, it seems particularly difficult to argue that the principle of proportionality is respected in the application of travel bans.<sup>299</sup> Many governments seem to assume that strong measures are strictly necessary and that, in case of doubt, public health is best served by erring on the side of the harshest measure.<sup>300</sup> There are, however, alternatives—some expressly suggested by WHO—that would be less restrictive of international travel, including social distancing, regular testing, quarantine, and contact tracing.<sup>301</sup> Quarantines and isolation also raise their own legal and ethical

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294 *Stellenbosch Consensus*, *supra* note 159, at 30-32. This principle is especially difficult to operationalize when countries are faced with “an unusual outbreak.” Yiu, Yiu & Li, *supra* note 235, at 7; *see also* Ramji-Nogales & Goldner Lang, *supra* note 293, at 597 (emphasizing the scientific uncertainty surrounding COVID-19).

295 *See* Hongjun Zhao et al., *COVID-19: Asymptomatic Carrier Transmission Is an Underestimated Problem* 148 *EPIDEMIOLOGY & INFECTION* 1 (2020); Andreas Kronbichler et al., *Asymptomatic Patients as a Source of COVID-19 Infections: A Systematic Review and Meta-Analysis*, 98 *INT’L J. INFECTIOUS DISEASES* 180 (2020).

296 *Siracusa Principles*, *supra* note 158, at ¶ 54.

297 Polly Price, *Infecting the Body Politic: Observations on Health Security and the Undesirable Immigrant*, 63 *U. KAN. L. REV.* 926 (2015).

298 Alessio Paces & Maria Weimer, *From Diversity to Coordination: A European Approach to COVID-19*, 11 *EUR. J. RISK REGUL.* 283, 286 (2020).

299 Richardson & Devine, *supra* note 179, at 26; Habibi et al., *supra* note 39, at 664.

300 Levy & Savulescu, *supra* note 252, at 13 (“[G]overnments may have an incentive to engage in spectacular interventions in the face of a public health crisis. The penalty, in terms of public opprobrium, for underreacting might be very much greater than the penalty for overreacting.”).

301 Meier, Habibi & Yang, *supra* note 39, at 1436; Gostin & Hodge Jr., *supra* note 259, at 1132; Micha Kaiser et al., *Interventions with Positive Side-Effects: COVID-19 Non-Pharmaceutical Interventions and Infectious Diseases in Europe*, *INST. LAB. ECON.* 12 (2020), <https://www.iza.org/publications/dp/13927/interventions-with-positive-side-effects-covid-19-non-pharmaceutical-interventions-and-infectious-diseases-in-europe>; Jakub Hlávka & Lisa Bari, *Travel Bans Should Be Based on Evidence, not Politics or Fear*, *STAT* (Jan. 22, 2021),

quandaries. Still, there is an alleged public health rationale to them: individuals are separated because they have been exposed to an infectious disease (quarantine) or have already been infected.<sup>302</sup>

Blanket travel bans are “indiscriminate, overbroad, excessive, or without evidentiary support” because there is no individualized risk assessment.<sup>303</sup> The Secretary-General of the United Nations himself acknowledges this, stating:

While international law permits certain restrictions on freedom of movement, including for reasons of security and national emergency like health emergencies, restrictions on free movement should be strictly necessary for that purpose, proportionate and non-discriminatory. The availability of effective and generalised testing and tracing, and targeted quarantine measures, can mitigate the need for more indiscriminate restrictions.<sup>304</sup>

In the toolbox of public health measures available during a pandemic, travel bans are at one end of the harshness scale. The problem is that these measures are easier to implement than convincing the entire population of a country to implement domestic restrictions.<sup>305</sup> It is easier to externalize the problem than to internalize solutions. In the words of one author, “border restrictions preserve possibly fictitious ideas that the threat is foreign, the State is competent, and the domestic population is and can be kept wholesome and healthy.”<sup>306</sup> It is telling that

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<https://www.statnews.com/2021/01/22/travel-bans-should-be-based-on-evidence-not-politics-or-fear>.

302 Wendy Parmet & Michael Sinha, *Covid-19 — The Law and Limits of Quarantine*, 382 *NEW ENG. J. MED.* 1 (2020); A. Wilder-Smith & D. O. Freedman, *Isolation, Quarantine, Social Distancing and Community Containment: Pivotal Role for Old-Style Public Health Measures in the Novel Coronavirus (2019-nCoV)*, 27 *J. TRAVEL MED.* 1 (2020). See Wiley, *supra* note 271, at 7 (“Imposing a travelers’ quarantine . . . requiring individuals entering the area to be separated from others for a reasonable incubation period, would provide a less restrictive alternative to completely closed borders.”); Lawrence Gostin, Eric Friedman & Sarah Wetter, *Responding to Covid-19: How to Navigate a Public Health Emergency Legally and Ethically*, 50 *HASTINGS CTR. REP.* 8, 11 (2020) (“Quarantine and isolation for Covid-19 should be ordered only if the person is known or highly suspected to have been exposed to the disease, and only for the maximum duration of incubation . . .”).

303 Gostin & Hodge Jr., *supra* note 259, at 1132.

304 *COVID-19 and Human Rights: We Are All in This Together*, UNITED NATIONS 4 (Apr. 2020), [https://www.un.org/sites/un2.un.org/files/un\\_policy\\_brief\\_on\\_human\\_rights\\_and\\_covid\\_23\\_april\\_2020.pdf](https://www.un.org/sites/un2.un.org/files/un_policy_brief_on_human_rights_and_covid_23_april_2020.pdf).

305 Kenwick & Simmons, *supra* note 8, at 10-11; Pillinger, *supra* note 58 (“From a public-health standpoint, encouraging people to wash their hands and cough into their elbows is good policy. But politically, it’s insufficient to instill public confidence in health authorities; more dramatic action is needed.”).

306 Kenwick & Simmons, *supra* note 8, at 10.

more countries adopted border restrictions than social distancing rules.<sup>307</sup>

Travel bans are favored by States but also offer the domestic population a placebo. A study presented in March 2020 revealed that most respondents believed domestic travel restrictions are not effective while simultaneously defending the closure of borders.<sup>308</sup> Previous studies have demonstrated that citizens overestimate the effectiveness of border restrictions.<sup>309</sup> People prefer to close borders than to stay home—even if the virus is circulating in their city—and travel bans allow them to externalize their fears.<sup>310</sup>

Crucially, the canon of proportionality also requires that measures be exceptional and temporally adjusted to what is strictly required to address the pandemic.<sup>311</sup> As stated by the Human Rights Committee, measures should be adopted “on a temporary basis”<sup>312</sup>; they should only be in place while the pandemic lasts.<sup>313</sup> Governments need to decide when to start implementing a measure and when to discontinue it.

Timing is of the essence. As mentioned, WHO made several statements where, without recommending the adoption of travel restrictions, it recognized that they might be effective under certain circumstances—namely, at the beginning of an outbreak.<sup>314</sup> According to WHO, this could allow countries to gain time and prepare their response measures.<sup>315</sup> There is a parallel between travel restrictions and derogations as tools that allow countries to “buy time.” Derogations, in general, are perceived by some authors as a rational response to uncertainty that allows governments to buy time and “breathing space” to confront a crisis.<sup>316</sup> WHO also recognizes that travel restrictions could be useful in countries with few international connections and limited response capacity.<sup>317</sup>

For travel restrictions to produce some effect, they must be adopted at the

307 *Id.* at 6.

308 *Public Divided on Whether Isolation, Travel Bans Prevent COVID-19 Spread; Border Closures Become More Acceptable*, IPSOS (March 24, 2020), <https://www.ipsos.com/en-hk/public-divided-whether-isolation-travel-bans-prevent-covid-19-spread-border-closures-become-more> (“While it might seem like a contradiction that we question whether isolation will stop the virus but still want closed borders, the public supports strong action from governments even if they might question its efficacy . . . .”) (quoting Darrell Bricker).

309 Worsnop, *supra* note 54, at 373.

310 Kenwick & Simmons, *supra* note 8, at 2, 19.

311 *General Comment No. 29: Derogations During a State of Emergency*, *supra* note 169, at ¶ 2; Toebe, *supra* note 32, at 496; Spadaro, *supra* note 28, at 322-323.

312 HUMAN RIGHTS COMM., *supra* note 283, at ¶ 2. The Committee adds that “[d]erogations must, as far as possible, be limited in duration, geographical coverage and material scope . . . .” *Id.* at ¶ 2a.

313 Federica Paddeu & Michael Waibel, *The Final Act: Exploring the End of Pandemics*, 114 AM. J. INT’L L. 698 (2020); von Bogdandy & Villarreal, *supra* note 68, at 21-22.

314 WORLD HEALTH ORG., *supra* note 71, at 10; sources cited *supra* notes 72-73.

315 Sources cited *supra* notes 71-73.

316 Hafner-Burton, Helfer & Fariss, *supra* note 165, at 675, 680.

317 WORLD HEALTH ORG., *supra* note 73.

earliest moment possible.<sup>318</sup> However, many countries only introduced travel bans several weeks into the pandemic when it was already too late to “stamp out” the virus.<sup>319</sup> In any case, such measures should be short in duration, proportional to public health risks, and reconsidered regularly.<sup>320</sup> Even if such measures seem necessary and proportional at an early stage of a pandemic, that is no longer the case once the virus is already spreading within the community. Even worse, as discussed below, in many countries travel bans remained in place well beyond the initial stage of the pandemic. Therefore, such measures cannot be considered exceptional and temporarily adjusted: they became more permanent features of the fight against COVID-19.

#### *D. Compatibility with Other Rights: Equality and Non-Discrimination*

The third major requirement is that public health measures be consistent with all other rights recognized in the ICCPR.<sup>321</sup> Regarding limitations to the freedom of movement, the Human Rights Committee stated:

The application of the restrictions permissible under [A]rticle 12, paragraph 3, needs to be consistent with the other rights guaranteed in the Covenant and with the fundamental principles of equality and non-discrimination. Thus, it would be a clear violation of the Covenant if the rights enshrined in [A]rticle 12, paragraphs 1 and 2, were restricted by making distinctions of any kind, such as on the basis of race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.<sup>322</sup>

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318 Chad Wells, *Impact of International Travel and Border Control Measures on the Global Spread of the Novel 2019 Coronavirus Outbreak*, 117 PROC. NAT'L ACAD. SCIS. 7504, 7507-08 (2020); Koopmans, *supra* note 233, at 74; von Tigerstrom & Wilson, *supra* note 43, at 2 (“By the time WHO acknowledged, in late February, that restrictions on travel might have some limited value, the window of opportunity to prevent a pandemic had long been closed.”).

319 This was the case in Europe. See Kevin Linka et al., *Outbreak Dynamics of COVID-19 in Europe and the Effect of Travel Restrictions*, 23 COMPUT. METHODS BIOMECHANICS & BIOMEDICAL ENG'G 710, 714 (2020); Sergio Carrera & Ngo Chun Luk, *In the Name of COVID-19: Schengen Internal Border Controls and Travel Restrictions in the E.U.*, EUR. PARLIAMENT 68-69 (2020), [https://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL\\_STU\(2020\)659506](https://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_STU(2020)659506).

320 Sources cited *supra* notes 72-73, 78.

321 *General Comment No. 27: Article 12 (Freedom of Movement)*, *supra* note 133, at ¶ 11.

322 *Id.* at ¶ 18; see also ICCPR, *supra* note 124, at art. 2(1) (“Each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property,

Measures adopted by states should not be arbitrary or discriminatory. In its discussion about the position of aliens under the covenant, the Human Rights Committee stated:

[T]he general rule is that each one of the rights of the Covenant must be guaranteed without discrimination between citizens and aliens. Aliens receive the benefit of the general requirement of non-discrimination in respect of the rights guaranteed in the Covenant, as provided for in [A]rticle 2 thereof. This guarantee applies to aliens and citizens alike. Exceptionally, some of the rights recognized in the Covenant are expressly applicable only to citizens ([A]rticle 25), while [A]rticle 13 applies only to aliens. However, the Committee's experience in examining reports shows that in a number of countries other rights that aliens should enjoy under the Covenant are denied to them or are subject to limitations that cannot always be justified under the Covenant.<sup>323</sup>

The Committee also added:

Once an alien is lawfully within a territory, his freedom of movement within the territory and his right to leave that territory may only be restricted in accordance with [A]rticle 12, paragraph 3. Differences in treatment in this regard between aliens and nationals, or between different categories of aliens, need to be justified under [A]rticle 12, paragraph 3. Since such restrictions must, *inter alia*, be consistent with the other rights recognized in the Covenant, a State [P]arty cannot, by restraining an alien or deporting him to a third country, arbitrarily prevent his return to his own country ([A]rticle 12, para. 4).<sup>324</sup>

Regarding derogations, the Human Rights Committee stated, in the context of COVID-19: "States parties may not resort to emergency powers or implement derogating measures in a manner that is discriminatory, or that violates other obligations that they have undertaken under international law, including under other international human rights treaties from which no derogation is allowed . . . ." <sup>325</sup>

The IHR also prescribe that measures adopted by States shall be applied in a

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birth or other status.").

<sup>323</sup> HUM. RTS. COMM., *supra* note 146, at ¶ 2.

<sup>324</sup> *Id.* at ¶ 8.

<sup>325</sup> HUM. RTS. COMM., *supra* note 283, at ¶ 2d.

transparent and non-discriminatory manner.<sup>326</sup> WHO considers “distributive justice” (the risks, burdens, and benefits of public health interventions to be shared fairly) as a significant ethical principle to consider when designing health measures.<sup>327</sup> It states:

[P]rinciples of distributive justice require that public health measures do not place unfair burdens on particular segments of the population. Policy-makers should pay specific attention to groups that are the most vulnerable to discrimination, stigmatization[,] or isolation, including racial and ethnic minorities, elderly people, prisoners, disabled persons, migrants[,] and the homeless.<sup>328</sup>

Measures restricting freedom of movement (and other human rights for that matter) should be neutral and take into account how they may discriminate in practice against certain groups.<sup>329</sup> The IHR enable WHO to recommend<sup>330</sup> States Parties refuse entry of suspect<sup>331</sup> and affected<sup>332</sup> persons and refuse entry of unaffected persons to affected areas.<sup>333</sup> But the regulations do not foresee the possibility of applying travel bans. These blank measures are not supported by any scientific evidence that those coming from outside pose a particularly high health risk. As stated by Vincent Chetail, “banning entry to any foreigners or those of a particular nationality is, by definition, a collective and automatic denial of admission without any other form of process.”<sup>334</sup> Quarantining all incoming travelers would be much fairer, as it would apply to all travelers, regardless of their status. As stated by WHO, health measures should be applied equitably:

Restrictions on freedom of movement should be applied in the same manner to all persons posing a comparable public health risk. Thus, individuals should not be subject to greater or lesser restrictions for reasons unrelated to the risks they may pose to

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326 IHR, *supra* note 3, at art. 42.

327 WORLD HEALTH ORG., *supra* note 32, at 29.

328 WORLD HEALTH ORG., *supra* note 198, at 9.

329 Criddle, *supra* note 256, at 51.

330 IHR, *supra* note 3, at art. 18(1).

331 *Id.* at art. 1(1) (“[S]uspect’ means those persons, baggage, cargo, containers, conveyances, goods or postal parcels considered by a State Party as having been exposed, or possibly exposed, to a public health risk and that could be a possible source of spread of disease . . .”).

332 IHR, *supra* note 3, at art. 1(1) (“[A]ffected’ means persons, baggage, cargo, containers, conveyances, goods, postal parcels or human remains that are infected or contaminated, or carry sources of infection or contamination, so as to constitute a public health risk.”)

333 *Id.* (“[A]ffected area’ means a geographical location specifically for which health measures have been recommended by WHO under these Regulations.”).

334 Chetail, *supra* note 46, at 2.

others, including membership in any disfavoured or favoured social group or class (for example, groups defined by gender, ethnicity, or religion).<sup>335</sup>

Discussing former U.S. President Donald Trump’s ban on asylum seekers, Lawrence Gostin stated:

It makes no sense. In public health, any time there is a categorical classification—any time there is a category about who you apply your measure to or who you don’t—is highly suspect. The courts suspect it. Public health people suspect it. There is no scientific evidence for it. And it’s discriminatory.<sup>336</sup>

The same logic applies to other categories of international travelers. Travel bans are discriminatory, targeting the mobility of foreigners and migrants. Countries that organized repatriation flights while keeping their borders closed to foreigners were showing that, after all, it was possible to uphold public health without restricting international mobility.<sup>337</sup>

Imposing travel bans based on the nationality of travelers reflects a form of “othering.” Social scientists use this concept to describe the practice of treating a group of people as if there is something wrong with them, a phenomenon frequently associated with migrants in health crises.<sup>338</sup> Again, this relates to the illusion that the health threat comes from “outside” and that by keeping “others” out, citizens are “safe.”<sup>339</sup> In addition to being a useless exercise in scapegoating, this posture distracts policymakers and the population from other measures that

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335 WORLD HEALTH ORG., *supra* note 198, at 27.

336 Joanna Naples-Mitchell, *There Is No Public Health Rationale for a Categorical Ban on Asylum Seekers*, JUST SEC. (Apr. 17, 2020), <https://www.justsecurity.org/69747/there-is-no-public-health-rationale-for-a-categorical-ban-on-asylum-seekers/>; Letter from Leaders of Pub. Health Schs., Med. Schs., Hosps., & Other U.S. Insts. to HHS Sec’y Alex Azar & CDC Dir. Robert R. Redfield (May 18, 2020), [https://www.publichealth.columbia.edu/sites/default/files/public\\_health\\_experts\\_letter\\_05.18.2020.pdf](https://www.publichealth.columbia.edu/sites/default/files/public_health_experts_letter_05.18.2020.pdf) (“There is no public health rationale for denying admission to individuals based on legal status.”); *see also* León Castellanos-Jankiewicz, *COVID-19 Symposium: U.S. Border Closure Breaches International Refugee Law*, OPINION JURIS (Apr. 3, 2020), <http://opiniojuris.org/2020/04/03/covid-19-symposium-us-border-closure-breaches-international-refugee-law/> (“Absent any proof that migrants constitute an important source of contagion, these new restrictions can hardly pass muster as being proportionate, legitimate or necessary, given that they seem disconnected from immediate public health concerns.”). Castellanos-Jankiewicz is discussing measures implemented by the Trump administration aimed at deporting migrants and asylum seekers, but his considerations apply nevertheless.

337 Ramji-Nogales & Goldner Lang, *supra* note 293, at 597-598.

338 Kim Dionne & Fulya Turkmen, *The Politics of Pandemic Othering: Putting COVID-19 in Global and Historical Context*, INT’L ORG. 1, 2-3 (2020) (online issue).

339 Lutterbeck, *supra* note 60, at 41.

could be much more effective.<sup>340</sup> This illusory sensation of security has also been termed “border bias”: “[p]eople consider political boundaries (i.e., state borders) to be physical barriers that can limit the spread of disasters.”<sup>341</sup>

Viruses do not discriminate; contagion knows no borders or nationalities. But measures based on nationality or residence do. As noted by Barbara von Tigerstrom and Kumanan Wilson:

Imposing restrictions based on nationality (rather than travel history) is always suspect, given the weak correlation between nationality and exposure to the virus. Excluding people based on the passport they carry also carries a greater risk of contributing to stigma and discrimination, and the IHR (2005) and other laws require states to respect human rights and avoid discrimination.<sup>342</sup>

In their reaction to the pandemic, many countries adopted a nationalistic response,<sup>343</sup> forbidding the entry of non-nationals. Travel restrictions based on nationality or residence status discriminate and stigmatize certain individuals or groups.<sup>344</sup> This type of measure leads to the “rise of a new ‘health securitization’ migration rhetoric,”<sup>345</sup> where foreigners are blamed for the spread of the epidemic. They undermine the right to work and make a living without offering major public health benefits. As stated by one author, “[t]he attempt to protect citizens by shutting borders and excluding non-nationals ignores the propensity of the virus to traverse borders at will, including in the bodies of citizens whose entry is unrestricted and unmonitored.”<sup>346</sup> This leads to discrimination between those within and outside borders and creates puzzling paradoxes:

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340 Dionne & Turkmen, *supra* note 338, at 11.

341 Arul Mishra & Himanshu Mishra, *Border Bias: The Belief That State Borders Can Protect Against Disasters*, 21 PSYCH. SCI. 1582, at 1583 (2010).

342 Von Tigerstrom & Wilson, *supra* note 43, at 2.

343 Peter Danchin et al., *The Pandemic Paradox in International Law*, 114 AM. J. INT’L L. 598, 600 (2020); Meier, Habibi & Yang, *supra* note 39, at 1436; Gostin, Habibi & Meier, *supra* note 38, at 378-379; Ferhani & Rushton, *supra* note 41, at 460; Sergio Carrera & Ngo Chun Luk, *Love Thy Neighbour? Coronavirus Politics and Their Impact on EU Freedoms and Rule of Law in the Schengen Area*, CTR. FOR EUR. POL’Y STUD. 37 (2020), <https://www.ceps.eu/ceps-publications/love-thy-neighbour>.

344 Lawrence Gostin, *International Infectious Disease Law: Revision of the World Health Organization’s International Health Regulations*, 291 J. AM. MED. ASS’N 2623, 2626 (2004); Robert Archer, *Pandemic Influenza Planning and Response—Transnational Issues for Governments*, in ADDRESSING ETHICAL ISSUES IN PANDEMIC INFLUENZA PLANNING: DISCUSSION PAPERS 85, 99 (2008).

345 Abhinav Chugh, *Will COVID-19 Change How We Think About Migration and Migrant Workers?*, WORLD ECON. F. (May 22, 2020), <https://www.weforum.org/agenda/2020/05/covid-19-coronavirus-migration-migrant-workers-immigration-policy-health-securitization-risk-travel-bubbles>.

346 Danchin et al., *supra* note 343, at 600.

But the irony is that in the context of a pandemic, such purported defense of sovereignty ultimately risks undermining it. This is evident in the tension between external border controls and internal protection measures. The opposing pulls of individual freedom and social order come to a head in the duality best described as “the right to protect, the freedom to infect”: whereby a state is buoyed by popular support for its exclusion of others but confronted by a populace unwilling to obey internal social distancing, lockdown, or mask-wearing requirements. Exclusion of others fits neatly into previous populist behavior, enjoying the same domestic support as populist border controls did pre-pandemic. The visible alien has become invisible: a disease rather than a person, but still couched in terms of the other. In contrast, internal measures are seen as a constraint on freedom, an unacceptable imposition on the lives of the everyday citizen.<sup>347</sup>

After several European states closed their borders, an exception emerged for migrant workers in qualifying “critical professions.”<sup>348</sup> Yet, this exception was not based on any public health rationale. While it is understandable to restrict unnecessary traveling, such as tourism, this type of measure implies that some people should be allowed to travel while others should not, even if their reasons are also relevant, for example, for family reunions.

A few countries went even further and closed their border to their own nationals and residents. This is especially problematic as it affects not only foreigners but also people with a stable connection to the country, such as nationals and residents. Determining whether travel bans are lawful depends on the personal scope of the applicable rules. The IHR apply to “travelers,” defined as “natural person[s] undertaking an international voyage.”<sup>349</sup> The IHR do not distinguish between nationals, residents, foreigners, etc. It applies to anyone who wishes to cross international borders. Differently, human rights treaties are more limited in their gamut, decomposing the freedom of movement into two different rights—the right to leave and the right to return, each one with its scope of application.

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<sup>347</sup> *Id.* at 604.

<sup>348</sup> See Manès Weisskircher, Julia Rone & Mariana Mendes, *The Only Frequent Flyers Left: Migrant Workers in the E.U. in Times of Covid-19*, OPEN DEMOCRACY (Apr. 20, 2020), <https://www.opendemocracy.net/en/can-europe-make-it/only-frequent-flyers-left-migrant-workers-eu-times-covid-19>.

<sup>349</sup> IHR, *supra* note 3, at art. 1(1) (An “international voyage” means “a voyage involving entry into the territory of a State other than the territory of the State in which that traveller commences the voyage.”) Richardson & Devine, *supra* note 179, at 13 (“The regulations specify a unique class of persons whose human rights may be impacted—travelers—as a subset of the class of all persons.”).

We have argued that denying entry to foreigners breaches the IHR as it is a disproportionate and discriminatory measure; there is no scientific evidence demonstrating that foreigners carry the disease any more than nationals do. Still, these measures are not a breach of the ICCPR as it does not recognize the right of aliens to enter or reside in the territory of a foreign country.<sup>350</sup> Differently, entry bans, when extended to nationals and residents, are a breach of the return to return, which the ICCPR protects. During a pandemic, it is only natural that people feel an urge to return “home.” While the right to return home may be limited when individuals are infected, they should be allowed to return as soon as possible, namely, once they no longer present a risk of transmitting the virus.<sup>351</sup> In the words of Gostin, Ronald Bayer, and Amy Fairchild, “people have a right to a place to reside and should not suffer the indignity of forced exclusion from their home country.”<sup>352</sup>

Because the right to return is the most uncontroversial facet of freedom of movement, it has received scarce attention in scholarship.<sup>353</sup> However, as in other respects, COVID-19 response measures raise the need to pay greater attention to how this human right is structured and implemented in practice. By closing their borders to their own nationals, States create two tensions. First, a tension between “resident and non-resident nationals, reinforcing a certain sense of the primacy of territory over nationality.”<sup>354</sup> Second, “a tension between resident and non-resident nationals and between national and non-national residents.”<sup>355</sup> It has been argued that, in the case of returning citizens, “the danger of transmission has to be weighed against a very clear stance by human rights in favor of the ability of nationals to re-enter their own country.”<sup>356</sup> Because of the broad concept adopted in the covenant, the same reasoning should apply to other individuals with a strong attachment to the country, namely permanent residents and potentially even foreigners on a student visa.

Migrant workers were particularly affected by absolute entry bans. The United Nations Committee on Migrant Workers and the United Nations Special Rapporteur on the Human Rights of Migrants called on States to “protect the human rights of migrants and their families, irrespective of their migration

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350 HUM. RTS. COMM., *supra* note 146, ¶ 5. *See* § 2.2c.

351 Gostin, Bayer & Fairchild, *supra* note 44, at 3235.

352 *Id.*

353 Mégret, *supra* note 37, at 323.

354 *Id.* at 323 (discussing the closure of borders by Morocco to its own nationals).

355 *Id.* at 326.

356 Mégret, *supra* note 37, at 323 (The right to return “is a freedom that cannot be denied lightly.”); Richardson & Devine, *supra* note 179, at 29 (“[A]ny COVID-19 restriction, such as closing borders, that does not allow individuals to return to their ‘own country’ would be overbroad and incompatible with the ICCPR.”).

status.”<sup>357</sup> In particular, they urged States to:

Guarantee the right of all migrants and their families to return to the country of which they are nationals. Many of them are stranded all over the world as they try to reach their home countries due to border closures or travel restrictions within countries. This obligation must be harmonized with international health standards and guidelines issued by national health authorities, and covers, according to the conditions of each State, measures of protection, access to information, and assistance.<sup>358</sup>

Migrant workers have also been affected indirectly through the imposition, by a limited number of countries, of exit bans. The right to leave is closely connected with the right to return, as one does not make sense without the other. Article 12(2) of the ICCPR gives “everyone” the right to “leave any country, including his own.” This right may be limited for public health reasons (as it is one of the “above-mentioned rights” referred to in Article 12(3)). However, such limitations need to be consistent with the other rights recognized in the Covenant, including the right to return. If migrant workers are barred from leaving their “host country,” they cannot exercise their right to return to their “home” country. The United Nations Committee on Migrant Workers and the United Nations Special Rapporteur on the Human Rights of Migrants seem to have this scenario in mind when they call upon States Parties to “[g]uarantee the right of all migrants and their families to return to the country of which they are nationals.”<sup>359</sup> Exit bans affect not only migrant workers but also other individuals (non-nationals, non-residents) who were abroad during the outbreak of the pandemic and did not have the chance to return to their home countries.

Finally, travel bans also undermine the protection of other fundamental human rights. The pandemic highlights the need to recognize the “interdependence and indivisibility” of human rights.<sup>360</sup> Particularly important in connection to international mobility is the right to family reunification. Article 23(1) of the ICCPR states that “[t]he family is the natural and fundamental group unit of society and is entitled to protection by society and the State.”<sup>361</sup> The right to family reunification—normally discussed in the context of migration laws—derives from

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357 Comm. on Migrant Workers & Special Rapporteur on the Hum. Rts. of Migrants, *Joint Guidance Note on the Impacts of the COVID-19 Pandemic on the Human Rights of Migrants*, UNITED NATIONS (May 26, 2020) <https://www.ohchr.org/Documents/Issues/Migration/CMWSPMJointGuidanceNoteCOVID-19Migrants.pdf>.

358 *Id.* at ¶ 13.

359 *Id.*

360 Andreassen et al., *supra* note 209, at 3-4.

361 ICCPR, *supra* note 124, at art. 23(1).

this provision.<sup>362</sup> As recognized by WHO, “[e]ven short-term restrictions on freedom of movement can have significant—and possibly devastating—financial and social consequences for individuals, their families, and their communities.”<sup>363</sup> Many countries that imposed travel bans provided no exemptions for nationals’ or residents’ family members.<sup>364</sup> As a result, families with different nationalities or residential statuses could not reunite.

In this regard, it is instructive to recall the words of the Human Rights Committee:

It is in principle a matter for the State to decide who it will admit to its territory. However, in certain circumstances an alien may enjoy the protection of the Covenant even in relation to entry or residence, for example, when considerations of non-discrimination, prohibition of inhuman treatment and *respect for family life arise*.<sup>365</sup>

Both legal (human rights) and scientific (medical) principles serve as standards against which the validity of additional health measures should be assessed. Because WHO’s guidance on the protection of human rights during pandemics has been weak, States have been able to freely claim that they are taking necessary or effective measures.<sup>366</sup> It seems difficult to demonstrate the public health rationale of travel bans, and therefore they breach Article 43 of the IHR. When it comes to the human rights level, one must distinguish according to the status of the individual. Entry bans covering nationals and residents clearly breach the right of return. Exit bans are also problematic because they affect the exercise of the right to return. Both types of measures indirectly prevent family members from exercising their right to family reunification. Foreigners do not have a right to entry to a foreign country but may be affected if they are prevented from leaving as they become unable to exercise their return to return to their home country.

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362 See, e.g., Gallya Lahav, *International Versus National Constraints in Family-Reunification Migration Policy*, 3 GLOB. GOVERNANCE 349 (1997); Ryszard Cholewinski, *Family Reunification and Conditions Placed on Family Members: Dismantling a Fundamental Human Right*, 4 EUR. J. MIGRATION & L. 271 (2002).

363 WORLD HEALTH ORG., *supra* note 198, at 27.

364 Guofu Liu, *COVID-19 and the Human Rights of National Abroad*, 114 AJIL UNBOUND 317, 319 (2020).

365 HUM. RTS. COMM., *supra* note 146, at ¶ 5 (emphasis added).

366 Alicia Yamin & Roojin Habibi, *Human Rights and Coronavirus: What’s at Stake for Truth, Trust, and Democracy?*, HEALTH & HUM. RTS. J. (Mar. 1, 2020), <https://www.hhrjournal.org/2020/03/human-rights-and-coronavirus-whats-at-stake-for-truth-trust-and-democracy>.

## III. REPORT, REVIEW, RE-OPEN, RESPECT?

Travel bans qualify as cases of additional health measures that significantly interfere with international traffic.<sup>367</sup> Therefore, governments that implement such measures must provide WHO with the public health rationale and relevant scientific information for the measure within forty-eight hours of implementation.<sup>368</sup> While the IHR do not clarify, it can be assumed that a public health rationale should consider the elements mentioned in Article 43(2): scientific principles, available scientific evidence of a risk to human health, and any available specific guidance or advice from WHO.<sup>369</sup> Again, the level of scientific evidence required to justify additional health measures is unclear. According to the Stellenbosch Consensus, “additional health measures must be supported by a public health rationale that is, at minimum, based on the scientific evidence appraised in paragraph 2.”<sup>370</sup>

The IHR emphasizes epidemiology over sovereignty.<sup>371</sup> If States Parties decide to disregard specific guidance or advice from WHO, they bear the burden of justifying their decision. It is not enough to laconically claim to be intervening in the name of public health.<sup>372</sup> Additional health measures must be “evidence-based,”<sup>373</sup> and the explanation of their public health rationale should be “adequate.”<sup>374</sup> Experience shows that States Parties often fail to comply with these duties.<sup>375</sup> This makes it impossible for WHO to exercise its power to, after assessing that information and other relevant information, request that the State Party reconsider the application of the measures.<sup>376</sup> According to Adam Ferhani and Simon Rushton, WHO “seems to have been powerless either to demand an explanation from non-reporting states or to challenge the justifications of those who had reported additional health measures.”<sup>377</sup>

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367 IHR, *supra* note 3, at art. 43(3).

368 *Id.* at arts. 43(3), 43(5). WHO shall share this information with other States Parties and share information regarding the health measures implemented. *Id.* at art. 43(3).

369 *Stellenbosch Consensus*, *supra* note 159, at 27-28.

370 *Id.* at 30.

371 Fidler, *supra* note 93, at 184.

372 Toebes, *supra* note 32, at 496.

373 *Report of the Review Committee on the Functioning of the International Health Regulations (2005) in Relation to Pandemic (H1N1) 2009*, WORLD HEALTH ORG. ¶28 (May 2011), [https://apps.who.int/gb/ebwha/pdf\\_files/WHA64/A64\\_10-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf).

374 *Implementation of the International Health Regulations (2005): Report of the Review Committee on the Role of the International Health Regulations (2005) in the Ebola Outbreak and Response*, WORLD HEALTH ORG. 80 (May 2016), [https://apps.who.int/gb/ebwha/pdf\\_files/WHA69/A69\\_21-en.pdf](https://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_21-en.pdf).

375 Ferhani & Rushton, *supra* note 41, at 463; *Stellenbosch Consensus*, *supra* note 159, at 44; Burci, *supra* note 70, at 213.

376 Burci, *supra* note 70, at 213. See IHR, *supra* note 3, at art. 43(4).

377 Ferhani & Rushton, *supra* note 41, at 469.

To the best of our knowledge, there is no publicly available information from WHO or other international organizations regarding additional health measures reported by states. This makes it impossible to know what arguments they used.<sup>378</sup> In their study about European Union (EU) Member State’s compliance with the requirements contained in the Schengen Borders Code, Sergio Carrera and Ngo Chun Luk concluded that “[n]one of the relevant ministries of interior provided any meaningful explanation of why they considered COVID-19 something ‘foreign’ from abroad when the virus was already present and spreading across their own territories and populations.”<sup>379</sup>

States Parties to the IHR have a duty to provide a public health rationale where their measures interfere significantly with international traffic. Even if not expressly stated, the situation is quite similar to the evidentiary burden under the Schengen Borders Code: E.U. Member States have an incremental burden of proof to justify and provide evidence on their proportionality.<sup>380</sup> The same idea should apply in the context of the IHR. The harsher and more intrusive the public health measure is, the more persuasive and rigorous the scientific evidence advanced to support it should be.<sup>381</sup> In addition, the burden of proof should increase as time goes by and measures remain in place.<sup>382</sup> If States Parties fail to justify their measures or present generic pretexts, they feed perceptions that travel restrictions are based on considerations other than public health (namely, concerns of an economic or political nature).<sup>383</sup>

In the human rights arena, the decision-making process by governments is also subject to close scrutiny. As stated in the Siracusa Principles, “[i]n determining whether derogation measures are strictly required by the exigencies of the situation

378 It can be assumed that at least New Zealand did report and justify its measures before WHO. Wilson, Barnard & Baker, *supra* note 239, at 3 (“While the WHO generally advises against travel restrictions, NZ has technically met its International Health Regulations (IHR) obligations by providing a rationale to WHO within the requisite timeframe . . .”).

379 Carrera & Luk, *supra* note 319, at 69.

380 *Id.* at 16.

381 Errol Mendes, *Restrictions on Mobility Rights of Canadians During the Pandemic: The Critical Need for Proper Scientific and Public Health Rationales*, 41 NAT’L J. CONST. L. 57, 74 (2020) (discussing health measures from the perspective of Canadian Constitutional law).

382 Carrera & Luk, *supra* note 139, at 16. In the authors’ opinion, most EU Member States failed to meet this test: “Most of the Ministries of the Interior have failed to provide evidence-based of the necessity and proportionality of border controls and travel bans, and their expected and documented impacts. . . . There has not been any robust independent evidence provided by the relevant national authorities to rationalise either the extra- or intra-EU travel restriction measures, which are prerequisites for conducting any proportionality test in EU borders and free movement law. And yet, any coercive public policies should be founded on compelling scientific evidence and presented with transparent, clear and robust respect for fundamental rights and ethical principles.” Carrera & Luk, *supra* note 343, at 28.

383 See, e.g., Ramji-Nogales & Goldner Lang, *supra* note 293, at 599; Chetail, *supra* note 46, at 2.

the judgment of the national authorities cannot be accepted as conclusive.”<sup>384</sup> While the ICCPR does not refer to scientific evidence and principles, it does require States to assess risks.<sup>385</sup> Governments have the burden of justifying their measures. As highlighted by the Human Rights Committee on its statement on derogations from the ICCPR in connection with COVID-19:

Where measures derogating from the obligations of States parties under the Covenant are taken, the provisions derogated from and the reasons for the derogation must be communicated immediately to the other States parties through the Secretary-General. *Notification by a State [P]arty must include full information about the derogating measures taken and a clear explanation of the reasons for taking them, with complete documentation of any laws adopted.*<sup>386</sup>

The Committee stated that several countries had already notified the Secretary-General of measures they had taken or were planning to take derogating from the ICCPR. Several other States Parties, however, had adopted measures without formal notification, and the Committee urged such States to notify the Secretary-General immediately.<sup>387</sup> The statement delineates the different requirements and conditions that States must comply with to align their measures with human rights standards. Governments cannot simply base their submissions on the need to calm public anxiety or avoid panic<sup>388</sup>—measures should not be “imposed merely because of an apprehension of potential danger.”<sup>389</sup> They should identify the measures they have implemented or plan to implement and explain why they believe they are appropriate to the risks created by the pandemic.<sup>390</sup>

The problem is that governments often file “notices of derogation [that] are too general, too brief, and do not give a clear indication of what articles . . . have been suspended.”<sup>391</sup> In the context of COVID-19, states do not even explain why

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384 *Siracusa Principles*, *supra* note 158, at ¶ 57.

385 Von Tigerstrom, *supra* note 179, at 63.

386 HUMAN RIGHTS COMM., *supra* note 283, at ¶ 2 (emphasis added).

387 *Id.* at ¶ 1. The Committee added that “the implementation of the obligation of immediate notification [is] essential for the discharge of its functions, as well as for the monitoring of the situation by other States parties and other stakeholders . . .” *Id.*

388 See Francisco-José Quintana & Justina Urriburu, *Modest International Law: COVID-19, International Legal Responses, and Depoliticization*, 114 AM. J. INT’L L. 687, 692 (2020).

389 *Siracusa Principles*, *supra* note 158, at ¶ 54.

390 *Id.* at ¶ 52.

391 JAIME ORÀÀ, HUMAN RIGHTS IN STATE OF EMERGENCY IN INTERNATIONAL LAW 77 (1992); see also Hartman, *supra* note 256, at 21. Laurence R. Helfer, *Rethinking Derogations from Human Rights Treaties*, 115 AM. J. INT’L L. 20, 21 (2021) (“Most notices of derogation are short simple statements listing which rights have been suspended and for how long, and citing to domestic laws or decrees; only a few states have offered more detailed justifications of their actions.”).

a derogation is necessary instead of a restriction.<sup>392</sup> If governments challenge the scientific authority of WHO's recommendations without even bothering to justify their decision or do so loosely, they widen the gap between scientific evidence and political action.<sup>393</sup> It is even harder to make such a determination when States do not even report the measures they implement.<sup>394</sup> As many of these measures are being lifted, competent bodies may never review them.<sup>395</sup>

In addition to the obligation to report, States Parties to the IHR also have obligations to review additional health measures within three months of their implementation.<sup>396</sup> The obligation to review such measures is a reminder of their temporary nature and the need to substantiate their public health rationale.<sup>397</sup>

The longer measures remain in place, the harder they become to justify. If travel bans could be justified in the early stages of the pandemic, they make less sense as time goes by. Travel bans are often presented as a way to "keep the ill out." However, in most countries, this strategy did not work as the virus was already within the borders. As stated by one author, "no two airports in the world are separated by more than [thirty-six] hours of flying time, a period shorter than the incubation time for most infectious diseases."<sup>398</sup> Several months after the first cases of local transmission, were countries with travel bans in place still trying to prevent the "arrival" of the virus? The virus had made its way through national borders, so keeping them closed was an exercise in futility.

States must review their measures taking into account scientific principles, available scientific evidence, and any specific guidance or advice from WHO.<sup>399</sup> In July 2020, WHO acknowledged that "[m]any countries ha[d] halted some or all international travel since the onset of the COVID-19 pandemic but now have plans to re-open travel," offering some advice for national health authorities when resuming international travel.<sup>400</sup> It also added:

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392 Niall Coghlan, *Dissecting COVID-19 Derogations*, VERFASSUNGSBLOG (May 5, 2020), <https://verfassungsblog.de/dissecting-covid-19-derogations>.

393 Petersen et al., *supra* note 239, at 88; Alberto Alemanno, *Taming COVID-19 by Regulation: An Opportunity for Self-Reflection*, 11 EUR. J. RISK REGUL. 187, 194 (2020). Alemanno presents travel bans as an example of unprepared decision-making processes that resulted in unscientific outcomes. *Id.* at 193-94 & n.59.

394 Richardson & Devine, *supra* note 179, at 2.

395 Helfer, *supra* note 3911, at 21.

396 See IHR, *supra* note 3, at arts. 43(6)-(8).

397 Stellenbosch Consensus, *supra* note 159, at 29.

398 Eric Carter, *When Outbreaks Go Global: Migration and Public Health in a Time of Zika*, MIGRATION POL'Y INST. (July 7, 2016), <https://www.migrationpolicy.org/article/when-outbreaks-go-global-migration-and-public-health-time-zika>.

399 IHR, *supra* note 3, at art. 43(6).

400 *Public Health Considerations While Resuming International Travel*, WORLD HEALTH ORG. (July 30, 2020), <https://www.who.int/news-room/articles-detail/public-health-considerations-while-resuming-international-travel>.

The gradual lifting of travel measures (or temporary restrictions) should be based on a thorough risk assessment, taking into account country context, the local epidemiology and transmission patterns, the national health and social measures to control the outbreak, and the capacities of health systems in both departure and destination countries, including at points of entry. Any subsequent measure must be proportionate to public health risks and should be adjusted based on a risk assessment, conducted regularly and systematically as the COVID-19 situation evolves and communicated regularly to the public.<sup>401</sup>

One wonders whether States will heed WHO's advice while re-opening borders as much as they did (not) when closing them.<sup>402</sup> Travel bans are intended to be exceptional and temporary: they are a "delay strategy," not a "preventative" one.<sup>403</sup> As stated by the Human Rights Committee, "[t]he restoration of a state of normalcy where full respect for the Covenant can again be secured must be the predominant objective of a State [P]arty derogating from the Covenant."<sup>404</sup> Similarly, when addressing the COVID-19 crisis, the Council of Europe stated that "the main purpose of the state of emergency regime (or alike) is to contain the development of the crisis and return, as quickly as possible, to the normality."<sup>405</sup> According to the Siracusa Principles, "[a] state party availing itself of the right of derogation pursuant to Article 4 shall terminate such derogation in the shortest time required to bring to an end the public emergency which threatens the life of the nation."<sup>406</sup> If travel bans remain in place indefinitely, people start questioning their effectiveness and wondering if governments are overlooking their economic and human rights impact.<sup>407</sup> There is a risk that travel bans become the "new normal" and are used by governments to pursue goals other than strictly the fight against the pandemic.<sup>408</sup> Experience shows that states frequently maintain derogations for long periods.<sup>409</sup>

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401 *Id.*

402 Von Tigerstrom & Wilson, *supra* note 43, at 3.

403 Borame Dickens et al., *Strategies at Points of Entry to Reduce Importation Risk of COVID-19 Cases and Reopen Travel*, 27 J. TRAVEL MED. 1, 2 (2020).

404 *General Comment No. 29: Derogations During a State of Emergency*, *supra* note 169, at ¶ 1; *see also* HUM. RTS. COMM., *supra* note 283, at ¶ 2a.

405 *Respecting Democracy, Rule of Law and Human Rights in the Framework of the COVID-19 Sanitary Crisis: A Toolkit for Member States*, COUNCIL OF EUR. (April 7, 2020), <https://rm.coe.int/sg-inf-2020-11-respecting-democracy-rule-of-law-and-human-rights-in-th/16809e1f40>.

406 *Siracusa Principles*, *supra* note 158, at ¶ 48.

407 Gostin, *supra* note 8, at 571.

408 Danchin et al., *supra* note 343, at 605.

409 Paddeu & Waibel, *supra* note 313, at 704.

A troubling question is what consequences, if any, these breaches of international law will have. One of the things the IHR and human rights law have in common is pervasive non-compliance.<sup>410</sup> There is no established mechanism to monitor and review compliance of States Parties with the IHR. According to the Siracusa Principles, “[e]ffective remedies shall be available to persons claiming that derogation measures affecting them are not strictly required by the exigencies of the situation.”<sup>411</sup> However, the IHR do not incorporate a system to investigate human rights violations either.<sup>412</sup> The ICCPR provides for a Human Rights Committee to which States Parties must periodically submit reports.<sup>413</sup> However, it has not been very effective. Without reports, there is no monitoring, much less enforcement.<sup>414</sup>

### CONCLUSION

Like prior agreements in the field of international health law, the IHR are repeatedly presented as a “balancing dynamic” between the protection of public health and the maintenance of international trade and travel.<sup>415</sup> This is admittedly “a difficult tightrope to walk.”<sup>416</sup> In the words of Gostin, “the international community cannot have it both ways—unimpeded travel and trade, with full public

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410 David Fidler, *The Future of the World Health Organization: What Role for International Law*, 31 VAND. J. TRANSNAT'L L. 1079, 1104 (1998).

411 *Siracusa Principles*, *supra* note 158, at ¶56. Some scholars have interpreted these safeguards to mean that the state must provide a justification and that the individual has the right to challenge the ruling against him. HANNUM, *supra* note 154, at 24-26. The Siracusa Principles are, admittedly, quite aspirational:

On the termination of a derogation pursuant to Article 4 all rights and freedoms protected by the Covenant shall be restored in full. A review of the continuing consequences of derogation measures shall be made as soon as possible. Steps shall be taken to correct injustices and to compensate those who have suffered injustice during or in consequence of the derogation measures.

*Siracusa Principles*, *supra* note 158, at ¶ 50.

412 WORLD HEALTH ORG., *supra* note 93, at 63; Sara Davies & Jeremy Youde, *The IHR (2005), Disease Surveillance, and the Individual in Global Health Politics*, 17 INT'L J. HUM. RTS. 133, 144 (2013); Asher, *supra* note 103, at 156; Negri, *supra* note 108, at 300.

413 ICCPR, *supra* note 124, at arts. 28, 40.

414 Asher, *supra* note 103, at 168.

415 *Global Crises—Global Solutions: Managing Public Health Emergencies of International Concern Through the Revised International Health Regulations*, WORLD HEALTH ORG. 8 (2002), <https://apps.who.int/iris/handle/10665/67300>; Lawrence Gostin & Rebecca Katz, *The International Health Regulations: The Governing Framework for Global Health Security*, 94 MILBANK Q. 264, 267 (2016); Negri, *supra* note 108, at 274; Paul DeMuro, *The International Health Regulations—Restricting Travel in Emergency Health Situations and Issues Health Care Providers Should Consider*, 19 HEALTH LAW. 14 (2007); *Stellenbosch Consensus*, *supra* note 159, at 66.

416 Simon Rushton, *Global Governance Capacities in Health: WHO and Infectious Diseases*, in GLOBAL HEALTH GOVERNANCE CRISIS, INSTITUTIONS AND POLITICAL ECONOMY 60, 73 (Adrian Kay & Owain Williams eds., 2009).

health protection.”<sup>417</sup>

While the stated purpose of the IHR is to “avoid unnecessary interference with international traffic and trade,”<sup>418</sup> the regulations make no reference to avoiding unnecessary interference with individual freedom.<sup>419</sup> The focus seems to be on minimizing the economic consequences of travel restrictions, not protecting individual rights.<sup>420</sup> Still, it can be said that the tenet of avoiding “unnecessary interference with international traffic” can be used as a parameter to protect the rights of individuals.<sup>421</sup> This balancing dynamic should also consider human rights rules and principles,<sup>422</sup> namely, freedom of movement.<sup>423</sup>

Only time will tell how much economic and social harm and suffering could have been avoided or at least mitigated had countries not rushed to close their borders. COVID-19 is a vivid reminder that governments need to conform to both the IHR and human rights rules and principles when designing and implementing measures to address public health emergencies. It is crucial to strengthen the connection between the two domains. Decision-making and implementation processes should not be left to vague standards and rhetorical proclamations. Otherwise, too much discretion is given to national governments in devising their own policies, often inspired by non-scientific considerations. A proper balancing exercise calls for visible signposts based on sound medical evidence and informed by international best practices.

To enhance compliance with the regulatory framework, the WHO should increase its “precision” or “determinacy.”<sup>424</sup> It is necessary to create visible markers about how and when States Parties may apply additional health measures that interfere with international mobility. This is no easy task, entailing a broad consensus—among medical but also legal experts—about the criteria that should determine the reasonable balance between public health and international mobility. It is also vital to increase the weight of human rights rules and principles in the balancing exercise between public health and freedom of movement. A coherent, holistic approach to international mobility requires a greater degree of precision about whether health measures comply with human rights standards.

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417 Gostin, *supra* note 344, at 2624.

418 IHR, *supra* note 3, at art. 2.

419 Heidi Lambertson, *Swatting a Bug without a Flyswatter: Minimizing the Impact of Disease Control on Individual Liberty Under the Revised International Health Regulations*, 25 PA. ST. INT’L L. REV. 531, 544 (2006).

420 *Id.*

421 DeMuro, *supra* note 415, at 73.

422 Lawrence Gostin, *Public Health Strategies for Pandemic Influenza: Ethics and the Law*, 295 J. AM. MED. ASS’N 1700, 1702-03 (2006); Gostin & Katz, *supra* note 415, at 267; Goldfarb, *supra* note 41, at 782.

423 Fidler & Gostin, *supra* note 189, at 87.

424 See Fernando Dias Simões, *Protecting International Travelers During Pandemics: Charting the Way Forward*, 31 MINN. J. INT’L L. (forthcoming 2022).

# Health AI for Good Rather Than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices

Sara Gerke\*

Abstract:

Artificial intelligence (AI), especially its subset machine learning, has tremendous potential to improve health care. However, health AI also raises new regulatory challenges. In this Article, I argue that there is a need for a new regulatory framework for AI-based medical devices in the U.S. that ensures that such devices are reasonably safe and effective when placed on the market and will remain so throughout their life cycle. I advocate for U.S. Food and Drug Administration (FDA) and congressional actions. I focus on how the FDA could—with additional statutory authority—regulate AI-based medical devices. I show that the FDA incompletely regulates health AI-based products, which may jeopardize patient safety and undermine public trust. For example, the medical device definition is too narrow, and several risky health AI-based products are not subject to FDA regulation. Moreover, I show that most AI-based medical devices available on the U.S. market are 510(k)-cleared. However, the 510(k) pathway raises significant safety and effectiveness concerns. I thus propose a future regulatory framework for premarket review of medical devices, including AI-based ones. Further, I discuss two problems that are related to specific AI-based medical devices, namely opaque (“black-box”) algorithms and adaptive algorithms that can continuously learn, and I make suggestions on how to address them. Finally, I encourage the FDA to broaden its view and consider AI-based medical devices as systems, not just devices, and focus more on the environment in which they are deployed.

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INTRODUCTION

Artificial Intelligence (AI) is rapidly entering health care and may fundamentally change the way physicians practice medicine in the future. AI, especially its subset Machine Learning (ML), shows great potential to improve health care by enabling precision medicine, where patients receive better diagnoses and treatment recommendations tailored to their individual needs. The United States (U.S.) Food and Drug Administration (FDA) has already permitted marketing of over 340 AI/ML-based medical devices.<sup>1</sup>

According to one recent estimate, the global health AI market size is expected to increase more than nine-fold, from \$6.9 billion in 2021 to \$67.4 billion by 2027.<sup>2</sup> The COVID-19 pandemic has also hastened the adoption of health AI.<sup>3</sup> The enormous venture capital investment in the U.S. indicates the rising deployment of AI in the health care market.<sup>4</sup> In 2020, the U.S. accounted for the largest health AI market share in North America as it is home to several giant technology companies that are investing strongly in the development of health AI-based

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1 U.S. Food & Drug Admin., *Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices* (Sept. 22, 2021), <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-ai-ml-enabled-medical-devices>. For non-FDA resources, see, for example, Stan Benjamins et al., *The State of Artificial Intelligence-Based FDA-Approved Medical Devices and Algorithms: An Online Database*, 3 NPJ DIGIT. MED., no. 118, at 2 (2020) (identifying 64 AI/ML-based medical devices that received FDA marketing authorization); Urs J. Muehlematter et al., *Approval of Artificial Intelligence and Machine Learning-Based Medical Devices in the USA and Europe (2015–20): A Comparative Analysis*, 3 LANCET DIGIT. HEALTH e195 (2021) (identifying 222 AI/ML-based medical devices that received FDA marketing authorization); Eric Wu et al., *How Medical AI Devices Are Evaluated: Limitations and Recommendations From an Analysis of FDA Approvals*, 27 NATURE MED. 582 (2021) (aggregating 141 FDA-approved AI devices); Am. Coll. Radiology, *Data Science Institute AI Central*, <https://models.acrdsi.org> (providing a database for FDA-cleared, AI-based medical devices in medical imaging) (last visited Mar. 19, 2022); *FDA-Approved A.I.-Based Algorithms*, MED. FUTURIST, <https://medicalfuturist.com/fda-approved-ai-based-algorithms> (last visited Mar. 19, 2022); and Casey Ross, *As the FDA Clears a Flood of AI Tools, Missing Data Raise Troubling Questions on Safety and Fairness*, STAT (Feb. 3, 2021), <https://www.statnews.com/2021/02/03/fda-clearances-artificial-intelligence-data>.

2 *Artificial Intelligence in Healthcare Market*, MARKET SAND MARKETS (Oct. 2021), <https://www.marketsandmarkets.com/Market-Reports/artificial-intelligence-healthcare-market-54679303.html>.

3 *Id.*; see also Sara Gerke et al., *Regulatory, Safety, and Privacy Concerns of Home Monitoring Technologies During COVID-19*, 26 NATURE MED. 1176 (2020) (raising concerns about the hasty adoption of home monitoring technologies); Carmel Shachar et al., *AI Surveillance during Pandemics: Ethical Implementation Imperatives*, 50 HASTINGS CTR. REP. 18 (2020) (discussing ethical implementation imperatives for AI surveillance during a pandemic).

4 Jason Schoettler, *Investors Are Piling Into Healthcare AI Start-Ups; There's Room for More*, VENTURE CAP. J. (Sept. 28, 2021), <https://www.venturecapitaljournal.com/investors-are-piling-into-healthcare-ai-start-ups-theres-room-for-more>.

products, such as Microsoft, Google, and IBM.<sup>5</sup>

Health AI also poses new legal challenges, including ensuring the products' safety and effectiveness<sup>6</sup>, obtaining informed consent<sup>7</sup>, providing an adequate level of privacy protection<sup>8</sup>, and comprehending and resolving liability issues<sup>9</sup>. As SpaceX and Tesla CEO/founder Elon Musk warned about AI in 2014 at the Massachusetts Institute of Technology's AeroAstro Centennial Symposium:

I'm increasingly inclined to think that there should be some regulatory oversight, maybe at the national and international level, just to make sure that we don't do something very foolish. I mean with artificial intelligence we're summoning the demon.<sup>10</sup>

But how does one ensure that AI is good rather than evil? As Elon Musk correctly pointed out, the world needs proper regulatory oversight, and this starts at the national level. Such oversight is especially essential in health care to ensure that AI does not leave behind the most vulnerable populations, such as racial and

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5 *Artificial Intelligence in Healthcare Market*, *supra* note 2.

6 See, e.g., Boris Babic et al., *Direct-To-Consumer Medical Machine Learning and Artificial Intelligence Applications*, 3 NATURE MACH. INTEL. 283 (2021); W. Nicholson Price II, *Artificial Intelligence in Health Care: Applications and Legal Implications*, 14 SCITECH LAW. 10 (2017); W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421 (2017).

7 See, e.g., Sara Gerke et al., *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, in ARTIFICIAL INTELLIGENCE IN HEALTHCARE 295, 301 (Adam Bohr & Kaveh Memarzadeh eds., 1st ed. 2020); I. Glenn Cohen, *Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?* 108 GEO. L.J. 1425 (2020).

8 See, e.g., Nathan Cortez, *Substantiating Big Data in Health Care*, 14 I/S: J.L. & POL'Y INFO. SOC'Y 61 (2017); Roger Allan Ford & W. Nicholson Price II, *Privacy and Accountability in Black-Box Medicine*, 23 MICH. TELECOMM. & TECH. L. REV. 1 (2016); Sara Gerke et al., *Ethical and Legal Aspects of Ambient Intelligence in Hospitals*, 323 JAMA 601 (2020); W. Nicholson Price II et al., *Shadow Health Records Meet New Data Privacy Laws*, 363 SCIENCE 448 (2019); W. Nicholson Price II & I. Glenn Cohen, *Privacy in the Age of Medical Big Data*, 25 NATURE MED. 37 (2019); Charlotte A. Tschider, *Regulating the Internet of Things: Discrimination, Privacy, and Cybersecurity in the Artificial Intelligence Age*, 96 DENV. L. REV. 87 (2018).

9 See, e.g., W. Nicholson Price II, *Medical Malpractice and Black-Box Medicine*, in BIG DATA, HEALTH LAW, AND BIOETHICS 295 (I. Glenn Cohen et al., eds., 1st ed. 2018); A. Michael Froomkin et al., *When AIs Outperform Doctors: Confronting the Challenges of a Tort-Induced Over-Reliance on Machine Learning*, 61 ARIZ. L. REV. 33 (2019); George Maliha et al., *Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation*, 99 MILBANK Q. 629 (2021); W. Nicholson Price II et al., *How Much Can Potential Jurors Tell Us about Liability for Medical AI?* 62 J. NUCLEAR MED. 15 (2021); W. Nicholson Price II et al., *Potential Liability for Physicians Using Artificial Intelligence*, 322 JAMA 1765 (2019); Andrew D. Selbst, *Negligence and AI's Human Users*, 100 B.U. L. REV. 1315 (2020); Kevin Tobia et al., *When Does Physician Use of AI Increase Liability?* 62 J. NUCLEAR MED. 17 (2020).

10 Massachusetts Institute of Technology, *Elon Musk at the MIT AeroAstro Centennial Symposium*, YOUTUBE, at 01:07:58 (July 2, 2015), [https://www.youtube.com/watch?v=4DUbiCQpw\\_4&ab\\_channel=ElonMuskSoundBites](https://www.youtube.com/watch?v=4DUbiCQpw_4&ab_channel=ElonMuskSoundBites).

ethnic minorities or people with disabilities, and benefits all patients. In particular, regulators like the FDA need to reconsider the current regulatory paradigm to ensure that AI-based products classified as medical devices (AI-based medical devices) are reasonably safe and effective when placed on the market and will remain so throughout their life cycle. In this regard, several regulatory issues need to be thoroughly examined and have not received enough attention in the legal literature.<sup>11</sup> This Article endeavors to start to remedy that by focusing on unresolved regulatory issues of AI-based medical devices in the U.S. and proposing solutions.

In this Article, I advocate for FDA and congressional actions. I focus on how the FDA could—with additional statutory authority—regulate AI-based medical devices. The current regulatory framework for AI-based medical devices is not only complex and opaque at various points, but there are also recent developments in this area, which makes it even more difficult to keep track of the applicable framework. I go beyond the current literature<sup>12</sup> by unraveling, inter alia, the complex network of relevant provisions in the Federal Food, Drug, and Cosmetic Act (FDCA) and (draft) guidance documents related to AI-based medical devices, and thereby creating transparency in the field. Only by thoroughly cataloguing and analyzing the applicable framework can one identify loopholes and flaws, make suggestions, and thus refashion the discourse and move forward. I also discuss new regulatory proposals in the field and suggest ways to strengthen them. For many of my suggestions, the FDA will need to request additional statutory authority. Once the FDA has acquired enough information to design a new premarket and postmarket regulatory framework for AI-based medical devices that would ensure that such devices would be reasonably safe and effective throughout their life cycle, Congress should enact legislation to enable the FDA to fully implement its new framework. With the additional statutory authority and its new Digital Health Center of Excellence,<sup>13</sup> the FDA would have the necessary resources to tackle the regulatory challenges raised by AI.

I argue that the FDA incompletely regulates health AI-based products, which

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11 A few regulatory issues have been discussed by, for example, Nathan Cortez, *Digital Health and Regulatory Experimentation at the FDA*, 21 YALE J.L. & TECH. 4 (2019); Barbara Evans & Pilar Ossorio, *The Challenge of Regulating Clinical Decision Support Software after 21st Century Cures*, 44 AM. J.L. & MED. 388 (2018); Price, *Artificial Intelligence in Health Care*, *supra* note 6; Price, *Regulating Black-Box Medicine*, *supra* note 6; and Nicolas P. Terry, *Assessing the Thin Regulation of Consumer-Facing Health Technologies*, 48 J.L. MED. & ETHICS 94 (2020).

12 *See, e.g.*, sources cited *supra* note 11.

13 The new Digital Health Center of Excellence is located in the Center for Devices and Radiological Health and is primarily focused on helping stakeholders get high-quality digital health products to patients. For more information, see Press Release, U.S. Food and Drug Admin., FDA Launches the Digital Health Center of Excellence (Sept. 22, 2020), <https://www.fda.gov/news-events/press-announcements/fda-launches-digital-health-center-excellence>.

may jeopardize patient safety and undermine public trust. For example, the medical device definition is too narrow, leaving out several risky health AI-based products that consequently are not subject to FDA regulation. Moreover, I show that although the 510(k)<sup>14</sup> premarket notification is the most frequently used type of premarket submission for AI-based medical devices, that pathway may not be sufficient to identify safety and effectiveness concerns. Hence, I propose a future regulatory framework for premarket review of medical devices, including AI-based ones, that would better ensure that devices are reasonably safe and effective when placed on the market. Further, I discuss two problems that are related to specific AI-based medical devices, namely opaque (“black-box”) algorithms and “adaptive” algorithms that can continuously learn, and I suggest ways to address them. I also encourage the FDA to broaden its view and consider AI-based medical devices as systems, not *just* devices, and focus more on the environment in which they are deployed. This system view is essential to ensure that AI-based medical devices are reasonably safe and effective and benefit patients.

This Article proceeds in five Parts. Part I briefly explains relevant terms in computer science. It also provides an overview of the potential benefits of health AI-based products.

Part II establishes that the current medical device definition, FDCA section 201(h)(1),<sup>15</sup> is too narrow. I argue that several risky health AI-based products currently fall outside of the FDA’s jurisdiction, such as certain clinical decision support (CDS) software functions. I propose that all CDS should be considered a priori medical devices under FDCA section 201(h)(1), and thus that Congress should consider amending the FDCA accordingly by deleting FDCA section 520(o)(1)(E).<sup>16</sup> I also suggest that Congress could amend the medical device definition to clearly include AI-based mortality prediction models and other models that are intended for use in the prediction or prognosis of disease or other conditions.

Part III shows that the FDA cleared most AI-based medical devices currently available on the U.S. market via the 510(k) pathway, raising significant safety and effectiveness concerns. It also examines the new 510(k) reforms. In particular, I argue that the new Safety and Performance Based Pathway likely will not apply to AI-based medical devices in the next few years. Even if it were applicable, the new pathway is voluntary and thus manufacturers would still have the option to submit a Traditional, Special, or Abbreviated 510(k) instead. I therefore propose a future regulatory framework for premarket review of medical devices, including AI-based medical devices. If the new Safety and Performance Based Pathway proves

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14 Federal Food, Drug, and Cosmetic Act (FDCA) § 510(k), 21 U.S.C. § 360(k).

15 FDCA § 201(h)(1), 21 U.S.C. § 321(h)(1).

16 FDCA § 520(o)(1)(E), 21 U.S.C. § 360j(o)(1)(E).

to be effective, it should replace the other 510(k) pathways and become the only available 510(k) pathway. In addition, my proposal includes modifying the De Novo pathway to also cover low to moderate risk medical devices that have a predicate but would not be eligible for the new 510(k) pathway. Finally, I argue that the FDA's new Software Pre-Cert Program—envisioned by the agency as a voluntary pathway for precertified companies that develop Software as a Medical Device (SaMD)—comes with its own challenges.

Part IV focuses on issues related to specific AI-based medical devices. First, I discuss the problem of AI/ML-based medical devices that are inherently black boxes and explainable versus interpretable AI/ML. I argue that the FDA should demand AI/ML makers use an interpretable AI/ML system if a white-box model performs better than or as well as a black-box model. I also show that the focus on explainable AI/ML in health care is deceptive and argue that regulators like the FDA should instead focus on ensuring safety and effectiveness. This goal can be achieved, for example, by requiring at least clinical trials for AI/ML-based medical devices that have a higher risk level. However, for AI/ML-based medical devices intended to be used to allocate scarce resources, such as organs or ventilators, the FDA should demand AI/ML makers use interpretable AI/ML systems rather than black boxes.

Second, I focus on what I call the “update problem.” AI/ML-based medical devices can only fully realize their potential if they continuously learn and adapt to novel situations. But how should regulators like the FDA make sure that these devices remain safe and effective throughout their life cycle and do not compromise patient safety? I argue that the FDA could implement a monitoring system, such as Sentinel, that continuously monitors AI/ML-based medical devices.

Part V discusses two aspects of the system view: (1) considering human-AI interaction and (2) improving patient outcomes. The FDA could require rigorous human factors testing for all AI-based medical devices that require premarket submission to demonstrate that users can read the labeling and use such devices correctly. The agency could also more frequently require AI makers to set up a training program with instructions on how to use their device and/or to include a detailed description of the recommended user training in the device labeling. Further, AI-based medical devices should not only be safe but should actually improve patient outcomes. This could be demonstrated by comparative studies that the FDA could require, where appropriate, either as a premarket or postmarket requirement, depending on whether the AI-based medical device in question is urgently needed on the market.

Finally, I conclude that much more thinking and work needs to be done to realize the potential of health AI and ensure that such products are reasonably safe

and effective.

## I. THE POTENTIAL OF HEALTH AI-BASED PRODUCTS

The term “artificial intelligence” (AI) was first coined in 1955 when the four computer scientists John McCarthy, Marvin Minsky, Claude Shannon, and Nathaniel Rochester applied for funding from the Rockefeller Foundation for a two-month, ten-man study of AI to be carried out in 1956 at Dartmouth College in Hanover, New Hampshire, in the U.S.<sup>17</sup> Since then, the term “AI” has been widely used with different meanings. For example, in a 2004 Article, McCarthy defined AI as follows:

It is the science and engineering of making intelligent machines, especially intelligent computer programs. It is related to the similar task of using computers to understand human intelligence, but AI does not have to confine itself to methods that are biologically observable.<sup>18</sup>

The FDA refers to John McCarthy’s definition.<sup>19</sup> There is no universal definition of AI to date, but the term is often used as an umbrella term that encompasses several subsets. In particular, its subset Machine Learning (ML) has become one of the most promising fields of computer science in recent years. ML uses algorithms to detect patterns in data.<sup>20</sup> Deep learning is a subset of ML that identifies data patterns by employing artificial neural networks with several layers.<sup>21</sup> Advances within deep learning are also major reasons for the success of health AI in recent years.

Many AI/ML algorithms are “black boxes,” meaning that the estimated function relating inputs to outputs is difficult or impossible for humans to understand.<sup>22</sup> For example, algorithms labeled as “deep learning” are considered

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17 JOHN MCCARTHY ET AL., A PROPOSAL FOR A DARTMOUTH SUMMER RESEARCH PROJECT ON ARTIFICIAL INTELLIGENCE (Aug. 31, 1955), <http://jmc.stanford.edu/articles/dartmouth/dartmouth.pdf>.

18 John McCarthy, What Is Artificial Intelligence? 2 (Nov. 24, 2004) (unpublished manuscript), [https://homes.di.unimi.it/borghese/Teaching/AdvancedIntelligentSystems/Old/IntelligentSystems\\_2008\\_2009/Old/IntelligentSystems\\_2005\\_2006/Documents/Symbolic/04\\_McCarthy\\_whatisai.pdf](https://homes.di.unimi.it/borghese/Teaching/AdvancedIntelligentSystems/Old/IntelligentSystems_2008_2009/Old/IntelligentSystems_2005_2006/Documents/Symbolic/04_McCarthy_whatisai.pdf).

19 U.S. FOOD & DRUG ADMIN., PROPOSED REGULATORY FRAMEWORK FOR MODIFICATIONS TO ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SAMd): DISCUSSION PAPER AND REQUEST FOR FEEDBACK 4 (2019), <https://www.fda.gov/media/122535/download>.

20 Kun-Hsing Yu et al., *Artificial Intelligence in Healthcare*, 2 NATURE BIOMED. ENG’G 719, 720 (2018).

21 *Id.*

22 See Boris Babic et al., *Beware Explanations from AI in Health Care*, 373 SCIENCE 284, 284

black-box AI/ML models.<sup>23</sup> The term “black boxes” can also refer to models that are not too complex to be understood by humans, but that are deliberately kept opaque by AI companies for intellectual property reasons.<sup>24</sup>

Most AI/ML algorithms are “adaptive”—they continuously learn and adapt to new conditions.<sup>25</sup> It is also possible to “lock” AI/ML algorithms in such a way that they do not change with use and provide the same outcome each time the same input data is applied to them.<sup>26</sup>

Computer vision is also a vital subset of AI that focuses on developing autonomous systems that can perform particular tasks that the human visual system can carry out, and in some cases even surpass the human system’s ability to do so.<sup>27</sup> Computer vision is essential for the growth of augmented reality, a technology that is often associated with mobile games such as Pokémon Go and blends digital and physical environments.<sup>28</sup> Robotics is a branch of technology that deals with the development and design of physical robots.<sup>29</sup> Sometimes robotics is also considered a subset of AI, but experts in the robotic world find it more appropriate to see AI and robotics as separate fields that overlap in cases of artificially intelligent robots.<sup>30</sup>

Health AI-based products are already in use in the U.S., and many more products are expected to be developed and enter the market in the coming years. In particular, it is anticipated that health AI will be applied not only in clinics but

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(2021); Boris Babic & Sara Gerke, *Explaining Medical AI Is Easier Said Than Done*, STAT (July 21, 2021), <https://www.statnews.com/2021/07/21/explainable-medical-ai-easier-said-than-done>.

<sup>23</sup> See sources cited *supra* note 22.

<sup>24</sup> See GREGORY DANIEL ET AL., DUKE MARGOLIS CTR. FOR HEALTH POL’Y, CURRENT STATE AND NEAR-TERM PRIORITIES FOR AI-ENABLED DIAGNOSTIC SUPPORT SOFTWARE IN HEALTH CARE 14 (2019), <https://healthpolicy.duke.edu/sites/default/files/2019-11/dukemargolisaienabledxss.pdf>; Price, *Regulating Black-Box Medicine*, *supra* note 6, at 430.

<sup>25</sup> See U.S. FOOD & DRUG ADMIN., *supra* note 19, at 3; Boris Babic et al., *Algorithms on Regulatory Lockdown in Medicine*, 366 SCI. 1202, 1203 (2019).

<sup>26</sup> See sources cited *supra* note 25.

<sup>27</sup> T. S. Huang, *Computer Vision: Evolution and Promise* (Sept. 13, 1996) (unpublished manuscript), <http://cds.cern.ch/record/400313/files/p21.pdf>; Priya Dialani, *Five Important Subsets of Artificial Intelligence*, ANALYTICS INSIGHT (May 14, 2020), <https://www.analyticsinsight.net/five-important-subsets-of-artificial-intelligence>.

<sup>28</sup> Jameson Toole, *Combining Artificial Intelligence and Augmented Reality in Mobile Apps*, HEARTBEAT (June 7, 2019), <https://heartbeat.fritz.ai/combining-artificial-intelligence-and-augmented-reality-in-mobile-apps-e0e0ad2cfddc>; *Fourth Workshop on Computer Vision for AR/VR, XR @ CORNELL* (June 15, 2020), <https://xr.cornell.edu/workshop/2020>.

<sup>29</sup> Dialani, *supra* note 27; Alex Owen-Hill, *What’s the Difference Between Robotics and Artificial Intelligence?* ROBOTIQ BLOG (Mar. 11, 2020), <https://blog.robotiq.com/whats-the-difference-between-robotics-and-artificial-intelligence>.

<sup>30</sup> See sources cited *supra* note 29.

also outside the traditional clinical setting.<sup>31</sup>

### A. Clinical Application

Health AI-based products are already used by U.S. health care providers and are expected to be implemented more frequently in the clinical setting in the future. Health AI shows great promise in medical imaging and disease diagnostics. For example, Digital Diagnostic's AI-based medical device, IDx-DR, detects greater than mild levels of diabetic retinopathy in diabetic patients ages twenty-two and older.<sup>32</sup> The system includes a special camera used by primary care physicians to take images of patient retinas and upload them to a cloud server.<sup>33</sup> The system is considered "autonomous," meaning that its decision—either to refer the patient to an eye doctor or to rescreen in twelve months—does not need to be checked by the primary care physician who uses the system.<sup>34</sup> IDx-DR has been used in clinical care at over twenty sites across the U.S.<sup>35</sup> Another example is Imagen's OsteoDetect, a computer-aided diagnosis and detection software powered by AI that helps providers to detect wrist fractures.<sup>36</sup>

The hope is that health AI-based products will increasingly help health care providers to detect diseases earlier and make more accurate diagnoses. Alongside health AI, robotics is expected to experience a boom in the coming years.<sup>37</sup> According to one recent estimate, the global medical robots market accounted for

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31 See, e.g., FROST & SULLIVAN, TRANSFORMING HEALTHCARE THROUGH ARTIFICIAL INTELLIGENCE SYSTEMS (2016), <https://docplayer.net/36848717-Transforming-healthcare-through-artificial-intelligence-systems.html>.

32 U.S. FOOD & DRUG ADMIN., DE NOVO SUMMARY CLASSIFICATION REQUEST FOR IDx-DR 1, 5 (2018), [https://www.accessdata.fda.gov/cdrh\\_docs/reviews/DEN180001.pdf](https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180001.pdf); *FDA News Release: FDA Permits Marketing of Artificial Intelligence-Based Device to Detect Certain Diabetes-Related Eye Problems*, U.S. FOOD & DRUG ADMIN. (Apr. 11, 2018), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-based-device-detect-certain-diabetes-related-eye>. For more information on IDx-DR, see *IDx-DR*, DIGITAL DIAGNOSTICS, <https://dxs.ai/products/idx-dr/idx-dr-overview> (last visited Mar. 19, 2022).

33 *FDA News Release: FDA Permits Marketing of Artificial Intelligence-Based Device to Detect Certain Diabetes-Related Eye Problems*, *supra* note 32.

34 *Id.*; *IDx-DR*, *supra* note 32.

35 Jack Carfagno, *IDx-DR, the First FDA-Approved AI System, is Growing Rapidly*, DOCWIRE NEWS (Nov. 12, 2019), <https://www.docwirenews.com/docwire-pick/future-of-medicine-picks/idx-dr-the-first-fda-approved-ai-system-is-growing-rapidly>.

36 U.S. FOOD & DRUG ADMIN., EVALUATION OF AUTOMATIC CLASS III DESIGNATION FOR OSTEODETECT: DECISION SUMMARY 1, 2 (2018), [https://www.accessdata.fda.gov/cdrh\\_docs/reviews/DEN180005.pdf](https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180005.pdf); *FDA News Release: FDA Permits Marketing of Artificial Intelligence Algorithm for Aiding Providers in Detecting Wrist Fractures*, U.S. FOOD & DRUG ADMIN. (May 24, 2018), <https://www.fda.gov/news-events/press-announcements/fda-permits-marketing-artificial-intelligence-algorithm-aiding-providers-detecting-wrist-fractures>.

37 PWC, WHAT DOCTOR? WHY AI AND ROBOTICS WILL DEFINE NEW HEALTH 22 (2017), <https://www.pwc.com/gx/en/industries/healthcare/publications/ai-robotics-new-health/ai-robotics-new-health.pdf>.

\$5.9 billion in 2020 and is expected to reach \$12.7 billion by 2025, and the U.S. is a key market player.<sup>38</sup> In particular, increased implementation of AI-assisted surgery appears likely in the future.<sup>39</sup> The use of autonomous systems as robot surgeons is also not far from reality. Considerable research resources are being invested in the development of smart surgical robots with different degrees of autonomy to perform technical tasks, such as suturing, localizing wounds, and removing tumors.<sup>40</sup> These innovations promise better results and wider access to specialized procedures for patients.<sup>41</sup>

Augmented reality is also anticipated to experience a strong upswing in the health care market in the next few years.<sup>42</sup> For example, the California-based company, EchoPixel, developed True 3D, an FDA-cleared augmented reality device software that provides an environment where health care professionals can view patient-specific holographic-like images of organs and tissues.<sup>43</sup> Medical imaging and diagnostics, alongside robotics and augmented reality, are just the beginning of many more potential clinical AI applications that may significantly change the way health care providers practice medicine.

### B. Outside the Clinical Setting

In the 21st century, large amounts of health data are gathered from individuals not only in clinical settings but also in daily life, such as through the internet, health applications (apps), Fitbits, and other products. For example, a recent study predicts that the total amount of data created worldwide will grow from 79 zettabytes in 2021 to 181 zettabytes in 2025.<sup>44</sup> The use of big data, coupled with

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<sup>38</sup> *Medical Robots Market*, MARKETSSANDMARKETS (2021), <https://www.marketsandmarkets.com/PressReleases/medical-robotic-systems.asp>.

<sup>39</sup> See, e.g., Sebastian Bodenstedt et al., *Artificial Intelligence-Assisted Surgery: Potential and Challenges*, 36 VISCERAL MED. 450 (2020); Tom J. M. van Mulken et al., *First-In-Human Robotic Supermicrosurgery Using a Dedicated Microsurgical Robot for Treating Breast Cancer-Related Lymphedema: A Randomized Pilot Trial*, 11 NATURE COMMUN. 757 (2020); see also Phil Britt, *How AI-Assisted Surgery Is Improving Surgical Outcomes*, ROBOTIC BUS. REV. (June 19, 2018), <https://www.roboticsbusinessreview.com/health-medical/ai-assisted-surgery-improves-patient-outcomes> (discussing the promise of AI-assisted surgery to improve surgical outcomes).

<sup>40</sup> Elizabeth Svoboda, *Your Robot Surgeon Will See You Now*, 573 NATURE S110, S110 (2019).

<sup>41</sup> See *id.*

<sup>42</sup> *Augmented Reality (AR) In Healthcare Market - Forecasts from 2020 to 2025*, RES. & MKTS. (2020), <https://www.researchandmarkets.com/reports/4801765/augmented-reality-ar-in-healthcare-market>; Toole, *supra* note 28.

<sup>43</sup> See Letter from Robert Ochs, Dir. Div. of Radiological Health, U.S. Food & Drug Admin. to Mark Job, EchoPixel Inc. (Mar. 3, 2017), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf17/K170167.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf17/K170167.pdf); ECHOPIXEL, <https://www.echopixeltech.com> (last visited Mar. 19, 2022).

<sup>44</sup> Arne von See, *Volume of Data/Information Created, Captured, Copied, and Consumed Worldwide From 2010 to 2025 (in Zettabytes)*, STATISTA (June 7, 2021), <https://www.statista.com/statistics/871513/worldwide-data-created>.

enhanced computing power, suggests that health AI will likely have rising importance in the future. Already today, the range of direct-to-consumer health AI-based apps and chatbots, on topics from diet guidance to psychological advice, is immense and is expected to increase even more in the next years.<sup>45</sup> For example, the health AI-powered chatbot, Ada, assesses users' most likely conditions based on their symptoms and recommends the next steps to seek appropriate care.<sup>46</sup> Another example is the pocket AI therapist, Youper, a self-help app designed by a San Francisco-based company that supports mental health.<sup>47</sup>

Wearable health care products such as smartwatches, patches, and fitness trackers are also in high demand, and the global market is expected to almost double from \$16.2 billion in 2021 to \$30.1 billion by 2026.<sup>48</sup> For example, in September 2018, the FDA permitted marketing of Apple's electrocardiogram (ECG) app, a consumer-facing medical device intended for use with the Apple Watch by people ages twenty-two and older that can create, store, record, display, and transfer a single channel ECG.<sup>49</sup> The FDA also authorized Apple's irregular rhythm notification feature, an app that is also intended for use with the Apple Watch and for notifying the user of possible atrial fibrillation (AFib).<sup>50</sup> Several companies are also working on the next future-of-health AI-based fitness products where virtual trainers plan a user's workout based on their individual preferences and needs, motivate the user to complete their workout, and recommend healthy eating.<sup>51</sup>

The boundaries between hospitals and homes are also becoming increasingly

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45 Boris Babic et al., *supra* note 6, at 283; Gerke et al., *supra* note 7, at 301; Remy Franklin, *11 Surprising Mobile Health Statistics*, MOBIUS MD (Oct. 25, 2021), <https://mobius.md/2021/10/25/11-mobile-health-statistics>.

46 Ada Health, *Ada – Check Your Health*, APPLE APP STORE PREVIEW (2022), <https://apps.apple.com/app/id1099986434?mt=8>; Leontina Postelnicu, *ADA Health's Chief Medical Officer on AI and Building Trust in Digital Health Tools*, MOBIHEALTHNEWS (Nov. 29, 2019), <https://www.mobihealthnews.com/news/emea/ada-health-s-chief-medical-officer-ai-and-building-trust-digital-health-tools>.

47 YOPER (2021), <https://www.youper.ai> (last visited Mar. 19, 2022); Youper, Inc., *Youper Online Therapy*, APPLE APP STORE PREVIEW (2022), <https://apps.apple.com/us/app/youper-online-therapy/id1060691513>.

48 *Wearable Healthcare Devices Market*, MARKETANDMARKETS (2021), <https://www.marketsandmarkets.com/Market-Reports/wearable-medical-device-market-81753973.html>.

49 Letter from Angela C. Krueger, Dep. Dir., Eng'g & Sci. Rev., Off. Device Evaluation, U.S. Food & Drug Admin. to Donna-Bea Tillman, Apple Inc. (Sept. 11, 2018), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf18/DEN180044.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180044.pdf).

50 Letter from Angela C. Krueger, Dep. Dir., Eng'g & Sci. Rev., Off. Device Evaluation, U.S. Food & Drug Admin. to Donna-Bea Tillman, Apple Inc. DEN180042 (Sept. 11, 2018), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf18/DEN180042.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180042.pdf).

51 Corey Lewis, *How AI Fitness Technology Will Take Your Health to The Next Level*, 1AND1 LIFE (Oct. 17, 2019), <https://www.1and1life.com/blog/ai-fitness-technology>.

porous. The American population is aging, and with this demographic shift comes the need to develop new digital health products that enable individuals to live an independent and healthy life at home as long as possible.<sup>52</sup> Computer vision-driven ambient intelligence systems use video capture to gather and interpret physical activity data.<sup>53</sup> These systems will likely be increasingly used not only in hospitals but also in patients' homes in the future. Remote patient monitoring is predicted to experience a boom in the next few years.<sup>54</sup> Such products, including those powered by AI, can help physicians to remotely monitor their patients' health conditions, such as diabetes, asthma, and cardiovascular disease, while improving clinical efficiency and reducing costs.<sup>55</sup> For example, the start-up Current Health offers an AI-powered wireless device worn on a patient's upper arm that continuously tracks vital signs, such as pulse, respiratory rate, and temperature.<sup>56</sup>

Home monitoring technologies have also been increasingly used during the COVID-19 pandemic to reduce personal contacts and thus exposure to the virus.<sup>57</sup> Further, robots can be helpful assistants in the COVID-19 pandemic. For example, the San Francisco-based company, RobotLAB, developed a self-driving humanoid robot, Cruzr, that is designed to be used in schools. Cruzr can measure the body temperature of up to sixty people in a minute and detect people who do not wear a face mask and alert the staff.<sup>58</sup>

## II. NARROW MEDICAL DEVICE DEFINITION

### A. Device Software Functions

Are health AI-based products classified as medical devices under U.S. law? This is a crucial question for manufacturers in particular, since medical devices usually must meet medical device requirements under the FDCA and are regulated by the FDA.<sup>59</sup> The term "medical device" is defined in FDCA section 201(h)(1) as follows:

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<sup>52</sup> Gerke et al., *supra* note 3.

<sup>53</sup> Gerke et al., *supra* note 8.

<sup>54</sup> *Remote Patient Monitoring (RPM) Market*, MARKETSDANDMARKETS (2021), <https://www.marketsandmarkets.com/Market-Reports/remote-patient-monitoring-market-77155492.html>; *The State of the Remote Patient Monitoring Market in 2019*, DEFINITIVE HEALTHCARE (2021), <https://blog.definitivehc.com/remote-patient-monitoring-market-2019>.

<sup>55</sup> *The State of the Remote Patient Monitoring Market in 2019*, *supra* note 54.

<sup>56</sup> CURRENT HEALTH, <https://www.currenthealth.com/products-page/product-remote-patient-monitoring> (last visited Mar. 19, 2022).

<sup>57</sup> Gerke et al., *supra* note 3.

<sup>58</sup> *Keeping Schools Virus-Safe Is Not an Easy Feat*, ROBOTLAB (2020), <https://www.robotlab.com/pandemic-covid19-health-robots>.

<sup>59</sup> See *infra* Section II.C. and Section III.A.

an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(A) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(B) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(C) intended to affect the structure or any function of the body of man or other animals, and

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term “device” does not include software functions excluded pursuant to section 520(o).<sup>60</sup>

In the context of health AI, it is particularly relevant whether software functions are classified as medical devices (device software functions). The FDA distinguishes between two relevant types of software functions related to medical devices: “Software in a Medical Device” (SiMD) and “Software as a Medical Device” (SaMD). SiMD is software that is integral to a medical device.<sup>61</sup> In contrast, SaMD is standalone software that is, on its own, a medical device.<sup>62</sup> In 2013, the International Medical Device Regulators Forum (IMDRF)—a volunteer group of medical device regulators from across the world, including the U.S., whose goal is to accelerate international medical device regulatory harmonization—recognized the increasing importance of software in health care and published a document on SaMD in which it defines the term as “software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device.”<sup>63</sup> The FDA embraced this

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60 FDCA § 201(h)(1), 21 U.S.C. § 321(h)(1).

61 *Software as a Medical Device (SaMD)*, U.S. FOOD & DRUG ADMIN. (Dec. 4, 2018), <https://www.fda.gov/medical-devices/digital-health/software-medical-device-samd>.

62 *Id.*

63 INT’L MED. DEVICE REGULS. F., SOFTWARE AS A MEDICAL DEVICE (SAMd): KEY DEFINITIONS 6 (2013), <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf>. The IMDRF SaMD Working Group also published two other guidance documents related to SaMD. See INT’L MED. DEVICE REGULS. F., “SOFTWARE AS A MEDICAL DEVICE”: POSSIBLE

definition and further clarified that it defines medical purposes “as those purposes that are intended to treat, diagnose, cure, mitigate, or prevent disease or other conditions.”<sup>64</sup> Apple’s irregular rhythm notification Apple Watch feature is an example of an AI/ML-based SaMD because it is standalone software intended for a medical purpose.<sup>65</sup> Another example of an AI/ML-based SaMD is IDx-DR, standalone software intended to be used to diagnose a medical condition, namely detecting greater than mild levels of diabetic retinopathy in diabetic adults.<sup>66</sup>

### B. *Non-Device Software Functions*

To assess whether the FDA adequately regulates health AI-based products, it is important to look at the agency’s statutory authority. Only by analyzing the law in-depth can one identify legal gaps that may jeopardize patient safety and undermine public trust.

FDCA section 201(h)(1) clarifies that there are certain software functions that do not fall under the medical device definition (non-device software functions) and are thus not subject to FDA regulation. FDCA section 520(o)(1)(A)–(E), added by the 21st Century Cures Act,<sup>67</sup> contains five categories of software functions that usually are *not* considered to be medical devices, namely software functions intended

- (A) for administrative support of a health care facility . . . ;
- (B) for maintaining or encouraging a healthy lifestyle . . . ;
- (C) to serve as electronic patient records . . . ;
- . . . .
- (D) for transferring, storing, converting formats, or displaying

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FRAMEWORK FOR RISK CATEGORIZATION AND CORRESPONDING CONSIDERATIONS (2014), <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf>; INT’L MED. DEVICE REGULS. F., SOFTWARE AS A MEDICAL DEVICE (SaMD): APPLICATION OF QUALITY MANAGEMENT SYSTEM (2015), <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-samd-qms.pdf>. In addition, the FDA published guidance on SaMD in which the agency adopts another 2017 guidance by the IMDRF SaMD Working Group on the clinical evaluation of SaMD. See U.S. FOOD & DRUG ADMIN., SOFTWARE AS A MEDICAL DEVICE (SaMD): CLINICAL EVALUATION (2017), <https://www.fda.gov/media/100714/download>. For further information on the IMDRF, see INT’L MED. DEVICE REGULS. F. (2021), <http://www.imdrf.org>.

64 U.S. FOOD & DRUG ADMIN., *supra* note 19, at 2.

65 For more information on Apple’s irregular rhythm notification feature, see *supra* Section I.B.

66 For more information on IDx-DR, see *supra* Section I.A.

67 21<sup>st</sup> Century Cures Act, Pub. L. No. 114–255, § 3060(a), 130 Stat. 1033, 1130-31 (2016) (codified at 21 U.S.C. § 360j(o)).

clinical laboratory test or other device data and results . . . ; [and]

(E) [to support certain clinical decisions.]<sup>68</sup>

The second and fifth categories are particularly relevant for health AI.

*1. Software Functions Intended for Maintaining or Encouraging a Healthy Lifestyle*

Under FDCA section 520(o)(1)(B), a software function is generally not covered by the term “medical device” in FDCA section 201(h)(1) if it is intended “for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition . . . .”<sup>69</sup>

In September 2019, the FDA issued the guidance “Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act” (Cures Act Guidance) in which the agency provides its current thinking and non-binding recommendations on FDCA section 520(o)(1)(B).<sup>70</sup> In particular, the FDA clarifies that its updated non-binding guidance “General Wellness: Policy for Low Risk Devices” (General Wellness Guidance) helps interpret FDCA section

68 *Id.* For exceptions, see FDCA § 520(o)(3), 21 U.S.C. § 360j(o)(3) (“Notwithstanding paragraph (1), a software function described in subparagraph (C), (D), or (E) of paragraph (1) shall not be excluded from the definition of device under section 201(h) if . . . (i) the Secretary makes a finding that use of such software function would be reasonably likely to have serious adverse health consequences . . .); and FDCA § 520(o)(4)(B)-(C), 21 U.S.C. § 360j(o)(4)(B)-(C) (“Nothing in this subsection shall be construed as limiting the authority of the Secretary to . . . (B) regulate software used in the manufacture and transfusion of blood and blood components to assist in the prevention of disease in humans; or (C) regulate software as a device under this Act if such software meets the criteria under section 513(a)(1)(C) [for Class III classification]”). But these exceptions are only for certain individual software functions. FDCA § 520(o)(2), 21 U.S.C. § 360j(o)(2) regulates products with multiple functions that contain at least one function that is not a medical device and one that meets the definition of a medical device. The FDA issued guidance for such products. See U.S. FOOD & DRUG ADMIN., MULTIPLE FUNCTION DEVICE PRODUCTS: POLICY AND CONSIDERATIONS—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2020), <https://www.fda.gov/media/112671/download>.

69 FDCA § 520(o)(1)(B), 21 U.S.C. § 360j(o)(1)(B). For some of the problems of the FDA’s regulatory framework for mobile health technologies before the 21<sup>st</sup> Century Cures Act, see Nathan G. Cortez et al., *FDA Regulation of Mobile Health Technologies*, 371 NEW ENG. J. MED. 372 (2014); and Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1137 (2014), who argues that without proper oversight, users will be flooded with mobile technologies that are unsafe and ineffective. A similar discussion is also continued after the 21<sup>st</sup> Century Cures Act. See, e.g., Babic et al., *supra* note 6.

70 U.S. FOOD & DRUG ADMIN., CHANGES TO EXISTING MEDICAL SOFTWARE POLICIES RESULTING FROM SECTION 3060 OF THE 21<sup>ST</sup> CENTURY CURES ACT—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019), <https://www.fda.gov/media/109622/download>.

520(o)(1)(B).<sup>71</sup>

Under the General Wellness Guidance, wellness products are products that present a low risk to users' and other individuals' safety and are intended for general wellness use only.<sup>72</sup> The FDA defines two different categories of general wellness intended uses:

- (1) an intended use that relates to maintaining or encouraging a general state of health or a healthy activity, or
- (2) an intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition.<sup>73</sup>

The FDA explains in its Cures Act Guidance that products that are intended “for maintaining or encouraging a healthy lifestyle” under FDCA section 520(o)(1)(B) means products that fall within the first category of general wellness intended uses.<sup>74</sup> Thus, FDCA section 520(o)(1)(B) is fulfilled in cases where software functions maintain or encourage “a general state of health or a healthy activity” (e.g., physical fitness, sleep management, relaxation and stress management, weight management, self-esteem, mental acuity, or sexual function) and are “unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.”<sup>75</sup> For example, an AI-based mobile app that plays music to relax and soothe a user and to manage stress and an AI-based mobile app that actively monitors and trends exercise activity are covered by FDCA section 520(o)(1)(B) and thus are not considered to be medical devices.<sup>76</sup>

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<sup>71</sup> *Id.* at 4–5; U.S. FOOD & DRUG ADMIN., GENERAL WELLNESS: POLICY FOR LOW RISK DEVICES—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019), <https://www.fda.gov/media/90652/download>.

<sup>72</sup> U.S. FOOD & DRUG ADMIN., *supra* note 71, at 2.

<sup>73</sup> *Id.* at 3.

<sup>74</sup> U.S. FOOD & DRUG ADMIN., *supra* note 70, at 4–5.

<sup>75</sup> *Id.* at 5; *see also* U.S. FOOD & DRUG ADMIN., *supra* note 71, at 3–4 (explaining the first category of general wellness intended uses).

<sup>76</sup> *See* U.S. FOOD & DRUG ADMIN., *supra* note 70, at 6–7; U.S. FOOD & DRUG ADMIN., *supra* note 71, at 7. The FDA defines the term “mobile app” as “a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server.” Mobile platforms are “commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature. Examples of these mobile platforms include mobile computers such as smart phones, tablet computers, or other

There is a fine line between the first and second categories of general wellness intended uses since both categories involve claims about or related to “sustaining or offering general improvement to functions associated with a general state of health.”<sup>77</sup> The difference is that the second category references diseases or conditions, while the first category does not.<sup>78</sup>

The second category of general wellness claims consists of two subcategories: “intended uses to promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, **may help to reduce the risk of**” or “**may help living well with** certain chronic diseases or conditions . . . .”<sup>79</sup> The claims should be generally accepted—i.e., the associations are described in official statements made by health care professional organizations, such as the American Heart Association, American Medical Association, and American College of Rheumatology, or in peer-reviewed scientific publications.<sup>80</sup>

In contrast to products that fall within the first category of general wellness intended uses, products that fall within the second category do not meet the requirements under FDCA section 520(o)(1)(B) since they relate to the prevention or mitigation of a disease or condition and are thus medical devices under FDCA section 201(h)(1).<sup>81</sup> An example is a health AI/ML-based SaMD that facilitates making healthy lifestyle choices such as eating a balanced diet that may help living well with the chronic disease type 2 diabetes.<sup>82</sup> Consequently, manufacturers need to think carefully about the intended use(s) of their health AI-based product, as this determines whether the product is classified as a medical device. The intended use may be shown, for example, by advertising materials, labeling claims, or manufacturers’ or their representatives’ written or oral statements.<sup>83</sup>

2. *Clinical Decision Support Software*

Under FDCA section 520(o)(1)(E), certain clinical decision support (CDS) software functions are excluded from the medical device definition in FDCA section 201(h)(1). FDCA section 520(o)(1)(E) reads:

The term device, as defined in section 201(h), shall not include a

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portable computers;” see U.S. FOOD & DRUG ADMIN., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 4, 18 (2019), <https://www.fda.gov/media/80958/download>.

77 U.S. FOOD & DRUG ADMIN., *supra* note 71, at 3–4.

78 *Id.*

79 *Id.* at 4 (emphasis in original).

80 *Id.* at 5.

81 U.S. FOOD & DRUG ADMIN., *supra* note 70, at 5–6.

82 See U.S. FOOD & DRUG ADMIN., *supra* note 71, at 5.

83 U.S. FOOD & DRUG ADMIN., *supra* note 76, at 5.

software function that is intended—

....

(E) unless the function is intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system, for the purpose of [criterion (1)]—

(i) displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines) [criterion (2)];

(ii) supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition [criterion (3)]; and

(iii) enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient [criterion (4)].<sup>84</sup>

The FDA issued a draft guidance in September 2019 that intends to describe the agency’s approach to CDS software functions (CDS draft guidance).<sup>85</sup> A software function is *CDS* under this guidance if the following criteria are met:

- Not intended to acquire, process, or analyze [criterion (1)];
- Intended for the purpose of displaying, analyzing, or printing medical information [criterion (2)]; and
- Intended for the purpose of supporting or providing recommendations [part of criterion (3)].<sup>86</sup>

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84 FDCA § 520(o)(1)(E), 21 U.S.C. 360j(o)(1)(E).

85 U.S. FOOD & DRUG ADMIN., CLINICAL DECISION SUPPORT SOFTWARE: DRAFT GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 5 (2019), <https://www.fda.gov/media/109618/download>.

86 *Id.* at 8 (alterations in original); see *infra* Figure 1.

CDS can be Device CDS or Non-Device CDS. Device CDS fails to meet part of criterion (3) (“to a health care professional) and/or all or part of criterion (4) (“enabling such health care professional to independently review the basis for such recommendations”) and thus is a medical device.<sup>87</sup> *Non-Device CDS* meets all four criteria in FDCA section 520(o)(1)(E) and thus is not a medical device.<sup>88</sup>

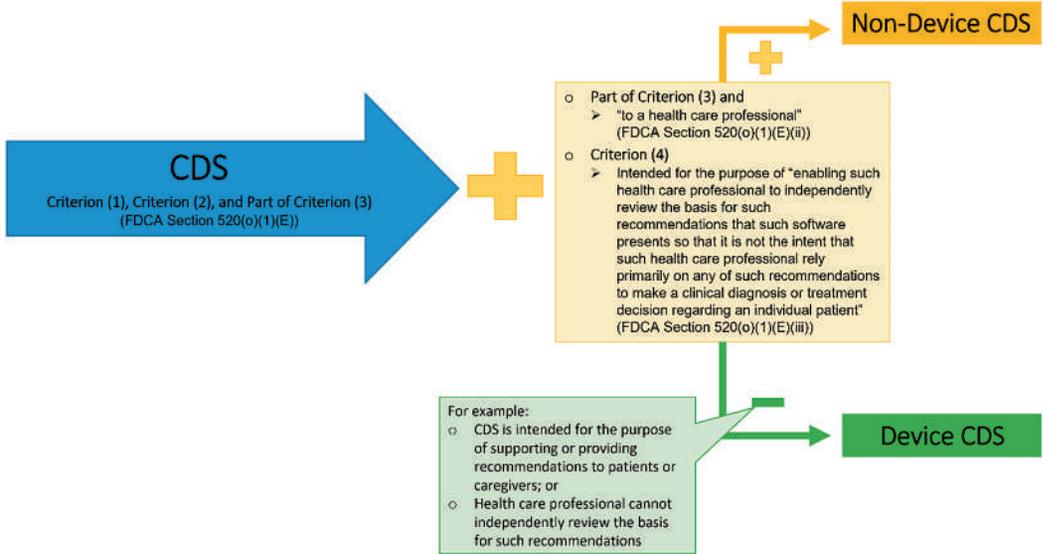


Figure 1: Device and Non-Device CDS

Blue shows the criteria—i.e., criterion (1), criterion (2), and part of criterion (3)—that software functions need to meet to be classified as CDS. Orange shows the criteria—i.e., part of criterion (3) and criterion (4)—that CDS need to additionally fulfill to be considered Non-Device CDS. Green shows Device CDS—i.e., they meet all criteria in the blue box but fail to fulfill part of criterion (3) and/or all or part of criterion (4) in the orange box.

The FDA describes in its CDS draft guidance, among other things, its current interpretation regarding criterion (4). In particular, the agency asks manufacturers of Non-Device CDS to describe—in plain language—their software functions as follows:

- 1) The purpose or intended use of the software function;

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<sup>87</sup> See U.S. FOOD & DRUG ADMIN., *supra* note 85, at 6–9.  
<sup>88</sup> *Id.*; see *infra* Figure 1.

- 2) The intended user (e.g., ultrasound technicians, vascular surgeons);
- 3) The inputs used to generate the recommendation (e.g., patient age and sex); and
- 4) The basis for rendering a recommendation.<sup>89</sup>

To describe the basis for a recommendation, irrespective of whether or not the software is proprietary and of the complexity of the software, the FDA clarifies that software developers “should describe the underlying data used to develop the algorithm and should include plain language descriptions of the logic or rationale used by an algorithm to render a recommendation.”<sup>90</sup> The agency also explains that the sources underlying the basis of the recommendation or the sources supporting the recommendation should be identified, available to, and understandable by the intended health care professional user.<sup>91</sup> Examples of identified and available sources include published literature, clinical practice guidelines with the version or date, or information the CDS developer has provided to the intended health care professional user.<sup>92</sup> Understandable sources include data points, for example, the meaning of which is well understood by the intended health care professional user.<sup>93</sup> However, criterion (4) is not fulfilled in cases where the meaning of the information on which the recommendation is based cannot “be expected to be independently understood by the intended . . . user.”<sup>94</sup> For example, if the inputs used to generate the recommendation were not identified, a health care professional would be unable “to independently review the basis for such recommendation that such software presents” and thus would be relying primarily upon it.<sup>95</sup>

### 3. *The Problem of Health AI-Based Products*

The FDA’s CDS draft guidance indicates that AI-based CDS are *not* a priori Device CDS and can be considered Non-Device CDS as long as they are intended for “a health care professional” (criterion (3)) and for the purpose of “enabling such health care professional to independently review the basis for such recommendation that such software presents so that it is not the intent that such

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<sup>89</sup> U.S. FOOD & DRUG ADMIN., *supra* note 85, at 12.

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

<sup>92</sup> *Id.*

<sup>93</sup> *Id.*

<sup>94</sup> *Id.*

<sup>95</sup> *Id.*

health care professional rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient” (criterion (4)). Two issues should be highlighted here. First, the term “health care professional” is important to distinguish between Device CDS and Non-Device CDS. The FDA does not define this term in its CDS draft guidance, but at least clarifies that CDS intended for the purpose of supporting or providing recommendations to patients or caregivers are Device CDS (and thus that patients and caregivers are *not* health care professionals).<sup>96</sup> Second, the FDA’s current thinking suggests that health care professionals will likely be unable “to independently review the basis for such recommendation” in cases where the AI systems rely on algorithms that are “black boxes.”<sup>97</sup> It will be challenging, or even impossible, for software developers of black-box AI/ML models, typically those that are labeled as “deep learning,”<sup>98</sup> to describe the basis for rendering a recommendation, such as the logic and rationale used by the algorithms. Manufacturers that keep their models opaque due to intellectual property reasons may also hesitate to describe the underlying data used to develop the algorithms. Thus, AI/ML algorithms, for which the inputs and logic are not explained, are Device CDS.<sup>99</sup>

But is criterion (4) (“independently review the basis”) convincing enough to draw the line between Device CDS and Non-Device CDS? The FDA uses a risk-based approach to its regulation of Device CDS by applying the IMDRF framework for risk categorization of SaMD.<sup>100</sup>

State of the health care situation or condition	Significance of the information provided by the SaMD to the health care decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Figure 2: SaMD Risk Categories Developed by the IMDRF<sup>101</sup>

96 *Id.* at 11.

97 For a definition of “black boxes,” see *supra* Part I. For more information on black-box AI/ML models, see *infra* Part IV.

98 *Id.*

99 See U.S. FOOD & DRUG ADMIN., *supra* note 85, at 21, 23.

100 *Id.* at 6; see *infra* Figure 2.

101 INT’L MED. DEVICE REGULS. F., “SOFTWARE AS A MEDICAL DEVICE”: POSSIBLE FRAMEWORK

Device CDS inform clinical management. The FDA intends to focus its regulatory oversight on those Device CDS that fall within the two red boxes. The agency does not currently intend to enforce applicable medical device requirements for some Device CDS that fall within the orange box.

The IMDRF framework in Figure 2 above explains two factors that are essential for the risk categorization of SaMD, which are (1) significance of the information provided by the SaMD to the health care decision and (2) state of the health care situation or condition. The first factor is divided into three categories—i.e., treat or diagnose, drive clinical management, and inform clinical management. The second factor is also divided into three categories—i.e., critical, serious, and non-serious.<sup>102</sup> There are four risk levels: level I (lowest risk) to level IV (highest risk).

The right column in Figure 2 is relevant for Device CDS. The IMDRF interprets the category *inform clinical management* as follows:

Informing clinical management infers that the information provided by the SaMD will not trigger an immediate or near term action:

- To inform of options for treating, diagnosing, preventing, or mitigating a disease or condition.
- To provide clinical information by aggregating relevant information (e.g., disease, condition, drugs, medical devices, population, etc.).<sup>103</sup>

Thus, Device CDS exclusively fall within this category and “inform clinical management” since they are intended for the purpose of “supporting or providing recommendations . . . about prevention, diagnosis, or treatment of a disease or condition . . . .”<sup>104</sup> Device CDS intended to provide information, such as diagnostic or treatment options or aggregating relevant clinical information, may support

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FOR RISK CATEGORIZATION AND CORRESPONDING CONSIDERATIONS, *supra* note 63, at 14 (Figure 2 has been slightly modified from its original form).

102 For more information on the IMDRF’s interpretation of these terms, see INT’L MED. DEVICE REGULS. F., “SOFTWARE AS A MEDICAL DEVICE”: POSSIBLE FRAMEWORK FOR RISK CATEGORIZATION AND CORRESPONDING CONSIDERATIONS, *supra* note 63, at 10–12.

103 *Id.* at 11.

104 FDCA § 520(o)(1)(E)(ii), 21 U.S.C. § 360j(o)(1)(E)(ii). Device CDS do not “drive clinical management” or “treat or diagnose,” *see supra* Figure 2 columns two and three, since both categories refer to SaMD that go beyond “supporting or providing recommendations,” *see* U.S. FOOD & DRUG ADMIN., *supra* note 85, at 14.

recommendations to health care professionals, caregivers, or patients.<sup>105</sup> They provide information that will not trigger a near term or immediate action—unlike SaMD that diagnose, screen, or detect a disease or condition.<sup>106</sup>

The FDA intends to focus its regulatory oversight on those Device CDS that inform clinical management for “critical” or “serious” health care situations or conditions, shown in the red boxes in Figure 2 above.<sup>107</sup> The agency does not currently intend to enforce applicable medical device requirements of the FDCA for some Device CDS that inform clinical management for “non-serious” health care situations or conditions, represented by the orange box in Figure 2.<sup>108</sup>

The IMDRF framework for risk categorization<sup>109</sup> is developed for SaMD but could also easily be applied to products that are not considered to be medical devices. Thus, criterion (4) of FDCA section 520(o)(1)(E) (“independently review the basis”) would only be convincing to draw the line between Device CDS and Non-Device CDS if it ensured that at least all risk level I and level II products that inform clinical management for “critical” or “serious” health care situations or conditions (compare the red boxes in Figure 2) were classified as medical devices under the FDCA and were thus subject to FDA regulation. However, unfortunately, this is not the case. It is easy to imagine AI-based CDS that, under current law, are considered Non-Device CDS but inform clinical management for “critical” or “serious” health care situations or conditions and thus could pose a risk to the safety of patients if they were not to function as intended.

As an example, consider Watson for Oncology developed by IBM.<sup>110</sup> Watson for Oncology is CDS that assesses information from a patient’s medical record and uses AI algorithms to provide physicians with individualized cancer treatment recommendations.<sup>111</sup> Watson did not undergo FDA review since it is considered Non-Device CDS that is intended for health care professionals who are able to “independently review the basis” for its recommendations.<sup>112</sup> However, the

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105 U.S. FOOD & DRUG ADMIN., *supra* note 85, at 7, 13–14.

106 *Id.* at 14.

107 *Id.* at 17.

108 *See infra* Section II.C.

109 *See supra* Figure 2.

110 IBM has recently sold main parts of its Watson Health business to Francisco Partners. *See* Casey Ross, *The Sale of Watson Health Assets Ends a Dark Chapter for IBM. For Its Buyer, the Opportunity Looks Brighter*, STAT (Jan. 21, 2022), <https://www.statnews.com/2022/01/21/ibm-watson-health-francisco-partners>.

111 *See* Gerke et al., *supra* note 7, at 301; *IBM Watson for Oncology*, IBM (2021), <https://www.ibm.com/products/clinical-decision-support-oncology>.

112 Jacqueline Mulryne et al., *What’s the Deal With Watson? Artificial Intelligence Systems and Medical Software Regulation in the U.S. and EU*, MONDAQ (Feb. 27, 2017), <https://www.mondaq.com/unitedstates/healthcare/571712/what39s-the-deal-with-watson-artificial-intelligence-systems-and-medical-software-regulation-in-the-us-and-eu>; David D. Luxton, *Should Watson Be Consulted for a Second Opinion?*, 21 AMA J. ETHICS E131 (2019).

supercomputer came under criticism in 2018 because of a STAT report that alleged it recommended “unsafe and incorrect” cancer treatments.<sup>113</sup> To IBM’s credit, the erroneous recommendations were apparently corrected by the company before the release of the product and its use on real patients.<sup>114</sup> Nevertheless, in light of patient safety, one would like to see Watson and similar products classified as medical devices (i.e., Device CDS) under the FDCA and subject to FDA regulation so that manufacturers must provide reasonable assurance of their safety and effectiveness. STAT also reported previously that the 21st Century Cures Act was hoped to be the impetus for the FDA to fully regulate medical advisory tools like Watson.<sup>115</sup> But IBM reportedly had an extensive team of lobbyists pushing hard for proposals to vitiate regulatory obstacles facing health software.<sup>116</sup> Perhaps as a result of this lobbying, the 21st Century Cures Act introduced FDCA section 520(o) that excludes certain categories of software functions, including several CDS, from the medical device definition.<sup>117</sup>

If one applied the SaMD risk categories established in the IMDRF framework<sup>118</sup> to Watson for Oncology, the AI-based product would probably be classified as a risk level II product: Watson informs clinical management by providing cancer treatment recommendations to physicians, and the state of a cancer patient’s health care situation or condition would be critical since accurate and timely diagnosis and treatment action would be vital to avoid death.<sup>119</sup> Thus, Watson and similar products are exactly the kinds of products that the FDA usually intends to focus its regulatory oversight on. However, such products currently slip off of the agency’s radar due to the fact that they fulfill all four criteria of FDCA

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113 Casey Ross & Ike Swetlitz, *IBM’s Watson Supercomputer Recommended “Unsafe and Incorrect” Cancer Treatments, Internal Documents Show*, STAT (July 25, 2018), <https://www.statnews.com/2018/07/25/ibm-watson-recommended-unsafe-incorrect-treatments>.

114 See Jo Cavallo, *Confronting the Criticisms Facing Watson for Oncology*, ASCOPOST (Sept. 10, 2019), <https://www.ascopost.com/issues/september-10-2019/confronting-the-criticisms-facing-watson-for-oncology>; Ross & Swetlitz, *supra* note 113.

115 Casey Ross & Ike Swetlitz, *IBM to Congress: Watson Will Transform Health Care, So Keep Your Hands off Our Supercomputer*, STAT (Oct. 4, 2017), <https://www.statnews.com/2017/10/04/ibm-watson-regulation-fda-congress>; see also Gerke et al., *supra* note 7, at 307 (discussing the Watson scandal).

116 See sources cited *supra* note 115.

117 21<sup>st</sup> Century Cures Act, Pub. L. No. 114–255, § 3060(a), 130 Stat. 1033 (2016) (codified at 21 U.S.C. § 360j); see Gerke et al., *supra* note 7, at 307; Ross & Swetlitz, *supra* note 115 (“The company’s fingerprints are all over legislation passed last year that exempted several types of health software from FDA jurisdiction. A former IBM executive helped draft the blueprint for the law.”).

118 See *supra* Figure 2.

119 Critical situations or conditions are “situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health.” See INT’L MED. DEVICE REGULS. F., “SOFTWARE AS A MEDICAL DEVICE”: POSSIBLE FRAMEWORK FOR RISK CATEGORIZATION AND CORRESPONDING CONSIDERATIONS, *supra* note 63, at 11.

section 520(o)(1)(E) and are thus classified as Non-Device CDS.<sup>120</sup> Consequently, under this analysis, criterion (4) seems insufficient to draw the line between Device CDS and Non-Device CDS.

Another problem is AI-based prediction/prognosis models that are intended to aid health care professionals in their decision-making. Are such models CDS? Imagine, for instance, an AI-based model that leverages data from electronic health records—without analyzing medical images—for predicting the development of hospital-acquired pressure injuries among surgical critical care patients.<sup>121</sup> Based on its prediction, the AI-based model provides recommendations to clinicians as to which patient should be assigned a specialty bed—which cannot be given to all patients for cost reasons<sup>122</sup>—and which patient should receive in-depth skin assessments.

In this example, it seems relatively straightforward to determine the answer to the question of whether the software is CDS. Criterion (1) of FDCA section 520(o)(1)(E) is fulfilled since the AI-based prediction tool is not “intended to . . . analyze a medical image” for predicting the development of pressure injuries.<sup>123</sup> Criterion (2) is also fulfilled since the tool is intended for the purpose of “analyzing . . . medical information about a patient . . .”<sup>124</sup> The AI-based prediction model is also intended to provide recommendations to clinicians as to which patient should be assigned a specialty bed to prevent the development of hospital-acquired pressure injuries and which patient should receive in-depth skin assessments to detect such injuries early and treat them at a reversible stage.<sup>125</sup> Hence, criterion (3) is also met since the tool is intended for the purpose of “supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment” of a hospital-acquired pressure injury.<sup>126</sup> Consequently, this AI-based prediction tool is considered CDS. Under current law, it would be classified as Device CDS only if the health care professional could not “independently review the basis for” its recommendations.<sup>127</sup>

Now consider an AI-based model that leverages data from electronic health records—without analyzing medical images—for predicting six-month mortality

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120 The FDCA has a few regulatory safeguards in place. *See, e.g.*, FDCA § 520(o)(3), (4)(B)-(C), 21 U.S.C. § 360j(o)(3), (4)(B)-(C). However, such exceptions are limited to particular software functions only.

121 *See, e.g.*, Jenny Alderden et al., *Predicting Pressure Injury in Critical Care Patients: A Machine-Learning Model*, 27 AM. J. CRITICAL CARE 461 (2018).

122 *See id.* at 461.

123 FDCA § 520(o)(1)(E), 21 U.S.C. § 360j(o)(1)(E).

124 FDCA § 520(o)(1)(E)(i), 21 U.S.C. § 360j(o)(1)(E)(i).

125 *See* Alderden et al., *supra* note 121, at 461.

126 FDCA § 520(o)(1)(E)(ii), 21 U.S.C. § 360j(o)(1)(E)(ii).

127 FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii); *see supra* Figure 1.

among cancer patients.<sup>128</sup> Is this model CDS under FDCA section 520(o)(1)(E)? Criteria (1) and (2) are fulfilled since the prediction model is not “intended to . . . analyze a medical image” for predicting mortality, but it is intended for the purpose of “analyzing . . . medical information about a patient.”<sup>129</sup> However, is this software also intended for the purpose of “supporting or providing recommendations . . . about prevention, diagnosis, or treatment of a disease or condition . . . [?]”<sup>130</sup>

This question is much more difficult to answer. The algorithm predicts whether a cancer patient is at high or low risk of dying within the next six months. The patient has already developed cancer, and thus the software is not intended for the purpose of supporting or providing recommendations about *prevention* of cancer.

The AI-based model is also not intended for the purpose of supporting or providing recommendations about *diagnosis* of a disease or condition since cancer has already been diagnosed in the patient. Instead, the model predicts that the patient could die within the next six months. Death may be the consequence of a disease or condition or several diseases or conditions but is *not* a disease or condition itself.

Further, one may argue that the output of the AI-based model may initiate a conversation between the physician and the patient about cancer treatment, and thus the software is at least indirectly intended for the purpose of supporting or providing recommendations about *treatment* of a disease. However, one may argue as well—probably much more convincingly—that the AI-based model’s prediction is intended to initiate early end-of-life discussions between physicians and cancer patients at high risk of dying within the next six months. If one accepts the latter argument, then the software would not be intended for the purpose of supporting or providing recommendations about treatment of a disease or condition but rather the opposite—i.e., to stop treatment, cut costs, and start palliative care. Consequently, it is unclear whether part of criterion (3) is fulfilled, and thus whether the AI-based mortality prediction model is CDS.

If one assumes that such a model is intended for the purpose of “supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition” and thus that it is CDS, then the classification of a Device or Non-Device CDS depends on whether the model is intended to enable a “health care professional to independently review the basis

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128 See, e.g., Ravi B. Parikh et al., *Machine Learning Approaches to Predict 6-Month Mortality Among Patients With Cancer*, 2 JAMA NETWORK OPEN e1915997 (2019).

129 FDCA § 520(o)(1)(E)(i), 21 U.S.C. § 360j(o)(1)(E)(i).

130 FDCA § 520(o)(1)(E)(ii), 21 U.S.C. § 360j(o)(1)(E)(ii).

for” its recommendations.<sup>131</sup>

However, if one assumes that the model is *not* intended for the purpose of “supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition,”<sup>132</sup> then the model may already not be considered a medical device under FDCA section 201(h)(1). The software is not “intended for use in the diagnosis of disease or other conditions, or in the . . . treatment, or prevention of disease . . . .”<sup>133</sup> The software is then also not intended for use in the “cure” of cancer, but rather for identifying patients at high risk of dying within the next six months and thus for enabling an early end-of-life discussion between the physician and that patient. One may argue that the model is at least indirectly intended for use in the “mitigation” of disease since it may contribute to the start of palliative care and thus may support a patient’s dying without pain. A convincing counterargument may be that the model only indirectly mitigates the symptoms of cancer (i.e., the pain) but not the disease itself. As a result, it is highly unclear whether mortality prediction models are medical devices under current law, and thus whether software developers need to comply with device requirements of the FDCA.

#### 4. *Amending Proposals*

I have argued above<sup>134</sup> that criterion (4) of FDCA section 520(o)(1)(E)<sup>135</sup> is not convincing to draw the line between Device CDS and Non-Device CDS because it does not ensure that at least all risk level I and level II products that inform clinical management for “critical” or “serious” health care situations or conditions are classified as medical devices under the FDCA and are subject to FDA regulation. It is easy to imagine AI-based CDS that are considered Non-Device CDS, although they inform clinical management for “critical” or “serious” health care situations or conditions.<sup>136</sup> Such Non-Device CDS could pose a risk to the safety of patients if they were not to function as intended. I therefore propose that—irrespective of whether CDS is intended to enable health care professionals “to independently review the basis for such recommendations that such software presents”—all CDS should be considered a priori medical devices under FDCA section 201(h)(1). Congress should consider amending the FDCA accordingly by deleting FDCA section 520(o)(1)(E).<sup>137</sup>

This proposal would promote patient safety since it would ensure that all risk

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131 FDCA § 520(o)(1)(E)(ii)-(iii), 21 U.S.C. § 360j(o)(1)(E)(ii)-(iii).

132 FDCA § 520(o)(1)(E)(ii), 21 U.S.C. § 360j(o)(1)(E)(ii).

133 FDCA § 201(h)(1)(B), 21 U.S.C. § 321(h)(1)(B).

134 See *supra* Section II.B.3.

135 See *supra* Figure 1.

136 See *supra* Figure 2.

137 FDCA § 520(o)(1)(E), 21 U.S.C. § 360j(o)(1)(E).

level I and level II products that inform clinical management for “critical” or “serious” health care situations or conditions would be classified as medical devices under FDCA section 201(h)(1) and thus would be subject to FDA regulation. It would also eradicate the current regulatory gray zone of whether a particular CDS is or is not a medical device. Criterion (4) is too vague to draw the line between Device CDS and Non-Device CDS. AI companies are trying very hard not to fall under the medical device definition, arguing that their CDS is intended for health care professionals who are able to “independently review the basis” for its recommendations.<sup>138</sup> A proper premarket review can also be seen as a safeguard against “automation bias.” Studies of human-computer interaction demonstrate that people tend to trust the machine, even if they have a reason to question it.<sup>139</sup> This is especially a danger in medicine as physicians are very busy.<sup>140</sup> So is it the physician who is currently the captain of the ship, or is it the CDS that is actually steering the ship? Furthermore, the proposal to classify all CDS as medical devices would simplify the current regulatory landscape and facilitate more transparency. Finally, the FDA could continue to focus its regulatory oversight on those Device CDS that inform clinical management for “critical” or “serious” health care situations or conditions and exercise its enforcement discretion for some Device CDS that inform clinical management for “non-serious” health care situations or conditions.<sup>141</sup>

For example, following this proposal, the AI-based CDS that leverages data from electronic health records for predicting the development of hospital-acquired pressure injuries among surgical critical care patients would be classified as a medical device, irrespective of whether the CDS is intended to enable the health care professional “to independently review the basis for” its recommendations.<sup>142</sup> It would be likely categorized as a risk level I SaMD since it informs clinical management for a “serious” health care situation or condition.<sup>143</sup> If patients’ hospital-acquired pressure injuries are not detected and treated early, they can

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138 Evans & Ossorio, *supra* note 11, at 390, 394 (arguing correctly that statements of intent by manufacturers or their representatives tend to be dispositive); *see also* Cortez, *supra* note 11, at 11 (arguing that the line between Device CDS and Non-Device CDS remains murky, as it has for decades).

139 Cortez, *supra* note 11, at 24. A recent FDA report also says, “Medical informatics experts expressed concern that providers may rely too heavily on CDS software to determine appropriate treatments.” U.S. FOOD & DRUG ADMIN., REPORT ON RISKS AND BENEFITS TO HEALTH OF NON-DEVICE SOFTWARE FUNCTIONS (2020), <https://www.fda.gov/media/143795/download>.

140 *Id.*

141 *See supra* Figure 2 (orange box); *see also infra* Section II.C (discussing the FDA’s enforcement discretion).

142 For this particular example, *see supra* Section II.B.3.

143 *See supra* Figure 2.

become irreversible and may require costly interventions (e.g., skin biopsies).<sup>144</sup>

In addition, the uncertainty of whether AI-based mortality prediction models are medical devices under current law must be addressed immediately since more and more hospitals are using them.<sup>145</sup> Such models are likely risk level II products since they inform clinical management for “critical” health care situations or conditions—i.e., the respective disease, such as cancer, or condition is likely life-threatening and timely and accurate diagnosis and treatment action is vital to avoid death or other serious deterioration of a patient’s health.<sup>146</sup> Thus, AI-based mortality prediction models may pose a risk to the safety of patients if they were not to function as intended. For example, a model could lead to the cessation of a patient’s treatment if it incorrectly predicts the patient’s early death. Consequently, AI-based mortality prediction models should be clearly classified as medical devices under FDCA section 201(h)(1) and subject to FDA regulation.

As a result, in addition to deleting FDCA section 520(o)(1)(E) in the form of an amendment, Congress could amend FDCA section 201(h)(1)(B)<sup>147</sup> as follows:

intended for use in the diagnosis of disease or other conditions, *or in the prediction or prognosis of disease or other conditions or mortality*, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

This broad definition would ensure that not only AI-based mortality prediction models but also other models that are intended for use in the prediction or prognosis of disease or other conditions would be clearly covered by the medical device definition. This proposal would promote patient safety and would also enable the FDA to continue focusing its regulatory oversight on those prediction/prognosis devices that may pose a moderate to high risk to patients and exercise enforcement discretion over those that are low risk.<sup>148</sup> A clear medical device definition would also help clarify the outer boundaries of the arena within

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144 Serious situations or conditions are “situations or conditions where accurate diagnosis or treatment is of vital importance to avoid unnecessary interventions (e.g., biopsy) or timely interventions are important to mitigate long term irreversible consequences on an individual patient’s health condition or public health.” INT’L MED. DEVICE REGULS. F., *supra* note 63, at 11, 12.

145 See, e.g., Rebecca Robbins, *An Experiment in End-Of-Life Care: Tapping AI’s Cold Calculus to Nudge the Most Human of Conversations*, STAT (July 1, 2020), <https://www.statnews.com/2020/07/01/end-of-life-artificial-intelligence>.

146 Critical situations or conditions are “situations or conditions where accurate and/or timely diagnosis or treatment action is vital to avoid death, long-term disability or other serious deterioration of health of an individual patient or to mitigating impact to public health.” INT’L MED. DEVICE REGULS. F., *supra* note 63, at 11.

147 FDCA § 201(h)(1)(B), 21 U.S.C. § 321(h)(1)(B).

148 For further discussion, see *infra* Section II.C.

which the FDA operates.<sup>149</sup>

Finally, Congress could amend FDCA section 520(o)(1)(B)<sup>150</sup> accordingly to reflect the previous change. The new version could read:

for maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition *or to the prediction or prognosis of a disease or condition or mortality;*

### C. Enforcement Discretion

#### 1. The FDA's Current Approach

The FDA currently intends to exercise enforcement discretion over many health AI-based products. The agency follows a risk-based approach and aims to focus its regulatory oversight exclusively on those device software functions whose functionality might pose a risk to the safety of patients if they were not to function as intended.<sup>151</sup> The FDA does not at present intend to enforce compliance with the regulatory requirements of the FDCA for software functions that are low risk and are medical devices or may meet the medical device definition.<sup>152</sup> For example, the FDA intends to exercise enforcement discretion over AI-based wellness products that are medical devices—i.e., low risk products that fall within the second category of general wellness intended uses.<sup>153</sup> Another example is AI-based mobile apps that may meet the medical device definition but pose a low risk to patients, such as an AI-based mobile app that uses GPS location data to alert people with asthma of environmental conditions that may cause symptoms.<sup>154</sup>

The agency also at this time considers two types of Device CDS that inform clinical management for “non-serious” health care situations or conditions<sup>155</sup> as low risk and thus the FDA does not intend to enforce compliance with the applicable medical device requirements of the FDCA.<sup>156</sup> The first type is Device CDS that is intended for the purpose of supporting or providing recommendations to a *caregiver or a patient* to inform clinical management for a “non-serious” health care situation or condition, as long as the medical device is intended for the

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149 PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 77 (4th ed. 2014).

150 FDCA § 520(o)(1)(B), 21 U.S.C. § 360j(o)(1)(B).

151 U.S. FOOD & DRUG ADMIN., *supra* note 76, at 2, 10.

152 *See id.*, at 2, 9, 12.

153 *See* U.S. FOOD & DRUG ADMIN., *supra* note 71, at 7, 8; *supra* Section II.B.1.

154 *See* U.S. FOOD & DRUG ADMIN., *supra* note 76, at 9, 22.

155 *See supra* Figure 2 (orange box).

156 U.S. FOOD & DRUG ADMIN., *supra* note 85, at 16.

caregiver or patient to be able “to independently review the basis for such recommendations that such software presents . . . .”<sup>157</sup>

The second type is Device CDS that is intended for the purpose of supporting or providing recommendations to a *health care professional* to inform clinical management for a “non-serious” health care situation or condition.<sup>158</sup> This Device CDS is *not* intended to enable the health care professional “to independently review the basis” of its recommendations, and thus the health care professional relies primarily upon it.<sup>159</sup>

In contrast, the FDA currently intends to focus its regulatory oversight on such Device CDS that is intended for a *caregiver or patient* to inform clinical management for a “non-serious” health care situation or condition and is *not* intended for the caregiver or patient to be able “to independently review the basis” of its recommendations.<sup>160</sup> Thus, the FDA considers “opaque” (“black-box”) Device CDS that are intended for the purpose of supporting or providing recommendations to *caregivers or patients* to inform clinical management for “non-serious” health care situations or conditions as riskier than similar Device CDS that are intended for *health care professionals*.<sup>161</sup> This distinction is convincing since health care professionals are usually clinically more experienced than patients and caregivers and thus may better manage the use of “opaque” Device CDS and will likely rely on additional sources to make a clinical diagnosis or treatment decision.

## 2. Proposal for a Regulatory Policy

If FDCA section 520(o)(1)(E) were deleted and FDCA section 201(h)(1)(B) and FDCA section 520(o)(1)(B) were amended by Congress as suggested,<sup>162</sup> the medical device definition would comprehensively include all CDS, AI-based mortality prediction models, and other models that are intended for use in the prediction or prognosis of disease or other conditions. These amending proposals would still enable the FDA to exercise its enforcement discretion over lower risk software functions that are medical devices or may meet the medical device definition. For example, the agency could exercise its enforcement discretion over low-risk prediction/prognosis devices and focus its regulatory oversight on those that pose a moderate to high risk to patients.

Concerning Device CDS, the FDA could decide not to enforce compliance

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157 *Id.* Compare FDCA § 520(o)(1)(E)(ii), 21 U.S.C. § 360j(o)(1)(E)(ii) (criterion 3), with FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii) (criterion 4).

158 U.S. FOOD & DRUG ADMIN., *supra* note 85, at 16.

159 *Id.*; see FDCA § 520(o)(1)(E)(iii), 21 U.S.C. § 360j(o)(1)(E)(iii) (criterion 4).

160 *Id.* at 17.

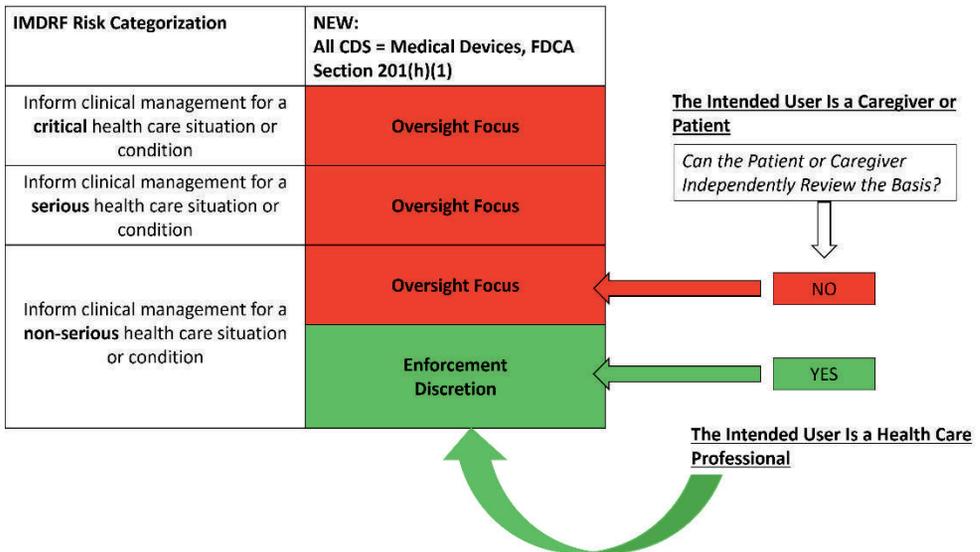
161 See *supra* Section II.B.3.

162 See *supra* Section II.B.4.

with the applicable medical device requirements of the FDCA for two types of Device CDS. First, the agency could exercise enforcement discretion over those Device CDS that are intended for a health care professional to inform clinical management for *non-serious* health care situations or conditions—irrespective of whether such Device CDS are intended to enable the health care professional to independently review the basis of their recommendations.<sup>163</sup>

Second, the FDA could also exercise enforcement discretion over those Device CDS that are intended for a caregiver or patient to inform clinical management for *non-serious* health care situations or conditions and are intended to enable the caregiver or patient to independently review the basis of their recommendations.<sup>164</sup> The risk of harm is relatively low in this scenario because independent review by the caregiver or patient of the basis of those Device CDS’ recommendations would likely reveal at least obviously flawed ones at relatively minimal consequences of error.

Thus, in this way, the FDA could focus its regulatory oversight on those Device CDS that inform clinical management for *critical or serious* health care situations or conditions, and those Device CDS that are intended for a caregiver or patient to inform clinical management for *non-serious* health care situations or conditions but that are *not* intended to enable the caregiver or patient to independently review the basis of their recommendations.<sup>165</sup>



163 See *infra* Figure 3.

164 *Id.*

165 *Id.*

Figure 3: Proposal for a Regulatory Policy for Device CDS

“Oversight Focus” means that the FDA would focus its regulatory oversight on those Device CDS. “Enforcement Discretion” means that the FDA would not intend to enforce compliance with the applicable device requirements of the FDCA.

III. SAFETY AND EFFECTIVENESS CONCERNS OF 510(K) CLEARANCES

A. 510(k) Premarket Notification and Other Premarket Pathways

Manufacturers intending to bring an AI-based medical device on the market should follow four steps:

- (1) discern the classification of the medical device and understand the applicable controls,
- (2) choose and prepare the proper premarket submission,
- (3) send the submission to the FDA and interact with the agency during its review, and
- (4) comply with the applicable controls.<sup>166</sup>

The first step contains a prerequisite that manufacturers find out whether their health AI-based product is considered to be a medical device under FDCA section 201(h)(1) and, if so, whether the FDA intends to exercise enforcement discretion over their medical device.<sup>167</sup> If the health AI-based product is a medical device under the FDCA and the FDA intends to focus its regulatory oversight on such a device, manufacturers then need to figure out how the agency has classified their medical device.<sup>168</sup> Medical devices, including device software functions, are categorized into three classes based on their risk degree: Class I (lowest risk), Class II (moderate risk), and Class III (highest risk).<sup>169</sup> The correct classification of the medical device is essential to understand the applicable controls.<sup>170</sup> In general, Class I medical devices are subject to general controls, Class II medical

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<sup>166</sup> See *How to Study and Market Your Device*, U.S. FOOD & DRUG ADMIN. (Oct. 14, 2020), <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device>.

<sup>167</sup> See *supra* Section II.C.

<sup>168</sup> *How to Study and Market Your Device*, *supra* note 166.

<sup>169</sup> *Id.*; see also U.S. FOOD & DRUG ADMIN., *supra* note 76, at 10 (clarifying that device software functions can be categorized into the three classes of medical devices).

<sup>170</sup> *How to Study and Market Your Device*, *supra* note 166.

devices are additionally subject to special controls, and Class III medical devices are subject to general controls and premarket approval.<sup>171</sup> Examples of general controls include labeling requirements,<sup>172</sup> medical device reporting,<sup>173</sup> establishment registration and medical device listing,<sup>174</sup> and quality system regulation.<sup>175</sup>

As a second step, manufacturers need to choose and prepare the correct premarket submission. The class of the particular medical device determines the submission type. There are four common types of premarket submissions:

- (1) 510(k) premarket notification,
- (2) Premarket Approval (PMA),
- (3) De Novo classification request, and
- (4) Humanitarian Device Exemption (HDE).<sup>176</sup>

Class I and Class II medical devices, for which a PMA is not required, require a 510(k) unless they are exempt.<sup>177</sup> Sponsors must demonstrate in a 510(k) that their medical device is “substantially equivalent” to a legally marketed device (predicate device) that is not subject to PMA.<sup>178</sup> The term “substantially equivalent” or “substantial equivalence” is defined in FDCA section 513(i)(1)(A) as follows:

the term “substantially equivalent” or “substantial equivalence” means, with respect to a device being compared to a predicate device, that the device has *the same intended use as the predicate device and* that the Secretary by order has found that the device—

- (i) has the *same technological characteristics* as the

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171 FDCA § 513(a)(1), 21 U.S.C. § 360c(a)(1); 21 C.F.R. pt. 814 (2022).

172 21 C.F.R. pt. 801 (2022).

173 *Id.* pt. 803.

174 *Id.* pt. 807.

175 *Id.* pt. 820.

176 *How to Study and Market Your Device*, *supra* note 166.

177 *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (Mar. 13, 2020), <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>. There are also a few Class III preamendment medical devices that may require a 510(k). *See Premarket Approval (PMA)*, U.S. FOOD & DRUG ADMIN. (May 16, 2019), <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma>.

178 *Id.*; *see also How to Find and Effectively Use Predicate Devices*, U.S. FOOD & DRUG ADMIN. (Sept. 4, 2018), <https://www.fda.gov/medical-devices/premarket-notification-510k/how-find-and-effectively-use-predicate-devices>.

predicate device, *or*

(ii)(I) has *different technological characteristics* and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that *demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.*<sup>179</sup>

The FDA defines the term “intended use” for purposes of substantial equivalence as “the general purpose of the device or its function, and encompasses the indications for use.”<sup>180</sup> The term “different technological characteristics” means “that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.”<sup>181</sup>

A medical device cannot be launched on the market until the FDA has issued a letter that states that the medical device is “substantially equivalent” to the predicate device and thus has “cleared” the device for commercial distribution.<sup>182</sup> The submitter of a 510(k) has several options for selecting a predicate. Examples for a predicate include a preamendment device—a medical device that was legally marketed before May 28, 1976—a medical device that has been cleared via the 510(k) pathway, a medical device that was initially launched on the market as a Class III medical device and was later reclassified to a Class I or II, or a medical device that received marketing authorization through the De Novo pathway and that is not exempt from the premarket notification requirements.<sup>183</sup>

There are three 510(k) Programs: (1) Traditional, (2) Special, and (3) Abbreviated. The Traditional 510(k) Program can be used under all circumstances.<sup>184</sup> In contrast, the Special and Abbreviated 510(k) Programs were developed in 1998 to facilitate the 510(k) review process for particular types of

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179 FDCA § 513(i)(1)(A), 21 U.S.C. § 360c(i)(1)(A) (emphasis added).

180 U.S. FOOD & DRUG ADMIN., THE 510(K) PROGRAM: EVALUATING SUBSTANTIAL EQUIVALENCE IN PREMARKET NOTIFICATIONS [510(K)]—GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 16 (2014), <https://www.fda.gov/media/82395/download>.

181 FDCA § 513(i)(1)(B), 21 U.S.C. § 360c(i)(1)(B).

182 *Premarket Notification 510(k)*, *supra* note 177.

183 *See How to Find and Effectively Use Predicate Devices*, *supra* note 178; *Premarket Notification 510(k)*, *supra* note 177.

184 *How to Prepare a Traditional 510(k)*, U.S. FOOD & DRUG ADMIN. (Sept. 12, 2019), <https://www.fda.gov/medical-devices/premarket-notification-510k/how-prepare-traditional-510k>.

submissions.<sup>185</sup> The Special 510(k) Program is an optional pathway and applicable for certain well-defined changes by the manufacturer to an already legally marketed predicate.<sup>186</sup> The Abbreviated 510(k) Program is also optional and intended for submissions that rely on the use of special controls, guidance documents, and/or voluntary consensus standards.<sup>187</sup>

However, the majority of Class I medical devices and some Class II medical devices are exempt from the 510(k) premarket notification requirement.<sup>188</sup> Even if a medical device is exempt and the second and third steps—i.e., prepare and submit a 510(k) to the FDA and receive marketing clearance—are not required, manufacturers still need to comply with other general controls (fourth step), such as establishment registration and medical device listing.<sup>189</sup>

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185 *Id.*; *Safety and Performance Based Pathway*, U.S. FOOD & DRUG ADMIN. (Aug. 27, 2021), <https://www.fda.gov/medical-devices/premarket-notification-510k/framework-safety-and-performance-based-pathway>. The FDA also issued nonbinding guidance for the Special 510(k) Program and Abbreviated 510(k) Program. See U.S. FOOD & DRUG ADMIN., *THE ABBREVIATED 510(K) PROGRAM: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF* (2019), <https://www.fda.gov/media/72646/download>; U.S. FOOD & DRUG ADMIN., *THE SPECIAL 510(K) PROGRAM: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF* (2019), <https://www.fda.gov/media/116418/download>. The FDA also issued nonbinding guidance for the content of premarket submissions for software devices, including stand-alone software; see U.S. FOOD & DRUG ADMIN., *GUIDANCE FOR INDUSTRY AND FDA STAFF: GUIDANCE FOR THE CONTENT OF PREMARKET SUBMISSIONS FOR SOFTWARE CONTAINED IN MEDICAL DEVICES* (2005), <https://www.fda.gov/media/73065/download>. This guidance document will soon be superseded by new guidance when final; the FDA has recently issued draft guidance on the premarket submissions' content of device software functions. See U.S. FOOD & DRUG ADMIN., *CONTENT OF PREMARKET SUBMISSIONS FOR DEVICE SOFTWARE FUNCTIONS* (2021), <https://www.fda.gov/media/155022/download>. The FDA has also issued nonbinding guidance for off-the-shelf software use in medical devices. See U.S. FOOD & DRUG ADMIN., *OFF-THE-SHELF SOFTWARE USE IN MEDICAL DEVICES: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF* (2019), <https://www.fda.gov/media/71794/download>.

186 *How To Prepare A Special 510(k)*, U.S. FOOD & DRUG ADMIN. (May 22, 2020), <https://www.fda.gov/medical-devices/premarket-notification-510k/how-prepare-special-510k>; U.S. FOOD & DRUG ADMIN., *THE SPECIAL 510(K) PROGRAM: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF* (2019), *supra* note 185, at 4.

187 U.S. FOOD & DRUG ADMIN., *THE ABBREVIATED 510(K) PROGRAM: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF*, *supra* note 185, at 3; *How to Prepare an Abbreviated 510(k)*, U.S. FOOD & DRUG ADMIN. (Jan. 23, 2019), <https://www.fda.gov/medical-devices/premarket-notification-510k/how-prepare-abbreviated-510k>.

188 *How to Study and Market Your Device*, *supra* note 168; see also *Class I and Class II Device Exemptions*, U.S. FOOD & DRUG ADMIN. (July 1, 2019), <https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-ii-exemptions> (providing information on Class I and Class II device exemptions).

189 21 C.F.R. pt. 807 (2022); *Class I and Class II Device Exemptions*, *supra* note 188; *Device Classification Panels*, U.S. FOOD & DRUG ADMIN. (Aug. 31, 2018), <https://www.fda.gov/medical-devices/classify-your-medical-device/device-classification-panels>; see also *Medical Device*

Class III medical devices usually require the most stringent type of premarket submission: a PMA.<sup>190</sup> To receive FDA PMA approval, the sponsor needs to provide valid scientific evidence that reasonably assures that the medical device is safe and effective for its intended use.<sup>191</sup> The FDA considers “valid scientific evidence,” for example, to be evidence from partially controlled studies, well-controlled investigations, studies and objective trials without matched controls, or well-documented case histories carried out by qualified experts.<sup>192</sup>

The De Novo classification request is for novel medical devices of low to moderate risk, for which there is no predicate device.<sup>193</sup> The FDA will carry out a risk-based assessment for classification of such novel medical devices into Class I or II.<sup>194</sup> Novel medical devices that are classified into Class I or II via the De Novo pathway may also be marketed and used as predicate devices for prospective 510(k) submissions.<sup>195</sup> Originally, the manufacturer needed to submit a 510(k) and receive a “not substantially equivalent” determination from the FDA before being eligible for the De Novo pathway.<sup>196</sup> This was changed in July 2012, and manufacturers who determine that there is no predicate now also have the option directly to submit a De Novo classification request.<sup>197</sup> Thus, the new De Novo pathway is more efficient and less time-consuming. The FDA has also recently issued a final rule, effective since January 3, 2022, to establish regulations for the

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*Exemptions 510(k) and GMP Requirements*, U.S. FOOD & DRUG ADMIN. (2021), <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm> (listing Class I and Class II exempt devices).

190 FDCA § 513(a)(1)(C), 21 U.S.C. § 360c(a)(1)(C); *How to Study and Market Your Device*, *supra* note 166; *see also* U.S. FOOD & DRUG ADMIN., *Premarket Approval (PMA)*, *supra* note 177 (explaining when a PMA is required).

191 U.S. FOOD & DRUG ADMIN., *Premarket Approval (PMA)*, *supra* note 177.

192 *PMA Clinical Studies*, U.S. FOOD & DRUG ADMIN. (May 22, 2020), <https://www.fda.gov/medical-devices/premarket-approval-pma/pma-clinical-studies>.

193 FDCA § 513(f)(1)-(2), 21 U.S.C. § 360c(f)(1)-(2); *De Novo Classification Request*, U.S. FOOD & DRUG ADMIN. (Jan. 7, 2022), <https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request>; *How to Study and Market Your Device*, *supra* note 166.

194 *De Novo Classification Request*, *supra* note 193.

195 *Id.* For an example (Proteus’s wearable sensor), see Sara Gerke et al., *Ethical and Legal Issues of Ingestible Electronic Sensors*, 2 NATURE ELECS. 329, 331 (2019). The FDA also issued several guidances related to the De Novo classification process. *See, e.g.*, U.S. FOOD & DRUG ADMIN., ACCEPTANCE REVIEW FOR DE NOVO CLASSIFICATION REQUESTS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2019), <https://www.fda.gov/media/116945/download>; U.S. FOOD & DRUG ADMIN., DE NOVO CLASSIFICATION PROCESS (EVALUATION OF AUTOMATIC CLASS III DESIGNATION): GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2021), <https://www.fda.gov/media/72674/download>.

196 *Evaluation of Automatic Class III Designation (De Novo) Summaries*, U.S. FOOD & DRUG ADMIN. (Jan. 25, 2022), <https://www.fda.gov/about-fda/cdrh-transparency/evaluation-automatic-class-iii-designation-de-novo-summaries>.

197 *See* FDCA § 513(f)(2), 21 U.S.C. 360c(f)(2); *Evaluation of Automatic Class III Designation (De Novo) Summaries*, *supra* note 196.

De Novo pathway that shall contribute greater clarity and transparency to the process, including the submission requirements and criteria for granting, accepting, withdrawing, or declining a De Novo request.<sup>198</sup> The hope is that more manufacturers take advantage of the De Novo pathway for new technologies.<sup>199</sup> Finally, HDE is for Class III medical devices that are intended to help patients with rare diseases or conditions.<sup>200</sup>

### B. Safety and Effectiveness Concerns

The FDA has already permitted marketing of over 340 AI/ML-based medical devices.<sup>201</sup> However, most AI-based medical devices currently available on the U.S. market were cleared via the 510(k) pathway. According to a new list of AI/ML-based medical devices marketed in the U.S., created by the FDA in September 2021, only 16 of 343 devices were authorized via the De Novo pathway, such as IDx-DR and OsteoDetect.<sup>202</sup> Only one device, QVCAD System for detecting mammography-occult lesions,<sup>203</sup> has so far received PMA approval. All other 326 AI/ML-based medical devices were 510(k)-cleared. For example, in January 2017, the FDA cleared Arterys Cardio DL as the first device software function that uses deep learning to analyze cardiovascular images captured by magnetic resonance scanners.<sup>204</sup> The device is intended to help radiologists, cardiologists, and other health care practitioners in making clinical decisions.<sup>205</sup> Another example is Viz.ai's notification-only, parallel workflow tool, Viz ICH, which the FDA cleared in March 2021.<sup>206</sup> Viz ICH uses an AI algorithm to analyze

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198 See Medical Device De Novo Classification Process, 86 Fed. Reg. 54826 (Oct. 5, 2021); *De Novo Classification Request*, *supra* note 193.

199 *FDA in Brief: FDA Proposes Improvements to the De Novo Pathway for Novel Medical Devices to Advance Safe, Effective, and Innovative Treatments for Patients*, U.S. FOOD & DRUG ADMIN. (Dec. 4, 2018), <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-proposes-improvements-de-novo-pathway-novel-medical-devices-advance-safe-effective-and>.

200 *How to Study and Market Your Device*, *supra* note 166.

201 See U.S. Food & Drug Admin., *supra* note 1.

202 *Id.* For more information on these two devices, see *supra* Section I.A.

203 Letter from Robert Ochs, Dir., Div. Radiological Health, U.S. Food & Drug Admin. to Robert M. Foley, Vice Pres., Regul. Affs., QView Medical, Inc. (Nov. 9, 2016), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf15/P150043A.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150043A.pdf).

204 Letter from Robert Ochs, Dir., Div. Radiological Health, U.S. Food & Drug Admin. to Golnaz Moeini, Dir. Quality & Reg., Arterys Inc. (Jan. 5, 2017), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/K163253.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163253.pdf); see also *Cardio AI*, ARTERYS, <https://arterys.com/clinicalapp/cardioapp> (last visited Mar. 19, 2022) (providing more information about Cardio AI).

205 See Letter from Robert Ochs to Golnaz Moeini, *supra* note 204, at 16.

206 Letter from Thalia T. Mills, Dir., Div. Radiological Health, U.S. Food & Drug Admin. to Gregory Ramina, Dir. Regul. Affs., Viz.ai, Inc. (Mar. 23, 2021), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf19/K193658.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193658.pdf). For more information on Viz ICH, see also *Viz ICH*, VIZ.AI (2022), <https://www.viz.ai/viz-ich>.

computed tomography (CT) images of the brain obtained in the acute setting and notifies a neurosurgical or neurovascular specialist where a suspected intracranial hemorrhage has been detected.<sup>207</sup>

The fact that most AI/ML-based medical devices currently available on the U.S. market were 510(k)-cleared also reflects the general picture that 510(k) is the most frequently used type of premarket submissions. For example, in 2017, over 3000 medical devices received 510(k) clearances, representing over 80% of all cleared or approved medical devices.<sup>208</sup> Some Class I or III medical devices are cleared through the 510(k) pathway, but the majority of 510(k)-cleared medical devices are classified as Class II devices, and thus are of moderate risk.<sup>209</sup> For example, Arterys CardioDL and Viz.ai's Viz ICH were both FDA cleared as Class II medical devices. However, this statistic is concerning since the 510(k) pathway has already been under criticism for a long time due to safety and effectiveness concerns.

### 1. *The Institute of Medicine Report*

The Institute of Medicine (IOM) published a report on the FDA 510(k) clearance process in 2011.<sup>210</sup> In its report, the IOM came to the following conclusion, among other things:

The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a premarket evaluation of safety and effectiveness as long as the standard for clearance is substantial equivalence to any previously cleared device.<sup>211</sup>

The IOM clearly communicates that “clearance” does *not* mean that the FDA “determined that the device is actually safe and effective . . . .”<sup>212</sup> The agency only confirms with a 510(k) clearance that the medical device is “substantially

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207 Letter from Thalia T. Mills to Gregory Ramina, *supra* note 206.

208 See FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on Transformative New Steps to Modernize FDA's 510(k) Program to Advance the Review of the Safety and Effectiveness of Medical Devices, (Nov. 26, 2018), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-jeff-shuren-md-director-center-devices-and>.

209 Thomas Sullivan, *Institute of Medicine Report Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, POL'Y & MED. (May 6, 2018), <https://www.policymed.com/2011/07/institute-of-medicine-report-medical-devices-and-the-publics-health-the-fda-510k-clearance-process-a.html>.

210 INST. MED., *MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS* (2011).

211 *Id.* at 5.

212 *Id.*

equivalent” to, and thus as safe and effective as, the predicate.<sup>213</sup> However, the classification of preamendment devices, for example, did not comprise an assessment of whether an individual device was safe and effective.<sup>214</sup> Thus, many old predicates were never individually assessed for safety and effectiveness.<sup>215</sup> Moreover, data show that a considerable number of manufacturers still rely on old predicates today. Nearly 20% of all current 510(k) clearances are based on predicates that are older than 10 years.<sup>216</sup> For example, Arterys Oncology DL uses a deep learning algorithm to assist with lung and liver cancer diagnosis.<sup>217</sup> This device was FDA cleared in 2018, although it relied on a medical diagnostic application for manipulation, viewing, comparison, and 3-D visualization of medical images as a predicate to demonstrate “substantial equivalence,” which in turn relied on another predicate, and so on, up to the reliance on preamendment devices marketed before May 28, 1976.<sup>218</sup>

It is important for users such as health care professionals and patients to understand that “clearance” does not mean “approval.” As discussed above,<sup>219</sup> PMA approval is based on a successful demonstration of reasonable assurance of the safety and effectiveness of the medical device. This needs to be provided by valid scientific evidence—i.e., usually by clinical studies. However, according to the list published on the FDA’s website, only one AI/ML-based medical device has received PMA approval so far.<sup>220</sup> In contrast, as mentioned, a 510(k) clearance only confirms that the medical device is “substantially equivalent” to the predicate. The 510(k) pathway usually does not require clinical evidence. In fact, the FDA generally requests clinical evidence for fewer than 10% of 510(k) submissions for moderate risk devices.<sup>221</sup> Thus, the agency often does not require AI makers to systematically document how the AI-based medical device was created, including

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213 *Id.* at 5, 6.

214 *Id.* at 6.

215 *See id.* at 6.

216 FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., *supra* note 208.

217 *See* Letter from Robert Ochs, Dir., Div. Radiological Health, U.S. Food & Drug Admin. to John Axerio-Cilies, Chief Operating Officer, Arterys Inc. (Jan. 25, 2018), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf17/K173542.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173542.pdf); Thomas J. Hwang et al., *Lifecycle Regulation of Artificial Intelligence- and Machine Learning-Based Software Devices in Medicine*, 322 JAMA 2285 (2019).

218 *See* Letter from Robert Ochs to John Axerio-Cilies, *supra* note 217; Letter from Donald J. St. Pierre, Acting Dir., Div. Radiological Devices, U.S. Food & Drug Admin. to Casey Conry, Sr. Project Engineer, Siemens Medical Solutions USA, Inc. (Aug. 16, 2010), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf10/K101749.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf10/K101749.pdf).

219 *See supra* Section III.A.

220 *See* U.S. Food & Drug Admin., *supra* note 1.

221 Vinay K. Rathi & Joseph S. Ross, *Modernizing the FDA’s 510(k) Pathway*, 381 NEW ENG. J. MED. 1891, 1892 (2019).

the validation of its performance with another dataset than the training dataset.<sup>222</sup> However, this is a critical step to ensure that such devices are safe and effective across various patient populations.<sup>223</sup>

Concerned that the 510(k) clearance process cannot assure safety and effectiveness, the IOM recommended that the FDA explore a new medical device regulatory framework for Class II devices:

The Food and Drug Administration should obtain adequate information to inform the design of a new medical-device regulatory framework for Class II devices so that the current 510(k) process, in which the standard for clearance is substantial equivalence to previously cleared devices, can be replaced with an integrated premarket and postmarket regulatory framework that effectively provides a reasonable assurance of safety and effectiveness throughout the device life cycle. Once adequate information is available to design an appropriate medical-device regulatory framework, Congress should enact legislation to do so.<sup>224</sup>

The IOM also articulated certain attributes to include in the new framework. The process should be risk-based, clear, straightforward, predictable, fair, self-sustaining, self-improving, and based on sound science.<sup>225</sup> The process should also “facilitate innovation that improves public health by making medical devices available in a timely manner and ensuring their safety and effectiveness throughout their life cycle,” and “should apply relevant and appropriate regulatory authorities and standards throughout the life cycle of devices to ensure safety and effectiveness.”<sup>226</sup>

Further, the IOM states in its 2011 report that the De Novo process may potentially serve as “a better regulatory model for premarket review of Class II devices.”<sup>227</sup> However, the IOM was also of the opinion that the De Novo process in its then-current form “is time-consuming and difficult for both the FDA and manufacturers to navigate.”<sup>228</sup> Thus, the IOM recommended the FDA explore a modified De Novo process to assess the safety and effectiveness of Class II

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<sup>222</sup> See Ross, *supra* note 1.

<sup>223</sup> See *id.*

<sup>224</sup> INST. MED., *supra* note 210, at 8.

<sup>225</sup> *Id.* at 9.

<sup>226</sup> *Id.*

<sup>227</sup> *Id.* at 11.

<sup>228</sup> *Id.* Since the IOM’s report in 2011, the De Novo Pathway has been changed and is now less time-consuming and more efficient. See *supra* Section III.A.

medical devices.<sup>229</sup> The IOM also suggested that the FDA “promptly call for PMA applications for or reclassify Class III devices that remain eligible for 510(k) clearance.”<sup>230</sup> Concerning software, the IOM recommended the FDA “develop procedures that ensure the safety and effectiveness of software used in devices, software used as devices, and software used as a tool in producing devices.”<sup>231</sup>

## 2. *The 510(k) Reforms and Critique*

To its credit, the FDA has committed to modernizing the 510(k) pathway—even though the agency did not follow the IOM’s recommendation of developing a new medical device regulatory framework for Class II devices. In November 2018, the FDA published a statement in which it communicated, among other things, three major goals to ensure that 510(k)-cleared medical devices meet the gold standard for safety and effectiveness:

- (1) promoting reliance on more modern predicates,
- (2) “up-classifying” medical devices, and
- (3) finalizing guidance establishing an alternative 510(k) pathway.<sup>232</sup>

The first goal of the FDA is to promote reliance on more modern predicates.<sup>233</sup> As discussed,<sup>234</sup> nearly one-fifth of all current 510(k) clearances are based on predicates that are more than ten years old. The FDA aims to drive manufacturers to rely on newer predicates that reflect modern technology and thereby promote innovation and improved safety.<sup>235</sup> For this reason, the agency suggested in its November 2018 statement to publish a list on its website of all cleared medical devices that are substantially equivalent to predicates that are older than ten years.<sup>236</sup> This list would intend to promote transparency and make it easier for users to decide between older and newer device type versions.<sup>237</sup> The FDA has not yet published such a list, perhaps due to the received criticism by some manufacturers

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229 See INST. MED., *supra* note 210, at 11.

230 *Id.* at 13.

231 *Id.*

232 See FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., *supra* note 208.

233 See *id.*

234 See *supra* Section III.B.1.

235 See FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., *supra* note 208.

236 See *id.*

237 See *id.*

who called the ten-year threshold “an arbitrary exclusion criterion.”<sup>238</sup> While this suggestion promotes newer predicates, it likely does not ensure that all newly cleared devices are reasonably safe and effective.

The FDA’s second goal is to continue the efforts of “up-classifying” medical devices. “Up-classifying” means that the agency re-assigns a medical device to Class III and requires PMA if the device raises considerable safety concerns.<sup>239</sup> The FDA has already up-classified some previously 510(k)-cleared devices to Class III so that these devices can no longer be put on the market through the 510(k) pathway.<sup>240</sup> Examples include metal-on-metal hip implants, automated external defibrillators, and vaginal mesh for the treatment of pelvic organ prolapse.<sup>241</sup> From 2012 to 2018, the FDA up-classified a total of approximately 1,500 medical devices.<sup>242</sup>

The FDA is aware that up-classifying medical devices is resource- and time-intensive, and thus established a third goal: finalizing guidance establishing an alternative 510(k) pathway.<sup>243</sup> In its Medical Device Safety Action Plan, the FDA discussed the plan to “establish a voluntary, more modern 510(k) pathway for demonstration of safety and effectiveness for certain moderate risk devices.”<sup>244</sup> Under this plan, manufacturers of particularly well-understood device types can use objective safety and performance criteria recognized or established by the FDA to demonstrate substantial equivalence.<sup>245</sup> In particular, this new pathway aims to provide more direct evidence of the performance and safety of a medical device.<sup>246</sup>

The agency achieved its goal and finalized its guidance “Safety and Performance Based Pathway” in September 2019.<sup>247</sup> The new pathway is optional and an expansion of the concept of the Abbreviated 510(k) Program for

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238 Ana Mulero, *FDA’s Proposal to Limit Device Predicates Fails to Garner Industry Support*, REGUL. FOCUS (May 14, 2019), <https://www.raps.org/news-and-articles/news-articles/2019/5/fdas-proposal-to-limit-device-predicates-fails-to>.

239 See FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., *supra* note 208.

240 See *id.*

241 *Id.* For further information on the safety scandal of metal-on-metal hip implants, see Brent M. Ardaugh, *The 510(k) Ancestry of a Metal-on-Metal Hip Implant*, 368 NEW ENG. J. MED. 97 (2013).

242 See FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., *supra* note 208.

243 See *id.*

244 U.S. FOOD & DRUG ADMIN., MEDICAL DEVICE SAFETY ACTION PLAN: PROTECTING PATIENTS, PROMOTING PUBLIC HEALTH 12 (2018), <https://www.fda.gov/media/112497/download>.

245 See *id.* at 1; FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., *supra* note 208.

246 See FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., *supra* note 208.

247 U.S. FOOD & DRUG ADMIN., SAFETY AND PERFORMANCE BASED PATHWAY: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION (2019), <https://www.fda.gov/media/112691/download>.

particularly well-understood device types.<sup>248</sup> The aim is to ensure that new devices' performance characteristics are assessed against a set of transparent, objective, and well-validated performance and safety metrics.<sup>249</sup> The FDA has issued several final and draft guidance documents that identify performance criteria and testing methodologies for particular device types, and more will likely follow in the future.<sup>250</sup> Examples of device types for which the FDA has published final guidance documents are spinal plating systems,<sup>251</sup> conventional Foley catheters,<sup>252</sup> and cutaneous electrodes for recording purposes.<sup>253</sup> Manufacturers have the option to use the performance criteria suggested in the final guidance documents to support "substantial equivalence," rather than directly comparing their medical device with that of a predicate.<sup>254</sup> The new Safety and Performance Based Pathway is applicable to manufacturers who intend to submit a 510(k) when three requirements are simultaneously met:

- (1) the device has the same indications for use as the predicate,
- (2) the technological characteristics do not raise different questions of safety and effectiveness than the predicate, and
- (3) the device meets all the FDA-recognized performance criteria.<sup>255</sup>

The new pathway is certainly laudable and seems promising but raises some issues, especially in the context of health AI. First, it is only available for those

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<sup>248</sup> See *id.* at 4; *Safety and Performance Based Pathway*, *supra* note 185. For more information on the Abbreviated 510(k) Program, see *supra* Section III.A.

<sup>249</sup> FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, on Latest Steps to Strengthen FDA's 510(k) Program for Premarket Review of Medical Devices (Jan. 22, 2019), <https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-jeff-shuren-md-director-center-devices-and-4>.

<sup>250</sup> *Safety and Performance Based Pathway*, *supra* note 185.

<sup>251</sup> U.S. FOOD & DRUG ADMIN., SPINAL PLATING SYSTEMS – PERFORMANCE CRITERIA FOR SAFETY AND PERFORMANCE BASED PATHWAY: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2020), <https://www.fda.gov/media/130867/download>.

<sup>252</sup> U.S. FOOD & DRUG ADMIN., CONVENTIONAL FOLEY CATHETERS – PERFORMANCE CRITERIA FOR SAFETY AND PERFORMANCE BASED PATHWAY: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2020), <https://www.fda.gov/media/130865/download>.

<sup>253</sup> U.S. FOOD & DRUG ADMIN., CUTANEOUS ELECTRODES FOR RECORDING PURPOSES – PERFORMANCE CRITERIA FOR SAFETY AND PERFORMANCE BASED PATHWAY: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF (2020), <https://www.fda.gov/media/130864/download>.

<sup>254</sup> See, e.g., *id.* at 3.

<sup>255</sup> See *Safety and Performance Based Pathway*, *supra* note 185; *supra* Section III.A.

device types for which the FDA has identified performance criteria. Although the FDA aims to publish more guidance documents identifying performance criteria for additional device types, this pathway targets those that are “well-understood.” AI-based medical devices are newer products that have only entered the U.S. market in recent years. There remains much to learn about health AI, including the optimal data to use to train the model. Thus, it is unlikely that the FDA will identify performance criteria and publish corresponding guidance documents for AI-based medical device types in the near future. As a result, the new Safety and Performance Based Pathway will likely not be applicable to AI-based medical devices in the next years.

Second, even if such guidance documents for certain well-understood AI-based medical device types were published in the future, this new pathway is voluntary and therefore manufacturers would still have the option to submit a Traditional, Special, or Abbreviated 510(k) instead. Thus, a direct comparison of the performance of the medical device to that of a predicate would still be possible under the Traditional and Special 510(k) without the agency’s determination that the device is actually safe and effective.

On January 8, 2021, during the last weeks of Donald Trump’s presidency, then Health and Human Services Secretary Alex Azar signed a surprising notice that aimed to make permanent certain regulatory flexibilities provided during the COVID-19 pandemic by exempting particular medical devices from 510(k) premarket notification requirements.<sup>256</sup> This notice, published in the Federal Register on January 15, 2021, exempted seven Class I medical devices, namely different types of gloves, from the 510(k) premarket notification requirement with immediate effect.<sup>257</sup> The notice also suggested to exempt 83 Class II medical devices and one unclassified medical device from the 510(k) premarket notification requirement and requested public comments within sixty days of publication in the Federal Register.<sup>258</sup> Several of the eighty-three medical devices proposed to be exempt from FDA review carry out tasks using AI, such as computer assisted detection software to help identify bone fractures, respiratory illnesses, lesions suspicious for cancer, and other medical issues.<sup>259</sup>

The notice justified these exemptions by stating that the 510(k) premarket

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256 Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Request for Information, Research, Analysis, and Public Comment on Opportunities for Further Science and Evidence-Based Reform of Section 510(k) Program, 86 Fed. Reg. 4088 (Jan. 15, 2021).

257 *Id.* at 4088, 4096.

258 *Id.* at 4088, 4096–98.

259 See *id.* at 4096–98; Casey Ross, “Slippery Slope Territory”: Health Officials Propose Waiving Regulatory Review of Medical AI Tools, STAT (Jan. 16, 2021), <https://www.statnews.com/2021/01/16/slippy-slope-territory-health-officials-propose-waiving-regulatory-review-of-medical-ai-tools>.

notification “is no longer necessary to assure the safety and effectiveness of those devices.”<sup>260</sup> Apparently such devices listed in the notice were associated with no or only few adverse events.<sup>261</sup> However, adverse events are tricky to detect in many AI-based medical devices since they interact with physicians. It can take time to identify health AI problems, such as hidden biases, and the absence or rarity of reported adverse events does not mean that the devices work as promised.<sup>262</sup> As argued above and below,<sup>263</sup> the FDA needs to tighten, rather than relax, its oversight of health AI to adequately protect patients’ health. In addition, this proposal appeared to contradict a newly released Action Plan for AI/ML-based SaMD issued by the FDA’s Digital Health Center of Excellence in January 2021.<sup>264</sup>

It was unlikely, however, that the Biden Administration would further pursue this proposal.<sup>265</sup> Indeed, on April 16, 2021, the Department of Health and Human Services and the FDA issued two related notices in the Federal Register. The first notice refers to the seven Class I medical devices (i.e., the different types of gloves).<sup>266</sup> It clarifies that the previous determination that these devices “no longer require premarket notification . . . is flawed” and that it is appropriate to reverse it.<sup>267</sup> The second notice withdraws the proposed exemptions for the eighty-three Class II medical devices and one unclassified medical device from the 510(k) premarket notification requirement.<sup>268</sup> It highlights that the Department of Health and Human Services did not notify the FDA before issuing the January notice and

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260 Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements, 86 Fed. Reg. at 4096.

261 *See id.* at 4096-4098; *see also* Ross, *supra* note 259 (quoting Karandeep Singh, who criticizes the notice).

262 *See, e.g.*, Ross, *supra* note 259.

263 *See, e.g., infra* Section III.B.3.

264 *Id.*; U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE/MACHINE LEARNING (AI/ML)-BASED SOFTWARE AS A MEDICAL DEVICE (SaMD) ACTION PLAN (Jan. 2021), <https://www.fda.gov/media/145022/download>. For more information on the new Action Plan, *see infra* Section IV.B.2. This also underscores the question about whether the FDA should become an independent federal agency distinct from the Department of Health and Human Services. *See, e.g.*, Eli Y. Adashi et al., *When Science and Politics Collide: Enhancing the FDA*, 364 Sci. 628, 630 (2019); Holly Fernandez Lynch, Steven Joffe & Matthew S. McCoy, *The Limits of Acceptable Political Influence Over the FDA*, 27 NATURE MED. 188, 189 (2021).

265 *See, e.g.*, Ross, *supra* note 1; Ross, *supra* note 259; Ronald A. Klain, *Regulatory Freeze Pending Review*, WHITE HOUSE (Jan. 20, 2021), <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/regulatory-freeze-pending-review>.

266 Medical Devices; Class I Surgeon’s and Patient Examination Gloves, 86 Fed. Reg. 20167 (Apr. 16, 2021).

267 *Id.* at 20167, 20170.

268 Making Permanent Regulatory Flexibilities Provided During the COVID-19 Public Health Emergency by Exempting Certain Medical Devices From Premarket Notification Requirements; Withdrawal of Proposed Exemptions, 86 Fed. Reg. 20174 (Apr. 16, 2021).

that the proposal by the Trump Administration was made “without adequate scientific support.”<sup>269</sup> Both April notices are to be welcomed and emphasize the importance of regulation to ensure the safety and effectiveness of medical devices, including those based on AI.

### 3. *Proposal for a Future Regulatory Framework for Premarket Review of Medical Devices, Including AI-Based Medical Devices*

If the Safety and Performance Based Pathway is found to be effective, the FDA should replace the Traditional, Special, and Abbreviated 510(k) with the new Safety and Performance Based Pathway entirely, thus making it the only available 510(k) pathway for eligible medical devices, including AI-based medical devices.<sup>270</sup> Having only one 510(k) pathway—alongside the other premarket pathways such as De Novo and PMA—would also make the process more streamlined for manufacturers. In particular, the Abbreviated 510(k) has been used only rarely in the past,<sup>271</sup> and thus keeping it in addition to the new Safety and Performance Based Pathway would only make the process unnecessarily complicated.

Indeed, it seems that the FDA may be open to this proposal. In its November 2018 statement, the FDA mentioned that its goal is to make the Safety and Performance Based Pathway “the primary pathway for devices eligible for 510(k) review.”<sup>272</sup> The FDA also said that the agency would like “this efficient new pathway to eventually supplant the practice of manufacturers comparing their new device technologically to a specific, and sometimes old, predicate device.”<sup>273</sup>

My proposal to make the new Safety and Performance Based Pathway the only applicable pathway for 510(k)-eligible medical devices, including AI-based medical devices, would also require that the current De Novo pathway be modified. For example, it will probably take several more years for the FDA to identify performance criteria for some (unlikely all) AI-based medical device types, and even if the FDA identified such criteria, some devices would perhaps not be able to meet all of the identified performance criteria. The scope of the De Novo pathway should thus be expanded to also cover those new devices that would not be appropriate for the new Safety and Performance Based Pathway. Consequently, the De Novo pathway could be applicable in two circumstances. First, as is currently the case, for novel medical devices of low to moderate risk,

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<sup>269</sup> *Id.* at 20176.

<sup>270</sup> See *infra* Figure 4.

<sup>271</sup> Rathii & Ross, *supra* note 221, at 1893.

<sup>272</sup> FDA Statement: Statement From FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., *supra* note 208.

<sup>273</sup> *Id.*

for which there is no predicate.<sup>274</sup> Second, for low and moderate risk medical devices that have a predicate, but where the new 510(k) Safety and Performance Based Pathway is not applicable because the FDA has, for example, not identified performance criteria for the respective device type.<sup>275</sup>

The FDA would need to design the exact differentiation criteria between the 510(k) Safety and Performance Based Pathway and the De Novo pathway, such as their precise scope, detailed requirements for submission, etc. As with the current regulatory framework, the majority of Class I medical devices and some Class II medical devices can still be exempt from the 510(k) premarket notification requirement as long as the exemptions are made with adequate scientific support. Congress should also enact legislation so that the suggested new regulatory framework for premarket review of medical devices, including AI-based medical devices, could be implemented.<sup>276</sup>

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274 See *supra* Section III.A.

275 See *infra* Figure 4.

276 See *infra* Figure 4.

Traditional Premarket Pathways	Software Pre-Cert Program
<p><b>(1) 510(k) Premarket Notification</b></p> <ul style="list-style-type: none"> <li>➤ <i>The Safety and Performance Based Pathway:</i> Typically for class II medical devices</li> </ul>	<ul style="list-style-type: none"> <li>➤ <b>Voluntary</b> pathway</li> <li>➤ For <b>precertified</b> companies of <b>SaMD</b></li> <li>➤ Perhaps someday also be expanded to <b>SiMD</b> or other <b>software that are accessories to hardware medical devices</b></li> </ul>
<p><b>(2) PMA</b></p> <ul style="list-style-type: none"> <li>➤ For class III medical devices</li> </ul>	
<p><b>(3) De Novo Classification Request</b></p> <ul style="list-style-type: none"> <li>➤ For novel medical devices of low to moderate risk, for which there is no predicate, or</li> <li>➤ For low to moderate risk medical devices that have a predicate, but the Safety and Performance Based Pathway is not applicable (e.g., the FDA has not identified performance criteria for the device type)</li> </ul>	
<p><b>(4) HDE</b></p> <ul style="list-style-type: none"> <li>➤ For class III medical devices that are intended to help patients with rare diseases or conditions</li> </ul>	

Figure 4: Proposal for a Future Regulatory Framework for Premarket Review of Medical Devices, Including AI-Based Medical Devices

The left column shows the traditional premarket pathways—i.e., 510(k) Premarket Notification, PMA, De Novo Classification Request, and HDE. The new framework would only have one 510(k) Pathway—i.e., the Safety and Performance Based Pathway. The new modified De Novo pathway would also apply in cases where a low or moderate risk device would have a predicate, but where the 510(k) Safety and Performance Based Pathway would not be applicable due to, for example, lack of FDA-identified performance criteria. The right column shows the Software Pre-Cert Program that would exist alongside the traditional premarket pathways.<sup>277</sup>

277 See *infra* Section III.C.

### C. *The New Software Pre-Cert Program*

#### 1. *Overview*

The FDA is currently carrying out a nine-company Pilot Program, launched in 2019, to explore how to best establish the so-called “Software Precertification (Pre-Cert) Program.”<sup>278</sup> Companies that are involved in the testing phase include Johnson & Johnson, Apple, Roche, Samsung, and Google’s sister-company Verily.<sup>279</sup> This Program aims to help the agency develop a future regulatory model for software-based medical devices.<sup>280</sup> The first version of the Software Pre-Cert Program is limited to SaMD. However, if the testing shows that the Program could also be leveraged for SiMD or other software that are accessories to hardware medical devices, the FDA will likely expand the Program.<sup>281</sup>

The Software Pre-Cert Program is designed as a voluntary pathway.<sup>282</sup> It would apply to manufacturers of SaMD that would be “precertified”—i.e., they would have demonstrated a culture of quality and organizational excellence—and would have agreed to monitor the real-world performance of their devices once they are launched on the U.S. market.<sup>283</sup> The new regulatory model aims to provide more efficient and streamlined regulatory oversight of SaMD and to promote innovation of digital health technologies.<sup>284</sup>

A key component of the Software Pre-Cert Program would be that the FDA or an FDA-accredited third-party would perform an Excellence Appraisal.<sup>285</sup> Companies would need to be granted a precertification status before being eligible for this pathway. They would need to demonstrate a culture of quality and organizational excellence.<sup>286</sup> At the moment, the FDA envisions the Excellence

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<sup>278</sup> *Digital Health Software Precertification (Pre-Cert) Program*, U.S. FOOD & DRUG ADMIN. (May 6, 2021), <https://www.fda.gov/medical-devices/digital-health/digital-health-software-precertification-pre-cert-program>.

<sup>279</sup> *Id.*

<sup>280</sup> *Id.*

<sup>281</sup> *Id.*; U.S. FOOD & DRUG ADMIN., DEVELOPING A SOFTWARE PRECERTIFICATION PROGRAM: A WORKING MODEL 9, 10 (January 2019), <https://www.fda.gov/media/119722/download>. For the definition of SaMD and SiMD, see *supra* Section II.A.

<sup>282</sup> U.S. FOOD & DRUG ADMIN., *supra* note 281, at 6.

<sup>283</sup> *Id.* at 6, 37; *Digital Health Software Precertification (Pre-Cert) Program*, *supra* note 278.

<sup>284</sup> U.S. FOOD & DRUG ADMIN., *supra* note 281, at 7; *Digital Health Software Precertification (Pre-Cert) Program*, *supra* note 278; *Precertification (Pre-Cert) Pilot Program: Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN. (Sept. 14, 2020), <https://www.fda.gov/medical-devices/digital-health-software-precertification-pre-cert-program/precertification-pre-cert-pilot-program-frequently-asked-questions>.

<sup>285</sup> U.S. FOOD & DRUG ADMIN., *supra* note 281, at 16–24. For more information on non-FDA certifiers, see Cortez, *supra* note 11, at 19 (arguing that it is a genuine innovation at the FDA).

<sup>286</sup> U.S. FOOD & DRUG ADMIN., *supra* note 281, at 16–24.

Appraisal to be based on five Excellence Principles:

- (1) patient safety,
- (2) product quality,
- (3) clinical responsibility,
- (4) cybersecurity responsibility, and
- (5) proactive culture.<sup>287</sup>

Companies that demonstrate excellence in product development in all five Excellence Principles would additionally be categorized into one of two precertification levels.<sup>288</sup> Level 1 Pre-Cert would be granted to companies that have limited or no experience in delivering SaMD.<sup>289</sup> Level 2 Pre-Cert would be awarded to companies that have a proven track record in developing, providing, and maintaining safe and effective SaMD.<sup>290</sup>

Once companies are granted precertification status, they would be able to bring their SaMD with a streamlined premarket review or without any premarket review to the U.S. market. Whether a streamlined premarket review would be required would depend on the risk categorization of their SaMD and their precertification level.<sup>291</sup> The FDA is determining the information needed for a streamlined premarket review.<sup>292</sup> The goal is to allow faster market access while simultaneously ensuring safety and effectiveness.<sup>293</sup>

To determine the risk level of the product, the FDA envisions leveraging the IMDRF framework for risk categorization of SaMD.<sup>294</sup> SaMD with a risk level I would *not* need to undergo any FDA premarket review. High risk SaMD with a risk level III or IV would need to undergo a premarket review but a streamlined version. Risk level II SaMD could be brought to market with no premarket review or a streamlined one depending on the precertification level of the respective company. If the company were awarded a Level 1 Pre-Cert, then a streamlined premarket review would be necessary. However, if the company were granted a Level 2 Pre-Cert, then its product would *not* need to undergo any FDA premarket review. Figure 5 gives an overview of which SaMD would need to undergo a

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287 *Id.* at 11; *Digital Health Software Precertification (Pre-Cert) Program*, *supra* note 278.

288 U.S. FOOD & DRUG ADMIN., *supra* note 281, at 23.

289 *Id.*

290 *Id.*

291 *Id.* at 25.

292 *Id.* at 31–36; *Digital Health Software Precertification (Pre-Cert) Program*, *supra* note 278.

293 U.S. FOOD & DRUG ADMIN., *supra* note 281, at 31.

294 *Id.* at 25–30. For more information on the IMDRF framework, *see supra* Section II.B.3.

streamlined premarket review or no premarket review at all.

State of the health care situation or condition	Significance of the information provided by the SaMD to the health care decision		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Figure 5: SaMD Risk Categorization Developed by the IMDRF<sup>295</sup> (modified to reflect whether an SaMD from a precertified company would need to undergo FDA premarket review under the Software Pre-Cert Program)

An SaMD that falls within one of the green boxes would not need to undergo any FDA premarket review. However, a streamlined premarket review would be required for an SaMD that falls within one of the red boxes. An SaMD that falls within one of the orange boxes would need to undergo a streamlined FDA premarket review if the company were Level 1 precertified. In contrast, if the company were Level 2 precertified, an SaMD that falls within the orange boxes would *not* need to undergo FDA premarket review.

The FDA envisions applying a Total Product Lifecycle (TPLC) approach.<sup>296</sup> Once the SaMD were marketed within the U.S., the precertified companies would monitor their real-world performance.<sup>297</sup> The FDA’s approach aims to ensure that SaMD are safe and effective during their entire life cycle—from premarket development to postmarket performance.<sup>298</sup>

## 2. Analysis

The current Pre-Cert Pilot Program is a sensible approach to assess whether the new regulatory model for SaMD assures that the devices are reasonably safe and effective. The Pre-Cert Pilot Program provides the opportunity to fine-tune the Program and to solve many open questions. For example, what would happen if a

<sup>295</sup> INT’L MED. DEVICE REGULS. F., *supra* note 63, at 14.

<sup>296</sup> For more information on the TPLC approach, see U.S. FOOD & DRUG ADMIN., *supra* note 281, at 12–14.

<sup>297</sup> *Digital Health Software Precertification (Pre-Cert) Program*, *supra* note 278. For more information on real-world performance, see U.S. FOOD & DRUG ADMIN., *supra* note 281, at 37–43.

<sup>298</sup> U.S. FOOD & DRUG ADMIN., *supra* note 281, at 13. To the update problem, see *infra* Section IV.B.

precertified company were acquired by another company? Already during the testing phase, Fitbit, one of the nine participating companies in the Pilot, was acquired by Google for \$2.1 billion.<sup>299</sup> The FDA has indicated that organizational restructuring or acquisition that impacts the assessed quality system and processes might trigger the need for an additional Excellence Appraisal.<sup>300</sup>

It will be interesting to see the Pre-Cert Pilot Program's final results and whether this Program that aims to establish trust and leverage transparency<sup>301</sup> can ensure that SaMD will be reasonably safe and effective throughout their life cycle.<sup>302</sup> This organization-based approach is undoubtedly an experiment with a new focus on assessing companies and products. It may hold valuable lessons for other countries and should be closely watched.<sup>303</sup> One point, however, is certain: It is a complicated endeavor, and the Pilot is already taking longer than initially expected.<sup>304</sup>

Perhaps one of the biggest challenges the agency currently faces is how the Software Pre-Cert Program would fit into the current traditional premarket pathways—i.e., 510(k), PMA, De Novo classification request, and HDE. For the Pilot, the FDA has leveraged the De Novo pathway.<sup>305</sup> The current Pilot is running in parallel with the traditional De Novo pathway. If a precertified company wants to place an SaMD on the U.S. market that is eligible for the De Novo process, it can submit a “Pre-Cert De Novo” during the testing period, and the FDA will run a traditional De Novo pathway in parallel.<sup>306</sup> Thus, the FDA can compare the Pre-Cert De Novo with the traditional De Novo and determine safety and effectiveness.

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299 Erin Brodwin & Mario Aguilar, *Two Ways Fitbit Could Boost Google's Health Ambitions*, STAT (Jan. 15, 2021), <https://www.statnews.com/2021/01/15/google-fitbit-clinical-trials>; Rick Osterloh, *Google Completes Fitbit Acquisition*, GOOGLE (Jan. 14, 2021), <https://blog.google/products/devices-services/fitbit-acquisition>.

300 U.S. FOOD & DRUG ADMIN., *supra* note 281, at 15.

301 *Id.* at 7.

302 See Cortez, *supra* note 11, at 20–22 (expressing skepticism of the Software Pre-Cert Program); see also Terry, *supra* note 11, at 96 (worrying about the fact that the Software Pre-Cert Program will likely remove more consumer-facing devices from direct regulatory scrutiny).

303 Gerke et al., *supra* note 7, at 310.

304 For an updated timetable, see U.S. FOOD & DRUG ADMIN., DEVELOPING THE SOFTWARE PRECERTIFICATION PROGRAM: SUMMARY OF LEARNINGS AND ONGOING ACTIVITIES 2 (Sept. 2020), <https://www.fda.gov/media/142107/download>.

305 U.S. FOOD & DRUG ADMIN., SOFTWARE PRECERTIFICATION PROGRAM: REGULATORY FRAMEWORK FOR CONDUCTING THE PILOT PROGRAM WITHIN CURRENT AUTHORITIES (Jan. 2019), <https://www.fda.gov/media/119724/download>; see also U.S. FOOD & DRUG ADMIN., SOFTWARE PRECERTIFICATION PROGRAM: 2019 TEST PLAN (Jan. 2019), <https://www.fda.gov/media/119723/download> (describing the FDA's 2019 test plan).

306 U.S. FOOD & DRUG ADMIN., SOFTWARE PRECERTIFICATION PROGRAM: 2019 TEST PLAN, *supra* note 305, at 3, 4; U.S. FOOD & DRUG ADMIN., SOFTWARE PRECERTIFICATION PROGRAM: REGULATORY FRAMEWORK, *supra* note 305, at 3. For more information, see *Software Precertification Program 2019 Mid-Year Update*, U.S. FOOD & DRUG ADMIN. (2019), <https://www.fda.gov/media/129047/download>.

To date, the Pilot has been restricted to SaMD of low to moderate risk for which there is no predicate, and thus are eligible for the De Novo pathway. SaMD with a predicate are not currently tested, except if they are eligible for 510(k) under a device classification created by the Pre-Cert De Novo. Only in this case could precertified companies submit a “Pre-Cert 510(k)” during the Pilot.<sup>307</sup>

The FDA has already come under criticism for the limited scope of the Pilot.<sup>308</sup> However, it seems that the FDA decided to implement the Pre-Cert Pilot Program under the De Novo pathway because the agency received pushback from Congress regarding its statutory authority to implement such a Program.<sup>309</sup> As a result, the FDA decided to leverage the De Novo pathway in the belief that the agency can test the Program within its current power.<sup>310</sup> However, even with this limited testing format, the FDA has been criticized by scholars and others for exceeding its statutory authority by implementing the Pre-Cert Pilot Program under the De Novo Pathway.<sup>311</sup>

Bakul Patel, the Director of the newly launched FDA’s Digital Health Center of Excellence,<sup>312</sup> expects that the FDA will need to ask Congress for statutory authority to fully implement the Software Pre-Cert Program.<sup>313</sup> This statement also finds support in the law: The FDA draws its authority from the FDCA and its

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307 U.S. FOOD & DRUG ADMIN., SOFTWARE PRECERTIFICATION PROGRAM: REGULATORY FRAMEWORK FOR CONDUCTING THE PILOT PROGRAM WITHIN CURRENT AUTHORITIES, *supra* note 305, at 3, 4; U.S. FOOD & DRUG ADMIN., SOFTWARE PRECERTIFICATION PROGRAM: 2019 TEST PLAN, *supra* note 305, at 2.

308 *See, e.g.*, David Lim, *FDA Targets De Novo Path to Shepherd Medical Software Through Pre-Cert*, MEDTECH DIVE (Jan. 8, 2019), <https://www.medtechdive.com/news/fda-targets-de-novo-path-to-shepherd-medical-software-through-pre-cert/545519>.

309 SCOTT THIEL & JASON BROOKE, REGUL. AFFS. PROS. SOC’Y, WILL THE FDA PRECERTIFICATION PILOT PROGRAM WORK? (May 2019), <https://guidehouse.com/-/media/www/site/insights/healthcare/2019/raps--fda-precertification-pilot-program--52419.pdf>.

310 U.S. FOOD & DRUG ADMIN., SOFTWARE PRECERTIFICATION PROGRAM: 2019 TEST PLAN, *supra* note 305, at 2; U.S. FOOD & DRUG ADMIN., *supra* note 281, at 2.

311 *See, e.g.*, Letter from Sen. Elizabeth Warren, Sen. Tina Smith & Sen. Patty Murray to Norman E. Sharpless, Acting Comm’r, U.S. Food & Drug Admin. & Jeffrey Shuren, Dir., Ctr. Devices & Radiological Health, U.S. Food & Drug Admin. 7, 8 (Oct. 30, 2019), <https://www.warren.senate.gov/imo/media/doc/2019.10.30%20Letter%20with%20Senators%20Murray%20and%20Smith%20to%20FDA%20requesting%20additional%20information%20on%20the%20agency's%20software%20pre-certification%20pilot%20program.pdf>; David Lim, *Top Democrats Question FDA Pre-Cert Program Safety, Statutory Authority*, MEDTECH DIVE (Oct. 11, 2018), <https://www.medtechdive.com/news/top-democrats-question-fda-pre-cert-program-safety-statutory-authority/539389>.

312 For more information on the new Digital Health Center of Excellence, *see supra* note 13 and accompanying text.

313 Greg Slabodkin, *FDA Still Trying to Fine-Tune Pre-Cert as Pilot Enters 2020*, MEDTECH DIVE (Mar. 25, 2020), <https://www.medtechdive.com/news/fda-pre-cert-software-device-pilot-enters-another-year/574822>.

amendments.<sup>314</sup> For any work the FDA wants to pursue outside of the FDCA and its amendments, the agency must obtain Congress's approval in the form of another amendment to the FDCA.<sup>315</sup> Looking at an earlier draft of the 21st Century Cures Act also suggests that the FDA must ask Congress for statutory authority to implement the Program fully. This earlier draft contained a provision that would have amended the FDCA and authorized the FDA to implement a new regulatory framework for health software,<sup>316</sup> but that provision was not incorporated into the final version of the Act.<sup>317</sup>

### 3. *Implementation Proposal*

So how could the Software Pre-Cert Program ideally be implemented in the future? It makes sense that the Software Pre-Cert Program would be implemented as a voluntary pathway, as it is currently designed. It is in the nature of things that not every company can be awarded a precertification status based on excellence. However, one needs to see in the long-term how many companies—e.g., a handful or hundreds—would ultimately use this pathway. In particular, the FDA needs to make sure that the Program would not de facto favor larger companies that have the necessary resources to undergo an Excellence Appraisal. The Program should also benefit small- and medium-sized enterprises. In the field of health AI, for example, there are many new start-ups that should also be given a realistic chance to get precertified and benefit from such a Program. Thus, it will be crucial for the FDA to closely watch the potential market effects of implementing the Software Pre-Cert Program. Such a Program could potentially bias the market toward established big players who are able to achieve a precertification status and thereby either quash innovation by new players or possibly over-incentivize intellectual property sales of health AI to precertified players. Thus, it will be crucial that the Software Pre-Cert Program distributes precertification status in a manner that promotes innovation at the same time as safety and effectiveness.

Suppose the FDA establishes the Software Pre-Cert Program's specific details, the Pilot proves to be effective, and the FDA has statutory authority. In that case, the agency theoretically would have two options regarding the Program's implementation. First, the agency could implement it similarly to the Pre-Cert Pilot Program, and even expand its scope so that precertified companies could submit, for example, a Pre-Cert 510(k) without the need for a device classification created by the Pre-Cert De Novo. At a later stage, the FDA could further expand the Program for SiMD and other software that are accessories to hardware medical

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314 THIEL & BROOKE, *supra* note 309, at 4.

315 *Id.*

316 See 21st Century Cures Act, H.R. 6, 114th Cong. § 2242 (2015).

317 See Cortez, *supra* note 11, at 25.

devices. Second, the Software Pre-Cert Program could run completely separate from the traditional premarket pathways as an independent voluntary pathway with its own conditions.<sup>318</sup>

Irrespective of whether the FDA would choose the first or second option, the traditional premarket pathways would continue to be available for those companies that do not receive precertification status. Thus, it will be all the more important that the traditional pathways are robust and ensure that medical devices, including AI-based medical devices, are reasonably safe and effective when placed on the market. Consequently, the FDA needs to address the safety and effectiveness concerns of the traditional premarket pathways as soon as possible and implement—after receiving additional statutory authority—a new regulatory framework, such as the one that I have suggested above.<sup>319</sup>

#### IV. PROBLEMS RELATED TO SPECIFIC AI-BASED MEDICAL DEVICES

##### A. *Black-Box AI/ML Models and Explainable Versus Interpretable AI/ML*

###### 1. *The Problem*

Another problem that needs to be addressed in the new suggested framework<sup>320</sup> is AI-based medical devices that are “black boxes.” As explained above, many high-performing AI/ML systems rely on algorithms that are “black boxes.”<sup>321</sup> Black-box algorithms are difficult or impossible for humans to understand.<sup>322</sup> Algorithms typically labeled as “deep learning” are black-box AI/ML models.<sup>323</sup> The term “black boxes” can also refer to algorithms that are deliberately black boxes because, for intellectual property reasons, developers do not want to disclose the details of how these algorithms work.<sup>324</sup> I focus here on the first group of algorithms, namely those that are inherently black boxes.

Noninterpretable black-box models have been shown to perform better than interpretable models in several practicable scenarios.<sup>325</sup> In particular, in health care, black-box AI/ML models often perform better, such as in image

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318 See *supra* Figure 4.

319 See *supra* Section III.B.3.

320 See *supra* Figure 4.

321 See *supra* Part I.

322 Babic et al., *supra* note 22, at 284; Babic & Gerke, *supra* note 22.

323 *Id.*

324 Price, *Regulating Black-Box Medicine*, *supra* note 6, at 430.

325 Hongfang Liu et al., *AI Model Development and Validation*, in *ARTIFICIAL INTELLIGENCE IN HEALTH CARE: THE HOPE, THE HYPE, THE PROMISE, THE PERIL* 124 (Michael Matheny et al., eds., 1st ed. 2019).

recognition.<sup>326</sup> However, especially in Europe, there is a movement for explainable AI/ML since various scholars argue that the EU General Data Protection Regulation (2016/679)<sup>327</sup> contains a “right to explanation” of automated decision-making.<sup>328</sup> In contrast, the U.S. follows a more market-driven approach, and the FDA has already permitted marketing of several AI/ML-based medical devices that use noninterpretable black-box models.<sup>329</sup> For example, Imagen’s OsteoDetect and Arterys Cardio DL both use deep learning.<sup>330</sup>

So which approach is the right one? Should regulators like the FDA continue to permit marketing of black-box AI/ML systems or only permit marketing of explainable and/or interpretable AI/ML?

One thing should be clear here: It is crucial to understand the difference between interpretable AI/ML and explainable AI/ML. As defined here, interpretable AI/ML uses a “white-box” model (i.e., a transparent system), such as a linear or simple decision tree model, instead of a black box.<sup>331</sup> The advantage of interpretable AI/ML algorithms is that they are open and understandable at a human level with reasonable effort.<sup>332</sup> In contrast, the term “explainable AI/ML” is understood here in connection with a black-box model that is used to make diagnoses or predictions.<sup>333</sup> A second explanatory algorithm—which is itself a white-box model—is developed that closely approximates the outputs of the black box.<sup>334</sup>

The issue with explainable AI/ML, however, is that because the second algorithm is usually not as accurate as the black box, it is normally used to develop

326 Babic et al., *supra* note 22.

327 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), 2016 O.J. (L. 119) 1.

328 For more information on this debate, see, for example, Andrew Burt, *Is There a ‘Right to Explanation’ for Machine Learning in the GDPR?*, IAPP (June 1, 2017), <https://iapp.org/news/a/is-there-a-right-to-explanation-for-machine-learning-in-the-gdpr>; Bryce Goodman & Seth Flaxman, *European Union Regulations on Algorithmic Decision Making and a “Right to Explanation”*, 38 AI MAG. 50 (2017); Sandra Wachter et al., *Why a Right to Explanation of Automated Decision-Making Does Not Exist in the General Data Protection Regulation*, 7 INT’L DATA PRIV. L. 76 (2017); Margot E. Kaminski, *The Right to Explanation, Explained*, 34 BERKELEY TECH. L.J. 189 (2019); Gerke et al., *supra* note 7, at 322.

329 Babic et al., *supra* note 22. See also Mark Ratner, *FDA Backs Clinician-Free AI Imaging Diagnostic Tools*, 36 NATURE BIOTEC. 673, 674 (2018) (quoting Eric Perakslis, former chief information officer at the FDA: “You are seeing FDA not just approving these tools, they are accelerating them”).

330 For more information on such devices, see *supra* Section I.A and Section III.B.

331 See Babic et al., *supra* note 22, at 284; Babic & Gerke, *supra* note 22.

332 See sources cited *supra* note 331.

333 *Id.*

334 *Id.*

only *post hoc* explanations for the outputs of the black box and not to make actual predictions.<sup>335</sup> In other words, explainable AI/ML offers post hoc explanations for black-box predictions without necessarily giving the *actual* reasons behind such predictions.<sup>336</sup> For example, imagine a black-box model predicting a patient's high risk of stroke.<sup>337</sup> The second explanatory algorithm might say that the black-box prediction is consistent with a linear model, which relies on one's smoking and blood pressure status.<sup>338</sup> However, this post hoc explanation may not be the actual reason why the black-box model predicted the patient's high risk of stroke. Explainable AI/ML only generates an "ersatz understanding."<sup>339</sup> Many other algorithmically generated explanations are easily conceivable here that are also consistent with the prediction of the black box.<sup>340</sup> For instance, it could also be the case that the patient's high risk of stroke is consistent with a decision tree, which relies on their diabetes and gender status.<sup>341</sup> Hence, in the context of explainable AI/ML, there is a high risk of a false impression that one better understands black-box predictions and thus a false sense of user (over)confidence in the explanations provided.<sup>342</sup>

Consequently, regulators like the FDA need to be cautious about requiring explainable AI/ML as a prerequisite of marketing authorization since its benefits in health care are not what they currently appear to be.<sup>343</sup> The gold standard should be that regulators require AI/ML makers to use an interpretable AI/ML system—if a white-box model performs better than or as well as a black-box AI/ML model—and focus on ensuring the model's safety and effectiveness. However, if there is sufficient proof that a black-box model performs better than a white-box model and is reasonably safe and effective, and the accuracy increase outweighs the loss of model interpretability, then regulators should generally permit marketing of the black-box AI/ML model as such (without requiring explainable AI/ML) to facilitate innovations. To achieve this goal, regulators could reach, at least in some cases, into an already existing toolbox: clinical trials.

## 2. *Clinical Trials*

For drugs and vaccines, clinical trials are the standard method to prove that

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335 *Id.*

336 Babic et al., *supra* note 22, at 285; Babic & Gerke, *supra* note 22.

337 Babic & Gerke, *supra* note 22.

338 *Id.*

339 Babic et al., *supra* note 22, at 285; Babic & Gerke, *supra* note 22.

340 Babic & Gerke, *supra* note 22.

341 *Id.*

342 Babic et al., *supra* note 22, at 285; Babic & Gerke, *supra* note 22.

343 Babic et al., *supra* note 22, at 286; Babic & Gerke, *supra* note 22.

they are reasonably safe and effective for their intended use. There are several steps involved in the drug and vaccine development process, one of which is clinical research. The FDA typically requires successful completion of three phases before granting marketing approval of a drug or vaccine.<sup>344</sup> For clinical trials of drugs, for example, Phase 1 is typically carried out with 20 to 100 healthy volunteers or people with the disease or condition to test safety and dosage; Phase 2 has up to several hundred people with the disease or condition and aims to evaluate the drug's efficacy and side effects; and Phase 3 is carried out on a large scale with about 300 to 3,000 volunteers who have the disease or condition and is designed to further assess the efficacy and to monitor adverse reactions.<sup>345</sup> In Randomized Clinical Trials (RCTs), participants are randomly allocated to separate groups that compare different treatments/interventions.<sup>346</sup> In this way, RCTs help to mitigate bias and assess efficacy.<sup>347</sup>

For some medical devices the FDA demands clinical studies.<sup>348</sup> These are typically medical devices that require a PMA.<sup>349</sup> Medical device trials are usually smaller than drug and vaccine trials, but they serve a similar purpose: to support a reasonable assurance that the medical device is safe and effective for its intended use.<sup>350</sup>

However, in the field of health AI, clinical trials are nearly nonexistent. As discussed above,<sup>351</sup> most AI-based medical devices that are currently available on the U.S. market received 510(k) clearances, for which the FDA usually does not request any clinical evidence. One example of an exception in the field is Digital Diagnostic's IDx-DR, which received marketing authorization via the De Novo pathway.<sup>352</sup> The AI company carried out a pivotal clinical study with 900 patients to show IDx-DR's performance.<sup>353</sup> However, even IDx-DR did not receive

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344 *Step 3: Clinical Research*, U.S. FOOD & DRUG ADMIN. (Jan. 4, 2018), <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research>; *Vaccine Development – 101*, U.S. FOOD & DRUG ADMIN. (Dec. 14, 2020), <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101>.

345 *Step 3: Clinical Research*, *supra* note 344.

346 *Randomized Clinical Trial*, NAT'L INSTS. HEALTH, <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/randomized-clinical-trial>.

347 *Id.*

348 See OWEN FARIS, CLINICAL TRIALS FOR MEDICAL DEVICES: FDA AND THE IDE PROCESS 9, <https://www.fda.gov/media/87603/download>; *supra* Section III.A.

349 *How to Study and Market Your Device*, *supra* note 166. For more information on investigational device exemptions, see *Investigational Device Exemption (IDE)*, U.S. FOOD & DRUG ADMIN. (Dec. 13, 2019), <https://www.fda.gov/medical-devices/how-study-and-market-your-device/investigational-device-exemption-ide>.

350 FARIS, *supra* note 348, at 5.

351 See *supra* Section III.B.

352 For more information about IDx-DR, see *supra* Section I.A.

353 U.S. FOOD & DRUG ADMIN., *supra* note 32; Michael D. Abramoff et al., *Pivotal Trial of an*

marketing authorization based on RCT evidence that the information provided by the AI-based medical device improved care.<sup>354</sup> A recent study has also shown that between 2011 and 2019 the FDA often permitted marketing of therapeutic medical devices via the De Novo pathway regardless of limited clinical evidence of effectiveness.<sup>355</sup> Moreover, the first two RCTs of AI/ML have only just been published in 2019.<sup>356</sup> By way of example, in one of these RCTs, 536 patients were randomly allocated to standard colonoscopy and 522 patients to colonoscopy with computer-aided diagnosis.<sup>357</sup>

When exploring a new regulatory framework for AI-based medical devices, the FDA should prefer the use of interpretable AI/ML systems in cases where white-box models perform as good as or better than black-box AI/ML models. Of course, the manufacturer must also provide reasonable assurance of the safety and effectiveness of a white box, which may also require the conduct of a clinical trial in a case where the device presents a higher risk level. However, suppose the black-box AI/ML model performs better in a specific case, and the accuracy improvement outweighs the loss of model interpretability. Rather than requiring explainable AI/ML, regulators should generally permit marketing of the black box, as long as the device has been proven to be reasonably safe and effective, such as via a clinical trial. There are drugs available on the U.S. market whose mechanisms of action are still unknown, such as Acetaminophen.<sup>358</sup> Nevertheless, such drugs are widely used since they have been shown to be reasonably safe and effective. Consequently, it seems likely that black-box AI/ML models do not affect the trust of patients and health professionals and thus their use, as long as they function as

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*Autonomous AI-Based Diagnostic System for Detection of Diabetic Retinopathy in Primary Care Offices*, 1 NPJ DIGIT. MED., no. 39 (2018).

354 Derek C. Angus, *Randomized Clinical Trials of Artificial Intelligence*, 323 JAMA 1043 (2020).

355 James L. Johnston et al., *Clinical Evidence Supporting US Food and Drug Administration Clearance of Novel Therapeutic Devices via the De Novo Pathway Between 2011 and 2019*, 180 JAMA INTERNAL MED. 1701 (2020); James L. Johnston et al., *Clinical Evidence Supporting FDA Clearance of First-of-a-Kind Therapeutic Devices via the De Novo Pathway Between 2011 and 2019*, <https://www.medrxiv.org/content/10.1101/2020.04.23.20077164v2>.

356 Haotian Lin et al., *Diagnostic Efficacy and Therapeutic Decision-Making Capacity of an Artificial Intelligence Platform for Childhood Cataracts in Eye Clinics: A Multicentre Randomized Controlled Trial*, 9 ECLINICALMED. 52 (2019); Pu Wang et al., *Real-Time Automatic Detection System Increases Colonoscopic Polyp and Adenoma Detection Rates: A Prospective Randomised Controlled Study*, 68 GUT 1813 (2019). For more information, see Myura Nagendran et al., *Artificial Intelligence Versus Clinicians: Systematic Review of Design, Reporting Standards, and Claims of Deep Learning Studies*, 368 BMJ m689 (2020).

357 Wang et al., *supra* note 356, at 1813.

358 See, e.g., K. Toussaint et al., *What Do We (Not) Know About How Paracetamol (Acetaminophen) Works?*, 35 J. CLINICAL PHARM. & THERAPEUTICS 617 (2010).

promised.<sup>359</sup>

Clinical trials can support a reasonable assurance that the AI/ML-based medical device is safe and effective for its intended use. In an ideal world, RCTs would perhaps be desirable for all AI/ML-based medical devices, especially black boxes, but are they really feasible? Clinical trials will work for some but not for all AI/ML models.<sup>360</sup> For example, they will work for those algorithms that divide patients into groups and propose a specific treatment.<sup>361</sup> However, some algorithms are intended to make recommendations that are highly personalized so that clinical trials would be challenging, perhaps even infeasible, and might overwhelm standard RCT designs.<sup>362</sup> Another problem is adaptive algorithms that can continuously learn and adapt to new conditions.<sup>363</sup> These AI/ML systems are not static, and thus the benefit of clinical trials will likely not last long since the algorithms change.<sup>364</sup> This is particularly problematic given that clinical trials are costly and time-consuming. For adaptive algorithms, regulators like the FDA need to focus their efforts especially on continuous risk monitoring.<sup>365</sup>

On the flip side, the lack of reliable evidence may jeopardize patient safety and undermine public trust in the FDA. Some people fear that AI companies live the motto “fail fast and fix it later.”<sup>366</sup> If this is true, the risk concerns for black-box AI/ML models are significant since the users cannot look inside the boxes and thus do not know whether their outputs are correct. Nathan Cortez has also correctly pointed out that “the lack of reliable evidence may depress demand and thus adoption of digital health products,” including AI.<sup>367</sup> On the other hand, Nicholson Price rightly warns that mandating clinical trials for black-box AI/ML models could “slow or stifle innovation.”<sup>368</sup>

This is a dilemma for regulators: An optimal path would be to facilitate innovation while ensuring that AI/ML models, especially black boxes, are reasonably safe and effective. It will be a challenge to juggle the different stakeholder interests. However, for the new regulatory framework for AI-based medical devices, the FDA should, where feasible and in light of patient safety, at

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359 See Liu et al., *supra* note 325.

360 Price, *Artificial Intelligence in Health Care*, *supra* note 6, at 11.

361 *Id.*

362 See Angus, *supra* note 354, at 1044; Price, *Artificial Intelligence in Health Care*, *supra* note 6, at 11.

363 For adaptive algorithms, see *supra* Part I.

364 W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 460 (2015). For the update problem, see *infra* Section IV.B.

365 See *infra* Section IV.B.3.

366 Liz Szabo, *A Reality Check On Artificial Intelligence: Are Health Care Claims Overblown?* KHN (Dec. 30, 2019), <https://khn.org/news/a-reality-check-on-artificial-intelligence-are-health-care-claims-overblown>.

367 Cortez, *supra* note 11, at 21.

368 Price, *Artificial Intelligence in Health Care*, *supra* note 6, at 11.

least require clinical trials for those AI/ML-based medical devices (i.e., interpretable AI/ML systems and black boxes) that have a higher risk level. The FDA could leverage the IMDRF framework for risk categorization of SaMD<sup>369</sup> to determine whether a clinical trial is needed. The FDA could, for example, require clinical evidence for all AI/ML-based medical devices that would be classified as risk level III or IV devices, and for some black boxes that would be classified as risk level II devices, such as those that fall into the category “treat or diagnose” or “drive clinical management.” It is justified to require clinical trials for AI/ML-based medical devices that are black boxes more often than for white boxes, since black boxes raise additional concerns because of their noninterpretability.

There may be also exceptions where one always wants to know *why* an AI/ML-based medical device made a particular recommendation and where the use of a black box would not be sufficient, even with a successful clinical trial that provides valid scientific evidence that the device is reasonably safe and effective for its intended use. For example, imagine a black-box prediction model is used for triage decisions during a pandemic to decide which patient should be prioritized for receiving a ventilator based on the patient’s risk of mortality. In such a life-or-death decision, one would like to know for concerns of justice—understood here as concerns about how one should fairly allocate scarce resources<sup>370</sup>—why the model concluded that patient X has a high or low risk of dying and thus should (not) be prioritized over patient Y. Consequently, AI-based mortality prediction models should not only be clearly classified as medical devices under FDCA section 201(h)(1) and subject to FDA regulation—as I have argued above<sup>371</sup>—but the FDA should also require AI makers to use interpretable systems from the outset in cases where their intended use poses concerns of justice. In general, for reasons of procedural fairness, if AI/ML-based medical devices are intended to be used to allocate scarce resources, such as ventilators or organs,<sup>372</sup> it would be appropriate and likely necessary for the FDA to demand the use of interpretable AI/ML systems even if black boxes performed better.

These are certainly not easy waters to navigate. But once the FDA has figured

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369 See *supra* Figure 2.

370 See Babic et al., *supra* note 22, at 286.

371 See *supra* Section II.B.4. In this scenario, the AI-based mortality prediction model would already not be CDS since the model would “drive clinical management,” which would go beyond “supporting or providing recommendations. See *supra* Figure 1 and Figure 2; INT’L MED. DEVICE REGULS. F., *supra* note 63, at 11; U.S. FOOD & DRUG ADMIN., *supra* note 85, at 14. Moreover, the model would perhaps already not be considered a medical device under FDCA § 201(h)(1); it is highly unclear whether it would be “intended for use in the . . . treatment . . . of disease . . .” FDCA § 201(h)(1)(B), 21 U.S.C. § 321(h)(1)(B); see *supra* Section II.B.3.

372 See Babic et al., *supra* note 22, at 286; Gali Katznelson & Sara Gerke, *The Need for Health AI Ethics in Medical School Education*, 26 ADVANCES HEALTH SCI. EDUC. 1447, 1453 (2021); Boris Babic et al., *Can AI Fairly Decide Who Gets An Organ Transplant?*, HARV. BUS. REV. (2020).

out the details of the new regulatory framework for AI-based medical devices, as suggested here, Congress should enact legislation to enable the FDA to implement it.

## *B. Update Problem*

### *1. Safety Concerns*

AI/ML-based SaMD are distinct from other medical devices insofar as they can learn from new data and improve their performance. This distinctive feature, however, poses challenges for regulators like the FDA. At the moment, the FDA typically only clears or approves AI/ML-based SaMD with “locked” algorithms.<sup>373</sup> “Locked” algorithms do not change with use and provide the same outcome each time the same input data is supplied.<sup>374</sup> In cases where an algorithm changes, the AI/ML-based SaMD will likely need to undergo another premarket review.<sup>375</sup> However, the problem is that to fully realize their potential, AI/ML-based SaMD need to constantly learn and thus require frequent updates, many of which involve algorithm architecture changes and retraining with new data sets.<sup>376</sup> But since these updates will likely require another round of premarket review, they may not be carried out. The manufacturer, for example, could be a small start-up that simply cannot afford the costs of one or multiple new premarket submissions.<sup>377</sup> Further, it may well be that a company refrains from carrying out necessary updates to not send the wrong message about the AI/ML’s current quality.<sup>378</sup> It could also be that the manufacturer wants to avoid the significant efforts and time involved in preparing a new submission, and thus decides to perform fewer updates than needed or, worse, no updates at all.

Consequently, this “update problem” raises new regulatory challenges for the FDA. An AI/ML-based SaMD that is not frequently updated may pose significant risks to patients. For example, imagine the FDA permits marketing authorization of an AI/ML-based SaMD that analyzes photos taken by the physician of a patient’s skin and assesses the risk for certain types of skin cancer, such as melanoma. In the U.S., skin cancer is the most common cancer, and early diagnosis

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<sup>373</sup> U.S. FOOD & DRUG ADMIN., *supra* note 19, at 3.

<sup>374</sup> *Id.* For locked algorithms, see *supra* Part I.

<sup>375</sup> U.S. FOOD & DRUG ADMIN., *supra* note 19, at 3, 6. For more information on when to submit a 510(k) for software changes to existing devices, see U.S. FOOD & DRUG ADMIN., DECIDING WHEN TO SUBMIT A 510(K) FOR A SOFTWARE CHANGE TO AN EXISTING DEVICE: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 16 (2017), <https://www.fda.gov/media/99785/download>.

<sup>376</sup> U.S. FOOD & DRUG ADMIN., *supra* note 19, at 6.

<sup>377</sup> Babic et al., *supra* note 25, at 1202.

<sup>378</sup> *Id.*

may be essential to avoid death.<sup>379</sup> However, suppose this AI/ML-based SaMD was trained mainly on images of white skin. Thus, this device will likely have high false-positive and false-negative results when used on patients with darker skin. For example, inflammation often appears pink or red on white skin, while it is violaceous or brown on black skin,<sup>380</sup> and there are many more differences related to skin color. In addition, although melanoma, the most serious skin cancer type, is rare in African American people, it is associated with a worse prognosis than in Caucasian people.<sup>381</sup> Thus, if melanoma goes undetected, for example, it can cost lives that could have been saved. However, if the illustrative AI/ML-based SaMD is used more frequently on patients with darker skin and more data are collected, the device can improve its clinical performance and make a more accurate diagnosis if updated. Of course, for an AI/ML-based SaMD like the one in this hypothetical example, the FDA should ensure that it does not receive marketing authorization in the first place and demand training of the algorithm on diverse data sets, including African American patients, to mitigate such bias. Regulators like the FDA could require AI/ML developers to sufficiently diversify training data in order to mitigate biases and ensure that AI/ML-based medical devices are reasonably safe and effective across various subpopulations.<sup>382</sup> However, even then, there is always a chance that a relevant subpopulation is unknown at the time of marketing authorization.<sup>383</sup> Thus, AI/ML-based SaMD with adaptive algorithms that continuously learn and adapt to new conditions could “unlock” the full potential of health AI and enable precision medicine.<sup>384</sup>

As a result, it is important that regulators like the FDA develop a regulatory

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379 3Derm Systems, Inc., *3Derm Announces Two FDA Breakthrough Device Designations for Autonomous Skin Cancer AI*, PR NEWSWIRE (Jan. 7, 2020), <https://www.prnewswire.com/news-releases/3derm-announces-two-fda-breakthrough-device-designations-for-autonomous-skin-cancer-ai-300982072.html>.

380 Art Papier, *To Begin Addressing Racial Bias in Medicine, Start With the Skin*, STAT (July 20, 2020), <https://www.statnews.com/2020/07/20/to-begin-addressing-racial-bias-in-medicine-start-with-the-skin>.

381 Krishnaraj Mahendraraj et al., *Malignant Melanoma in African-Americans*, 96 MED. 1 (2019). For more information about melanoma, see *Melanoma*, MAYO CLINIC (Jan. 20, 2022), <https://www.mayoclinic.org/diseases-conditions/melanoma/symptoms-causes/syc-20374884>.

382 See, e.g., Ross, *supra* note 1 (criticizing a lack of transparency in the current FDA approach that also seems to be inconsistent); Casey Ross, *Could AI Tools for Breast Cancer Worsen Disparities? Patchy Public Data in FDA Filings Fuel Concern*, STAT (Feb. 11, 2021), <https://www.statnews.com/2021/02/11/breast-cancer-disparities-artificial-intelligence-fda>.

383 Babic et al., *supra* note 25, at 1202 (providing an example on HIV vaccine studies, where a relevant subpopulation—uncircumcised men who had high titers of preexisting antibodies against Ad5 and who both had sex with men—were unknown *ex ante*). For more information on immune activation with HIV vaccines, see Anthony S. Fauci et al., *Immune Activation with HIV Vaccines*, 344 SCI. 49 (2014).

384 See *supra* Part I for adaptive algorithms.

framework that promotes innovation and updates of AI/ML-based SaMD, while ensuring that the devices remain safe and effective throughout their life cycle.

## 2. *The FDA's TPLC Approach and Action Plan*

To its credit, the FDA has already spent a considerable amount of time thinking about how to address the update problem. In April 2019, the FDA released a discussion paper in which the agency proposed a regulatory framework for modifications to AI/ML-based SaMD (“discussion paper”).<sup>385</sup> As envisioned in its Software Pre-Cert Program, the FDA intends to apply a Total Product Lifecycle (TPLC) approach for AI/ML-based SaMD that would enable such devices to continuously learn and improve while providing adequate safeguards.<sup>386</sup> As discussed above, to fully implement the Pre-Cert TPLC approach, where particular companies would be “precertified,” the FDA would need to ask Congress for additional statutory authority.<sup>387</sup>

The TPLC approach for AI/ML-based SaMD suggested in the FDA’s discussion paper would apply exclusively to those AI/ML-based SaMD that are subject to premarket submission.<sup>388</sup> AI/ML-based SaMD that are Class I or Class II exempt are not within the scope of this suggested approach.<sup>389</sup> In particular, the TPLC approach would rely on a *predetermined change control plan* that manufacturers could optionally submit during the initial premarket review of their AI/ML-based SaMD.<sup>390</sup> This plan would include *SaMD Pre-Specifications* and an *Algorithm Change Protocol*.<sup>391</sup> SaMD Pre-Specifications delineate the types of anticipated modifications.<sup>392</sup> The Algorithm Change Protocol is the associated methodology that the manufacturer has in place to implement those modifications and to control their risks to patients.<sup>393</sup>

The FDA divides the types of anticipated modifications into three broad categories:

- (1) performance,
- (2) inputs, and

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385 U.S. FOOD & DRUG ADMIN., *supra* note 19.

386 *Id.* at 3, 4; for the Pre-Cert Program, *see supra* Section III.C.

387 *See supra* Section III.C.

388 U.S. FOOD & DRUG ADMIN., *supra* note 19, at 8.

389 *Id.*

390 *Id.* at 10.

391 *Id.*

392 *Id.*

393 *Id.*

(3) intended use.<sup>394</sup>

The first category includes modifications that improve clinical and analytical performance, such as an increased sensitivity of the AI/ML-based SaMD at detecting breast cancer.<sup>395</sup> The second category is modifications that change the inputs used by the algorithm, such as adding different input data types.<sup>396</sup> For the third category, the FDA leverages the IMDRF framework for risk categorization of SaMD.<sup>397</sup> It includes those types of modifications that result in a change in the:

- state of the health care situation or condition (e.g., expanding the intended patient population to include children), and such modifications are explicitly claimed by the manufacturer; or
- intended condition or disease (e.g., expanding the use of an AI/ML-based SaMD to detect a second type of cancer); or
- significance of the information provided by the SaMD (e.g., a change from “drive clinical management” to “treat or diagnose”).<sup>398</sup>

According to the FDA’s proposal in its discussion paper, a manufacturer of an AI/ML-based SaMD could submit a predetermined change control plan for many scenarios.<sup>399</sup> However, the FDA considers SaMD Pre-Specifications and Algorithm Change Protocols inappropriate in cases where the AI/ML-based SaMD’s intended use or risk may significantly change.<sup>400</sup> An example would be a change from a “non-serious” to a “critical” health care situation or condition, such as an AI/ML-based SaMD that initially uses skin images to manage scar healing and is updated to diagnose melanoma.<sup>401</sup>

In its discussion paper, the FDA also highlights that the TPLC approach can only fully be adopted by enabling real-world performance monitoring of AI/ML-

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394 *Id.* at 6.

395 *Id.*

396 *Id.* at 7.

397 For more information on the IMDRF framework for risk categorization of SaMD, see *supra* Section II.B.3.

398 See U.S. FOOD & DRUG ADMIN., *supra* note 19, at 7. For SaMD risk categories developed by the IMDRF, see *supra* Figure 2.

399 U.S. FOOD & DRUG ADMIN., *supra* note 19, at 7.

400 *Id.*

401 *Id.* For SaMD risk categories developed by the IMDRF, see *supra* Figure 2.

based SaMD and increased user transparency.<sup>402</sup> Manufacturers would be expected to commit to both of these principles.<sup>403</sup> For example, they would need to provide periodic reporting to the FDA on updates that were carried out based on the predetermined change control plan.<sup>404</sup> However, there are still numerous questions unanswered, such as: How much data would have to be provided? How can manufacturers demonstrate transparency about performance improvement, labeling changes, or algorithm updates of AI/ML-based SaMD?<sup>405</sup>

Many details of the FDA's proposed regulatory framework in its discussion paper still need to be figured out.<sup>406</sup> In January 2021, the newly launched FDA's Digital Health Center of Excellence issued an Action Plan for AI/ML-Based SaMD.<sup>407</sup> This Action Plan is a response to stakeholder feedback to the discussion paper and outlines five actions the FDA aims to take:

- (1) Updating the FDA's proposed regulatory framework laid out in its discussion paper, including publishing draft guidance on the predetermined change control plan.
- (2) Encouraging the development of Good Machine Learning Practice.
- (3) Supporting a patient-centered approach by holding, for example, a public workshop on AI/ML-based medical device labeling to promote transparency to users.
- (4) Fostering efforts on the development of methods to assess and improve machine learning algorithms, including to identify and eliminate bias.
- (5) Advancing real-world performance pilots together with stakeholders.<sup>408</sup>

### 3. *The Need for Continuous Risk Monitoring*

The FDA's vision of relying on SaMD Pre-Specifications and Algorithm Change Protocols in many scenarios is flawed because manufacturers often do not know at the time of the initial premarket review what updates will be required in

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402 U.S. FOOD & DRUG ADMIN., *supra* note 19, at 14.

403 *Id.*

404 *Id.*

405 *Id.* at 15.

406 *Id.* at 4.

407 U.S. FOOD & DRUG ADMIN., *supra* note 264.

408 *See id.* at 7.

the future.<sup>409</sup> Only after the marketing authorization and use of the AI/ML-based SaMD in clinical practice do many necessary updates become apparent. Thus, it is especially important for the FDA to focus on continuous risk monitoring once the AI/ML-based SaMD is legally launched on the U.S. market.<sup>410</sup> The agency needs to look out for new risks due to AI/ML features, such as covariate shift, concept drift, and instability.<sup>411</sup>

Covariate shift occurs when the data the algorithm was trained on before marketing authorization is different from the input distribution of new data.<sup>412</sup> For example, an AI/ML-based SaMD may be trained on data from a nursing home with only patients over sixty-five but shall now be deployed in a large municipal hospital with a diverse patient population.

Concept drift exists in cases where there is a change of the true relation between inputs and outputs.<sup>413</sup> Take an AI/ML-based SaMD, for example, that makes recommendations on breast cancer risk by analyzing the results of mammograms. Suppose the device does not track the patient's race. However, the breast density varies between Caucasian women and African American women, and African American women are also more likely to die from malignant tumors than are Caucasian women.<sup>414</sup> Thus, depending on the patient's race, the same image may result in two different probabilistic diagnoses.<sup>415</sup>

Instability describes a situation where an AI/ML-based SaMD does not treat similar patients similarly.<sup>416</sup> For example, an AI/ML-based SaMD that detects lung cancer and classifies medically similar lung lesions entirely differently is unstable.

For continuous monitoring of AI/ML-based SaMD, the FDA could, for example, leverage its national monitoring system Sentinel.<sup>417</sup> The FDA launched

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409 Babic et al., *supra* note 25, at 1203-04.

410 *See id.* at 1204.

411 *Id.* at 1203-04.

412 *Id.* at 1203. For more information on covariate shift, see, for example, Steffen Bickel et al., *Discriminative Learning for Differing Training and Test Distributions* (2007) (unpublished manuscript), <https://icml.cc/impls/conferences/2007/proceedings/papers/303.pdf>.

413 Babic et al., *supra* note 25, at 1203.

414 *Id.* at 1202; Amrita Khalid, *Google's AI for Mammograms Doesn't Account for Racial Differences*, QUARTZ (Jan. 9, 2020), <https://qz.com/1781123/googles-ai-for-mammograms-doesnt-account-for-race>. For statistics on breast cancer, see KAISER FAM. FOUND., COVERAGE OF BREAST CANCER SCREENING AND PREVENTION SERVICES (Sept. 26, 2019), <https://www.kff.org/womens-health-policy/fact-sheet/coverage-of-breast-cancer-screening-and-prevention-services>.

415 *See* Babic et al., *supra* note 25, at 1202-03. For more examples, see Boris Babic et al., *When Machine Learning Goes Off the Rails*, HARV. BUS. REV. (Jan.-Feb. 2021), <https://hbr.org/2021/01/when-machine-learning-goes-off-the-rails>.

416 Babic et al., *supra* note 22, at 1203-04.

417 *See* Babic et al., *supra* note 25, at 1204; I. Glenn Cohen et al., *The European Artificial Intelligence Strategy: Implications and Challenges for Digital Health*, 2 LANCET DIGIT. HEALTH

the Sentinel Initiative in response to Congress' mandate in the FDA Amendments Act of 2007<sup>418</sup> to develop novel ways to evaluate the safety of marketed medical products.<sup>419</sup> The FDA also announced in September 2019 that Sentinel will expand to three coordinating centers, one of which, the Sentinel Operations Center, is focusing, among other topics, on AI.<sup>420</sup>

In addition to using a national monitoring system and having an appropriate division of labor,<sup>421</sup> a continuous risk monitoring approach for AI/ML-based SaMD should consist of at least three other elements:

- (1) retesting,
- (2) simulated checks, and
- (3) adversarial stress tests.<sup>422</sup>

First, AI/ML-based SaMD should be continuously retested on all previous cases.<sup>423</sup> Second, AI/ML-based SaMD should be constantly used on “simulated patients” to assess whether their behavior is reliable with regard to an adequate diversity of patient types.<sup>424</sup> For example, previous patient data could be used to create “simulated patients.”<sup>425</sup> Third, one could perform algorithmic stress tests throughout the AI/ML-based SaMD's life cycle, borrowing from cybersecurity practices.<sup>426</sup> In particular, AI/ML is vulnerable to adversarial attacks, where a slight change—(almost) undetectable to the human eye—in how inputs are presented to the system alters its output, leading to an incorrect conclusion.<sup>427</sup> This is especially worrisome in cases where the AI/ML-based SaMD is intended to detect, for example, a type of cancer, such as skin cancer, and incorrectly classifies the mole with 100% confidence as malignant instead of benign.<sup>428</sup> Thus, it is

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e376, e377 (2020); *FDA's Sentinel Initiative*, U.S. FOOD & DRUG ADMIN. (Oct. 18, 2019), <https://www.fda.gov/safety/fdas-sentinel-initiative>.

418 Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823.

419 *FDA's Sentinel Initiative*, *supra* note 417; *see also* SENTINEL, <https://www.sentinelinitiative.org> (last visited Mar. 19, 2022) (providing an overview of Sentinel).

420 *FDA's Sentinel Initiative*, *supra* note 417.

421 Monitoring of AI/ML-based SaMD should be carried out by different actors than those developing such devices. *See* Babic et al., *supra* note 25, at 1204.

422 *See id.*

423 *Id.*

424 *Id.*

425 *Id.*

426 *Id.*

427 Samuel G. Finlayson, *Adversarial Attacks on Medical Machine Learning*, 363 SCI. 1287 (2019).

428 *Id.* at 1287-88.

essential that AI/ML-based SaMD rigorously undergo algorithmic stress tests throughout their entire life cycle.

As a result, a robust continuous risk monitoring approach, like the one suggested above, can help to ensure that AI/ML-based SaMD remain safe and effective throughout their life cycle. This approach also allows the FDA to quickly recall an AI/ML-based SaMD from the market if necessary.

## V. SYSTEM VIEW

It is essential that the FDA broadens its view and considers AI-based medical devices as systems, not *just* devices.<sup>429</sup> The agency should focus more on the environment in which AI-based medical devices are deployed. This system view is crucial to ensure that AI-based medical devices are reasonably safe and effective as well as benefit patients. In this Part, I carve out two components of the system view: (1) considering human-AI interaction and (2) improving patient outcomes.

### A. Considering Human-AI Interaction

Generally, when AI-based medical devices enter medical practice, they will interact with humans to varying degrees (from little to collaboratively). Thus, it is essential that regulators like the FDA broaden their view and systematically consider the interaction between the human and the AI. The system view is especially relevant for AI-based medical devices because their performance in the actual practice setting is less predictable than that of traditional medical devices, such as crutches or contact lenses.<sup>430</sup> AI-based medical devices can be biased, opaque, and/or adaptive. Human factors and the interaction of these complex systems with the environment will likely increase variance between such medical devices' performance in simulated testing settings and real life.<sup>431</sup>

For example, imagine an AI-based medical device that is developed and used in a highly specialized clinic and makes sophisticated recommendations to specialist personnel in that clinic. The device shall now be deployed in another hospital in a rural area that is not as specialized as the clinic who developed it and has far fewer medical specialists. It may well be that the recommendations the AI makes are not feasible, useful, safe, and/or cost-effective for less specialized personnel in a rural hospital.<sup>432</sup> In other words, as Mildred Cho puts it: "Systems

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<sup>429</sup> Sara Gerke et al., *The Need for a System View to Regulate Artificial Intelligence/Machine Learning-Based Software as Medical Device*, 3 NPI DIGIT. MED., no. 53 (2020).

<sup>430</sup> *Id.* at 2.

<sup>431</sup> *Id.*

<sup>432</sup> Timo Minssen, Sara Gerke, Mateo Aboy, Nicholson Price & Glenn Cohen, *Regulatory Responses to Medical Machine Learning*, 7 J. L. & BIOSCI. 1, 17 (2020).

developed in one hospital often flop when deployed in a different facility.”<sup>433</sup> Thus, AI bears the risk of “contextual” bias.<sup>434</sup>

Although perhaps desirable, it will likely not be feasible to require licenses at the level of an individual clinic.<sup>435</sup> However, the FDA could at least require rigorous human factors testing for *all* AI-based medical devices that require premarket submission. This would include, for example, a demonstration that users can use the AI-based medical device correctly based merely on reading the labeling and that they can correctly interpret its output and understand that such devices bear the risks of false-positive and false-negative readings. If it is an AI-based home monitoring technology, which is used without (direct) supervision by a health care professional, human factors testing should also include that users do not over-rely on its output and comprehend when to seek medical care.<sup>436</sup> To its credit, the FDA required human factors testing for a few AI-based medical devices that received marketing authorization via the De Novo pathway, such as for IDx-DR and Apple’s irregular rhythm notification feature.<sup>437</sup> However, such testing should be standardized and required for all AI-based medical devices that are subject to premarket submission. It is also important that the testing be carried out in actual practice settings since the results will likely vary with the human involvement in decision-making.<sup>438</sup>

Another issue in the human-AI interaction is training and education. A good, although non-AI, example is the da Vinci surgical system. Da Vinci is a robot that helps surgeons to perform minimally invasive surgery. The surgeon uses a console, and the da Vinci system translates the surgeon’s hand movements.<sup>439</sup> The FDA first cleared the system in 2000, but since then, unfortunately, many patients have suffered severe complications, some of which even resulted in death.<sup>440</sup> One of the reasons for such complications was a lack of training of the surgeons with the device.<sup>441</sup>

Training and education, in particular, are crucial for all users of AI-based

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433 Szabo, *supra* note 366.

434 Nicholson Price, *Medical AI and Contextual Bias*, 33 HARV. J.L. & TECH. 66 (2019).

435 Gerke et al., *supra* note 429, at 3.

436 Gerke et al., *supra* note 3, at 1178.

437 U.S. FOOD & DRUG ADMIN., *supra* note 32; Letter from Angela C. Krueger to Donna-Bea Tillman, *supra* note 50.

438 Gerke et al., *supra* note 429, at 4.

439 *About Da Vinci Systems*, INTUITIVE (2022), <https://www.davincisurgery.com/da-vinci-systems/about-da-vinci-systems>.

440 Kristin Compton, *Da Vinci Surgical System*, DRUGWATCH (2021), <https://www.drugwatch.com/davinci-surgery>; see also Emily R. Siegel et al., *The Da Vinci Surgical Robot: A Medical Breakthrough With Risks for Patients*, NBC NEWS (Dec. 19, 2018), <https://www.nbcnews.com/health/health-news/da-vinci-surgical-robot-medical-break-through-risks-patients-n949341> (telling the story of Laurie Featherstone, an injured patient).

441 Siegel et al., *supra* note 440.

medical devices since their outcomes can vary considerably the more human involvement there is.<sup>442</sup> For example, in February 2020, the FDA permitted marketing of the first cardiac ultrasound (echocardiography) software, called Caption Guidance, via the De Novo pathway.<sup>443</sup> The software uses AI to help the user capture images of patients' hearts.<sup>444</sup> The peculiarity of the software is that it can be used by non-experts, such as nurses with only a few days of training.<sup>445</sup> Thus, since more AI-based medical devices, similar to IDx-DR and Caption Guidance, that can be used by non-experts are likely to enter the U.S. market in the near future, training and education of the users of such devices at regular intervals will be even more important. Hence, even if the FDA does not regulate the practice of medicine, the agency could more often demand that AI makers set up a training program with instructions on how to use the AI-based medical device, such as the agency did in the case of IDx-DR.<sup>446</sup> Alternatively or additionally, the FDA could more frequently require AI-makers to include a detailed description of the recommended user training in the labeling of the AI/ML-based medical device, as was the case, for example, for Caption Guidance.<sup>447</sup>

A research team at Duke University is also thinking about new ways of labeling health AIs, similar to “nutrition labels” that contain facts on the intended use of the system and how it should be used.<sup>448</sup> More initiatives such as the one at Duke are needed to better understand what content such labeling should include to promote user transparency and comprehension of the benefits, shortcomings, and risks of AI-based medical devices and to mitigate user errors. It is thus to be welcomed that the FDA has recently organized a public workshop on transparency of AI/ML-based medical devices, in which the topic of labeling was also discussed,

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442 Gerke et al., *supra* note 429, at 2.

443 Letter from Robert Ochs, Deputy Dir. Radiological Health, U.S. Food & Drug Admin. to Sam Surette, RA/QA Manager, Caption Health, Inc. (Feb. 7, 2020), [https://www.accessdata.fda.gov/cdrh\\_docs/pdf19/DEN190040.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190040.pdf); *FDA News Release: FDA Authorizes Marketing of First Cardiac Ultrasound Software That Uses Artificial Intelligence to Guide User*, U.S. FOOD & DRUG ADMIN. (Feb. 7, 2020), <https://www.fda.gov/news-events/press-announcements/fda-authorizes-marketing-first-cardiac-ultrasound-software-uses-artificial-intelligence-guide-user>.

444 *Id.*

445 *Id.*; Casey Ross, *AI Has Arrived in Medical Imaging. Now the FDA Needs to Monitor Its Impact on Patients*, STAT (Feb. 28, 2020), <https://www.statnews.com/2020/02/28/ai-medical-imaging-fda-monitor-impact-patients>.

446 U.S. FOOD & DRUG ADMIN., *supra* note 32, at 11; Gerke et al., *supra* note 429.

447 Letter from Robert Ochs to Sam Surette., *supra* note 443, at 3.

448 See Mark P. Sendak et al., *Presenting Machine Learning Model Information to Clinical End Users With Model Facts Labels*, 3 NPJ DIGIT. MED., no. 41 (2020); Erin Brodwin, *With 'Nutrition Labels' and an Anthropologist's Eye, Duke Pioneers a New Approach to AI in Medicine*, STAT (Oct. 5, 2020), <https://www.statnews.com/2020/10/05/duke-artificial-intelligence-hospital-medicine>.

to gather input from stakeholders.<sup>449</sup>

Another example to see the challenges of the interaction between the human and the AI is mortality prediction models. As I have established and argued above,<sup>450</sup> it is highly unclear whether AI-based mortality prediction models are medical devices under current law, but they should be. Imagine that the model predicts the patient will die in the next 12 months. However, the patient's physician did not foresee this. What should the physician do? Should the physician rely on the AI or ignore its prediction? Should the physician start an end-of-life discussion with the patient? Should the physician tell the patient about the AI? Imagine that the physician decides to talk to the patient about the possibility of death in the next 12 months but does not mention the AI. Is this the right choice? What happens if the AI turns out to be wrong and the physician stops (instead of continues) the patient's treatment?

These are tricky questions that have not received enough attention, even though many hospitals are already using these systems on real patients.<sup>451</sup> Suppose a health AI-based product is intended to be used in critical, sensitive situations, such as predicting a patient's death. In that case, it is essential that society starts a discussion about transparency and whether the patient has a right to know that an AI was involved and may have influenced the physician's decision to stop or continue treatment. The interaction between the human and the AI is crucial for a successful outcome. The hospitals that deploy such AIs should develop best practice guidance on how to use these tools. Even if the FDA does not regulate the practice of medicine, there is still something the agency can do. First, as argued above,<sup>452</sup> the FDA could ask Congress to amend the FDCA and clearly classify AI-based mortality prediction models as medical devices and ensure that they are reasonably safe and effective when launched on the U.S. market and used to make such sensitive predictions. Second, once AI-based mortality prediction models are clearly classified as medical devices, the FDA could then demand that AI makers set up a training program with instructions on how to use the device and/or require them to include a detailed description of the recommended user training in the labeling of the device. Third, the FDA may also consider requiring—similar to the case of emergency use authorizations for medical devices<sup>453</sup>—AI makers to

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449 *Virtual Public Workshop - Transparency of Artificial Intelligence/Machine Learning-Enabled Medical Devices*, U.S. FOOD & DRUG ADMIN. (Oct. 14, 2021), <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-public-workshop-transparency-artificial-intelligence-machine-learning-enabled-medical-devices>.

450 See *supra* Section II.B.3 and Section II.B.4.

451 See, e.g., Robbins, *supra* note 145; Rebecca Robbins & Erin Brodwin, *An Invisible Hand: Patients Aren't Being Told About the AI Systems Advising Their Care*, STAT (July 15, 2020), <https://www.statnews.com/2020/07/15/artificial-intelligence-patient-consent-hospitals>.

452 See *supra* Section II.B.4.

453 Gerke et al., *supra* note 3, at 1179.

develop fact sheets for health professionals and patients (the latter written in plain language) that help them to better understand the device, such as its intended use, its benefits, and its risks. In the fact sheet for health professionals, the manufacturer could also include practical information on how best to handle the situation and predictions by the AI.

In general, a discussion with all stakeholders in the field should begin with the question of whether patients (should) have a right to know about the involvement of an AI-based prediction model. Some hospitals are currently using those systems without telling their patients.<sup>454</sup> Is that morally justifiable? Instead of hiding new AI-based products behind the scenes, is it not better to be frank upfront and promote trust in the doctor-patient relationship? I. Glenn Cohen has recently written about informed consent and medical AI, arguing that “the existing legal doctrine of informed consent does not robustly support an obligation to disclose the use of medical AI/ML,” with some exceptions, such as when the patient explicitly asked for the basis of the decision making and is misinformed by the physician.<sup>455</sup> Cohen mentioned in an interview that trust in the health care system and AI could be undercut if patients “were to find out, after the fact, that there’s a rash of this being used without anyone ever telling them.”<sup>456</sup> Thus, this discussion about the human-AI interaction is crucial and needs to happen now among stakeholders, including patients. As can be seen, many open questions have yet to be answered regarding the human-AI interaction, but the system view can help regulators like the FDA and stakeholders see these issues and address them.

### B. *Improving Patient Outcomes*

The second lesson the system view gives us is that AI-based medical devices do not only need to be safe but should also improve patient outcomes. This is a crucial point, but it has, unfortunately, been neglected so far. As the chess player, Garry Kasparov, correctly pointed out: “Weak human + machine + better process was superior to a strong computer alone and, more remarkably, superior to a strong human + machine + inferior process.”<sup>457</sup> Thus, the decisive point is the “process,” and if one does not know more about the process of the AI-based medical device, one does not know whether it will improve outcomes.<sup>458</sup> Kasparov teaches us that

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454 Robbins, *supra* note 145. Empathy may also play an important role here. See Nicolas Terry, *Appification, AI, and Healthcare’s New Iron Triangle*, 20 J. HEALTH CARE L. & POL’Y 117, 159–67 (2018).

455 Cohen, *supra* note 7, at 1467 (2020).

456 Robbins & Brodwin, *supra* note 451.

457 GARRY KASPAROV, *DEEP THINKING: WHERE MACHINE INTELLIGENCE ENDS AND HUMAN CREATIVITY BEGINS* 214 (2017).

458 Gerke et al., *supra* note 429, at 2.

even if one has an accurate health AI—which is itself challenging to achieve—human factors and the environment in which the product will be deployed need to be considered to ensure that the health AI actually benefits patients.

It seems that so far, however, most AI-based medical devices have not been shown to improve patient outcomes. For example, it is unclear whether IDx-DR, which has already been used in clinical care at over twenty sites across the U.S., improves patient outcomes.<sup>459</sup> To its credit, the company is currently carrying out several studies to examine whether diabetic patients who receive a positive result of more than a mild level of diabetic retinopathy are going to the ophthalmologist and receiving care.<sup>460</sup> The company has also recently launched a care coordination model that will ensure that patients with a positive result receive follow-up care.<sup>461</sup> These are laudable actions, but a rare exception in the field. Thus, the FDA could step in and require, for example, comparative studies for AI-based medical devices where appropriate that demonstrate better outcomes with versus without the device. The FDA could either demand them as a premarket or postmarket requirement, depending on whether the AI-based medical device is urgently needed on the market. Again, the challenge faced by regulators will be to properly balance the different stakeholder interests. The optimal way would be facilitating innovation while simultaneously ensuring that the U.S. market will not be flooded with useless products that do not improve patient outcomes and are also not otherwise valuable, such as products that do not even reduce the labor burden on physicians.

Another example is mobile health apps. There are over 400,000 mobile health apps on the market, but little data on whether or not they actually benefit patients.<sup>462</sup> Most of them, as discussed earlier,<sup>463</sup> are not classified as medical devices and are not FDA reviewed. However, even the ones that are considered to be medical devices have not necessarily been shown to do more good than harm. Take, for example, Apple's irregular rhythm notification feature that is intended to notify the user of possible AFib.<sup>464</sup> Most users of the Apple Watch are young and healthy people who usually are not considered at risk for suffering AFib.<sup>465</sup> Around

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459 Carfagno, *supra* note 35.

460 *Id.*

461 *Id.*

462 See Stephan Fihn et al., *Deploying AI in Clinical Settings*, in *ARTIFICIAL INTELLIGENCE IN HEALTH CARE: THE HOPE, THE HYPE, THE PROMISE, THE PERIL* 151, 152 (Michael Matheny et al. eds., 1st ed. 2019); Michael Georgiou, *Developing a Healthcare App in 2022: What do Patients Really Want?*, *IMAGINATION* (Dec. 15, 2021), <https://www.imagination.net/blog/developing-a-mobile-health-app-what-patients-really-want>.

463 See *supra* Section II.B.1.

464 For more information on the app, see *supra* Section I.B.

465 Casey Ross, *COVID-19 Apps and Wearables Are Everywhere. Can They Actually Benefit Patients?*, *STAT* (Aug. 4, 2020), <https://www.statnews.com/2020/08/04/covid19-wearables-apps-patient-care>.

70% of individuals with Afib are between 65 and 85 years old.<sup>466</sup> In addition, diagnostic tools can always have false-positive and false-negative results. This may perhaps also be the reason why Apple narrowed the app's indications for use: the app is explicitly "not intended to provide a notification on every episode of irregular rhythm suggestive of Afib" and "is not intended to replace traditional methods of diagnosis or treatment."<sup>467</sup> Still, it is likely that many users do not know that Apple's app is not for diagnosis and therefore the irregular rhythm notification feature gives them a false sense of security. For example, they may think that they are healthy and skip a necessary doctor's appointment because they do not receive alarming notifications from the app. Thus, more user transparency of the indications of use for health apps is needed. Moreover, younger people may also be confronted with a false notification suggestive of Afib and may suffer a shock that can develop further into real psychological or physical harm. In addition, individuals with false notifications may likely sit in the waiting rooms of cardiologists and use unnecessary resources of an already overburdened health care system.<sup>468</sup> In contrast, the ones who would likely benefit most from Apple's app, namely the elderly, are less likely to use the Apple Watch.<sup>469</sup> Thus, it is also essential to make sure that all population groups, particularly the vulnerable ones such as the elderly, benefit from health AI-based products.<sup>470</sup> Furthermore, users who received a notification by using Apple's app and are diagnosed with brief Afib by their cardiologist will likely receive blood-thinning medications as a result. However, one does not know yet whether patients will actually benefit from such medications—or suffer from bleeding risk—and thus whether they would have been better off not to have been diagnosed with brief Afib in the first place.<sup>471</sup> Some people may certainly benefit from Apple's app who would have otherwise perhaps suffered a stroke, but some may not.<sup>472</sup> Thus, regulators like the FDA should apply the system view to not only promote user transparency but also

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466 Peter M. Kistler et al., *Electrophysiologic and Electroanatomic Changes in the Human Atrium Associated With Age*, 44 J. AM. COLL. CARDIOLOGY 109, 109 (2004).

467 See Letter from Angela C. Krueger to Donna-Bea Tillman, *supra* note 50.

468 Heather Landi, *With Apple's Launch of an ECG Device, Digital Health Leaders, Cardiologists See Possibilities, and Limitations*, HEALTHCARE INNOVATION (Sept. 18, 2018), <https://www.hcinnovationgroup.com/interoperability-hic/article/13030721/with-apples-launch-of-an-ecg-device-digital-health-leaders-cardiologists-see-possibilities-and-limitations>.

469 See, e.g., Mikey Campbell, *Apple Watch, Other Wearables Increasingly Used to Manage Chronic Health Conditions, Study Says*, APPLEINSIDER (Aug. 30, 2018), <https://appleinsider.com/articles/18/08/30/apple-watch-other-wearables-increasingly-used-to-manage-chronic-health-conditions-study-says>.

470 For more information on promoting health equity and AI, see Nicolas Terry, *Of Regulating Healthcare AI and Robots*, 21 YALE J.L. & TECH. 133, 186–89 (2019).

471 Landi, *supra* note 468.

472 *Id.*

require comparative studies for AI-based medical devices where appropriate to ensure that patients actually benefit from these devices.

### CONCLUSION

AI, especially its subset ML, has tremendous potential to improve health care. However, health AI also raises new regulatory challenges. In particular, a new regulatory framework for AI-based medical devices is needed to ensure that such devices are reasonably safe and effective when placed on the market and will remain so throughout their life cycle. Suppose the FDA does not “tame the demon,” as Elon Musk would say. In that case, the agency would not have realized the great potential of health AI and patient safety would be jeopardized. Moreover, disparities in health care would likely be exacerbated instead of reduced, presumably to the detriment of vulnerable populations such as racial and ethnic minorities, the economically disadvantaged, the elderly, or people with disabilities.

In this Article, I have especially tried to unpack the complex network of relevant provisions in the FDCA and (draft) guidance documents related to AI-based medical devices. I have shown that the FDA is not yet ready for health AI and that there are significant safety and effectiveness concerns associated with the current regulatory framework. I have advocated for FDA and congressional actions, and I have focused on how the FDA could, with additional statutory authority, regulate AI-based medical devices. What follows are my central claims.

First, the current medical device definition, FDCA section 201(h)(1),<sup>473</sup> is too narrow for health AI. Congress should consider amending the definition to include all CDS, AI-based mortality prediction models, and other models that are intended for use in the prediction or prognosis of disease or other conditions. This suggestion also requires that FDCA section 520(o)(1)(E)<sup>474</sup> is deleted and that FDCA section 520(o)(1)(B)<sup>475</sup> is amended accordingly to reflect the new medical device definition. The FDA should also remain free to exercise its enforcement discretion over lower risk device software functions or lower risk software functions that may meet the medical device definition.

Second, the 510(k) pathway may not be sufficient to identify safety and effectiveness concerns of medical devices. The FDA’s reforms to address these issues are welcome. However, the new Safety and Performance Based Pathway will likely not be applicable to AI-based medical devices in the near future and is only intended as a voluntary pathway. The Traditional, Special, or Abbreviated 510(k) pathways thus continue to be available to manufacturers. Consequently, I propose a new regulatory framework for premarket review of medical devices,

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473 FDCA § 201(h)(1), 21 U.S.C. § 321(h)(1).

474 FDCA § 520(o)(1)(E), 21 U.S.C. § 360j(o)(1)(E).

475 FDCA § 520(o)(1)(B), 21 U.S.C. § 360j(o)(1)(B).

including AI-based medical devices, that would better ensure that medical devices are reasonably safe and effective when placed on the U.S. market. In particular, I argue that the new Safety and Performance Based Pathway—if found to be effective—should replace the Traditional, Special, and Abbreviated 510(k) pathways and become the only available 510(k) pathway. In addition, the De Novo Pathway should be modified to also cover those low to moderate risk medical devices that have a predicate but would not be applicable for the new Safety and Performance Based Pathway. Further, the FDA’s envisioned Software Pre-Cert Program raises its own regulatory challenges. If the FDA establishes the Software Pre-Cert Program’s specific details, the Pilot proves to be effective, and the agency has statutory authority, the FDA could either implement the Software Pre-Cert Program similarly to the Pre-Cert Pilot Program or entirely separate from the traditional premarket pathways with its own conditions.

Third, the FDA should demand that AI/ML makers use an interpretable AI/ML model if such a model performs better than or as well as the black-box model for its intended use. If the black-box model performs better, the FDA should generally permit its marketing to facilitate innovation, as long as there is sufficient proof that it is safe and effective. A focus on explainable AI/ML is deceptive because the explanations provided are only *ex post* approximations of the black-box algorithms’ decisions instead of the actual reasons for them. The FDA should, where feasible, require clinical trials at least for those AI/ML-based medical devices that have a higher risk level. The FDA could leverage the IMDRF framework for risk categorization of SaMD to determine cases where clinical trials are needed. However, in cases where AI/ML-based medical devices are intended to be used to allocate scarce resources, such as ventilators or organs, the FDA should insist on the use of interpretable AI/ML systems.

Fourth, AI/ML-based medical devices can only fully realize their potential if they continuously learn and adapt to novel situations. To address the update problem, the FDA needs to focus on continuous risk monitoring and implement a monitoring system, such as Sentinel, to continuously monitor AI/ML-based SaMD.

Fifth, the FDA should broaden its view and consider AI-based medical devices not just as devices but as systems. In particular, the FDA could require rigorous human factors testing for all AI-based medical devices that require premarket submission to demonstrate that users can read the labeling and use them correctly. The agency could also more often require the AI maker to set up a training program with instructions on how to use the AI-based medical device and/or to include a detailed description of the recommended user training in the device labeling. In addition, more emphasis should be placed on the AI-based medical devices’ ability to improve patient outcomes, not only be safe. This could

be demonstrated by comparative studies that the agency could demand, where appropriate, either as a premarket or postmarket requirement, depending on whether the AI-based medical device in question is urgently needed on the U.S. market.

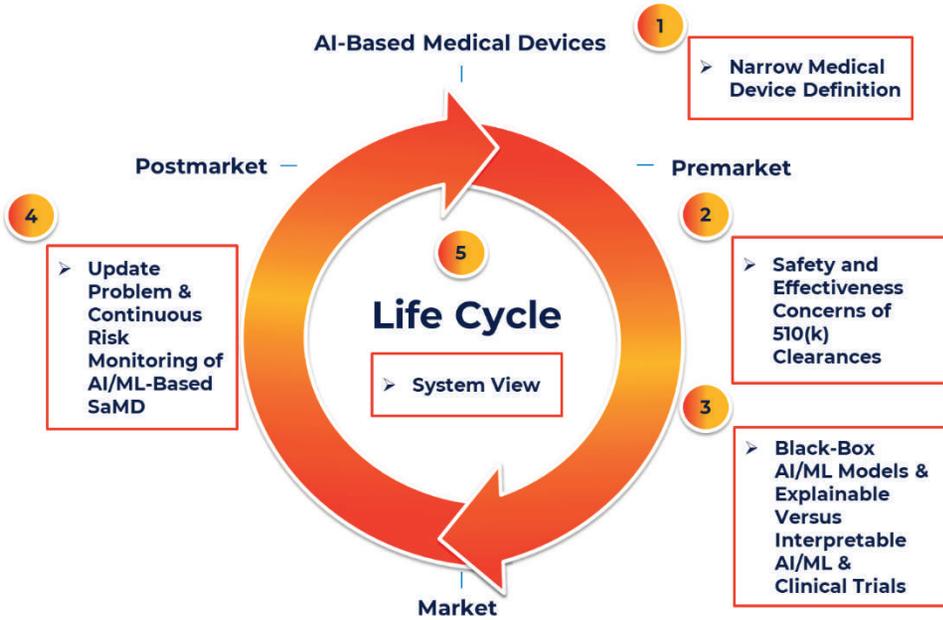


Figure 6: Overview of the Central Claims

Points 1-5 show the central claims. They are arranged in the life cycle of AI-based medical devices — i.e., from premarket to postmarket.

Finally, I conclude that much more work and thinking is required to deliver the full potential of health AI and ensure that such products are reasonably safe and effective. Since the law often lags behind technological advances, it is likewise important that manufacturers design their health AI-based products ethically—irrespective of whether they are classified as medical devices and are subject to FDA regulation. This would, among other things, require AI companies to diversify training data to mitigate biases and ensure that AI-based products are reasonably safe and effective across various subpopulations and remain so throughout their life cycle. Lastly, national, and even international, ethical guidelines for health AI-based products should be developed to establish minimum ethical standards for the design process of such products.

# **Paid Donation: Reconciling Altruism and Compensation in Oocyte Transfer**

**Saylor S. Soinski\***

Abstract:

In the United States, legislation, case law, and professional guidelines have not kept pace with the rapid proliferation of oocyte transfer—commonly known as “egg donation.” As a result, private agencies have disproportionately shaped the oocyte market. Although the market structure has negative consequences for oocyte providers, prohibiting or limiting compensation will not resolve the potential for exploitation. Oocyte transfer has generally relied on altruistic rhetoric, mobilizing the language of “donation” and painting oocytes as freely given gifts. The focus on altruism is gendered, colored by expectations of ideal womanhood and motherhood, and requires oocyte providers to subordinate their own needs. This Comment proposes a federal regulatory framework that would expand existing FDA and CDC programs to affirm the multiple motivations of oocyte providers and establish uniform safeguards.

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## INTRODUCTION

In the United States, assisted reproductive technology (ART) has developed rapidly, leading to and following from new understandings of fertility, bodies, and families. The expansion of ART has also encouraged consideration of how reproductive-technology markets may protect or threaten individual liberty.<sup>1</sup> Oocyte transfer, in which immature ova are extracted from one person and implanted into another, is especially relevant to this theme; the implications of a free-market approach have been the focus of most legislation and litigation to date.<sup>2</sup> These implications are increasingly important as the practice becomes more prevalent. The annual number of oocyte-transfer cycles increased from 10,801 in 2000 to 18,306 in 2010.<sup>3</sup> In 2016, the most recent year for which data was available, there were 24,300 oocyte-transfer cycles in the United States.<sup>4</sup> Nonetheless, there is still little consensus on whether and how oocyte providers should be compensated.

Federal statutes on the topic are nonexistent, and compensation for oocytes is unregulated in nearly every state.<sup>5</sup> There is a similar dearth of case law; the one

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1 Mary Lyndon Shanley, *Collaboration and Commodification in Assisted Procreation: Reflections on an Open Market and Anonymous Donation in Human Sperm and Eggs*, 36 LAW & SOC'Y REV. 257, 258 (2002) (writing that “[t]he way in which we think about and justify [ART] engages important themes of liberal political theory,” including “the extent to which a free market may protect or undercut individual liberty”).

2 Although oocyte and sperm transfer both involve reproductive materials, their symmetry is merely superficial. Radhika Rao, *Coercion, Commercialization, and Commodification: The Ethics of Compensation for Egg Donors in Stem Cell Research*, 21 BERKELEY TECH. L.J. 1055, 1063 (2006). Oocyte transfer is much more invasive, and the potential health risks are far more serious due to hormone treatments given to providers and the surgical nature of oocyte extraction. *Id.* Further, the price of sperm and ova differs by as many as three orders of magnitude, with sperm valued between \$50 and \$100 and oocytes valued as highly as \$150,000. *Id.* Finally, oocyte transfer is distinct from sperm transfer because of the cultural implications of motherhood and the impact of gender on regulation of reproductive materials. Shanley, *supra* note 1, at 265. Due to the meaningful differences between oocyte and sperm transfer as it relates to invasiveness, risk, compensation, and cultural context, this Comment will only discuss oocyte transfer.

3 Jennifer F. Kawwass et al., *Trends and Outcomes for Donor Oocyte Cycles in the United States, 2000-2010*, 310 JAMA 2426, 2428 (2013).

4 Diane Tober et al., *Alignment Between Expectations and Experiences of Egg Donors: What Does It Mean to be Informed?*, 12 REPROD. BIOMEDICINE & SOC'Y ONLINE 1, 2 (2021).

5 See Nancy J. Kenney & Michelle L. McGowan, *Egg Donation Compensation: Ethical and Legal Challenges*, 4 MEDICOLEGAL & BIOETHICS 15, 19 (2014); Kitty L. Cone, *Eggs for Sale: The Scrambled State of Legislation in the Human Egg Market*, 35 U. ARK. LITTLE ROCK L. REV. 189, 192 (2012). There are two exceptions: Louisiana and Florida. Louisiana prohibits compensation for oocytes in no uncertain terms. LA. STAT. ANN. § 9:122 (West 2021) (“The sale of a human ovum, fertilized human ovum, or human embryo is expressly prohibited.”). In contrast, Florida permits “[o]nly reasonable compensation directly related to the donation of eggs.” FLA. STAT. ANN. § 742.14 (West 2021).

significant case addressing compensation for oocyte transfer settled out of court.<sup>6</sup> While a handful of nongovernmental organizations have promulgated guidelines limiting compensation, these organizations lack any enforcement power and have been largely ignored by fertility clinics.<sup>7</sup> As a result, private agencies dominate the industry, resulting in the rise of unethical practices including the recruitment of underage providers and varied compensation based on race or ethnicity.<sup>8</sup>

Despite the fact that oocyte providers are paid anywhere from \$1,500 to \$150,000 per cycle;<sup>9</sup> the centrality of compensation in legislation and litigation; and the mixed motivations reported by oocyte providers,<sup>10</sup> oocyte transfer is typically referred to as “egg donation.” Further, parties to oocyte transfer tend to identify altruism as the primary motivation for oocyte providers.<sup>11</sup> The prioritization of altruism demonstrates a lingering resistance to the very idea of an oocyte market in which reproductive materials are exchanged for money. This resistance is amplified by gendered stereotypes of women as selfless providers of reproductive labor.<sup>12</sup> Centering altruism and failing to address oocyte providers’ interest in compensation harms providers by constraining their ability to advocate for their own medical care and communicate truthfully about their motivations.<sup>13</sup>

In order to allow oocyte providers to disclose altruistic and financial motivations while accounting for the real risks of inappropriate compensation, this Comment proposes that the federal government implement a regulatory scheme creating consistent national standards and protections for oocyte providers. In

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6 *Kamakahi v. Am. Soc’y for Reprod. Med. & Soc’y for Assisted Reprod. Tech.*, 11-cv-01781-JCS (N.D. Cal. 2015).

7 See *infra* Section I.B.3.

8 See *infra* Section I.B.4.

9 Kimberly D. Krawiec, *Sunny Samaritans and Egomaniacs: Price-Fixing in the Gamete Market*, 72 *LAW & CONTEMP. PROBS.* 59, 66 (2009).

10 Anna Curtis, *Giving ‘Til It Hurts: Egg Donation and the Costs of Altruism*, 22 *FEMINIST FORMATIONS* 80, 95 (2010).

11 Kenney & McGowan, *supra* note 5, at 18.

12 Rene Almeling, *Selling Genes, Selling Gender: Egg Agencies, Sperm Banks, and the Medical Market in Genetic Material*, 72 *AM. SOCIO. REV.* 319, 319 (2007) (reporting that results of interview and observational data from egg agencies and sperm banks show “gendered norms inspire more altruistic rhetoric in egg donation than in sperm donation, producing different regimes of bodily commodification for women and men”). Discussions of reproductive technologies necessarily complicate the distinction between sex, defined as a biological category, and gender, defined by personal identity and sociocultural roles. *Id.* at 321. While this distinction is critical to fully account for a wide range of gender identities and avoid biological essentialization, discussions of human reproduction must refer to sexed bodies and attend to biological factors. RENE ALMELING, *SEX CELLS: THE MEDICAL MARKET FOR EGGS AND SPERM* 174 (2011). This is especially the case when attempting to analyze how cultural constructions of gender influence markets for reproductive materials. While people of different genders may provide oocytes, I will focus on oocyte providers who identify as women in order to analyze the relationship between sociocultural constructions of womanhood and the female-coded body.

13 See *infra* Section II.C.

addition, consistency across states would validate families created using ART and recognize the labor of oocyte providers. The federal government already has the authority to regulate oocyte transfer under the Food and Drug Administration (FDA), and the Center for Disease Prevention and Control (CDC) collects data from all fertility clinics in the United States.<sup>14</sup> Thus, an expansion of systems already in place would allow federal actors to enable participatory policymaking and design regulations that would maintain oocyte supply, improve the wellbeing of oocyte providers, and destigmatize compensated oocyte transfer.

This Comment argues against a system that envisions altruism and compensation as a binary, instead proposing a federal regulatory scheme that would allow parties to center altruism while reducing the potential for exploitation through social norms or compensation. Part I details the current system of oocyte transfer in the United States, unpacking the network of key participants and illuminating how a lack of meaningful regulation has allowed private actors to disproportionately shape the oocyte market. Part II argues that the current motivations for oocyte-transfer regulation are inadequate due to parties' reliance on gendered altruistic rhetoric, then explores the advantages and disadvantages of both altruistic rhetoric and compensation. Part III proposes a structure for federal regulation of the oocyte market that considers both altruism and compensation as legitimate motivations in order to promote the safety and autonomy of oocyte providers.

## I. CURRENT STATE OF OOCYTE TRANSFER

As oocyte transfer becomes more prevalent, regulations, case law, and legislation have not kept pace. As a result, private agencies wield the most influence over the development and management of the oocyte market. This Part provides background information on ART and oocyte transfer, then describes the market's primary actors, their interactions with each other, and how the absence of effective regulation has allowed private groups to disproportionately influence the market.

### *A. Background*

ART has existed in some form for millennia.<sup>15</sup> At present, the CDC defines

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<sup>14</sup> 21 C.F.R. § 1271 (2020) (establishing FDA authority over transferred oocytes); *National ART Surveillance*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Mar. 12, 2021), <https://www.cdc.gov/art/nass/index.html>.

<sup>15</sup> For example, researchers have found that Vedic populations existing between 1500 and 500 B.C.E. were familiar with artificial insemination. Radhey Shyam Sharma, Richa Saxena & Rajeev Singh, *Infertility & Assisted Reproduction: A Historical & Modern Scientific Perspective*, 148 INDIAN J. MED. RSCH. S10, S11 (2018).

ART as “all fertility treatments in which either eggs or embryos are handled.”<sup>16</sup> Due to the medical complexity of the operation, oocyte transfer became possible relatively recently,<sup>17</sup> and the practice is rapidly growing. From 2005 to 2016, the overall demand for transferred eggs increased by fifty percent.<sup>18</sup> Supply has risen to meet increased demand in areas that allow for compensation, with donors being paid up to \$150,000 for a single extraction cycle.<sup>19</sup>

Due to the relative recency of oocyte-transfer technology, the long-term risks of oocyte provision are not yet known.<sup>20</sup> However, studies suggest that the medications used in preparation for oocyte provision expose providers to dangerous health risks.<sup>21</sup> While there is disagreement over the extent and likelihood of these effects, potential risks include psychological problems; ovarian hyperstimulation syndrome; infertility; and breast, ovarian, and endometrial cancers.<sup>22</sup> Though not addressed in this Comment, the absence of comprehensive information about health outcomes for providers generates important questions about informed consent and appropriate compensation.<sup>23</sup>

The United States is an outlier as one of the only countries that permits compensation for oocyte transfer, creating an international market based in the

16 *What is Assisted Reproductive Technology?*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last visited Mar. 6, 2022), <http://www.cdc.gov/art/whatis.html>. The Center for Disease Control (CDC) notes that ART does “NOT include treatments in which only sperm are handled . . . or procedures in which a woman takes medicine only to stimulate egg production.” *Id.*

17 The first pregnancy using transferred ova was reported in 1983. Michelle Sargent, *Regulating Egg Donation: A Comparative Analysis of Reproductive Technologies in the United States and United Kingdom*, 4 MICH. J. PUB. AFFS. 1, 2 (2007).

18 Tober, *supra* note 4, at 2.

19 Rao, *supra* note 2, at 1063.

20 Tober, *supra* note 4, at 2 (“[O]ne of the most striking facts about in vitro fertilization is how little is known with certainty about the long term health outcomes for women who undergo this procedure.” (quoting INST. MED. & NAT’L RSCH. COUNCIL, ASSESSING THE MEDICAL RISKS OF HUMAN OOCYTE DONATION FOR STEM CELL RESEARCH 4 (2007))).

21 Cone, *supra* note 5, at 198. While outcomes for oocyte providers are understudied, oocyte providers have shown an increased incidence of ovarian failure, reduced fertility, and cancer. *Id.*

22 *Id.* at 199-201.

23 Issues related to informed or “true” consent are outside the scope of this Comment and therefore are not closely analyzed. For an overview of the challenges of providing informed consent to prospective providers, see Naomi Cahn & Jennifer Collins, *Fully Informed Consent for Prospective Egg Donors*, 16 AMA J. ETHICS 49 (2014). See also Amanda Skillern, Marcelle Cedars & Heather Huddleston, *Egg Donor Informed Consent Tool (EDICT): Development and Validation of a New Informed Consent Tool for Oocyte Donors*, 99 FERTILITY STERILITY 1733 (2013) (designing an informed consent questionnaire for oocyte providers); Amanda A. Skillern, Marcelle I. Cedars & Heather G. Huddleston, *Oocyte Donors’ Comprehension as Assessed by EDICT (Egg Donor Informed Consent Tool)*, 101 FERTILITY & STERILITY 248 (2014) (reporting outcomes of using an informed consent questionnaire to assess oocyte providers’ comprehension of the process and risks); A.D. Gurmankin, *Risk Information Provided to Prospective Oocyte Donors in a Preliminary Phone Call*, 1 AM. J. BIOETHICS 3 (2001) (finding that a majority of surveyed oocyte transfer agencies provided “incomplete and/or inaccurate risk information” to potential providers).

United States.<sup>24</sup> Despite its global centrality, the U.S. oocyte market is essentially unregulated.<sup>25</sup> This lack of regulation has allowed unethical behaviors by institutional or individual parties to remain unchecked. For example, medical practitioners recommend that oocyte providers limit themselves to six provisions because of uncertainty about health risks.<sup>26</sup> However, some providers conceal previous provisions to remain eligible, and some agencies intentionally avoid asking about earlier provision cycles.<sup>27</sup> Further, oocyte transfer agencies are rarely operated by medical professionals despite the highly medicalized nature of the work, creating another set of bioethical concerns.<sup>28</sup>

### *B. Actors Shaping Oocyte Transfer*

There are four central actors with the capacity to meaningfully shape the oocyte market: government actors, courts, nongovernmental organizations, and private ART agencies. This Section describes the efforts and impact of each of these actors.

#### *1. Government Actors*

Statutes about oocyte transfer are limited, and politicians avoid engaging with the potentially incendiary issue.<sup>29</sup> There are no federal statutes regarding oocyte transfer, and most states do not have any legislation about compensation for oocyte

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<sup>24</sup> Robert Klitzman, *Buying and Selling Human Eggs: Infertility Providers' Ethical and Other Concerns Regarding Egg Donor Agencies*, 17 BMC MED. ETHICS 71, 72 (2016).

<sup>25</sup> The only existing regulations are recommended guidelines that largely go unfollowed. *Infra* Section I.B.1 & Section I.B.4.

<sup>26</sup> See, e.g., *FAQ: Common Questions for Egg Donors*, UCSF HEALTH, <https://www.ucsfhealth.org/education/faq-common-questions-for-egg-donors>.

<sup>27</sup> Klitzman, *supra* note 24, at 78.

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*; see also Erin Heidt-Forsythe & Heather Silber Mohamed, *The Politics of Assisted Reproduction, Explained*, WASH. POST (May 13, 2018), <https://www.washingtonpost.com/news/monkey-cage/wp/2018/05/13/on-mothers-day-here-are-5-things-to-know-about-the-politics-of-assisted-reproduction> (describing various religious groups' opposition to ART and other stigma surrounding the technology); RUTH DEECH & ANNA SMAJDOR, *FROM IVF TO IMMORTALITY: CONTROVERSY IN THE ERA OF REPRODUCTIVE TECHNOLOGY* (2007) (detailing some of the many potential controversies that may arise with expanded ART).

providers.<sup>30</sup> Currently, only Louisiana explicitly prohibits the sale of human ova.<sup>31</sup> Florida is the only state to explicitly permit such sales, allowing “reasonable compensation directly related to the donation of eggs” but failing to define “reasonable compensation.”<sup>32</sup> A potential model for future regulations, California is the only state that directly regulates fertility clinics.<sup>33</sup> The California Family Code includes detailed instructions for how ART agencies should manage client funds and imposes limits on agencies’ own financial interest in provision.<sup>34</sup> Additionally, the Code sets standards for assisted-reproduction agreements and procedural requirements for courts assessing such agreements.<sup>35</sup> While clearly concerned with protecting the interests of oocyte providers and recipients alike, California has stopped short of regulating compensation amounts or other elements more likely to directly influence the market.

## 2. Courts

Case law surrounding oocyte transfer is extremely limited, and many complications and instances of malpractice go unaddressed.<sup>36</sup> The most relevant piece of case law, *Kamakahi v. American Society for Reproductive Medicine*, arose

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30 The following states do not statutorily address compensation or other requirements for oocyte transfer: Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, the District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, Washington, Virginia, West Virginia, Wisconsin and Wyoming. Some state statutes banning the sale of body parts broadly contain exceptions for renewable materials such as blood or hair. However, it is not clear whether oocytes are considered renewable resources. Although their number is finite, they are so multitudinous as to function more similarly to blood than to a kidney. See Rao, *supra* note 2, at 1057. Some states currently rely on the 2002 Uniform Parentage Act (UPA) for any mention of oocyte transfer, but the UPA only covers parentage rights. These states are Alabama, ALA. CODE § 26-17-101 to 26-17-905 (2021), Delaware, DEL. CODE ANN. tit. 13, §§ 8-101 to 8-904 (West 2021), New Mexico, N.M. STAT. ANN. §§ 40-11A-701 to 903 (2018), North Dakota, N.D. CENT. CODE §§ 14-20-01 to 14-20-66 (2021), Texas, TEX. FAM. CODE ANN. §§ 160.001-763 (West 2021), Utah, UTAH CODE ANN. §§ 78B-15-101 to 78B-15-902 (West 2021), and Washington, WASH. REV. CODE ANN. §§ 26.6a.005-903 (West 2021). Other states similarly only address parentage rights, including Colorado, COLO. REV. STAT. ANN. § 19-4-16 (West 2021), New Hampshire, N.H. REV. STAT. ANN. § 168-B:6 (2021), Oklahoma, OKLA. STAT. ANN. tit. 10, § 557 (West 2021), Virginia, VA. CODE ANN. § 20-158 (West 2021), and Wyoming, WYO. STAT. ANN. §§ 14-2-401 to 14-2-408 (West 2021).

31 LA. STAT. ANN. § 9:122 (West 2021) (“The sale of a human ovum, fertilized human ovum, or human embryo is expressly prohibited.”).

32 FLA. STAT. ANN. § 742.14 (West 2021).

33 CAL. FAM. CODE §§ 7960-62 (West 2021).

34 *Id.* § 7961.

35 *Id.* § 7962.

36 Cone, *supra* note 5, at 196 n.23 (listing incidents where serious complications or malpractice that negatively affected oocyte providers did not lead to any change in the case law).

in response to guidelines set out by regulatory organizations.<sup>37</sup> The complaint, filed on behalf of a class of oocyte providers, alleged that compensation-limiting guidelines promulgated by the American Society for Reproductive Medicine (ASRM) were a “naked price-fixing” agreement.<sup>38</sup> If this were true, the guidelines would be a per se violation of the Sherman Act—a federal statute that prohibits activities that restrict commerce and competition.<sup>39</sup> This per se designation would mean the guidelines were so injurious that they should be presumed illegal without inquiry into whether actual harm occurred.<sup>40</sup> Because this case ultimately settled out of court, the application of antitrust law to the oocyte industry remains one of first impression.

### 3. Nongovernmental Organizations

Attempts at regulation have mainly come in the form of suggested guidelines proliferated by ASRM, the National Academy of Sciences (NAS), and the California Institute for Regenerative Medicine (CIRM). The NAS and CIRM guidelines categorically prohibit payments for oocyte transfer.<sup>41</sup> ASRM guidelines formerly prohibited compensation above \$10,000 and required “justification” for payments in excess of \$5,000.<sup>42</sup> Now, they do not suggest a specific price range, instead simply requiring that compensation “be fair and not used as an undue enticement that will lead prospective donors to discount risks.”<sup>43</sup> None of these recommendations carries the force of law; rather, these organizations encourage stakeholders and funding agencies to promote compliance by imposing sanctions or withholding funding.<sup>44</sup> Because organizations like NAS, CIRM, and ASRM cannot monitor compliance or enforce their guidelines, their attempts at regulation have been largely ineffective. Despite widespread membership in these

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37 *Kamakahi v. Am. Soc’y for Reprod. Med. & Soc’y for Assisted Reprod. Tech.*, 11-cv-01781-JCS (N.D. Cal. 2015).

38 Complaint for Petitioner at 16, *Kamakahi v. Am. Soc’y for Reprod. Med. & Soc’y for Assisted Reprod. Tech.*, 11-cv-01781-JCS (N.D. Cal. 2015) (No. 3:11-cv-01781). See also Kimberly D. Krawiec, *Egg-Donor Price Fixing and Kamakahi v. American Society for Reproductive Medicine*, 16 *AMA J. ETHICS* 57, 58 (2014) (discussing the content of the complaint).

39 Sherman Antitrust Act, 15 U.S.C. §§ 1-38 (2018).

40 Krawiec, *supra* note 38, at 58. Considering the ineffectiveness of the regulations, it is unlikely the providers would have been able to demonstrate actual harm had occurred as a result of the guidelines.

41 Rao, *supra* note 2, at 1057.

42 Stephanie Karol, *The Market for Egg Donation*, 28 *DUKE J. ECON* 1, 2 (2016).

43 Ethics Committee of the American Society for Reproductive Medicine, *Financial Compensation of Oocyte Donors: An Ethics Committee Opinion*, 116 *FERTILITY & STERILITY* 319, 322 (2021). The ASRM guidelines also require that compensation not be conditioned on retrieval or number of oocytes retrieved, that donors not be required to pay for an interrupted cycle, and that compensation not “vary according to the number or quality of oocytes retrieved.” *Id.*

44 Rao, *supra* note 2, at 1057.

organizations, most clinic advertisements and policies do not comply with the guidelines.<sup>45</sup>

#### 4. Private ART Agencies

In the absence of effective statutes, case law, or professional regulations, private ART agencies have a strong influence on the landscape of the oocyte market. Although some fertility clinics are affiliated with hospitals,<sup>46</sup> the industry was initially comprised of standalone clinics. However, the \$25 billion industry<sup>47</sup> has drawn the attention of private-equity investors who buy shares from doctors who co-own fertility clinics.<sup>48</sup> Unsurprisingly, these investors prioritize expansion of the market with little concern for the consequences of commodification.<sup>49</sup> One in vitro fertilization (IVF) doctor-turned-investor expressed his desire to expand the reach of ART by saying the industry “need[s] the IVF version of the Holiday Inn.”<sup>50</sup>

These actors are financially incentivized to advocate against meaningful guidelines or restrictions on oocyte transfer.<sup>51</sup> One study found that a majority of

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45 One study found that “81% of agency and 96% of clinic ads on Craigslist were non-compliant with ARSM guidelines,” including 85% of those agencies and clinics that were registered with the Society of Assisted Reproductive Technologies (SART), another regulatory organization. Klitzman, *supra* note 24, at 72. In 2016, almost 60% of egg donor agencies explicitly stated that they vary compensation based on donor traits in direct violation of ARSM guidelines. *Id.* Around 46% of agency websites sought donors younger than the ASRM-recommended age limit of 21. *Id.* See also Aaron D. Levine, *Self-Regulation, Compensation, and the Ethical Recruitment of Oocyte Donors*, 40 HASTINGS CTR. REV. 25, 28-33 (2010) (“[A] study examined how well sixty-six oocyte donor and surrogacy agencies that had previously signed an agreement with SART to abide by ASRM guidelines had actually complied with them. The study found that a ‘substantial number of egg donor agencies in the United States’ had not.” (citing Janelle Luk & John C. Petrozza, *Evaluation of Compliance and Range of Fees Among American Society for Reproductive Medicine-listed Egg Donor and Surrogacy Agencies*, 53(11) J. REPROD. MED. 847 (2008))).

46 See, e.g., REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY, <https://www.mountsinai.org/care/obgyn/services/reproductive-endocrinology-infertility> (last visited Dec. 31, 2021); FERTILITY CENTER, <https://www.massgeneral.org/obgyn/fertility> (last visited Dec. 31, 2021); FERTILITY CENTER, <https://www.yalemedicine.org/departments/fertility-center> (last visited Dec. 31, 2021).

47 *The Fertility Business is Booming*, ECONOMIST, <https://www.economist.com/business/2019/08/08/the-fertility-business-is-booming>. One research firm has predicted that by 2026, the global fertility industry will be worth \$41 billion. *Id.*

48 Rebecca Robbins, *Investors See Big Money in Infertility. And They’re Transforming the Industry*, STAT (Dec. 4, 2017), <https://www.statnews.com/2017/12/04/infertility-industry-investment>.

49 Private equity firms are also interested in cutting costs and monetizing patient data. *The Fertility Business is Booming*, *supra* note 47.

50 Robbins, *supra* note 48.

51 See, e.g., Rachel Strodel, *Fertility Clinics Are Being Taken Over by For-Profit Companies Selling False Hope*, NBC THINK (Mar. 1, 2020), <https://www.nbcnews.com/think/opinion/fertility->

oocyte-transfer agencies provided “incomplete and/or inaccurate” information to potential providers in violation of organizational guidelines.<sup>52</sup> Further, these agencies have been found to run advertisements that do not comply with guidelines,<sup>53</sup> vary compensation based on donor traits including race and ethnicity,<sup>54</sup> and seek providers who are younger than the recommended minimum age of 21.<sup>55</sup> The director of the division of Medical Ethics at New York University’s School of Medicine described the fertility industry as “a field characterized by strong anti-regulatory sentiment because it evolved as a business, not a research enterprise.”<sup>56</sup> As a result, ineffective organizational guidelines and limited state statutes are the only sources of regulation available to counter the outsized influence of private ART agencies.

## II. ALTRUISM AND GENDER IN THE CURRENT SYSTEM

Altruism plays a prominent role in oocyte transfer, as evidenced by the parlance of “donation.” However, existing regulations and attempts at further regulation have ignored the role of altruism, instead focusing too extensively on compensation. The failure of regulations to acknowledge and address the influence of altruistic rhetoric leaves oocyte providers unprotected from gendered social pressures that lead to unsafe behaviors, such as an unwillingness to voice medical concerns. Section II.A details the two central motives for existing regulation before arguing that these motives are inadequate to protect oocyte providers in a system whose primary virtue is altruism. Section II.B describes the prevalence of altruistic rhetoric in oocyte transfer, and Section II.C contextualizes this prevalence as it relates to gender. This Part concludes with a discussion of the harms created by an obsession with altruism (Section II.D), the benefits of altruistic rhetoric (Section II.E), and the benefits of compensation (Section II.F).

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clinics-are-being-taken-over-profit-companies-selling-false-ncna145671. Some critics argue that ASRM actually intends to limit government regulation, as the ineffectiveness of their own regulations advances the business interests of their members. Michael Ollove, *States Not Eager to Regulate Fertility Industry*, PEW RSCH. (Mar. 18, 2015), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2015/3/18/states-not-eager-to-regulate-fertility-industry>.

<sup>52</sup> A.D. Gurmankin, *Risk Information Provided to Prospective Oocyte Donors in a Preliminary Phone Call*, 1 AM. J. BIOETHICS 3 (2001) (finding that a majority of surveyed oocyte transfer agencies provided “incomplete and/or inaccurate risk information” to potential providers).

<sup>53</sup> Klitzman, *supra* note 24, at 72.

<sup>54</sup> *Id.*

<sup>55</sup> *Id.*

<sup>56</sup> *Id.*

### *A. Motives for Regulation*

Attempts at regulation have generally been driven by two motivations. The first is the fear that payment will unduly influence women to provide oocytes, and some regulatory actors believe that prohibitions on payment are necessary to ensure true consent.<sup>57</sup> Concerns arise when payment is either so high that it would entice women who would not otherwise choose to provide or so low that the amount would only attract those in desperate need of money.<sup>58</sup> The fear of exploitation is accompanied by the fear that financial incentives will encourage potential providers to lie about their medical history in order to extend their eligibility or increase their chances of being matched with a recipient.<sup>59</sup>

The second concern that drives regulation is more philosophical: the fear that payment commodifies the components of human life in a way that is morally or ethically unsound. The ethical debate about paying women for oocytes has often hinged on whether oocytes inhabit (or ought to inhabit) a special category of objects that cannot or should not be commodified.<sup>60</sup> Parties fear that payment will degrade the value or meaning of something they believe should remain wholly separate from market forces.<sup>61</sup> This concern stems from the assumption that a “gift” object, which can be exchanged but is not commodified, is fundamentally different from a “commodity.”<sup>62</sup> That is, to commodify an object by trading it in the market changes something fundamental to the object itself.

Considering these motivations, it is perhaps unsurprising that regulatory standards and state statutes have focused almost entirely on compensation. However, due to the centrality of altruism, even effective restrictions or prohibitions on compensation would not sufficiently address the potential for exploitation in oocyte provision. While compensation does raise legitimate concerns, it also has advantages for providers who may be more willing to advocate for their own needs when compensated.<sup>63</sup> In addition, a fixation on providers’ altruistic motivations can place additional burdens on providers attempting to navigate a complex exchange relationship.<sup>64</sup> In other words, existing motives for regulation are inadequate because they overplay the risks of compensation and neglect the risks generated by a “donation” system.

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57 Rao, *supra* note 2, at 1057; *see supra* note 23 (discussing consent generally).

58 Rao, *supra* note 2, at 1062.

59 Karol, *supra* note 42, at 15.

60 Kenney & McGowan, *supra* note 5, at 17.

61 Rao, *supra* note 2, at 1057.

62 For writing on the distinction between exchange goods and gifts, *see generally*, Jonathan Parry, *The Gift, the Indian Gift, and the ‘Indian Gift,’* 21 *MAN* 453 (1986).

63 *See infra* Section II.F.

64 *See infra* Section II.D.

### B. Altruism in Oocyte Transfer

That regulation has almost exclusively attempted to set limits on payment reflects discomfort with the idea of a compensated human ova market. Additionally, institutions involved in oocyte transfer demonstrate an aversion to considering the transfer a market exchange, even while they provide large sums of money in exchange for a discrete product.<sup>65</sup> Indeed, when confronted with this tension, participants in the fertility industry insist they are not in the business of purchasing eggs, instead preferring to use the term “donation.”<sup>66</sup> Parties to oocyte transfer thus frame the oocyte as a gift and avoid the discomfort of openly commodifying human parts.<sup>67</sup>

Further, the focus on the oocyte as a gift indicates parties’ preference for a provider who is motivated by an internal inclination towards altruism. One physician stated that despite paying providers thousands of dollars, they “like to see some altruism.”<sup>68</sup> An analysis of eighty-nine oocyte-transfer agency websites found that the language used centered emotion, caring, and kindness.<sup>69</sup> In fact, some oocyte-transfer institutions directly contrasted altruism with an interest in compensation. One website stated, “Egg donation can be a rewarding and satisfying experience, but any woman considering the procedure primarily for financial reasons is discouraged from participating.”<sup>70</sup> A number of agency websites include advice or models for oocyte providers writing “donor statements.” Each includes guidance on how a provider should explain why they are participating—none of which mentions compensation. Instead, the agencies encourage women to “discuss what motherhood means to [them] . . . , if [they] know someone who has struggled with infertility, or why [they] have decided donating [their] eggs is something [they] feel *compelled* to do for others.”<sup>71</sup>

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65 Karol, *supra* note 42, at 1.

66 Kenney & McGowan, *supra* note 5, at 18.

67 Karol, *supra* note 42, at 1. For more on obfuscation techniques used by parties to “disreputable” exchanges, see Gabriel Rossman, *Obfuscatory Relational Work and Disreputable Exchange*, 32 SOCIO. THEORY 43 (2014).

68 Rene Almeling, *Gender and the Value of Bodily Goods: Commodification in Egg and Sperm Donation*, 72 LAW & CONTEMP. PROBS. 37, 46 (2009). The physician considered altruism to be an indication that a provider is “less likely to have regrets down the line.” *Id.*

69 Curtis, *supra* note 10, at 87 (“Half [of the websites] made a direct pitch to recruit donors by using words like ‘altruism,’ ‘gift,’ ‘miracle,’ and ‘making dreams happen.’”).

70 *Id.* at 88.

71 *Tips for Completing Your Egg Donor Profile*, SHADY GROVE FERTILITY, <https://www.shadygrovefertility.com/become-egg-donor/completing-egg-donor-profile> (emphasis added). Another website encourages women to “go deep” and “[w]rite about how [they] feel [their] gift will have an impact on the lives of the hopeful parents,” as well as “what [they] hope to gain from the experience.” *Advice for Writing a Good Egg Donor Profile*, OVATION DONOR SRVS., <https://www.ovationeggdonor.com/egg-donors/advice-for-writing-a-good-egg-donor-profile>. One model letter states, “Every time I have injected myself with this medication, I have been very happy

### *C. Altruism and Gender*

Framing an oocyte as an inconvertible gift even while exchanging it for money betrays the influence of gender on the work of transfer institutions and the experience of oocyte providers. Whereas compensation for sperm providers has never received much attention, compensation for oocyte providers has been hotly contested in the public sphere.<sup>72</sup> The merits of compensated oocyte transfer have been questioned in the headlines of geographically and ideologically diverse newspapers,<sup>73</sup> been the subject of many personal essays,<sup>74</sup> and garnered charged comments from politicians.<sup>75</sup> While the increased costs and risks of oocyte provision as opposed to sperm provision might demand an increased response, the difference is at least partly generated by gendered assumptions about parties' investment in reproduction and their biological materials. That is, women are expected to feel an attachment to their reproductive material, whereas men are not. In an interview, a physician-researcher who ran an oocyte- and sperm-provision center explicitly stated their belief that “[men] have less attachment of their sperm than women do of their eggs.”<sup>76</sup>

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knowing that you and your family are so close to having your own child.” Egg Donor & Surrogacy Program, *Donor Angel Letter to Recipients*, HATCH EGG DONATION & SURROGACY (Nov. 30, 2017), <https://www.hatch.us/blog/letter-from-egg-donor-to-recipient>.

<sup>72</sup> Almeling, *supra* note 68, at 45.

<sup>73</sup> E.g., Jacoba Urist, *How Much Should a Woman Be Paid for Her Eggs?*, ATLANTIC (Nov. 4, 2015), <https://www.theatlantic.com/health/archive/2015/11/how-much-should-a-woman-be-paid-for-her-eggs/414142>; Rose Evelev, *Should Women Be Paid for Their Eggs?*, SMITHSONIAN MAG (Aug. 15, 2013), <https://www.smithsonianmag.com/smart-news/should-women-be-paid-for-their-eggs-85973>; David Tuller, *Payment Offers to Egg Donors Prompt Scrutiny*, N.Y. TIMES (May 10, 2010), <https://www.nytimes.com/2010/05/11/health/11eggs.html>; Gina Kolata, *Price of Donor Eggs Soars, Setting Off a Debate on Ethics*, N.Y. TIMES (Feb. 25, 1998), <https://www.nytimes.com/1998/02/25/us/price-of-donor-eggs-soars-setting-off-a-debate-on-ethics.html>; Jan Hoffman, *Egg Donations Meet a Need and Raise Ethical Questions*, N.Y. TIMES (Jan. 8, 1996), <https://www.nytimes.com/1996/01/08/us/egg-donations-meet-a-need-and-raise-ethical-questions.html>.

<sup>74</sup> E.g., Erika W. Smith, *I Donated My Eggs & This Is What It Was Like*, REFINERY29 (Feb. 11, 2020), <https://www.refinery29.com/en-us/egg-donor-stories>; Lauryn Chamberlain, *I'm an Egg Donor. Why Was It So Difficult for Me to Tell People That?*, MARIE CLAIRE (Aug. 10, 2021), <https://www.marieclaire.com/health-fitness/a37170635/egg-donor-shame>; Justine Feron, *The Eggs I Sold, the Baby I Gained*, N.Y. TIMES (Jan. 22, 2021), <https://www.nytimes.com/2021/01/22/well/family/egg-donor-complications.html>; Jamaine Krige, *I (or 3) in a Million: My Experience as a Repeat Egg Donor*, HEALTHLINE (Oct. 28, 2020), <https://www.healthline.com/health/parenting/my-experience-as-a-repeat-egg-donor>.

<sup>75</sup> Cf. Michael Hiltzik, *Column: Should We Pay Women to Donate Their Eggs for Research? No, and here's why*, L.A. TIMES (July 22, 2016), <https://www.latimes.com/business/hiltzik/la-fi-hiltzik-egg-donors-20160722-snap-story.html> (reporting that California Governor Jerry Brown vetoed a bill that would have allowed women to be compensated for providing oocytes for scientific research on the basis that “[n]ot everything in life is for sale, nor should it be”).

<sup>76</sup> Almeling, *supra* note 68, at 46 (quoting Interview by Rene Almeling with Physician-

The emphasis on altruism is distinctly gendered. Historically, when society has suggested altruism rather than money as the motivation for labor, the activity in question has generally been considered “women’s work.”<sup>77</sup> While some studies have noted the ways in which organizations produce and rely on altruism, they have typically disregarded the role of gender.<sup>78</sup> However, researchers have found that women are expected to perform more uncompensated emotional labor in their jobs. For example, a foundational 1977 study found women occupied more “nurturing” roles in U.S. corporations,<sup>79</sup> and professions that center empathy are still largely dominated by women.<sup>80</sup> Additionally, women are more likely to be perceived as motivated by altruism rather than financial compensation.<sup>81</sup> This phenomenon is especially strong in oocyte transfer, as it is amplified by ideals of motherhood that paint women as selfless. While oocyte providers may be seen as giving the “gift of motherhood” to a recipient, sperm providers are not typically portrayed as giving the “gift of fatherhood” to intended fathers. While this framing may be comforting for oocyte providers and recipients alike, it can translate into material harms for providers.

#### *D. Dangers of Altruistic Rhetoric*

The gendered rhetoric of altruism negatively impacts providers by framing oocyte transfer as a contract that does not create mutual obligations between providers and recipients. This lack of mutuality creates a power imbalance that plays out in the rest of the provider-recipient relationship. As this Section explains, a focus on providers’ altruism puts women at risk by rendering them less likely to advocate for their own medical care and creating a stigma that burdens their ability to communicate about their motivations.<sup>82</sup>

Parties’ preference for altruism can lead to the expectation that an oocyte provider will act with a lack of self-concern, reducing her voice and agency in her own medical care. Researchers have found that oocyte providers who view their

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Researcher #3 (March 2006)).

77 Curtis, *supra* note 10, at 94 (quoting Lori Andrews, *Surrogate Motherhood: The Challenge for Feminists*, in *THE ETHICS OF REPRODUCTIVE TECHNOLOGY* 205-19 (Kenneth Alpern, ed., 1992)).

78 Almeling, *supra* note 12, at 322.

79 *Id.* (citing ROSABETH M. KANTER, *MEN AND WOMEN OF THE CORPORATION* (1977)).

80 *See, e.g.*, Katherine Hekker, *Women Are the Majority in Education, Yet Still Find Themselves Overlooked for Promotions and Making Less Than Their Male Peers*, *BUS. INSIDER* (Jun. 30, 2021), <https://www.businessinsider.com/women-teachers-administrators-gender-pay-gap-public-schools-education-2021-6> (reporting that in 2018, 76% of U.S. teachers were women).

81 Almeling, *supra* note 12, at 322.

82 These issues arise in addition to the problematic reification of gendered stereotypes. *See* Curtis, *supra* note 10, at 82 (describing how gendered rhetoric relies on outdated and sexist ideologies).

contribution as a sacrificial gift are less alert for potential health risks.<sup>83</sup> In contrast, oocyte providers who are able to acknowledge financial motivations demonstrate higher expectations for their doctors and recipients.<sup>84</sup> Expectations of altruism also encourage women to provide oocytes more frequently, even when they did not initially plan to provide again. These later provisions occur when a provider feels a sense of loyalty or investment in the recipients' family,<sup>85</sup> allowing social pressures to inappropriately influence a private medical decision.

For women, altruism is seen as the most acceptable motivation for providing reproductive materials.<sup>86</sup> Further, the industry continues to be dominated by the idea that financial motivations, to some extent, preclude the existence of altruistic motivations.<sup>87</sup> This perception of mutual exclusivity conflicts with the real motivations reported by oocyte providers. A study of nine possible motivations found that altruism and compensation together were the primary motivational factors for women to become oocyte providers.<sup>88</sup> These findings are affirmed by qualitative research in which oocyte providers reported altruistic and financial motivations in equal measure.<sup>89</sup>

Forcing oocyte providers to report altruism as their sole or primary motivation creates a situation in which they must hide information from their medical providers. In an interview, one oocyte provider said that her financial motivations made her "feel like a horrible person."<sup>90</sup> Feelings of shame and a need for secrecy burden oocyte providers as they attempt to make complex medical and ethical decisions. Women must hide any interest in financial compensation while the same work is not required of men.<sup>91</sup> These effects also extend beyond the individual as an expression of the social discomfort that still surrounds compensation for women's labor.<sup>92</sup> Stigma around compensation for oocyte transfer risks reinforcing the idea that compensation for women's labor is inappropriate or unnecessary.<sup>93</sup>

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83 *Id.* at 93.

84 *Id.* at 95.

85 *Id.*

86 See Section II.A.

87 Curtis, *supra* note 10, at 83.

88 Sherrie A. Kossoudji, *The Economics of Assisted Reproduction* 10 (IZA Bonn, Discussion Paper No. 1458, 2005).

89 Curtis, *supra* note 10, at 95 (noting that many interviewed oocyte providers were "motivated by both altruism and the desire to be financially compensated").

90 *Id.* at 82.

91 ALMELING, *supra* note 12, at 56.

92 Curtis, *supra* note 10, at 83; see also Gabrielle Meagher, *Is It Wrong to Pay for Housework?*, 17 *HYPATIA* 52, 52 (2002) ("Commerce seems most controversial in those activities—sex, procreation, personal care and housework—traditionally understood to be rightly undertaken by wives within matrimonial rather than market relationships.").

93 Krawiec, *supra* note 38, at 63.

### *E. Advantages of Altruistic Rhetoric*

Despite the negative impacts of prioritizing altruism, an attempt to remove altruistic rhetoric from the discourse is neither advisable nor realistic. Discomfort with the sale of body parts for monetary gain—especially reproductive parts—is so deeply embedded in cultural norms that altruistic rhetoric is likely to persist absent a significant cultural shift in understandings of motherhood and reproductive labor.<sup>94</sup> Relieving some of this discomfort is not necessarily an obfuscation of reality; oocyte providers continue to report altruism as a significant motivation even when their answers are anonymous.<sup>95</sup> It is important for oocyte providers to be able to refer to their provision in the way that feels most truthful and comfortable.

Maintaining altruistic rhetoric also prevents what behavioral economists term “crowd-out effects.”<sup>96</sup> A crowd-out effect occurs when the introduction of an extrinsic incentive (in this case, money) displaces an intrinsic incentive (in this case, feelings of altruism) and leads to reduced participation.<sup>97</sup> For example, empirical studies have shown that individuals might be less willing to donate blood when offered payment, as the offer reduces the amount of intrinsic motivation felt by the potential donor.<sup>98</sup> One explanation for this effect could be that extrinsic incentives diminish “image motivation,” as someone may behave pro-socially by donating blood or providing oocytes to encourage others to think of them as kind or generous.<sup>99</sup> Another possible explanation is that the amount of money exchanged is viewed as a “price,” which providers see as changing something integral to the bodily product,<sup>100</sup> devaluing their contribution, or indicating something unpleasant about the task.<sup>101</sup>

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94 *Id.* at 90. Oocyte transfer has been called “egg donation” since the first years of the technology. See, e.g., Associated Press, *Clinic in Ohio Starts Egg Donor Plan*, N.Y. TIMES, July 15, 1987, at A16, <https://www.nytimes.com/1987/07/15/us/clinic-in-ohio-starts-egg-donor-plan.html>; Nadine Brozan, *Rising Use of Donated Eggs for Pregnancy Stirs Concern*, N.Y. TIMES, Jan. 18, 1988, at A1, <https://www.nytimes.com/1988/01/18/us/rising-use-of-donated-eggs-for-pregnancy-stirs-concern.html>; Frances Grandy Taylor, *Some Women Donate Their Eggs so Others Can Have Children*, HARTFORD COURANT (Feb. 13, 1996), <https://www.courant.com/news/connecticut/hc-xpm-1996-02-13-9602130038-story.html>.

95 See *supra* notes 86-93 and accompanying text.

96 Emir Kamenica, *Behavioral Economics and Psychology of Incentives*, 4 ANN. REV. ECON. 427, 444 (2012).

97 *Id.*; WILLIAM J. CONGDON ET AL., POLICY AND CHOICE: PUBLIC FINANCE THROUGH THE LENS OF BEHAVIORAL ECONOMICS 124 (2011).

98 CONGDON, *supra* note 97, at 124.

99 Uri Gneezy et al., *When and Why Incentives (Don't) Work to Modify Behavior*, J. ECON. PERSPS. 191, 201 (2011).

100 This concern parallels one of the central motives for regulation discussed in Section II.A. See text accompanying notes 60-63.

101 Bruno S. Frey & Reto Jegen, *Motivation Crowding Theory: A Survey of Empirical Evidence*

By prioritizing a rhetoric of altruism, parties to oocyte transfer may incidentally avoid the “crowding out” of intrinsic motivations, instead painting compensation as a means to facilitate the altruistic act or a reward for one’s generosity.<sup>102</sup> The language of donation obscures the exchange, making it more difficult for an outside party to determine the actors’ motivations (which, based on the data, are most likely to be a mix of extrinsic and intrinsic).<sup>103</sup> In this way, providers retain image motivation, as they will be recognized as motivated by intrinsic generosity rather than financial incentives. Providers also avoid the implication that compensation is a “price” for a body part and the stigma associated with commodification of the body. Finally, if compensation is viewed as a technicality or a reward for an altruistic act, providers are unlikely to feel their contribution is devalued or that the task is so unpleasant as to require compensation.<sup>104</sup>

#### *F. Advantages of Compensation*

Due to the invasive, personal, and potentially dangerous nature of oocyte provision, prohibiting compensation would likely reduce oocyte supply far below the demand. Further, compensation for oocyte provision is critical as the reproductive labor market simultaneously becomes more complex and more commonplace. Seeking compensation for potentially dangerous, highly valued labor should not be a subversive act. Compensating oocyte provision recognizes that a woman may act altruistically without complete self-sacrifice. While there are fears that compensation is exploitative, the current hesitancy to conceive of a “paid donation,” in which a woman holds altruistic and financial motivations in equal measure, also has negative effects for oocyte providers.<sup>105</sup> Additionally, prohibitions on compensation that reduce the supply of available oocytes could potentially encourage an unregulated black market for oocytes in which providers would likely be undercompensated and less aware of health risks.<sup>106</sup> As a result, a prohibition on monetary compensation for oocyte transfer will not remedy exploitation.

Altruism and compensation are not mutually exclusive, and in fact, the acceptance of both motivations best protects the safety and wellbeing of oocyte

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7-9 (CESifo, Working Paper No. 245, 2000).

102 *See also id.* at 6 (arguing that external incentives crowd out intrinsic motivation if individuals perceive them to be controlling but “crowd in” intrinsic motivation if individuals perceive them to be supportive).

103 Oliver Schilke & Gabriel Rossman, *It’s Only Wrong If It’s Transactional*, 83 AM. SOCIO. REV. 1079, 1086 (2018).

104 Frey & Jegen, *supra* note 101, at 7-9.

105 *See supra* Section II.D.

106 Kenney & McGowan, *supra* note 5, at 18.

providers. Altruistic rhetoric has advantages for oocyte providers, as it acknowledges the more-than-commodity status of the oocyte and the sincere commitment of many providers. However, an overemphasis on altruism—especially in a highly gendered context—can harm providers by rendering them less willing to advocate for their own needs or encouraging them to undertake dangerous behaviors like repeated provision. In turn, though excessive compensation may unduly influence a potential provider, compensation allows providers to advocate for themselves and receive recognition for their labor. Parties with different motivations and varied information struggle to negotiate these exchange relationships, and they exacerbate risks and complications by acting as if altruism is the primary motivation of everyone involved. Current regulatory structures have generally stopped at attempts to limit compensation, upholding the damaging notion that acceptable oocyte transfer is driven by altruism.

### III. PROPOSAL FOR FEDERAL REGULATION

An oocyte market that relies on either altruism or compensation alone will fail providers and recipients alike. Instead, the federal government should implement regulations that permit compensation for oocyte transfer, prohibit ongoing unethical practices, and set contract requirements and safety standards for oocyte provision. Safety standards should codify and expand on those touched upon in existing nongovernmental guidelines, including setting age limits and capping the number of cycles per provider. Additionally, the government could set a floor on informed consent requirements, allowing states or professional organizations to require more detailed consent. Such regulations would allow for an expanded understanding of oocyte providers' motivations that would lead to reduced stigma and improved wellbeing. This Part discusses a potential remedy in two parts: a conceptual reimagining of altruism and compensation as harmonious and the ability to implement a federal regulatory scheme under the FDA.

#### *A. Abandoning the Altruism/Compensation Binary*

Acknowledging the potential for oocyte providers to simultaneously hold altruistic and financial motivations creates new possibilities for comprehensive protection. Such recognition would expand oocyte providers' vocabulary to express their concerns and negotiate elements of their experience, as they would not have to conceal interest in compensation.<sup>107</sup> Whereas gift-giving rhetoric limits some of the commodification present in traditional market exchanges, discussion about compensation can give oocyte providers the freedom to be openly self-interested and reduce the potential for coercion. Additionally, continued

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<sup>107</sup> Curtis, *supra* note 10, at 95.

compensation in tandem with recognition of the gift-like socioemotional elements of the exchange will ensure a supply of oocytes that meets demand. A system in which providers, recipients, and oocyte-transfer agencies can be transparent about their motivations is more likely to reduce exploitation of oocyte providers.

### *B. Providing for Federal Regulation*

It is true that setting compensation too high may unduly induce individuals to become oocyte providers. Further, inappropriate compensation may specifically entice the most economically vulnerable and hence the least likely to have options for legal recourse.<sup>108</sup> Especially considering that the long-term health outcomes for oocyte providers are still unknown,<sup>109</sup> oocyte provision demands meaningful regulation.<sup>110</sup> While it is possible for parties to bring cases on behalf of providers affected by the current lack of regulation, these cases have been unsuccessful in setting new standards for oocyte transfer,<sup>111</sup> and complex regulatory schemes should not be designed by judges.<sup>112</sup>

As the federal government and state governments alike seek to expand access to ART,<sup>113</sup> the federal government must be the source of this regulation. The current arrangement, in which there is a limited and inconsistent collection of state statutory laws, makes it difficult for parties to predict the outcome of high-stakes

108 Rao, *supra* note 2, at 1062.

109 See, e.g., Milenko Martinovich, *Uncovering the Long-Term Health Outcomes for Egg Donors*, SCI. CARING (Mar. 2020), <https://scienceofcaring.ucsf.edu/research/uncovering-long-term-health-outcomes-egg-donors>.

110 Cf. Samantak Ghosh, *The Taking of Human Biological Products*, 102 CALIF. L. REV. 511, 528-29 (2014) (“If commodification and exploitation of the human body is a concern, there is no reason to believe that an unregulated market is a better substitute.”).

111 See, e.g., Cone, *supra* note 5, at 196 n.23 (explaining that donors who experience serious complications are often paid to settle or struggle to win difficult medical-malpractice actions).

112 See, e.g., Robert M. Howard & Jeffrey A. Segal, *A Preference for Deference? The Supreme Court and Judicial Review*, 57 POL. RSCH. Q. 131 (2004). Some judges have spoken openly about the biases they would bring to fertility litigation. Jennifer Bendery, *Republicans to Confirm Lifetime Federal Judge Opposed to Fertility Treatments*, HUFFPOST (Dec. 3, 2019), [https://www.huffpost.com/entry/sarah-pitlyk-judge-fertility-treatment\\_n\\_5de69777e4b0913e6f865cb6](https://www.huffpost.com/entry/sarah-pitlyk-judge-fertility-treatment_n_5de69777e4b0913e6f865cb6) (reporting that the Senate confirmed a lifetime federal judge who opined that ART has “grave effects on society, including diminished respect for motherhood and the unique mother-child bond”).

113 A federal bill that would require private health insurance plans to cover infertility treatments and fertility preservation has been introduced in the House and the Senate. Access to Infertility Treatment and Care Act, H.R. 4450, 117th Cong. (as introduced in House, July 16, 2021); Access to Infertility Treatment and Care Act, S. 2960, 115th Cong. (as introduced in Senate, May 4, 2018). A similar bill focused on veterans has been introduced in the House. Veterans Infertility Treatment Act of 2021, H.R. 1957, 117th Cong. (as introduced in House, Mar. 17, 2021). For a list of 17 states with laws requiring insurance companies to cover or offer coverage for infertility treatment, see *State Laws Related to Insurance Coverage for Infertility Treatment*, NAT'L CONF. OF ST. LEGIS. (Mar. 12, 2021), <https://www.ncsl.org/research/health/insurance-coverage-for-infertility-laws.aspx>.

conflicts including parentage disagreements, misuse of oocytes, or failure to obtain informed consent.<sup>114</sup> The lack of consensus may cause hesitation for parties who would otherwise engage in mutually beneficial agreements. More importantly, it threatens the legitimacy of families created using ART, both in the legal arena and the public eye. Federal regulations permitting compensation for oocyte provision would give individuals and families much-needed certainty.

While the Tenth Amendment gives states primary authority over healthcare decisions, the federal government has the authority to regulate oocyte transfer under the FDA.<sup>115</sup> Transferred reproductive tissue is regulated as “human cells, tissues, and cellular and tissue-based products,”<sup>116</sup> meaning that oocyte transfer clinics must register with the FDA,<sup>117</sup> comply with “donor eligibility guidelines,”<sup>118</sup> and undergo inspection.<sup>119</sup>

The federal government is best positioned to enable participatory policymaking in this area and engage with multiple stakeholders in designing a regulatory scheme. In addition to FDA regulations, the CDC currently collects data from all fertility clinics in the United States, calculating success rates for each clinic and presenting this information through the National Assisted Reproductive Technology Surveillance System.<sup>120</sup> As a result of the Fertility Clinic Success Rate and Certification Act of 1992, all ART programs are required to report certain data to the federal government annually.<sup>121</sup> Further, in *Perez v. Commissioner*, the U.S. Tax Court held that payment for oocyte provision is subject to federal income tax.<sup>122</sup> As a result, the federal government is already receiving information from and communicating standards to fertility clinics and oocyte providers.

Legislative actors should center oocyte providers as the stakeholders most marginalized by lack of regulation and resistance to compensation. Importantly, regulation by the FDA or CDC would affirm the idea that oocytes are fundamentally different from any other commodity and should be treated differently under the law. It is unclear what financial incentive will maximize provider wellbeing and the availability of oocytes. It is also unclear how much

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114 Jody L. Madeira & Susan L. Crockin, *Legal Principles and Seminal Legal Cases in Oocyte Donation*, 110 FERTILITY STERILITY 1209, 1211 (2018).

115 21 C.F.R. § 1271 (2020).

116 *Id.* § 1271.3.

117 *Id.* § 1271.10.

118 *Id.* § 1271.1(a).

119 *Id.* § 1271.400. *See also* Katherine McKeen, *Cracking the Egg Donation Market*, REGUL. REV. (Oct. 13, 2021), <https://www.theregreview.org/2021/10/13/mckeen-cracking-egg-donation-market> (“In short, FDA regulates who can be an egg donor—but does not regulate how the for-profit egg donation industry treats donors.”).

120 National ART Surveillance, CTRS. FOR DISEASE CONTROL AND PREVENTION (Mar. 12, 2021), <https://www.cdc.gov/art/nass/index.html>.

121 Pub L. No. 102-493, 106 Stat. 3145 (1992).

122 *Perez v. Commissioner of Internal Revenue*, 144 T.C. 51 (2015).

altruistic rhetoric, and in what form, would accomplish the same goals. Considering the relevance of a complex system of gender norms and the inability to regulate private-agency rhetoric, framing decisions are best left to individual parties. However, by permitting compensation across the board and setting enforceable guidelines for compensation and safety, the federal government can facilitate an expansive conception of women's labor, improve the wellbeing of oocyte providers, and destigmatize compensated oocyte transfer.

### CONCLUSION

Regulations, case law, and legislation have not kept pace with the rapid development and proliferation of oocyte transfer. The limited laws that do exist focus almost exclusively on prohibiting or limiting compensation. As a result, private agencies have been the actors tasked with setting standards for provider safety and compensation. Individuals must navigate this space while struggling with the perceived tension between self-interest and altruism. This tension has generally been handled by veiling providers' financial interest and privileging an image of oocytes as freely given gifts.

While inappropriate compensation can lead to exploitation of oocyte providers, banning compensation and relying on altruistic rhetoric alone does not fare much better. The focus on altruism in the oocyte market is distinctly gendered, colored by the expectation that the ideal woman (and especially the ideal mother) is generous, nurturing, and fundamentally selfless. This framing renders oocyte providers less likely to advocate for their own healthcare and medical wellbeing and forces them to hide a significant part of their motivation for provision: financial gain. Importantly, this same work is not required of their sperm-providing counterparts.

Some of the risk of exploitation can be alleviated by rejecting the notion that women are unable to be simultaneously self and other regarding. This conceptual shift could be facilitated by a federal regulatory framework that expands existing FDA and CDC relationships with fertility clinics and considers the interests of oocyte providers. Codified standardization of the oocyte market would not only protect oocyte providers, but also legitimize families created using ART, affirm the idea that oocytes are fundamentally different from other commodities, and validate women's labor as worthy of compensation.

