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## ARTICLES

**Decentralizing STD Surveillance: Toward Better Informed Sexual Consent**

*Mary D. Fan*

**Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children**

*Mary Holland*

## RESPONSE

**Updating Constitutional Doctrine: An Extended Response to the Critique of Compulsory Vaccination**

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## NOTE

**Reshaping the American Concept of Consumer Interest in the Food Policy Debate**

*Lang Liu*





## TABLE OF CONTENTS

### ARTICLES

- 1      Decentralizing STD Surveillance: Toward Better Informed Sexual Consent**  
*Mary D. Fan*

- 39     Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children**  
*Mary Holland*

### RESPONSE

- 87     Updating Constitutional Doctrine: An Extended Response to the Critique of Compulsory Vaccination**  
*Michael H. Shapiro*

### NOTE

- 171    Reshaping the American Concept of Consumer Interest in the Food Policy Debate**  
*Lang Liu*



# Decentralizing STD Surveillance: Toward Better Informed Sexual Consent

Mary D. Fan\*

INTRODUCTION .....	3
I. THE STD-SURVEILLANT STATE UNDER STRAIN .....	5
A. BUDGET CUTS AND THE BELEAGUERED PUBLIC HEALTH PARADIGM .....	6
B. HEAVIER BURDENS BORNE BY THE SOCIALLY MARGINALIZED.....	8
1. THE HISTORICAL USUAL OUT-GROUP SUSPECTS.....	9
2. CONTINUED HEIGHTENED FOCUS.....	10
II. AN EVOLVING PUBLIC HEALTH CHALLENGE THAT CUTS ACROSS COMMUNITIES.....	14
A. SHIFTING SOCIAL AND SEXUAL NORMS IN THE MARKETPLACE FOR SEX AND ROMANCE .....	15
1. THE PREVALENCE OF CASUAL SEX CULTURE .....	16
2. THE ONLINE MEAT/MEET MARKET .....	18
B. EPIDEMIOLOGICAL RAMIFICATIONS .....	22
1. CONCURRENT PARTNERSHIPS AND STD SPREAD.....	24
2. INTERNET-MEDIATED SEX SEEKING AND NETWORK JUMPING.....	26
III. DEVOLVING INFORMATION AND POWER TO ENABLE INFORMED CONSENT.....	28

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A. SEEDING A HEALTHIER INFORMATION CULTURE: PROMOTING DDF-  
VERIFICATION..... 28

B. PHYSICIAN FLAGS: IMPROVING IDENTIFICATION OF ACTORS IN NEED OF  
INTERVENTION..... 32

C. OBJECTIONS AND ANSWERS..... 35

CONCLUSION ..... 38

## INTRODUCTION

For six years, Tony Perkins met scores of women through the online site plentyoffish.com and exposed them to AIDS.<sup>1</sup> At least twenty-six women are pressing criminal charges for his failure to warn and endangerment of their health.<sup>2</sup> The women in the Perkins case are being tested for HIV, the virus that causes AIDS.<sup>3</sup> As of February 2010, none of the women had tested positive for the disease.<sup>4</sup> The Texas women who Philippe Padieu met, often online, and exposed to HIV were not so fortunate.<sup>5</sup> Padieu transmitted HIV to at least six of the women.<sup>6</sup>

The cases from America's heartland came as a shock.<sup>7</sup> But they should not. Rather, they illustrate the need for better earlier intervention. The cases also illustrate the need to dislodge narratives about who is vulnerable to infection and who is not. Historically, sexually transmitted diseases have been treated as an affliction of the morally degenerate "Other" and the consequence of deviation from the dominant sexual culture.<sup>8</sup> However, sexual culture and our national sexual health have evolved. Sexually transmitted diseases (STDs, also referred to as STIs)<sup>9</sup> are widespread and spreading further.<sup>10</sup> There are nineteen million new

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1. John Tuohy, *'Seducer' Had His Way – And A Secret*, INDIANAPOLIS STAR, Feb. 25, 2010, at A1, available at 2010 WLNR 3953964.

2. Kevin O'Neal, *More Charges Filed in AIDS-Disclosure Case*, INDIANAPOLIS STAR, Mar. 17, 2010, at A19, available at 2010 WLNR 5567375.

3. Tuohy, *supra* note 1.

4. *Id.*

5. Diane Jennings, *Man Who Spread HIV Gets 45 Years*, DALL. MORNING NEWS, May 30, 2009, at 1B, available at 2009 WLNR 10294840.

6. *Id.*

7. See, e.g., Transcript, 20/20: *HIV Positive Man Busted by Women He Lied to, Victims Speak Out* (ABC television broadcast Sept. 19, 2009), available at 2009 WLNR 18608524 (detailing case and resulting alarm).

8. See, e.g., M.W. Adler, *The Terrible Peril: A Historical Perspective on the Venereal Diseases*, 281 BRIT. MED. J. 206, 207-09 (1980) (discussing that, historically, medical commissioners believed venereal diseases were "intimately connected with vicious habits," to be abated by "rais[ing] moral standards," and how morally fallen others, often foreign women and prostitutes, were blamed); Allan M. Brandt, *AIDS in Historical Perspective: Four Lessons from the History of Sexually Transmitted Diseases*, 78 AM. J. PUB. HEALTH 367, 367-68 (1988) (noting that venereal disease was conceived as a threat, that it was the consequence of deviation from Victorian sexual values, and that, in modern times, HIV/AIDS fears also reflect social constructs that "strongly associate [HIV/AIDS] with behaviors which have been traditionally considered deviant"); see also *id.* at 367-68 (contrasting the xenophobia surrounding syphilis with the homophobia and moral opprobrium surrounding HIV/AIDS).

9. STIs stands for the broader, less affectively-evocative umbrella term "sexually transmitted infections," which captures a wider range of ailments. Both terms are used in the literature. In this Article, I use STDs because the policy prescriptive is focused on the most concerning sexually transmitted diseases.

10. For more statistics, see *infra* Part I.

STD infections each year, according to Centers for Disease Control and Prevention (CDC) estimates.<sup>11</sup> Transmission is facilitated by social, cultural, and technological shifts and the increasingly prevalent phenomena of online connections with near-strangers, concurrent partners, and casual partners—whether one party realizes her partner is having sex with others or not.<sup>12</sup>

Sexual culture has changed since the early 1900s, when the nation's STD surveillance paradigm crystallized.<sup>13</sup> These social shifts strain our STD surveillance polices and laws, which remain strongly shaped by the inherited paradigm of the past.<sup>14</sup> Surveillance strategies include disease reporting, sexual contact tracing, and data collection regarding individuals infected with STDs, such as the four nationally reportable diseases of Chlamydia, gonorrhea, syphilis, and chancroid, and HIV/AIDS under certain state statutes.<sup>15</sup> Information and power is centralized in the state, which receives, stores, and sometimes acts—albeit with increasing infrequency in a time of severe budgetary strain—on information reluctantly reported by healthcare providers.<sup>16</sup>

Because of targeted intervention and concentrated surveillance in low-income health settings, socially and economically marginalized groups continue to bear the heaviest burden of surveillance.<sup>17</sup> Sexual culture shifts and the resulting health ramifications, however, cut across traditional social categories such as class, age, sexual orientation, and race.<sup>18</sup> Interventions aimed at improving informed consent to sexual health risks should also cut across communities. There is an information deficit in the meet/meat marketplace<sup>19</sup> of

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11. *Sexually Transmitted Diseases in the United States, 2008*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/std/stats08/trends.htm> (last updated Nov. 16, 2009).

12. See, e.g., Kevin A. Fenton, *Time for Change: Rethinking and Reframing Sexual Health in the United States*, 7 J. SEXUAL MED. (Supp.) 250, 250-51 (2010) (detailing factors accelerating risks and STD spread).

13. For an illuminating history of the rise of the STD surveillance paradigm of control, see AMY L. FAIRCHILD ET AL., *SEARCHING EYES: PRIVACY, THE STATE AND DISEASE SURVEILLANCE IN AMERICA* 7-15, 33-49, 60-70 (2007).

14. See *infra* Part I.

15. See generally CTRS. FOR DISEASE CONTROL & PREVENTION, *HIV SURVEILLANCE REPORT* 5-78 (2009) (collecting HIV/AIDS data based on confidential name-based reporting laws implemented in all 50 states as of April 2008); CTRS. FOR DISEASE CONTROL & PREVENTION, *SEXUALLY TRANSMITTED DISEASE SURVEILLANCE, 2009* 1, 5-134 (2010) (data) [hereinafter *STD SURVEILLANCE*].

16. See, e.g., FAIRCHILD, *supra* note 8, at 61-62, 79-80 (detailing physician reluctance); Helen Ward, *Partner Notification and Contact Tracing*, 33 MED. 28, 29 (2005) (describing contact tracing); see also *infra* Section I.A (discussing budgetary strain).

17. See *infra* Section I.B.

18. See *infra* Part II.

19. I use this as shorthand for the colloquial concept of the “meat market” of parties, bars, dance clubs, and other venues where people seek potential sexual partners and the online marketplace for meeting people explored *infra* Section II.B. See JONATHAN GREEN, *CASSELL'S DICTIONARY OF SLANG* 933 (2d ed. 2005) (defining meat market as slang since the 1950s for “anywhere that people gather for the primary purpose of finding sexual partners”).

increasingly prevalent casual sex and, consequently, a need for reliable information. The lack of reliable information leads to reliance on inaccurate and often racially biased heuristics—cognitive rules of thumb—about who is “safe” and who is not.<sup>20</sup>

This Article explores how public health policies can respond to changing sexual culture and the need for more reliable information sharing. Specifically, it recommends facilitating voluntary test results sharing and priority flagging of actors most in need of intervention. Such approaches devolve power into the hands of people in the marketplace by creating a system of decentralized carrots and sticks. The carrot strategy seeds a healthier culture of verification through the incentive of enabling individuals to become more marketable as a potential sex partner. More reliable verification may be enabled through password-protected results web pages that may be readily shared with potential partners, facilitating informed consent to sex and enhancing marketability.

The stick strategy focuses on the challenge of potentially problematic actors who repeatedly infect partners without disclosing disease status. The Article advocates for utilizing the better vantage of doctors to identify potentially problematic actors based on reports by patients, in the privacy of the doctor’s office, about individuals whom the patient believes deceived them and, potentially, others. In a time when budget-strapped public health authorities are in triage mode and unable to engage in contact tracing for all cases, a priority flag approach would be more efficient in identifying potentially problematic actors in need of stronger surveillance and educational intervention. This method of identification is also salutary because it relies on accounts of behavior warranting concern, rather than on heuristics about who is high-risk that may reinforce old stigmas and stereotypes.

This Article proceeds in three parts. Part I discusses the traditional state-centric out-group focus of STD surveillance and the survival by transformation of aspects of the paradigm today. Part II discusses the information deficit in the marketplace for sex and romance and how the deficit impedes informed consent to sex. Part III argues for decentralizing and devolving power to seed a healthier culture of informed consent and to improve the identification of actors most in need of intervention based on behavior.

## I. THE STD-SURVEILLANT STATE UNDER STRAIN

The patchwork of public health laws regulating sexually transmitted diseases bears the imprint of the fears of the past. Disease control law is an agglomeration of state responses to shifting historical health concerns, impeded in efficacy by the antiquity of the provisions.<sup>21</sup> Part of this heritage of the past, carried forward

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20. See *infra* Part III.

21. Lawrence O. Gostin et al., *The Law and the Public's Health: A Study of Infectious Disease*

into the present on different rationales, is an expensive and cumbersome model of concentrating information and power in the state.<sup>22</sup> Another aspect of this heritage is the concentration of the heaviest interventions and surveillance on the socially marginalized—prostitutes, sexual minorities, people of color, and the poor.<sup>23</sup> Section I.A discusses the expensive state-centric model of STD surveillance. Section I.B discusses the disparate burdens of surveillance and intervention that the socially and economically marginalized continue to bear.

### *A. Budget Cuts and the Beleaguered Public Health Paradigm*

Contact tracing, also called partner notification, was a practice that took root during the 1920s attempt to control syphilis.<sup>24</sup> This approach remains the cornerstone of public health management of sexually transmitted diseases today. The goal of contact tracing is to remove nodes of further transmission through testing, counseling, and education.<sup>25</sup> The vast majority of state public health laws explicitly provide for contact tracing for communicable diseases, particularly HIV/AIDS and other sexually transmitted diseases.<sup>26</sup> Reflecting an often-tense alliance between physicians and public health authorities, the laws mandate that doctors (and, in some statutes, other professionals such as nurses and school officials) report sexually transmitted diseases to public health authorities on pain of sanctions.<sup>27</sup> For example, California regulations state, “It shall be the duty of every health care provider, knowing of or in attendance on a case or suspected case of any of the diseases or conditions listed [below], to report to the local

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*Law in the United States*, 99 COLUM. L. REV. 59, 102 (1999).

22. Section I.A analyzes this approach.

23. For a history, see FAIRCHILD, *supra* note 13, at 7, 9-10; and Gostin et al., *supra* note 21, at 110.

24. Matthew Hogben et al., *Partner Notification & Management Interventions*, in BEHAVIORAL INTERVENTIONS FOR PREVENTION AND CONTROL OF SEXUALLY TRANSMITTED DISEASES 170-71 (Sevgi O. Aral et al. eds., 2007).

25. See, e.g., M. Hogben et al., *Physicians' Opinions About Partner Notification Methods: Case Reporting, Patient Referral and Provider Referral*, 80 SEXUALLY TRANSMITTED INFECTIONS 30, 30-31 (2004) (breaking cycle); Patricia Kissinger & David Malebranche, *Partner Notification: A Promising Approach To Addressing the HIV/AIDS Racial Disparity in the United States*, 33 AM. J. PREVENTATIVE MED. S86, S86-S87 (2007) (changing behavior through notification).

26. See Lawrence O. Gostin & James G. Hodge, Jr., *Piercing the Veil of Secrecy in HIV/AIDS and Other Sexually Transmitted Diseases: Theories of Privacy and Disclosure in Partner Notification*, 5 DUKE J. GENDER L. & POL'Y 9, 28 tbl.A (1998).

27. See, e.g., CAL. HEALTH & SAFETY CODE § 121022(a) (West 2011) (imposing duty to report on healthcare providers); 410 ILL. COMP. STAT. 325/5(a) (2011) (imposing duty on physicians, nurses, physician's assistants and nurses to report); IND. CODE §§ 16-41-2-2, 16-41-2-3 (imposing reporting requirements on physicians); MICH. COMP. LAWS §§ 333.5114a (2011) (imposing duty to report on governmental entities and persons obtaining from an HIV-positive subject a positive HIV test result); TEX. HEALTH & SAFETY CODE § 81.042 (West 2011) (imposing duty to report on doctors, school officials, nurses, nursing home and home health administrators and other actors).



health officer for the jurisdiction where the patient resides.”<sup>28</sup> Reportable STDs include diseases such as HIV, syphilis, chlamydia, gonorrhea, and viral hepatitis.<sup>29</sup> Failure of healthcare providers to report the diseases is criminalized as a misdemeanor<sup>30</sup> and is also a citable offense by the California Medical Board.<sup>31</sup>

In an era when public health funding has been “in chronic decline,” labor-intensive contact tracing is proving too costly to pursue in many cases.<sup>32</sup> In contact tracing, a doctor asks a patient who has been diagnosed with a communicable STD to voluntarily disclose his or her sexual contacts, including potential transmitters and infectors.<sup>33</sup> The goal is to notify sexual contacts disclosed by the infected patient, termed the “index case,” so they can get tested and treated.<sup>34</sup> Notification can be delivered in one of three ways. In “provider notification,” health officials do the notification, whereas in “patient referral,” the patient does the notification. Under a “conditional referral” regime, the patient has a specified period in which to notify the partners and if the patient does not do so, the provider does the notification.<sup>35</sup>

While statutory regimes vary somewhat in the details,<sup>36</sup> the most typical approach is for doctors to report information to public health officials, who must track down all the reported contacts.<sup>37</sup> Officials encourage reported contacts to get tested and may offer counseling and education.<sup>38</sup> The investigation continues by seeking the sexual contacts of each reported contact, in an expanding network.<sup>39</sup> The processes of tracking down, notifying, and counseling about testing and risk reduction repeat until all traceable contacts have been reached.<sup>40</sup>

The manpower-intensive process of contact tracing and notification is putting strain on budget-strapped public health agencies, which have few employees to do the work of many.<sup>41</sup> Out of necessity, agencies have had to

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28. CAL. CODE REGS. tit. 17, § 2500(b) (2011).

29. *Id.* at § 2500(j).

30. CAL. HEALTH & SAFETY CODE § 120295 (West 2011) (making a violation “punishable by a fine of not less than fifty (\$50) nor more than one thousand (\$1,000), or by imprisonment for not more than 90 days, or by both”).

31. CAL. CODE REGS. tit. 16, §§1364.10-1364.11 (2011).

32. Gostin et al., *supra* note 21, at 95.

33. Ward, *supra* note 16, at 28, 29.

34. Gostin & Hodge, *supra* note 26, at 26-34.

35. Pamina M. Gorbach et al., *To Notify or Not To Notify: STD Patients' Perspectives of Partner Notification in Seattle*, 27 SEXUALLY TRANSMITTED DISEASES 193, 193-94 (2000).

36. See Gostin & Hodge, *supra* note 26, at 28 tbl.A.

37. Nancy E. Kass & Andrea C. Gielen, *The Ethics of Contact Tracing Programs and Their Implications for Women*, 5 DUKE J. GENDER L. & POL'Y 89, 90-91 (1998).

38. *Id.*

39. *Id.*

40. *Id.*

41. See, e.g., Gostin et al., *supra* note 21, at 95 (detailing budget cuts); Chris Joyner, *Public Health: Protect or Neglect?*, CLARION-LEDGER, June 26, 2006, at A4, available at 2006 WLNR

deploy a triage approach with much curtailed ability to engage in labor-intensive contact tracing and notification.<sup>42</sup> With few overburdened officials to work on thousands of new cases, people are slipping through gaping cracks in the system.<sup>43</sup>

*B. Heavier Burdens Borne by the Socially Marginalized*

In addition to cumbersome contact tracing, another vestige of the past that lingers in the present, preserved through a transformed rationale, is the focus on socially marginalized groups.<sup>44</sup> This emphasis can seem like good sense: in a world of limited resources, interventions should target populations that statistically seem hardest hit by the problem and are most in need of help.<sup>45</sup> While it is true that historically marginalized communities disproportionately bear the burdens of this category of affliction, as with other disproportionately distributed social burdens,<sup>46</sup> the danger is losing sight of the responsibility and risk of all across communities. Indeed, researchers believe that data submitted to the CDC by public agencies substantially underreport disease prevalence among whites of higher socioeconomic status and overreport prevalence among minorities who are disproportionately economically disadvantaged and must turn to public clinics.<sup>47</sup> Because data are more readily collected through public

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25319621 (noting funding cut for the state health department of 40 percent in the past five years, the elimination of 2900 positions and that prevention programs across the nation are similarly suffering).

42. See, e.g., *Public Health: Protect or Neglect?*, *supra* note 41.

43. *Id.*

44. Reva Siegel influentially theorized the phenomenon of preservation-through-transformation of the impact of laws that disproportionately target the marginalized, even as justificatory rhetoric changes in sex equality and antidiscrimination law. See, e.g., Reva Siegel, “*The Rule of Love*”: *Wife-Beating as Prerogative and Privacy*, 105 YALE L.J. 2117, 2180-88 (1996).

45. See, e.g., Gary Marks et al., *Meta-Analysis of High-Risk Sexual Behavior in Persons Aware and Unaware They Are Infected with HIV in the United States*, 39 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 446, 451 (2005) (arguing for public health campaigns that target young men who have sex with men [MSM], particularly young MSM of color, and routine HIV testing “in high HIV prevalence areas” and venues that “attract high-risk persons”).

46. See, e.g., Donna Hubbard McCree & Matthew Hogben, *The Contribution to and Context of Other Sexually Transmitted Diseases and Tuberculosis in the HIV/AIDS Epidemic Among African Americans*, in AFRICAN AMERICANS AND HIV/AIDS: UNDERSTANDING AND ADDRESSING THE EPIDEMIC 3 (Donna Hubbard McCree et al. eds., 2010) (detailing the significant disparities in prevalence rates of chronic diseases, including cancer, cardiovascular diseases, hypertension, diabetes and HIV/AIDS among ethnic minorities in the United States). This article also reports that African Americans are the most disproportionately impacted by chlamydia, gonorrhea and HIV because of structural inequities including higher poverty, higher incarceration rates and lack of healthcare access. *Id.*

47. See, e.g., E. O. Laumann et al., *Monitoring the AIDS Epidemic in the United States: A Network Approach*, 244 SCIENCE 1186, 1186-89 (1989) (reporting that data provided to the CDC may substantially underestimate prevalence among whites of higher socioeconomic status, overrepresent minorities, and overstate prevalence in the East while understating prevalence in the

programs, heavier surveillance of socially marginalized groups—who are often also economically marginalized and more reliant on these programs—may skew prevalence statistics.<sup>48</sup> Such skewed statistics aggravate the sense that STDs are about “them” rather than the collective “us.” This perception entrenches heuristics about who is “safe” and who is not.<sup>49</sup>

### *1. The Historical Usual Out-Group Suspects*

Which marginalized groups are deemed suspect has varied with the prevailing narratives and fears of the time. Socially and economically marginalized groups targeted for heavier intervention have ranged from immigrants, to prostitutes, to racial minorities. In the era of rapid industrialization at the turn of the eighteenth century, for example, immigrants packed into teeming cities were deemed reservoirs of prostitution and venereal diseases.<sup>50</sup> Dr. Howard Kelly, then one of the nation’s leading gynecologists, colorfully claimed, “The tide of [venereal disease] has been raising [sic] continually owing to incessant impouring [sic] of a large foreign population with lower ideals.”<sup>51</sup>

Prostitutes—often perceived as doubly foreign because of their alleged foreign origin and their outsider status in a culture where sex was reserved for marriage—became the target for campaigns of control.<sup>52</sup> Prostitutes were blamed for debauching men, who in turn spread the affliction to the “pure,” “innocent,” American woman.<sup>53</sup> Prostitutes were targeted for “reglementation”—compulsory medical inspection and “treatment” with highly toxic and ineffective remedies for syphilis.<sup>54</sup>

Traces of this past linger in contemporary law. New Jersey law, for example,

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Midwest).

48. See, e.g., ALLAN M. BRANDT, *NO MAGIC BULLET: A SOCIAL HISTORY OF VENEREAL DISEASE IN THE UNITED STATES SINCE 1880*, at 158 (1987) (noting concern among black physicians that STD prevalence statistics were overreported for black communities, which were subject to greater surveillance because of impoverishment and reliance on public health systems); Taunya L. Banks, *Women and AIDS – Racism, Classism and Sexism*, 17 N.Y.U. REV. L. & SOC. CHANGE 351, 354 (1990) (cautioning that prevalence statistics may unfairly stigmatize women of color because statistics are mainly gathered from publicly funded health programs where disproportionately economically marginalized women of color must get their healthcare whereas “the extent of underreporting among white women is unknown”); William C. Miller et al., *Prevalence of Chlamydial and Gonococcal Infections Among Young Adults in the United States*, 291 JAMA 2229, 2229-34 (2004) (arguing that “reporting bias and minority groups’ disproportionate use of publicly funded clinics may affect previous prevalence estimates derived from clinics,” but “these sources of bias cannot explain the racial/ethnic disparities” in the study’s general population sample).

49. See *infra* Part III for a discussion of studies reporting reliance on heuristics for who is “safe.”

50. BRANDT, *supra* note 48, at 20-21.

51. *Id.* at 23.

52. *Id.* at 21, 31-35.

53. *Id.* at 31-32.

54. See Gostin & Hodge, *supra* note 26, at 17-18.

defines prostitutes as a class categorically suspected of having venereal diseases and subject to testing at any time.<sup>55</sup> New York law provides for compulsory STD examination of people arrested for prostitution or patronizing prostitutes.<sup>56</sup> This approach of targeting certain groups for particularly harsh interventions is commonly provided for by statute.<sup>57</sup>

Another approach with historical roots is the targeting of people of color for stronger interventions because of the perception of higher risk. During the World War I era, black troops were required to undergo compulsory prophylaxis because of the belief that black troops had much higher rates of venereal disease infection.<sup>58</sup> In the 1930s, Surgeon General Thomas Parran resolved to make venereal disease “The Next Great Plague to Go” and implemented “Wasserman dragnets” for testing groups deemed at higher risk for venereal disease, including the black community.<sup>59</sup>

The association of black people with syphilis at the height of “syphilophobia” between the two world wars revealed the “stereotyping moralism” surrounding the control of venereal disease.<sup>60</sup> Medical opinion deemed respectable in some quarters posited that the longstanding scourge of syphilis originated in Africa and that black skin arose from syphilitic sores.<sup>61</sup> Black physicians took issue with the claims that the dreaded disease was rampant among black communities, noting that surveillance was skewed and heavier in communities of color.<sup>62</sup> Then, as now, structural inequities did produce higher prevalence rates, but statistics were also skewed because of the stronger surveillance and resultant data collection in disadvantaged communities, which are disproportionately communities of color, reliant on public health services.<sup>63</sup>

## 2. Continued Heightened Focus

In contemporary times, heavier intervention and surveillance continues to be advocated for the most vulnerable groups, which are defined in terms of risk, but also map onto the socially marginalized. Early in the HIV epidemic, for example, groups targeted for intervention were “traditional ‘high-risk’ groups,” such as commercial sex workers.<sup>64</sup> Because sex workers typically operate outside of

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55. N.J. STAT. ANN. § 26:4-32 (West 2011).

56. N.Y. PUB. HEALTH LAW § 2302 (McKinney 2011).

57. Gostin et al., *supra* note 21, at 110.

58. BRANDT, *supra* note 48, at 116.

59. *Id.* at 138-39, 152.

60. *Id.* at 158-59.

61. MARIANNA TORGONICK, *GONE PRIMITIVE: SAVAGE INTELLECTS, MODERN LIVES* 104 (1990).

62. BRANDT, *supra* note 48, at 158-59.

63. See sources cited *supra* note 48.

64. Theresa M. Exner et al., *A Review of HIV Interventions for At-Risk Women*, 1 AIDS & BEHAV. 93, 94 (1997).

political and legal recognition and protections, they are most susceptible to heaviest state intervention.

A larger dilemma for a society that has evolved in its desire for racial equality is the continued heavy burdens of surveillance on minority communities. There has been a shift to behavior-based or regional definitions of risk rather than the explicit racialized narratives of the past. Yet racial communities still bear heavier burdens because disadvantaged communities of color are overrepresented among HIV-seroprevalent geographic regions.<sup>65</sup>

The prevalence of STDs is greater among the most marginalized, particularly intersectionally marginalized groups, including women of color and men of color who have sex with men.<sup>66</sup> The same behavior, such as intercourse without a condom, may pose greater risks for people in disadvantaged minority communities because greater prevalence of disease in the community increases the likelihood of encountering an infected partner.<sup>67</sup> From an ecological perspective, “advantages and disadvantages tend to cluster cross-sectionally and accumulate longitudinally” in the health of communities.<sup>68</sup> The disparities are stark for African American men who have sex with men (MSM). Though African American MSM have fewer partners than white MSM, African American MSM experience nearly twice the rate of HIV infection of white MSM.<sup>69</sup>

At the intersection of the most pronounced historic gender and racial inequities, African American women experience the greatest racial disparities in infection.<sup>70</sup> Infection rates for African American women are between four and twenty-one percent greater than for any other racial and gender group.<sup>71</sup> The HIV incidence rate of African American women is nearly fifteen times that of white women and over three times that of Hispanic women.<sup>72</sup> African American women are less likely to receive treatment for HIV and more likely to die early because of it.<sup>73</sup> As of 2002, AIDS was the leading cause of death among African

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65. See Kim M. Williams & Cynthia M. Prather, *Racism, Poverty and HIV/AIDS Among African Americans*, in AFRICAN AMERICANS AND HIV/AIDS: UNDERSTANDING AND ADDRESSING THE EPIDEMIC, *supra* note 46, at 31, 36 (reporting that regions experiencing the greatest economic disadvantage, racial segregation, and the greatest concentrations of communities of color are disproportionately impacted by HIV/AIDS).

66. Pamina M. Gorbach & King M. Holmes, *Transmission of STIs/HIV at the Partnership Level: Beyond Individual-Level Analyses*, 80 J. URBAN HEALTH iii15, iii18 (2003).

67. McCree & Hogben, *supra* note 46, at 3, 5.

68. David Blane, Editorial, *Social Determinants of Health – Socioeconomic Status, Social Class, and Ethnicity*, 85 AM. J. PUB. HEALTH 903, 904 (1995).

69. Rebecca Voelker, *Studies Illuminate HIV's Inequalities*, 299 JAMA 269, 269 (2008).

70. Martina Morris et al., *Concurrent Partnerships and HIV Prevalence Disparities By Race*, 99 AM. J. PUB. HEALTH 1023, 1024 (2009).

71. *Id.*

72. *HIV in the United States*, CENTERS FOR DISEASE CONTROL & PREVENTION 2, <http://www.cdc.gov/hiv/resources/factsheets/PDF/us.pdf> (last updated Nov. 7, 2011).

73. LINDA LEWIS ALEXANDER ET AL., *NEW DIMENSIONS IN WOMEN'S HEALTH* 194 (2009).

American women aged twenty-five to thirty-four years old.<sup>74</sup>

Hispanic women, likewise subject to economic marginalization, also suffer greater HIV incidence rates than non-Hispanic white women.<sup>75</sup> HIV incidence among Hispanics is more than three times the rate for non-Hispanic whites, with the disparity concentrated in Hispanic women, who are more than five times more likely than non-Hispanic white women to have HIV.<sup>76</sup>

Minority groups are disproportionately impacted by STD and HIV infections because a disproportionate number are economically and socially marginalized.<sup>77</sup> Disadvantaged groups are often concentrated in higher-risk communities marked by poverty, decreased access to healthcare and heightened surveillance when public healthcare is sought.<sup>78</sup> Structural socioeconomic context leads to more severe health burdens borne by communities of color because of the following factors: (1) larger proportions of the community incarcerated in dangerous and unhealthy conditions; (2) a skewed female-to-male ratio because men of color die younger and are incarcerated at a substantially disproportionate rate; (3) residential segregation; and (4) circumscribed access to health services.<sup>79</sup> Inequities in status and access to resources, physical abuse, and other power imbalances may also deter minority women from insisting on condom use and increase exposure to forced sex and other practices that heighten vulnerability and risk.<sup>80</sup>

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74. Gina M. Wingood & Ralph J. DiClemente, *HIV Prevention for Heterosexual African-American Women*, in *AFRICAN AMERICANS AND HIV/AIDS: UNDERSTANDING AND ADDRESSING THE EPIDEMIC*, *supra* note 46, at 211, 211.

75. Rosa M. González-Guarda et al., *HIV Risks, Substance Abuse and Intimate Partner Violence Among Hispanic Women and their Intimate Partners*, 19 J. ASS'N NURSES AIDS CARE 252, 252 (2008).

76. *Id.*

77. See, e.g., *Poverty Rate by Race/Ethnicity, States (2008-2009), US (2009)*, STATEHEALTHFACTS.ORG, <http://www.statehealthfacts.org/comparebar.jsp?ind=14&cat=1> (last visited Nov. 9, 2009) (reporting that 35% of blacks and 34% of Hispanics lived in poverty in the United States, compared to 12% of whites in 2008-2009).

78. Koray Tanfer et al., *Gender, Race, Class and Self-Reported Sexually Transmitted Disease Incidence*, 27 FAM. PLANNING PERSP. 196, 197 (1995); see also INST. OF MED., *UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTHCARE* 5-7, 35 (Brian D. Smedley et al. eds., 2002) (discussing evidence of racial disparities and inequities in healthcare treatment and access to healthcare); Miller, *supra* note 48, at 2234 (2004) (heightened surveillance); Wingood & DiClemente, *supra* note 74, at 216-18 (discussing higher-risk communities with less access to partners and resources).

79. Sandra D. Lane et al., Guest Editorial, *Structural Violence and Racial Disparity in HIV Transmission*, 15 J. HEALTH CARE FOR POOR & UNDERSERVED 319, 320-23, 326 (2004); Russell K. Robinson, *Racing the Closet*, 61 STAN. L. REV. 1463, 1525-32 (2009).

80. Gorbach & Holmes, *supra* note 66, at iii16. Researchers posit that higher rates of intimate-partner violence and fear among Hispanic women over requesting a condom contribute to the higher rates of HIV that Hispanic women suffer. González-Guarda, *supra* note 75, at 252, 253. Hispanic women face more than twice the rate of intimate-partner violence of non-Hispanic women, even when socioeconomic variables are controlled, and a study found that Hispanic women who suffered intimate-partner violence were more than six times as likely to have an STD.

The socioeconomically marginalized also bear heavier burdens of intervention. As public health officials try to shift strategy toward routine screening, controversy has stymied deployment of this tactic for the general population. Unable to deploy these strategies broadly, officials instead find it is more feasible to pursue routine screening among the economically and socially disadvantaged, who are concentrated in high-STD prevalence areas and dependent on publicly funded clinics.<sup>81</sup> Routine screening, which can be mandatory or have an opt-out option, is typically performed on certain groups over which the state has greater power or who are deemed at higher risk, such as immigrants or pregnant women, particularly those who cannot afford private healthcare.<sup>82</sup> The CDC currently recommends routine screening of pregnant women for a host of STDs including syphilis, hepatitis B, chlamydia, gonorrhea, and hepatitis C.<sup>83</sup> Screening pregnant women for HIV/AIDS, however, has been intensely controversial. Supporters argue that early antiretroviral therapy could dramatically reduce the risk of transmission of the virus from mother to child, but opponents worry about discriminatory treatment, diminished privacy, and the targeting of women.<sup>84</sup>

The CDC also has called for routine HIV screening of all people aged thirteen to sixty-four unless HIV prevalence in the patient population is less than 0.1%.<sup>85</sup> Proponents of widespread screening note that an estimated twenty-one to twenty-five percent of HIV-infected people do not know they are infected and detection would reduce the likelihood of transmission.<sup>86</sup> Diagnosis would also help prolong life expectancy with the advent of Highly Active Antiretroviral Therapy (HAART).<sup>87</sup> While general routine screening remains unpalatable in many quarters, cities with large communities of color that suffer

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*Id.* at 253, 256.

81. *See, e.g.*, Banks, *supra* note 48, at 352, 372 (noting that government-provided or funded facilities will be the ones implementing proposed routine screening and poor women of color most often receive their healthcare through these facilities).

82. Benjamin Armbruster & Margaret L. Brandeau, *Optimal Mix of Screening and Contact Tracing for Endemic Diseases*, 209 MATHEMATICAL BIOSCIENCES 386, 387 (2007).

83. *Id.*

84. For overviews of the debate, see Erin Nicholson, *Mandatory HIV Testing of Pregnant Women: Public Health Policy Considerations and Alternatives*, 9 DUKE J. GENDER & L. 175, 183-86 (2002); and Leslie E. Wolf et al., *Legal Barriers to Implementing Recommendations for Universal Prenatal HIV Testing*, 32 J.L. MED. & ETHICS 137, 138 (2004).

85. Ctrs. for Disease Control & Prevention, *Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings*, 55 MORBIDITY & MORTALITY WKLY. REP., Sept. 22, 2006, at 1, 2, 7, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm>.

86. *See, e.g.*, Gillian D. Sanders et al., *Cost-Effectiveness of Screening for HIV in the Era of Highly Active Antiretroviral Therapy*, 352 NEW ENG. J. MED. 570, 580 (2005).

87. *Id.* (noting the inadequacy of current approaches to testing because HIV-positive people are not being identified and arguing that “the case for systematic voluntary HIV screening in healthcare settings is now compelling” because treatment with Highly Active Antiretroviral Therapy would reduce the likelihood of transmission even if risky behavior remained unchanged).

disproportionately from high infection rates are turning toward mass screening. Washington, DC has deployed a pilot program that screens high school students for chlamydia and gonorrhea, which are at epidemic levels in the city and heighten vulnerability to HIV infection.<sup>88</sup> The pilot is modeled after a Philadelphia program for routine STD testing of students.<sup>89</sup> Baltimore, Chicago, New Orleans, and New York are among other cities planning similar pilot programs.<sup>90</sup>

We have come a long way from the days when former President George H.W. Bush was booed for suggesting routine HIV/AIDS screening.<sup>91</sup> Yet routine screening remains deeply controversial and very expensive—costing an estimated eighty-six million dollars a year.<sup>92</sup> Critics also argue that the strategy is not cost-effective because, given individuals' ability to opt out, the strategy only focuses on people more apt to choose to mitigate risk rather than those most in need of intervention.<sup>93</sup> There is also concern that the program would have an uneven focus on the socially and economically marginalized, resulting in differential privacy for those who can afford private healthcare and further underscoring the sense that HIV and other STDs are a problem afflicting people on the fringes.<sup>94</sup>

## II. AN EVOLVING PUBLIC HEALTH CHALLENGE THAT CUTS ACROSS COMMUNITIES

It is critical to look past the prevailing narratives of who is high risk (and who is not), and understand that STDs are an evolving public health challenge that cuts across social strata, sexual orientation, race, economic advantage, and other axes of differentiation. The economically advantaged historically have been better able to afford private healthcare providers that offer a greater shield, hiding the extent of the problem.<sup>95</sup> But the nature of the risk and its ability to “jump”

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88. Darryl Fears & Nelson Hernandez, *D.C. to Offer STD Tests to All High School Students*, WASH. POST, Aug. 5, 2009, <http://www.washingtonpost.com/wpdyn/content/article/2009/08/04/AR2009080403402.html>.

89. *Id.*

90. *Id.*

91. Marlene Cimon & Harry Nelson, *Bush Is Booed as He Defends AIDS Proposals*, L.A. TIMES, June 2, 1987, [http://articles.latimes.com/1987-06-02/news/mn-4306\\_1\\_aids-virus](http://articles.latimes.com/1987-06-02/news/mn-4306_1_aids-virus).

92. David R. Holtgrave, *Costs and Consequences of the US Centers for Disease Control and Prevention's Recommendations for Opt-Out HIV Testing*, 4 PLOS MED. 1011, 1015 (2007).

93. James M. Hyman et al., *Modeling the Impact of Random Screening and Contact Tracing in Reducing the Spread of HIV*, 181 MATHEMATICAL BIOSCIENCES 17, 19 (2003).

94. See, e.g., Banks, *supra* note 48, at 352, 354-55, 359, 363, 370-72 (discussing dangers of differential focus on the most marginalized); see also Note, *Name Brands: The Effects of Intrusive HIV Legislation on High-Risk Demographic Groups*, 113 HARV. L. REV. 2098, 2103-10 (2000) (discussing concern that intrusive HIV policies will disproportionately impact minority communities).

95. See, e.g., FAIRCHILD, *supra* note 13, at 75-79 (detailing underreporting and the resistance



social networks is greater because of shifts such as technologically extended networks.<sup>96</sup> These social, cultural, and technological shifts lead to an information deficit that poses public health challenges and impedes fully informed and autonomous consent to risk.<sup>97</sup>

#### *A. Shifting Social and Sexual Norms in the Marketplace for Sex and Romance*

In our consumerist-networked society, approaches to sex once taboo or outré are becoming normalized, including casual sex and shopping for partners online. The shift is sweeping across age groups, though it is most pronounced in the most sexually active age demographic of college-aged youths. The phenomenon of “casual sex” is so prevalent that sex scholars write of a “hookup culture,” especially on college campuses.<sup>98</sup> Hookup is a colloquial term for a casual sexual encounter, typically, but not always, between people who do not know each other well.<sup>99</sup> This casual sexual contact can vary from kissing and fondling to oral, vaginal, and anal intercourse.<sup>100</sup>

The term hookup is itself becoming antiquated in our acronym and text-

of private physicians to contact tracing).

96. See, e.g., KATHERINE BOGLE, *HOOKING UP: SEX, DATING, AND RELATIONSHIPS ON CAMPUS* 2, 11-20 (2008) (collecting reports and describing phenomenon); Anthony Paik, “*Hookups, Dating, and Relationship Quality: Does the Type of Sexual Involvement Matter?*,” 39 SOC. SCI. RES. 739, 739-80 (2010) (collecting studies pronouncing the “demise of dating” and exploring the rise in and prevalence of casual sex, as well as the shortening of time between acquaintance with someone and sex).

97. See, e.g., P.M. Gorbach et al., *Don't Ask, Don't Tell: Patterns of HIV Disclosure Among HIV Positive Men Who Have Sex with Men with Recent STI Practising High Risk Behavior in Los Angeles and Seattle*, 80 SEXUALLY TRANSMITTED INFECTIONS 512, 512 (2004) (finding substantial nondisclosure of HIV-positive men to partners in unprotected sex for an array of reasons and observing that absent such information “HIV negative men lack the ability to make fully informed choices about their level of risk”); Samuel W. Perry et al., *Self-Disclosure of HIV Infection to Sexual Partners After Repeated Counseling*, 6 AIDS EDUC. & PREVENTION 403, 407 (1994) (finding substantial percentages of nondisclosure even after counseling, particularly in casual sex contexts).

98. See, e.g., Caroline Heldman & Lisa Wade, *Hookup Culture: Setting a New Research Agenda*, 7 SEXUALITY RES. & SOC. POL'Y 323 (2010) (analyzing reasons for rise of hookup culture); Elizabeth L. Paul & Kristen A. Hayes, *The Casualties of 'Casual' Sex: A Qualitative Exploration of the Phenomenology of College Students' Hookups*, 19 J. SOC. & PERS. RELATIONSHIPS 639, 656 (2002) (studying the phenomena of college campus hookups).

99. Elizabeth L. Paul et al., “*Hookups*”: *Characteristics and Correlates of College Students' Spontaneous and Anonymous Sexual Experiences*, 37 J. SEX RES. 76, 76 (2000) (defining hookup as “a sexual encounter usually lasting one night, between two people who are strangers or brief acquaintances”). But see Robyn L. Fielder & Michael P. Carey, *Prevalence and Characteristics of Sexual Hookups Among First-Semester Female College Students*, 36 J. SEX & MARITAL THERAPY 346, 354-55 (2010) (noting first-semester female students surveyed frequently hooked up with someone they knew relatively well, such as a friend or ex-boyfriend).

100. Fielder & Carey, *supra* note 99, at 351; see also Paul & Hayes, *supra* note 98, at 645 (noting that forty-one percent of students surveyed described sexual intercourse as typical hookup behavior).

happy culture. A new array of acronyms has arisen to describe casual sexual arrangements and facilitate advertising for them, particularly in online advertising for sexual partners. Common acronyms include “NSA” (No Strings Attached),<sup>101</sup> “FWB” (Friends with Benefits),<sup>102</sup> and “DDF” (Drug and Disease Free).<sup>103</sup> These sexual arrangements often facilitate “partner concurrency”—having more than one sexual partner in a time period—a phenomenon with public health consequences for the rapid spread of disease.<sup>104</sup> This section explores the two most pronounced shifts in sexual culture with epidemiological implications: the rise of casual sex and online meeting and mating.

### 1. *The Prevalence of Casual Sex Culture*

Researchers on modern sociality have pronounced traditional dating’s demise and the rise of casual sex between people who know a lot less about each other than in the past.<sup>105</sup> As social scripts are rewritten, sex outside of relationships and concurrent relationships are becoming normalized.<sup>106</sup> Estimates suggest that between one-half and three-quarters of college students have had one or more casual sexual encounters.<sup>107</sup> A study of students at a large Northeastern university, for example, found that between seventy and seventy-eight percent of undergraduates have hooked up at least once.<sup>108</sup> Among those that had, the average number of hookups over the span of college was 10.28.<sup>109</sup> Another

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101. See *No, It Doesn’t Mean National Security Agency*, ATLANTA J.-CONST., Mar. 2, 2008, at C2, available at 2008 WLNR 4133965 (defining term).

102. See Melissa A. Bisson & Timothy R. Levine, *Negotiating a Friends with Benefits Relationship*, 38 ARCHIVES SEXUAL BEHAV. 66, 67 (2009) (collecting studies and exploring dynamics of FWB relationships among 125 undergraduates from a large Midwestern university).

103. See Leon Hale, *Learning About the Personals*, HOUS. CHRONICLE, Mar. 14, 1995, [http://www.chron.com/CDA/archives/archive.mpl/1995\\_1261993/learning-about-the-personals.html](http://www.chron.com/CDA/archives/archive.mpl/1995_1261993/learning-about-the-personals.html) (defining term).

104. See, e.g., Anthony Paik, *The Contexts of Sexual Involvement and Concurrent Sexual Partnerships*, 42 PERSP. ON SEXUAL & REPROD. HEALTH 33, 34 (2010) (noting association between sex with casual dating partners or friends and concurrent sex partners).

105. See, e.g., BOGLE, *supra* note 96, at 11-33; LAURA SESSIONS STEPP, UNHOOKED: HOW YOUNG WOMEN PURSUE SEX, DELAY LOVE AND LOSE AT BOTH 4 (2007) (“Young people have virtually abandoned dating and replaced it with . . . sexual behaviors that are detached from love and commitment . . .”); Fielder & Carey, *supra* note 99, at 354-55; Heather Littleton et al., *Risky Situation or Harmless Fun? A Qualitative Examination of College Women’s Bad Hook-Up and Rape Scripts*, 60 SEX ROLES 793, 793-95 (2009).

106. See Paul & Hayes, *supra* note 98, at 640-41, 656 (collecting studies).

107. See, e.g., Marina Epstein et al., “Anything from Making Out to Having Sex”: Men’s Negotiations of Hooking Up and Friends With Benefits Scripts, 46 J. SEX RES. 414, 414 (2009); Littleton, *supra* note 105, at 793.

108. See, e.g., Paul, *supra* note 99, at 81 (surveying 555 undergraduates at large Northeastern university and finding that 78 percent had engaged in a hookup at least once); Paul & Hayes, *supra* note 98, at 644 (surveying 187 students at a mid-sized Northeastern college and finding that seventy-eight percent of them had hooked up at least once).

109. Paul & Hayes, *supra* note 98, at 644; see also Paul, *supra* note 99, at 80 (10.8 average).

survey, focusing on first-semester female college students, found that sixty percent of the young women had already experienced oral, vaginal, or anal sex hookups at that early juncture in their college careers.<sup>110</sup>

A substantial number of students also have had a FWB arrangement permitting regular sex without commitment or romantic attachment.<sup>111</sup> Surveys on the prevalence of FWB arrangements suggest forty-nine to sixty-two percent of undergraduates have engaged in such conduct.<sup>112</sup> The main reported reason for such an arrangement was the convenience of having someone available for recreational sex without expectation of exclusivity.<sup>113</sup> While the terms of the arrangements vary, the lack of commitment or romantic relationship often provides the flexibility needed to have multiple partners in the same period.<sup>114</sup> The FWB arrangement is thus frequently associated with concurrent partnerships, which are an important factor in driving the spread of disease between intersecting and overlapping networks.<sup>115</sup>

Such cultural change affects non-college-aged people as well. A study of urban men and women aged eighteen through thirty-nine, for example, found that thirty-one percent of men and twenty-six percent of women had concurrent partners.<sup>116</sup> In a survey of adults aged eighteen to fifty-nine, one in five people reported having sex outside of a romantic relationship and a quarter said that they or their partner had more than one sex partner.<sup>117</sup> In the National Survey of Sexual Health and Behavior, a strikingly “sizeable minority of women and men in all age cohorts” reported that their last sexual encounter was with a “friend,” rather than with a romantic or dating partner; this lead the investigators to observe that the FWB phenomenon, “might also be common across all age groups.”<sup>118</sup> Indeed, data suggests that women between the ages of twenty-seven and forty-five are more inclined to have sex with someone they just met and engage in more sexual activity than younger women.<sup>119</sup> Researchers posit that

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110. Fielder & Carey, *supra* note 99, at 354.

111. See, e.g., Bisson & Levine, *supra* note 102, at 68 (finding that sixty percent of 125 undergraduates at a large Midwestern university surveyed had at least one FWB).

112. *Id.* at 67.

113. *Id.* at 69.

114. See, e.g., Mikayla Hughes et al., *What's Love Got to Do with It? Exploring the Impact of Maintenance Rules, Love Attitudes, and Network Support on Friends with Benefits Relationships*, 69 W. J. COMM. 49, 50, 61-62 (2005).

115. See Paik, *supra* note 104, at 34.

116. Lisa E. Manhart et al., *Sex Partner Concurrency: Measurement, Prevalence and Correlates Among Urban 18-39-Year-Olds*, 29 SEXUALLY TRANSMITTED DISEASES 133, 136 (2002).

117. Paik, *supra* note 104, at 36-37.

118. Debby Herbenick et al., *An Event-Level Analysis of the Sexual Characteristics and Composition Among Adults Ages 18 to 59: Results from a National Probability Sample in the United States*, 7 J. SEXUAL MED. (Supp.) 346, 359 (2010).

119. Judith A. Easton et al., *Reproduction Expediting: Sexual Motivations, Fantasies, and the Ticking Biological Clock*, 49 PERSONALITY & INDIVIDUAL DIFFERENCES 516, 517, 519 (2010); see

older women show such willingness because of declining fertility and an evolutionary drive to “capitalize on their remaining fertility.”<sup>120</sup> A convergence of factors, including skyrocketing divorce rates, shifts in gender roles and norms, medical and technological advances, and other social shifts, mean that even those raised with the social mores of another age are not immune from sexual culture change.<sup>121</sup>

Departing markedly from the model of sex within marriage of eras past, people now do not know their sexual partners as well and have scant relational repercussions to fear if unfortunate discoveries are made the morning after – or a few months after. A study of FWB relationships found that only 9.8% of them became romantic.<sup>122</sup> A study of hookups found that forty-nine percent of those who had sexual intercourse during the hookup never saw their partner again.<sup>123</sup> The traditional constraint of relational or social repercussions is thus dramatically diminished.

## 2. *The Online Meat/Meet Market*

The phenomenon of people knowing less about their sexual partners—and having more of them, perhaps concurrently—is facilitated and accelerated by shifts in technology-mediated connections. The rise of computer-mediated sociality has been rapid with the number of Internet users increasing dramatically from 20 million to 240 million in just a decade, from 1998 to 2007, as computers became affordable and ubiquitous.<sup>124</sup> The online meat/meet market serves as a massive hub connecting and expanding networks of people who might otherwise never meet.<sup>125</sup> As online partner seeking becomes more socially acceptable, the

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also John Cloud, *The Science of Cougar Sex: Why Older Women Lust*, TIME, July 9, 2010, <http://www.time.com/time/magazine/article/0,9171,2007422,00.html> (reporting on study findings).

120. Easton, *supra* note 119, at 519-20.

121. Vanessa Schick et al., *Sexual Behaviors, Condom Use, and Sexual Health of Americans Over 50: Implications for Sexual Health Promotion for Older Adults*, 7 J. SEXUAL MED. 315, 315-316, 323 (2010).

122. Bisson & Levine, *supra* note 102, at 68 tbl.1; see also Paik, *supra* note 96, at 749 (finding “lower relationship quality” in nonromantic sexual relationships and finding that “many individuals who become sexually involved in nonromantic contexts never expect to have sex again with their partner” though some encounters do turn into recurrent sexual involvement, FWB arrangements or dating relationships).

123. Paul, *supra* note 99, at 81. Only twelve percent of all hookups reported resulted in a romantic relationship, with an average duration of four months. *Id.*

124. Katherine M. Hertlein & Megan Webster, *Technology, Relationships, and Problems: A Research Synthesis*, 34 J. MARITAL & FAM. THERAPY 445, 445 (2008).

125. See Rebecca D. Heino et al., *Relationshopping: Investigating the Market Metaphor in Online Dating*, 27 J. SOC. & PERS. RELATIONSHIPS 427, 429 (2010) (arguing that the marketplace is a salient metaphor through which online daters view the experience); Jeffrey D. Klausner et al., *Tracing a Syphilis Outbreak Through Cyberspace*, 284 JAMA 447, 449 (2000) (noting that online outlets “enable persons who otherwise might not meet each other to initiate contact in cyberspace and then meet in person”).

ways we meet are expanding beyond the traditional contexts of school, work, community, and the clustering of geography and class.<sup>126</sup> Internet-mediated sociality has been dubbed “the new sexual revolution”<sup>127</sup> that “may radically change the nature of recognized sexual behaviors, much as did the birth control pill in the 1960s.”<sup>128</sup>

Internet-mediated meeting is sometimes celebrated as a way to transcend traditional barriers of physical appearance, age, and other markers of differentiation, permitting freer intimacy and connectivity.<sup>129</sup> Virtual meeting without cumbersome real-time baggage enables people to explore and experiment, shedding the limitations of identity and typical scripts expected based on gender, class and age.<sup>130</sup> This enables exploration of fetishes, fantasies, and desires otherwise suppressed in the physical world.<sup>131</sup> Internet-mediated sexual liberation is therefore celebrated as an avenue for getting over one’s hang-ups from the comfort of one’s living room.<sup>132</sup> Online communities devoted to formerly socially taboo activities can provide reinforcement for similarly minded individuals, normalizing inclinations formerly hidden away.<sup>133</sup>

Most powerfully, the Internet expands the marketplace for meeting people, particularly as online connections are shedding the old stigma that they are the resort for the desperate or weird.<sup>134</sup> An estimated sixteen million Americans have used online meeting services.<sup>135</sup> Sites such as Craigslist, Match.Com, Plenty of Fish, Gay.Com and other venues help people connect in expanded

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126. See Al Cooper & Eric Griffin-Shelley, *Introduction. The Internet: The Next Sexual Revolution*, in *SEX & THE INTERNET: A GUIDEBOOK FOR CLINICIANS 5* (Al Cooper ed., 2002) (describing transcending of real-time constraints).

127. *Id.* at 2.

128. James F. Quinn & Craig J. Forsyth, *Describing Sexual Behavior in the Era of the Internet: A Typology for Empirical Research*, 26 *DEVIANT BEHAV.* 191, 196-97 (2005).

129. Cooper & Griffin-Shelley, *supra* note 126, at 5.

130. See, e.g., Nicola M. Döring, *The Internet’s Impact on Sexuality*, 25 *COMPUTERS HUM. BEHAV.* 1089, 1095 (2009) (describing sexually empowering fantasy exploration); Kimberly S. Young, *Internet Sex Addiction: Risk Factors, Stages of Development and Treatment*, 52 *AM. BEHAV. SCIENTIST* 21, 23, 28 (2008) (describing a fifty-one-year-old grandmother raised Mormon in rural Utah who was able to explore sexual domination fantasies she had kept “bottled up inside” and a fifty-two-year-old Vancouver nurse who explored her fantasy to be a dominatrix).

131. See, e.g., Cooper & Griffin-Shelley, *supra* note 126, at 5 (discussing how the Internet breaks down interpersonal communication barriers); Jennifer L. Gibbs et al., *Self-Presentation in Online Personals: The Role of Anticipated Future Interaction Self-Disclosure, and Perceived Success in Internet Dating*, 33 *COMM. RES.* 152, 156 (2006) (noting intimacy acceleration).

132. See, e.g., REGINA LYNN, *THE SEXUAL REVOLUTION 2.0* (2006).

133. Quinn & Forsyth, *supra* note 128, at 201-03.

134. Gibbs, *supra* note 131, at 153; Amy Harmon, *Online Dating Sheds Its Stigma as Losers.Com*, *N.Y. TIMES*, June 29, 2003, <http://www.nytimes.com/2003/06/29/us/online-dating-sheds-its-stigma-as-loserscom.html?pagewanted=all&src=pm>.

135. Catalina Toma et al., *Separating Fact from Fiction: An Examination of Deceptive Self-Presentation in Online Dating Profiles*, 34 *PERSONALITY & SOC. PSYCH. BULL.* 1023, 1023 (2008).

configurations.<sup>136</sup> These widened networks mean, however, that people have less reliable information than existed in old contexts of meeting where community knowledge provides a check.<sup>137</sup> Internet sites such as Adult FriendFinder and Craigslist also facilitate FWB and casual sex seeking in addition to long-term relationship (LTR)-seeking.<sup>138</sup> While data regarding the prevalence of online sex seeking is scarce and probably skewed through underreporting, we have some statistics. One 2006 British survey indicated that ten percent of heterosexual men and about five percent of heterosexual women had used the Internet to seek sex partners within the previous twelve months.<sup>139</sup> For gay men, the percentage that had used the Internet to find a sex partner rose to about 43.5%.<sup>140</sup>

Such sites still suffer from a scarcity of women willing to sign on, with a five-to-one-male-to-female ratio for an online meeting venue AdultSpace.com, for example, and OnLineBootyCall.com offering a \$10,000 reward for the person who recruits the most women to the site. Critics nonetheless claim that the plethora of sites threaten to turn sex into a “grocery market experience.”<sup>141</sup> Indeed, users often view the online meeting and mating experience through the metaphor of the marketplace, in terms of searches, self-presentation, and playing the numbers to hedge bets in case connections do not work out.<sup>142</sup>

While shopping for romantic and sexual partners is streamlined by searches based on age, race, body shape and profession, other information such as past partners, reputation, and “real” goals for meeting are more opaque than they were in the past, when friends and community members supplied history, background and information.<sup>143</sup> Despite the lack of reliable contextual information about people we meet online, surveys indicate that communication behind the safety of a computer screen helps accelerate the rapidity with which sex is reached by creating a sense of intensified intimacy.<sup>144</sup>

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136. Online daters use “uncertainty-reduction” strategies, such as Googling prospective partners, to try to make up for the information deficit. See, e.g., Jennifer L. Gibbs et al., *First Comes Love, then Comes Google: An Investigation of Uncertainty Reduction Strategies and Self-Disclosure in Online Dating*, 38 COMM. RES. 70 (2011).

137. *Id.* at 71.

138. See, e.g., Douglas Quenqua, *Recklessly Seeking Sex on Craigslist*, N.Y. TIMES, Apr. 17, 2009, <http://www.nytimes.com/2009/04/19/fashion/19craigslist.html?pagewanted=all>.

139. Graham Bolding et al., *Heterosexual Men and Women Who Seek Sex Through the Internet*, 17 INT’L J. STD & AIDS 530, 532, 533 (2006).

140. *Id.*

141. Zosia Bielski, *One Click Stands*, GLOBE & MAIL (Toronto), Apr. 9, 2009, <http://www.theglobeandmail.com/life/article967802.ece>.

142. Heino, *supra* note 125, at 431, 437-39; see also, e.g., Mark Davis, *E-Dating, Identity and HIV Prevention: Theorising Sexualities, Risk and Network Society*, 28 SOC. HEALTH & ILLNESS 457, 468 (2008) (finding that “E-daters were focused on presenting themselves in desirable ways”).

143. Jeffrey A. Hall et al., *Strategic Misrepresentation in Online Dating: The Effects of Gender, Self-Monitoring and Personality Traits*, 27 J. SOC. & PERS. RELATIONSHIPS 117, 126, 132 (2010) (discussing masking of relationship history and other personal attributes).

144. See, e.g., Gibbs et al., *supra* note 131, at 156 (discussing acceleration of a sense of

This sense of intimacy fostered online, however, may be based on falsehoods. Surveys assessing actual experience indicate that misrepresentation is rife online, and online-daters cite misrepresentation as a primary concern.<sup>145</sup> Because meetings arranged online are disembedded from context and more reliable real-time information indicators, users may invent false online personas to engage in behavior otherwise difficult to initiate.<sup>146</sup> A study of 5020 people who met others online found that, while women were more likely to misrepresent their weight, men were more likely to dissemble about an array of facts, from age to relationship goals.<sup>147</sup> There is a strong incentive to lie in the online meet market in the hopes of building a sense of intimacy and connection and maximizing the chances of a face-to-face meeting.<sup>148</sup>

Secret philanderers pose a particularly pronounced problem. Cheaters who misrepresent their relationship status pose potential harm to both the duped party, and the unwitting partner who thinks that, because she is in a monogamous relationship she does not need to take safeguards.<sup>149</sup> False representations of relationship status are rife online.<sup>150</sup> In one study, forty percent of online daters

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intimacy); *Social Networking Leads to Sex Faster?*, REUTERS, Jan. 25, 2011, <http://www.reuters.com/article/2011/01/25/us-sex-survey-odd-idUSTRE7004IJ20110125?feedType=RSS&sp=true> (reporting that nearly 80 percent of women and 58 percent of men believe that social networking tools leads to sex faster and 38 percent of women reporting they slept with someone faster because of digital intimacy).

145. Hall, *supra* note 143, at 118; *see also* Gibbs, *supra* note 131, at 169-70 (finding the most common misrepresentations identified by experienced online daters were “physical appearance (86%), relationship goals (49%), age (46%), income (45%), and marital status (40%)”).

146. *See, e.g.*, Döring, *supra* note 130, at 1095-96 (describing how online personas can change race, shed physical handicaps, change ages, and become extraordinary, escaping the real-time bonds of being unexceptional); Quinn & Forsyth, *supra* note 128, at 202-03 (discussing connections difficult to arrange in real-time to explore “deviant” sexuality).

147. Hall, *supra* note 143, at 126, 129.

148. *Id.* at 126, 132.

149. *See, e.g.*, Beatriz Lia Avila Mileham, *Online Infidelity in Internet Chat Rooms: An Ethnographic Exploration*, 23 COMPUTERS HUM. BEHAV. 11, 12-13 (2007) (exploring online cheating).

150. *See, e.g.*, Gus Goswell, *Cheating Common in Cyber Sex World*, AUSTL. BROADCASTING CORP., Sept. 24, 2009, <http://www.abc.net.au/news/2009-09-24/cheating-common-in-cyber-sex-world/1441284> (reporting on study finding that more than half of internet users engaging in cybersex were either in a serious real-time relationship or married); Lyda Longa, *Study: Internet Infidelity on the Rise*, DAYTONA BEACH NEWS-J., July 18, 2003, at 1A, *available at* 2003 WLNR 16092650 (reporting on University of Florida study on online infidelity and therapists’ accounts of rise in relationship crises precipitated by online relationships); Yvonne Martin, *Online Adultery Rife*, PRESS (New Zealand), June 10, 2006, at 1, *available at* 2006 WLNR 9984170 (reporting on research by Melbourne’s Swinburne University finding that online daters are “almost as likely to be living with a partner (41 percent) as to be single (46 percent)”); Marie Szaniszló, *Point, Click and Cheat*, BOS. HERALD, Dec. 14, 2003, at 3, *available at* 2003 WLNR 633589 (reporting on research indicating that Internet chatting is one of the fastest causes of breakups, accounting for potentially one-third of divorces nationally); Johanna Weidner, *Married but . . . Searching for More: Websites Help Would-Be Adulterers*, WATERLOO REGION RECORD, Feb. 16, 2008, at W1, *available at* 2008 WLNR 3063710 (reporting the claim that “a third of people on dating sites were married and

reported that, in their experience, marital status is commonly misrepresented.<sup>151</sup> In another study, thirteen percent of women who found sexual partners online reported that the sex partners lied about marital status.<sup>152</sup> Because the Internet enables connections outside of community networks, the social repercussions and checks against cheating are more readily dodged.<sup>153</sup> Online infidelity has become so prevalent that some sites have a “married but looking” box and others have arisen to cater to married individuals wanting to cheat.<sup>154</sup>

Because people connecting online often anticipate off-line real-time meetings eventually, the details they fudge or misrepresent are often those difficult to detect in a face-to-face interaction, such as STD status.<sup>155</sup> People may be euphemistic about STD status, leaving daters to read between ambiguous lines.<sup>156</sup> Studies of HIV-positive people who fail to disclose their status to their sexual partners indicate that one commonly proffered reason for not disclosing was that individuals felt a lessened sense of responsibility or concern for the sexual partner in the casual encounter context.<sup>157</sup> The information deficit on STD status is thus particularly pronounced when it comes to casual sex.

### *B. Epidemiological Ramifications*

The social and sexual culture changes discussed above have epidemiological implications. STD prevalence data demonstrate cause for concern. One in four

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lying”).

151. Gibbs, *supra* note 131, at 169-70.

152. Mary McFarlane et al., *Women, the Internet and Sexually Transmitted Infections*, 13 J. WOMEN'S HEALTH 689, 692 (2004).

153. See, e.g., DAVID GREENFIELD, VIRTUAL ADDICTION: HELP FOR NETHEADS, CYBERFREAKS AND THOSE WHO LOVE THEM 104-107 (1999) (explaining that online-facilitated intimacy enables the timid who might otherwise not descend into adultery to proceed); MARLENE M. MAHEU & RONA B. SUBOTNIK, INFIDELITY ON THE INTERNET: VIRTUAL RELATIONSHIPS AND REAL BETRAYAL 4, 15 (2001) (describing “upheaval in social mores” through intimacies created online and the ease of meeting new partners while maintaining at least initial anonymity).

154. See, e.g., Melody McDonald, *Cheaters Site Big in Texas*, HOUS. CHRONICLE, June 14, 2010, at B2, available at 2010 WLNR 12178442 (reporting strong success of cheating site in Texas, with 355,000 members, 108,000 of whom are women); Patricia Montimurri, *Michiganders Flock to Web Site for Flings with Married Cheaters*, DETROIT FREE PRESS, June 28, 2009, available at 2009 WLNR 12345194 (reporting on popularity of site and profiling one married man who secretly had sex with ten women through it).

155. Gibbs, *supra* note 131, at 157 (discussing constraints on misrepresentation because of prospect of face-to-face meeting); Toma et al., *supra* note 135, at 1024-25, 1032 (finding that eighty-one percent of online daters studied lied, but often about small things difficult to detect in face-to-face interactions because of the anticipation of meeting offline).

156. Davis, *supra* note 142, at 468.

157. See, e.g., Gorbach et al., *supra* note 97, at 514 (noting that many men surveyed “expressed that if they were having casual sex with no interest in an ongoing relationship then they were unlikely to disclose” because there “was less sense of obligation to disclose to those who were viewed as only sex partners” and where feelings for the partner were lacking).



women aged fourteen to nineteen has been infected with at least one STD.<sup>158</sup> Since 2000, the number of adolescents between the aged of thirteen and nineteen diagnosed with HIV has been steadily increasing.<sup>159</sup> While college-aged youths, the demographic most active in the “hook up culture” have been dubbed the “epicenter of the HIV/AIDS epidemic,”<sup>160</sup> health officials have also expressed concern about rising HIV rates among youths below college age.<sup>161</sup> Adolescents and youths aged fifteen to twenty-four experience nearly half of all new STD infections, though these young people represent only twenty-five percent of the sexually experienced population.<sup>162</sup> But risk is not limited to the young and most sexually active. The rates of infection are also rising in older people, including the over-50 demographic.<sup>163</sup>

A host of studies warn that concurrent partnerships, and the expanded networks of sexual partners facilitated by the online meet market, help spread disease.<sup>164</sup> The subsections below discuss how the spread of STDs is fueled by concurrent partnerships associated with, and facilitated by, casual sex arrangements and internet-mediated connectivity.

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158. Fenton, *supra* note 12, at 250.

159. CTRS. FOR DISEASE CONTROL & PREVENTION, HIV SURVEILLANCE IN ADOLESCENTS AND YOUNG ADULTS, at slide 15 (2010), available at <http://www.cdc.gov/hiv/topics/surveillance/resources/slides/adolescents/index.htm>.

160. Adededi S. Adefuye et al., *HIV Sexual Risk Behaviors and Perception of Risk Among College Students: Implications for Planning Interventions*, 9 BMC PUB. HEALTH 281, 282 (2009).

161. See, e.g., Christina Boyle, *HIV Rates Rise in City Teens*, N.Y. DAILY NEWS, May 18, 2008, at 25, <http://www.nydailynews.com/news/hiv-rate-rise-city-teens-article-1.330471> (reporting that HIV infection among New York City teens has risen to the highest level since 2001, with the number of infected people between ages 13 and 19 rising 29% between 2004 and 2006); Steve Blow, *Dallas County Groups Join to Fight Rise in HIV Among the Young*, DALL. MORNING NEWS, Sept. 17, 2010, <http://www.dallasnews.com/news/columnists/steve-blow/20100917-Dallas-County-groups-join-to-fight-2677.ece> (noting a 30% rise in HIV infections among young people aged 13 to 24 in Dallas County and quoting concern of behavioral intervention specialist that “[i]t’s above an epidemic. It’s a pandemic”); Christiana Sciaudone, *Youth at Risk for HIV: Health Officials Eye Rise in Cases*, STAMFORD ADVOCATE, July 31, 2005, at A1, available at 2005 WLNR 25529181 (reporting alarm among health officials over infection rates among youth, particularly minority youths, in light of CDC data indicating that about 50% of new HIV infections are in people under 25 and the rates of infection are increasing among heterosexual youths); *HIV, AIDS Rise Sharply Among Teens in Michigan*, KALAMAZOO GAZETTE, Dec. 1, 2009, [http://www.mlive.com/news/kalamazoo/index.ssf/2009/12/post\\_29.html](http://www.mlive.com/news/kalamazoo/index.ssf/2009/12/post_29.html) (reporting that for the fourth year in a row, HIV infection rates among Michigan teens have increased with the rate of new diagnoses among 13 to 19-year-olds doubling between 2003 and 2007).

162. STD SURVEILLANCE, *supra* note 15, at 63.

163. Sarah Boseley, *HIV Rates Double Among the Over-50s*, THE OBSERVER (UK), July 24, 2010, <http://www.guardian.co.uk/lifeandstyle/2010/jul/25/hiv-increases-in-middle-age>.

164. See, e.g., Sevgi O. Aral, *Partner Concurrence and the STD/HIV Epidemic*, 12 CURRENT INFECTIOUS DISEASE REP. 134, 134-35 (2010); Manhart et al., *supra* note 116, at 136; Paik, *supra* note 104, at 38.

### 1. Concurrent Partnerships and STD Spread

Social taboos may have protective effects that are lost when the taboo erodes.<sup>165</sup> Such is the case with the social norm against concurrent sexual partnerships. Laying aside moralizing to look at health ramifications, an array of studies indicate that having overlapping sexual partners in a short period of time—the “concurrent partnerships” phenomenon common in casual sex culture—powerfully sustains epidemic levels of STDs such as chlamydia, gonorrhea, syphilis, and HIV.<sup>166</sup> Concurrent partnerships are important to fueling communicable disease spread because such partnerships maximize the probability that an infected individual will, in the period of infectiousness or highest infectiousness, transmit the disease to uninfected individuals who then pass the disease to others in their sexual network.<sup>167</sup> In contrast, traditional monogamy confers “the protective effect of sequence” in that earlier partners are not exposed to the diseases of the later partner.<sup>168</sup>

Contact tracing after STD outbreaks has frequently found rapid spread to be facilitated by two individuals with concurrent partners, which leads to the intersection of tightly connected clusters of interconnecting dyads.<sup>169</sup> Concurrent partnerships are particularly potent in fueling the spread of HIV because infectiousness is particularly high in the brief window after infection, rendering timing an important element.<sup>170</sup>

Risk is further amplified by concurrent partnerships because people in such arrangements tend not to know each other well. People who become sexually involved within the first week of a relationship are more likely to have concurrent sexual partners, in part because sex within the first week is strongly associated with casual nonromantic relationships.<sup>171</sup> Studies indicate that concurrent partnerships are also more prevalent in a context where people have fewer social ties to their sexual partners.<sup>172</sup> The lack of social ties means there are

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165. Cf. Johan Colding & Carl Folke, *Social Taboos: Invisible Systems of Resource Management and Biological Conservation*, 11 *ECOLOGICAL APPLICATIONS* 584, 585-96 (2001) (discussing resource conservation effects of social taboos that act as modes of management).

166. See, e.g., Gorbach & Holmes, *supra* note 66, at iii15, iii16, iii21 (collecting studies); Sara J. Nelson et al., *Measuring Sex Partner Concurrency: It's What's Missing that Counts*, 34 *SEXUALLY TRANSMITTED DISEASES* 801, 801 (2007) (collecting studies); Paik, *supra* note 104, at 33 (collecting studies finding that concurrent sexual partnerships are “a critical factor in the spread of STDs”); Mark L. Williams, *An Investigation of Concurrent Sex Partnering in Two Samples of Drug Users Having Large Numbers of Sex Partners*, 17 *INT'L J. STD & AIDS* 309, 309 (2006) (collecting studies).

167. Aral, *supra* note 164, at 134-35.

168. *Id.*

169. Paik, *supra* note 104, at 33 (collecting studies).

170. Jeffrey W. Eaton et al., *Concurrent Sexual Partnerships and Primary HIV Infection: A Critical Interaction*, 15 *AIDS BEHAV.* 687, 687 (2011).

171. Paik, *supra* note 104, at 40.

172. *Id.* at 35.

less reliable sources of information regarding the sexual partner to inform consent and risk exposure.

People engaged in concurrent sexual practices may also engage in other behavior associated with higher risk of STDs, including have many partners.<sup>173</sup> For example, a study of urban young adults aged eighteen to thirty-nine noted a stepwise increase in the proportion of individuals with concurrent partners as the number of partners increased.<sup>174</sup> Among men with fifteen or more lifetime sexual partners, fifty-two percent also had concurrent sexual partners.<sup>175</sup> Concurrent partnerships are associated with behavior that is now used to approximate members of the sexually transmitted disease core.

The “sexually transmitted disease core” or “core group” are terms referring to the small proportion of the population whose behavior drives the maintenance of endemic levels of STDs.<sup>176</sup> There are various definitions of the core group based on such factors as having a large number of infected sexual contacts, having a substantially higher number of sexual partners than the average person in the population, and having a rapid rate of partner change.<sup>177</sup>

It bears underscoring that, while the disease burden is unevenly distributed across class and race because of structural inequities (as discussed in Section I.B), membership in the core group of riskiest spreaders may cut across class and race. One study found that women in the highest socioeconomic status (SES) and education group were actually *more* likely than those of lower SES to be in the core at age twenty-one though less likely at age eighteen.<sup>178</sup> Among men, those in the highest SES and with the highest education were *as* likely to be in the core at twenty-one or twenty-six years of age though less likely at eighteen.<sup>179</sup> While those with a low education level were more likely to be in the core at eighteen years of age, by twenty-one and twenty-six those with higher education were equally or more likely to be core group members.<sup>180</sup> With regard to race, recent studies have shown that African Americans and Hispanics actually use condoms *more* frequently than non-Hispanic whites, thus dampening transmission efficiency and the likelihood of being a core group member.<sup>181</sup>

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173. See, e.g., Manhart, *supra* note 116, at 136 (finding stepwise relationship); Paik, *supra* note 104, at 38 (finding likelihood of men reporting concurrent partnerships increases as the number of their prior sexual partners increases).

174. Manhart, *supra* note 116, at 136.

175. *Id.*

176. Olivier Humblet et al., *Core Group Evolution Over Time*, 30 SEXUALLY TRANSMITTED DISEASES 818, 818 (2003). For a full discussion see *infra*, Subsection IV.C.1.

177. James C. Thomas & Myra J. Tucker, *The Development and Use of the Concept of a Sexually Transmitted Disease Core*, 174 J. INFECTIOUS DISEASES S134, S135 (1996).

178. Humblet et al., *supra* note 176, at 821, 822.

179. *Id.*

180. *Id.*

181. Stephanie A. Sanders et al., *Condom Use During Most Recent Vaginal Intercourse Event Among a Probability Sample of Adults in the United States*, 7 J. SEXUAL MED. 362, 370 (2010).

## 2. Internet-Mediated Sex Seeking and Network Jumping

The second cultural shift with important ramifications for STD management is the turn to Internet-mediated sex seeking. “The Internet changes everything” is one of our contemporary cultural adages.<sup>182</sup> The Internet changes the speed, ease and risks of sex. A host of studies suggest that those who seek sex online are at greater risk for contracting an STD.<sup>183</sup> Online sex seeking has serious public health ramifications because Internet-mediated relationality expands webs of transmission and enables diseases to jump networks.<sup>184</sup> Moreover, Internet-mediated connections often come with information deficits because of the lack of traditional contextual sources of information such as community reputation—or even the barest check of gossip in a shared context such as a gym locker room identifying a particular individual as a problematic player.<sup>185</sup>

The power and the danger of Internet-mediated relationality is its ability to connect people outside of customary physical-space networks. When people who meet online finally connect in person, it is often outside of traditional geographical contexts. Online sex seekers often drive long distances of one hundred miles or more to meet a partner found over the Internet.<sup>186</sup> The expansion and connection of networks that might otherwise never intersect in a context that provides less reliable information to make informed choices enables more rapid spread of disease.<sup>187</sup>

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182. See, e.g., Rob Walker, *When Funny Goes Viral*, N.Y. TIMES SUNDAY MAG., July 16, 2010, <http://www.nytimes.com/2010/07/18/magazine/18ROFL-t.html?pagewanted=all> (discussing culture of web devotees and prevalence of the phrase).

183. See, e.g., Eric G. Benotsch et al., *Men Who Have Met Sex Partners Via the Internet: Prevalence, Predictors and Implications for HIV Prevention*, 31 ARCHIVES SEXUAL BEHAV. 177, 182 (2002) (finding Internet partner-seeking “was a significant predictor of having multiple partners for high-risk sexual activities”); Klausner, *supra* note 125, at 449 (finding greater likelihood of contracting syphilis when meeting partner through Internet); McFarlane, *supra* note 152, at 693 (finding women met sexual partners via the Internet have “high self-reported rates of STI, are not regularly using condoms, and are engaging in anal, oral, and vaginal sex” with those partners); Mary McFarlane et al., *The Internet as a Newly Emerging Risk Environment for Sexually Transmitted Diseases*, 284 JAMA 443, 445-46 (2000) (finding that those who reported seeking sex partners online were more likely to have had a STD had a greater number of partners); Jochen Peter & Patti M. Valkenburg, *Who Looks for Casual Dates on the Internet? A Test of the Compensation and Recreation Hypotheses*, 9 NEW MEDIA & SOC’Y 455, 456 (2007) (collecting studies).

184. See discussion *supra* Subsection II.A.2.

185. *Id.*

186. See, e.g., McFarlane, *supra* note 152, at 692 (finding that sixty-four percent of women who had a sex partner found online traveled more than 100 miles to meet and have sex with them); Mary McFarlane et al., *Young Adults on the Internet: Risk Behaviors for Sexually Transmitted Diseases and HIV*, 31 J. ADOLESCENT HEALTH 11, 13, 15 tbl.3 (2002) (reporting findings that “the Internet may be growing in its importance to young adults’ sex lives”).

187. See, e.g., McFarlane, *supra* note 152, at 693 (noting that the long distances traveled in meeting Internet sex partners “could result in new sexual mixing patterns, thus altering the epidemiology of sexually transmitted diseases” and because the Internet amasses people over long distances “one infected traveler can spread an STI [sexually transmitted infection] or HIV much

The ability of the Internet to reconfigure social networks is only one aspect of its risk-enhancing power. Another aspect is *who* is attracted to sex seeking online. Studies of online sex seekers find they tend to be “high sensation-seekers” more willing “to take physical and social risks” to experience “varied, novel and complex sensations.”<sup>188</sup> Studies also indicate that online sex-seekers are more sexually permissive and more likely to engage in casual sex with concurrent partners.<sup>189</sup>

Of course not all people who look for a partner online are “sexual adventurers.”<sup>190</sup> In a time when online dating is becoming more socially acceptable, and high divorce rates are sending people back into the dating arena, many may be looking for love and romance. The online boundaries between sex seekers and those looking for an LTR, however, are as permeable as a click of a button. In an environment where misrepresentation is rife, those looking for love online after divorce may instead find themselves connecting with a high-risk sexual adventurer maximizing the chances of a connection by posting or responding outside sections signaling a search for a casual encounter.<sup>191</sup> The recombination of networks and potential for intersection between low-risk and high-risk networks may lead to fresh infections that sustain the rate of STDs in the population.<sup>192</sup> Containing diseases within high-infection networks can dampen the reproduction rate, because the disease is not spreading to the uninfected.<sup>193</sup> The intersections between a high-risk and low-risk network that can occur in contexts such as an online dater looking for love after a divorce connecting instead with a sexual adventurer, or someone engaging in Internet-mediated infidelity while continuing to have unprotected sex with an unwitting long-term partner, allows the infection to jump networks and spread.

Moreover, because of the self-advertising imperative in the online

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faster and with much greater efficiency than ever imagined”).

188. Peter & Valkenburg, *supra* note 183, at 460-62.

189. *See id.* at 460-61, 472; *see also* Döring, *supra* note 130, at 1097 (summarizing literature suggesting that the “association of Internet sex-seeking and increased likelihood of unsafe sex could be explained by mere *self-selection*”).

190. *See* Kathleen E. Toomey & Richard B. Rothenberg, Editorial, *Sex and Cyberspace – Virtual Networks Lead to High-Risk Sex*, 284 JAMA 485, 486 (2000) (describing the activities of “sexual adventurers” in cyberspace).

191. *See, e.g.*, Gibbs et al., *supra* note 131, at 170 (discussing users’ experiences with misrepresentation of relationship goals).

192. *See* McFarlane, *supra* note 152, at 693 (noting that Internet-facilitated connections can result in “new sexual mixing patterns, thus altering the epidemiology of sexually transmitted diseases”).

193. *See, e.g.*, Ken T.D. Eames & Matt J. Keeling, *Modeling Dynamic and Network Heterogeneities in the Spread of Sexually Transmitted Diseases*, 99 PROC. NAT’L ACAD. SCI. 13330, 13330 (2002) (“[M]ost infected nodes [in a network of connected individuals] have infected neighbors, by whom they were infected or to whom they have transmitted infection. This aggregation reduces the average number of susceptible partners per infected individual and consequently slows the propagation of the epidemic.”).

marketplace for sex and romance, ads and representations may be deliberately opaque, euphemistic, ambiguous, and suggestive. For example, one study noted that some online daters removed the box directly stating their HIV serostatus offered by Gay.Com (an online dating site) and instead indicated that they practiced safe sex “sometimes,” rather than “always,”—an oblique code to suggest they were HIV-positive, but in a sexier way.<sup>194</sup> Someone not versed in the code, however, may not realize the information broadcast. Daters may not probe past an ad’s claim that the poster is DDF—after all, to put a spin on one online dater’s wry insight, “[t]here is nothing sexy about discussing [whether] you’re HIV positive prior to doing the deed . . . .”<sup>195</sup> With a deficit of information, people often need to steer by ambiguous cultural cues.<sup>196</sup> These deficits create public health consequences and impede an individual’s ability to make informed choices about sexual health.

### III. DEVOLVING INFORMATION AND POWER TO ENABLE INFORMED CONSENT

As public health authorities search for ways to reorient the STD control paradigm, the way forward must address the information deficit intensified by shifts in how people meet partners today. Reforms should also help supplant highly imperfect assumptions about who is “safe,” and who is not. Such assumptions lead to the entrenchment of discriminatory stereotypes, and a false sense of security and complacency about health and transmission risk among socially perceived “safe” groups. More reliable information would enable people to make more accurate judgments on the individual level and allow more efficient intervention based on behavioral information rather than group-level judgments about risk.

This Part argues that the way forward is to seed private-public partnerships that put power and information in the hands of the people in order to facilitate truly informed decisionmaking and consent, rather than concentrating it away in the state. Physicians may play important roles, acting as intermediaries for information empowerment of their patients and enabling more efficient uses of resources by prioritizing contacts that warrant greater attention from overburdened health authorities.

#### *A. Seeding a Healthier Information Culture: Promoting DDF-Verification*

In our contemporary context of prevalent casual sex and Internet-mediated connections, there is an unmet, strong desire for more reliable information to replace highly imperfect heuristics about who is “safe.” The desire for, and value

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194. See, e.g., Davis, *supra* note 142, at 469-70, 472 (quoting online daters).

195. *Id.* at 470.

196. See *id.* at 472 (quoting interviewee who related that whenever he saw that a poster said he practiced safe sex “sometimes,” he would skip the profile because “they are probably positive”).

of, disease-status information is demonstrated by the ubiquity of the DDF representation as an advertising point and request in ads seeking romantic or sexual partners. The market demand for the information is also demonstrated by the fact that over sixty percent of women<sup>197</sup> and around sixty-four percent of young people aged eighteen to twenty-four<sup>198</sup> who met sexual partners online discussed HIV and STD status with their partners. Among individuals twenty-five and older the rate of inquiry was even higher—75.6% discussed HIV status and 67.8% inquired about other STDs as well.<sup>199</sup>

In the absence of reliable ways to verify self-serving representations, people resort to heuristics about who is “clean” or “safe” based on appearance. Heuristics are cognitive rules of thumb for making hard decisions by substituting a simpler question.<sup>200</sup> Heuristics may suffer from inaccuracies and biases in the prevailing culture (e.g., race and class biases), as well as in cognition (e.g., optimism bias and the sense that bad things befall others different from the actor).<sup>201</sup> Studies report the use of crude verification approaches and heuristics like “inspecting the partner for sores or crusts”<sup>202</sup> or relying on the partner’s physical appearance and presentation.<sup>203</sup> Assumptions about prevalence of STDs in demographic groups, including racial group membership, also impact the nature of risk-assessment heuristics.<sup>204</sup>

More reliable information can alleviate the resort to highly imperfect and potentially discriminatory heuristics. In another context, privacy professor Lior Strahilevitz has argued that access to more reliable data may alleviate resort to illegitimate discriminatory proxies like race.<sup>205</sup> Increased availability of information might shift decisionmakers away from relying on troubling group-based stereotypes, permitting them to make more accurate information-assisted

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197. McFarlane, *supra* note 152, at 691 tbl.1.

198. McFarlane, *supra* note 186, at 14 tbl.2.

199. *Id.*

200. Daniel Kahneman, *A Perspective on Judgment and Choice: Mapping Bounded Rationality*, 58 AM. PSYCHOLOGIST 697, 707 (2003).

201. See Thomas Gilovich & Dale Griffin, *Introduction—Heuristics and Biases: Then and Now*, in *HEURISTICS AND BIASES: THE PSYCHOLOGY OF INTUITIVE JUDGMENT* 1, 3 (Thomas Gilovich et al. eds., 2002) (discussing common biases that skew judgment and decisionmaking).

202. Blair Beadnell et al., *Preventing Sexually Transmitted Diseases (STD) and HIV in Women: Using Multiple Sources of Data to Inform Intervention Design*, 4 COGNITIVE & BEHAV. PRAC. 325, 332 (1997).

203. Michael Hennessy et al., *Evaluating the Risk and Attractiveness of Romantic Partners when Confronted with Contradictory Cues*, 11 AIDS & BEHAV., 479, 485-88 (2007).

204. See, e.g., Elijah G. Ward et al., *Perception of HIV/AIDS Risk Among Urban, Low-Income, Senior-Housing Residents*, 16 AIDS EDUC. & PREVENTION 571, 573-74, 582 (2004) (noting “demographic factors can shape subjective risk perception indirectly by affecting one’s view of self or others through popular assumptions about group categorization and/or cultural interpretation of HIV/AIDS risk typographies” and collecting studies so indicating).

205. Lior Jacob Strahilevitz, *Reputation Nation: Law in an Era of Ubiquitous Personal Information*, 102 NW. L. REV. 1667, 1681-82 (2008).

individuated judgments.<sup>206</sup> More reliable information has the double effect of facilitating more accurate, and less biased, decisionmaking. Judgments are based on individualized assessments, rather than group stereotypes.

The power to seed a healthier information culture and to incentivize testing is within our grasp. It would simply require a small tweak in the way STD test results are delivered and a strategy shift in public health advertising campaigns. Currently, there are myriad ways to receive test results; for example, by calling a phone line, receiving results in the mail, or even a no-news-is-good-news approach.<sup>207</sup> A better approach is to provide negative test results on a readily readable, password-protected standardized online site. If someone had truly recently tested DDF, this person would be able to supply the password to a prospective sexual partner for rapid, easy verification. While providing the verification password to a potential partner is voluntary, people have an incentive to share to increase their desirability in a marketplace where DDF status is both an advertising point and a requested item of information by those seeking partners.

Because the goal is to provide more reliable and trustworthy sources of information, standardization and centralization of the password-protected information is critical. When we bank, or when we check our stored personal information, we discern reliable databases from sham or untrustworthy sites based on trust in a limited, readily recognizable and well-known pool of sites with familiar addresses.<sup>208</sup> Similarly, the retrievable results must be in a recognizable, centralized online forum in which people may repose trust. Ideally, there should be one trusted web address from which people can log in, to avoid reliability being undermined by a plethora of fake sites.

In tandem with the provision of a more reliable method of DDF verification, a public health campaign should be deployed to seed a culture of verification. Currently, risk is amplified because in the casual sex context, many take the approach that if the partner does not ask, then they will not tell.<sup>209</sup> Strategies used in health campaigns over the years, from promoting condom use to transforming the social meaning of smoking from “glamorous” to “gross,” may be deployed in a campaign to make verification cool.<sup>210</sup> Studies of intervention have underscored

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206. *Id.* at 1670.

207. See, e.g., Deborah Kacanek et al., *Young Incarcerated Men's Perceptions of and Experiences with HIV Testing*, 97 AM. J. PUB. HEALTH 1209, 1212, 1214 (2007) (no news is good news); *Assessing Your HIV or STD Risk*, AIDS HEALTH PROJECT, [http://www.ucsf-ahp.org/HTML2/services\\_test\\_assessing.html](http://www.ucsf-ahp.org/HTML2/services_test_assessing.html) (last visited Nov. 10, 2011) (calling in).

208. Cf. Robert McMillan, *Phishing Sites Explode on the Web*, PC WORLD, Feb. 26, 2007, [http://www.pcworld.com/article/129288/phishing\\_sites\\_explode\\_on\\_the\\_web.html](http://www.pcworld.com/article/129288/phishing_sites_explode_on_the_web.html) (describing phishing sites and strategies for avoiding phony sites such as typing in trusted addresses).

209. See, e.g., Gorbach, *supra* note 97, at 514, 516 (reporting on the don't ask-don't tell approach among HIV-positive men who fail to disclose to casual sex partners despite unprotected sex).

210. See Gostin et al., *supra* note 21, at 73, 80 (citing examples).



the import of media, for ill and good, in promoting sexual practices.<sup>211</sup> Promotion by influential celebrities may go a long way to transforming social custom surrounding sex, seeding a culture of verification, and highlighting that STDs and AIDS/HIV are not an affliction of some “Other,” but a risk to which all may be subject. For example, famous basketball player Magic Johnson’s HIV serostatus revelation and public health promotion were important in spreading HIV/AIDS awareness and ameliorating the intense stigma surrounding the disease.<sup>212</sup>

Rather than the harder hammer of criminal or tort law, cultural norm shifting can be a cheaper, more effective way to achieve the social good of improved public health.<sup>213</sup> The accumulated experience with HIV-prevention efforts over the years has generated lessons about pathways for effective social norm-shifting and behavior-shaping intervention.<sup>214</sup> A meta-analysis of the array of strategies pursued found that approaches that intervene in social meaning by improving attitudes and changing social norms were more effective in fostering behavioral modifications than cruder appeals to fear.<sup>215</sup> Fear appeals are better suited for the blunt end of securing eschewal of an activity and ill-suited for the subtleties of influencing sexual health.<sup>216</sup>

Even after culture-shifting campaigns, not everyone will choose to verify, just as people still smoke and still engage in unprotected casual sex. But the provision of a more reliable way to verify and education promoting verification can ensure that the many people who *do* want to make fully informed choices are empowered to do so. Enabling more reliable password-protected online access to test results puts control over information in the hands of those who own it, while changing the incentives for voluntary information sharing to promote public health and informed consent.

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211. See, e.g., Khiya Marshall et al., *A Systematic Review of Evidence-Based Behavioral Interventions for African American Youth at Risk for HIV/STI Infection, 1988-2007*, in AFRICAN AMERICANS AND HIV/AIDS: UNDERSTANDING AND ADDRESSING THE EPIDEMIC, *supra* note 46, at 151, 154-55 (meta-analysis of studies and analysis of power of media).

212. Judith Tedlie Moskowitz et al., *The Association Between Magic Johnson’s HIV Serostatus Disclosure and Condom Use in At-Risk Respondents*, 34 J. SEX RES. 154, 160 (1997) (finding a significant proportion of the population at heightened risk for HIV changed their behavior in response to Magic Johnson’s disclosure and terming his announcement a “critical moment” for social change).

213. See, e.g., Cass R. Sunstein, *Social Norms and Social Roles*, 96 COLUM. L. REV. 903, 947 (1996) (arguing that governmental norm-changing may sometimes be the cheapest, most effective way to regulate).

214. Dolores Albarracín et al., *A Test of Major Assumptions About Behavior Change: A Comprehensive Look at the Effects of Passive and Active HIV-Prevention Intervention Since the Beginning of the Epidemic*, 131 PSYCHOL. BULL. 856, 856-57 (2005).

215. *Id.* at 882.

216. *Id.*

*B. Physician Flags: Improving Identification of Actors in Need of Intervention*

Effective disease control also requires a better way for facilitating intervention and ensuring accountability for actors whose conduct creates a particularly concerning risk to public health. The second devolution of power into the hands of people involves the ability to pinpoint those most in need of intervention in a time of budgetary strain in public health departments. We need a better avenue for people who have experienced violations of their autonomy through fraudulently attained consent to sex to report problematic actors without having to suffer the harms and slings of the traditional tort and criminal law contexts.<sup>217</sup>

Patients who learn they are infected are often angry with a partner for transmission and believe the transmission was intentional.<sup>218</sup> Women, especially, often express anger because a positive STD diagnosis led to the realization that their trust was breached and their health was endangered without their knowledge or consent.<sup>219</sup> And women are the fastest-growing demographic for HIV/AIDS infections.<sup>220</sup> Many state laws criminalize knowingly or intentionally exposing another person to HIV, AIDS and other STDs through sexual contact.<sup>221</sup> Yet

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217. See Mary D. Fan, *Sex, Privacy and Public Health in a Casual Encounters Culture*, 45 U.C. DAVIS L. REV. (forthcoming 2011) (critiquing law's traditional arsenal of criminal and tort law as avenues of redress for STD transmission).

218. Gorbach, *supra* note 35, at 199 (reporting on anger).

219. *Id.* at 198; see also, e.g., Miriam R. Chacko et al., *Understanding Partner Notification (Patient Self-Referral Method) by Young Women*, 13 J. PEDIATRIC ADOLESCENT GYNECOLOGY 27, 30 (2000) (finding thirty-nine percent of young adult women participating in partner notification discussed who gave the infection to who).

220. See, e.g., Rebecca Voelker, *Women Shoulder Growing HIV/AIDS Burden*, 293 JAMA 281 (2005) (reporting on the phenomenon).

221. See, e.g., CAL. HEALTH & SAFETY CODE § 120291 (West 2011) ("Any person who exposes another to [HIV] by engaging in unprotected sexual activity when the infected person knows at the time of the unprotected sex that he or she is infected with HIV, has not disclosed his or her HIV-positive status, and acts with the specific intent to infect the other person with HIV, is guilty of a felony punishable by imprisonment in the state prison for three, five, or eight years. Evidence that the person had knowledge of his or her HIV-positive status, without additional evidence, shall not be sufficient to prove specific intent."); FLA. STAT. § 384.24 (2011) ("It is unlawful for any person who has chancroid, gonorrhea, granuloma inguinale, lymphogranuloma venereum, genital herpes simplex, chlamydia, nongonococcal urethritis (NGU), pelvic inflammatory disease (PID)/acute salpingitis, or syphilis, when such person knows he or she is infected with one or more of these diseases and when such person has been informed that he or she may communicate this disease to another person through sexual intercourse, to have sexual intercourse with any other person, unless such other person has been informed of the presence of the sexually transmissible disease and has consented to the sexual intercourse."); 720 ILL. COMP. STAT. 5/12-5.01 (2011) (making it a felony for someone knowing he or she is infected with HIV to expose another to bodily fluids in a manner that could result in transmission of HIV unless the other person knowingly consents to the risk); IOWA CODE § 709C.1 (2011) (same as Illinois); MD. CODE ANN., HEALTH-GEN. § 18-601.1 (West 2011) (making it a misdemeanor to knowingly transfer or attempt to transfer HIV to another); MICH. COMP. LAWS § 333.5210 (2011) (making it a felony for someone knowing he or she is HIV-infected to engage in sexual penetration of another

criminal prosecutions are rare.<sup>222</sup> The few that surface are often lurid, headline-grabbing, and shockingly egregious, such as: (1) the Philippe Padieu case of a serial HIV spreader who allegedly infected at least six women in Texas;<sup>223</sup> (2) the case of Nushawn Williams, who infected at least thirteen women and an infant with HIV and exposed at least forty women and girls to the virus, sparking a “one-man epidemic;”<sup>224</sup> or (3) the case of Philadelphia insurance actuary Edward I. Savitch who allegedly exposed several hundred underage teenage boys to HIV, before public health authorities got involved.<sup>225</sup>

In practice, criminalization of transmission is extremely controversial<sup>226</sup> with arguably little deterrence gained—in part because of the infrequency of prosecution and because people make sexual decisions based on more complex factors than the distant shadow of law.<sup>227</sup> Criminalization actually provides

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without first informing partner of serostatus); N.Y. PUB. HEALTH LAW § 2307 (McKinney 2011) (“Any person who, knowing himself or herself to be infected with an infectious venereal disease, has sexual intercourse with another shall be guilty of a misdemeanor.”); VA. CODE ANN. §§ 18.2-67.4:1, (2011) (making it a felony for a person “knowing he is infected with HIV, syphilis, or hepatitis B” to have “sexual intercourse, cunnilingus, fellatio, anallingus or anal intercourse with the intent to transmit the infection to another person” and a misdemeanor for such an individual with knowledge of infection to engage in the specified sexual conduct without disclosing disease status); see also Andrew M. Francis & Hugo M. Mialon, *The Optimal Penalty for Sexually Transmitting HIV*, 10 AM. L. & ECON. REV. 388, 389 (2008) (noting that twenty-eight states criminalize exposure to HIV and in most make it a felony to knowingly expose another person HIV through risky sexual activity without disclosing HIV status); Zita Lazzarini et al., *Evaluating the Impact of Criminal Laws on HIV Risk Behavior*, 30 J. L. MED. & ETHICS 239, 241-43 & tbl.1, 246 (2002) (tabulating features of laws in the twenty-five states that have disease transmission or exposure statutes comparatively); James B. McArthur, Note, *As the Tide Turns: The Changing HIV/AIDS Epidemic and the Criminalization of HIV Exposure*, 94 CORNELL L. REV. 707, 709 (2009) (collecting HIV/AIDS exposure laws in twenty-one states, all passed before 2000).

222. See Lazzarini et al., *supra* note 221, at 244-45 (finding no prosecutions under general communicable disease or STD exposure statutes and 164 convictions over the entire United States for HIV exposure or transmission during a five-year period – mostly involving conduct such as nonconsensual sex, prostitution or assault that are also generally criminalized).

223. See, e.g., Padieu v. State, No. 05-09-00796, 2010 WL 5395656 (Tex. App. Dec. 30, 2010) (affirming conviction).

224. Jennifer Frey, *Jamestown and the Story of “Nushawn’s Girls,”* WASH. POST, June 1, 1991, <http://www.washingtonpost.com/wp-srv/style/features/jamestown0601.htm>.

225. United States *ex rel.* Savitz v. Gallagher, 800 F. Supp. 228, 230 (E.D. Pa. 1992) (explaining charges in Savitz case); Michael deCourcy Hinds, *Philadelphia Suspect: A Troubled Life*, N.Y. TIMES, Apr. 2, 1992, <http://www.nytimes.com/1992/04/02/us/philadelphia-suspect-a-troubled-life.html> (describing the Savitz case).

226. The controversy over criminalization of HIV exposure is international as well as national, with the United Nations weighing in against criminalization. See, e.g., UNAIDS, INTERNATIONAL CONSULTATION ON THE CRIMINALIZATION OF HIV TRANSMISSION 20-23 (2007) (expressing dismay over international trend towards criminalization and concern over stigmatization).

227. See, e.g., Scott Burris et al., *Do Criminal Laws Influence HIV Risk Behavior? An Empirical Trial*, 39 ARIZ. ST. L.J. 467, 489 (2007) (finding perverse consequences and little evidence of deterrence). But see, e.g., Gorbach et al., *supra* note 97, at 514, 516-17 (finding, to their surprise in light of the anti-criminalization literature, that HIV-positive high-risk individuals surveyed reported disclosure because of concern over criminalization, suggesting a deterrent effect

perverse incentives and a windfall to those who do not get tested, because they can mount a defense of lack of knowledge.<sup>228</sup> Moreover, putting enforcement in the criminal context deters victims from seeking redress because of the chilling effect of having to enter the criminal justice arena with its negative publicity, loss of privacy, and intimidating police and prosecutors.<sup>229</sup> In judging credibility, jurors especially tend to penalize victims who do not conform to norms of “proper” behavior or who have had prior consensual sex with a partner.<sup>230</sup> People who engage in consensual casual sex based on a representation by their partner that he or she is disease-free face difficult, entrenched, gendered stereotypes, and judgments that might prevent recovery or vindication.<sup>231</sup>

Intervention with potentially problematic individuals should come before multiple people are infected and lives are irrevocably changed. Budget-strapped public health authorities in triage mode need a better way to identify priorities in contact tracing.<sup>232</sup> Training physicians to identify and flag priority contacts for public health authorities is a more efficient way to marshal limited public health investigatory resources. Physicians already have a duty to collect the names of sexual contacts of infected individuals and report the information to public health authorities.<sup>233</sup> A more efficient approach to help budget-strapped public health departments identify priority cases involves doctors flagging cases where patient accounts suggest a sexual contact is engaging in behavior of greatest concern. Problematic behavior that raises priority flags could include deception to gain uninformed consent to sex.

Historically, physicians have been reluctant, yet crucial, participants in information gathering for contact tracing.<sup>234</sup> A longstanding official concern is the tension between protecting patient privacy and the duty to protect the public

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for some, at least).

228. See, e.g., Francis & Mialon, *supra* note 221, at 391-97 (discussing perverse incentives of knowledge-based criminal penalties regime).

229. The dangers of coming forward are illustrated by the women in the case of serial STD spreader Philippe Padieu, who were called “sluts” and “deserving whores.” *20/20: Women Who Contracted HIV from Serial Dater Speak Out* (ABC television broadcast Sept. 17, 2009), <http://abcnews.go.com/2020/women-contracted-hiv-speak/story?id=8594640>.

230. See, e.g., K. L’Armand & A. Pepitone, *Judgments of Rape: A Study of Victim-Rapist Relationship and Victim Sexual History*, 8 PERSONALITY & SOC. PSYCH. BULL. 134, 135-38 (1982) (finding biases based on prior sexual history and history of consensual and casual sex); Kristen M. Williams, *Few Convictions in Rape Cases: Empirical Evidence Concerning Some Alternative Explanations*, 9 J. CRIM. JUST. 29, 36 (1981) (noting only nine percent of rape cases involving ex-boyfriends, ex-spouses or cohabitating partners resulted in conviction in DC).

231. See Mary Crawford & Danielle Popp, *Sexual Double Standards: A Review and Methodological Critique of Two Decades of Research*, 40 J. SEX RES. 13, 13, 20-25 (2003) (discussing double standard and social censure for women who engage in casual sex and the “bad girl/whore” perception).

232. See *supra* Section I.A., discussing the present contact-tracing paradigm under strain.

233. See *supra* Section I.A., discussing history.

234. For a history, see FAIRCHILD, *supra* note 13, at 77-80.

health by facilitating surveillance.<sup>235</sup> Unofficially, many physicians may also find conversations with patients about sexual history awkward and discomfiting; they may even discourage such discussion by changing the topic or through nonverbal cues such as avoiding eye contact or turning their back on patients when talking about sexual behavior.<sup>236</sup> Training doctors to overcome their personal sense of difficulty in inquiring about sexual history is a challenge in medical training.<sup>237</sup> Moreover physicians, and particularly specialists, may view themselves as managers of disease and believe that counseling and consideration of social history should be someone else's task.<sup>238</sup>

Yet doctors have immense authority and ability to effect change, if they choose, because patients repose great trust in their doctors and often wish their doctors would talk to them about sexual history.<sup>239</sup> Doctors are best situated to hear patients' accounts of disease acquisition and better understand which contacts identified by patients should be a priority for public health officials. Flagging priority contacts is not a breach of loyalty to the patient. Indeed, it may better serve a patient who feels betrayed and wants to keep others from being similarly harmed, but does not want to risk resorting to the criminal or tort law systems. Training physicians to listen to patient accounts and flag problematic contacts would better serve public health and patients who may be concerned about problematic actors but find the process for redress daunting. In a time when cases are slipping through the cracks because a few beleaguered public health officials are doing the work of many, a priority flag system that deploys a private-public partnership to help steer the discretion and power of the state would better ensure that the most important cases receive attention.

### *C. Objections and Answers*

The biggest potential objections regarding the proposed reforms involve data quality and storage concerns. First, would verification of recent testing results give people a false sense of security? One's sexual health status may have

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235. *See id.*

236. *See, e.g.,* Ronald M. Epstein et al., *Awkward Moments in Patient-Physician Communication About HIV Risk*, 128 ANNALS INTERNAL MED. 435, 437-38, 440 (1998) (reporting such behavior).

237. Steven A. Haist et al., *Improving Students' Sexual History Inquiry and HIV Counseling with an Interactive Workshop Using Standardized Patients*, 19 J. GEN. INTERNAL MED. 549, 549, 552 (2004).

238. *See, e.g.,* Lisa R. Metsch et al., *Delivery of HIV Prevention Counseling by Physicians at HIV Medical Care Settings in 4 US Cities*, 94 AM. J. PUB. HEALTH 1186, 1190 (2004) (suggesting that infectious disease specialists were focused on primary prevention and may have believed counseling is better done by others).

239. *See, e.g., id.* at 1186 (arguing that doctors have great authority because patients trust and seek their counsel and this potential needs to be better utilized); *see also* Epstein et al., *supra* note 236, at 440 (noting that patients wanted to talk to their physicians about HIV, but effective discussion was often stymied by physician discomfiture).

changed since the test because of subsequent encounters. Moreover, a test may miss a recent infection, such as HIV, because it takes an average of twenty-five days for an HIV-infected person's body to develop sufficient antibodies for detection on HIV antibody tests.<sup>240</sup> Second, regarding verification databases, how do we protect against fraudulent verification sites? And how do we protect against abuses that may arise from storage of sensitive information? Third, regarding priority flagging, what about the risk of false claims by distraught patients in a highly emotional context? And should we limit government storage and use of priority flag information reported by physicians to public health authorities?

First, it is true that test results are no guarantee. Notice of this fact and encouragement to take precautions should be concisely and saliently displayed. However, recent testing and willingness to share the results with a partner signals concern for one's sexual health and that of one's partner. And in a nation where in 2003 an estimated twenty-five percent of people that had HIV did not know it because they were not tested, recent testing is better than no testing.<sup>241</sup> As described in Part II, people are engaging in riskier configurations of sex with or without a system of better verification. People are doing it anyway; the question is whether public health approaches can better inform their decisionmaking.

Second, the data storage concerns resonate with longstanding fears about the dangers of data storage and dissemination in health privacy contexts. As early as 1977, the Supreme Court in *Whalen v. Roe* opined, "We are not unaware of the threat to privacy implicit in the accumulation of vast amounts of personal information in computerized data banks or other massive government files."<sup>242</sup> Nevertheless, the *Whalen* Court upheld a New York statute that required reporting the names of buyers of certain dangerous prescription drugs to public health authorities.<sup>243</sup> The Court noted that "an essential part of modern medical practice" involved information disclosures to public health agencies, among other entities, and cited, as an example, venereal disease reporting requirements.<sup>244</sup>

While data quality and storage concerns suggest the need for safeguards, this does not mean eschewing reform altogether. In considering objections, we must be cautious not to let policy progress be undermined by a "fallacious form of reasoning" induced by status quo bias that assumes reforms should be eschewed unless the "innovation can be implemented without risk of undesirable consequences."<sup>245</sup> The baseline for measurement should not be a hypothetical

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240. *HIV Testing Basics for Consumers*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hiv/topics/testing/resources/qa/index.htm> (last updated Apr. 9, 2010).

241. Ctrs. for Disease Control & Prevention, *supra* note 85, at 2.

242. *Whalen v. Roe*, 429 U.S. 589, 605 (1977).

243. *Id.* at 604.

244. *Id.* at 602.

245. See Dan M. Kahan, *What's Really Wrong with Shaming Sanctions*, 84 TEX. L. REV. 2075, 2079 (2006) (discussing this problem in evaluating policy innovations).

ideal state, but rather the challenges of our reality.<sup>246</sup> What we should be asking is whether problems can be ameliorated without the costs of a reform outweighing the benefits. Safeguards surrounding information use and storage can ameliorate costs while still realizing the benefits of the proposals.

Regarding the verification database, the best way to guard against fraudulent information is strong data security surrounding a single gateway web site that points people who enter their passwords to the doctors' databases where testing results are stored. The web site can be an index-pointer system similar to the FBI's use of a centralized index that "points" the searcher to the relevant database storing the information.<sup>247</sup> A single address guards against a proliferation of false sites that use screen shots and imitative design to look legitimate.<sup>248</sup> An index-pointer system responds to the fear of centralized storage of private health information like STD status. In a form of decentralization by design, the central interface points the verifier to the right site among participating physicians' offices. Most importantly, penalties can be prescribed for unauthorized use and dissemination of STD status information penalties for misuse of STD status information in other disease reporting contexts.<sup>249</sup>

Third, regarding the proposal of priority flagging by physicians based on patient reports, the biggest concern is reliability. A subsidiary issue is storage of priority flag information based on potentially unreliable information. But in traditional criminal and tort avenues for redress, there also is the risk of false reporting. The concern, however, is that while the very costliness of seeking criminal or tort remedies may deter spurious claims, false claims might more readily arise in the comfort and privacy of a physician's office.

We must measure such concern against the baseline of our current practices. We already have contact reporting to public health officials, which comes with the risk of transmitting inaccurate information.<sup>250</sup> The proposed reform is perhaps more worrying because of the priority flag attached to certain sexual contacts. This issue can be addressed through investigation—a priority flag is not an adjudication, but rather a way to enable investigators to more efficiently expend their time in contact tracing and encouraging testing. Moreover, storage concerns may be addressed by limiting the uses of the data and the length of retention of

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246. *See id.* (discussing baselines for evaluation).

247. For an account of the index-pointer system, see, for example, Mary De Ming Fan, *Reforming the Criminal Rap Sheet: Federal Timidity and the Traditional State Functions Doctrine*, 33 AM. J. CRIM. L. 31, 58 (2005).

248. *See, e.g.*, Barbara Quint, *The Market for Virtue in the Virtual*, INFO. TODAY, Oct. 1, 2001, at 8, 10 (recommending that false sites should be avoided by going to known trusted sites).

249. *See, e.g.*, MASS. GEN. LAWS ch. 111, § 119 (2011) (providing records pertaining to venereal disease "shall not be public records" and prescribing sanctions for unauthorized disclosure); N.J. STAT. ANN. § 26:4-41 (West 2011) (restricting disclosures); N.Y. PUB. HEALTH LAW § 2785 (2011) (restricting disclosure and prescribing sanctions).

250. *See supra* Section I.A (discussing contact tracing).

priority flag information and details.

### CONCLUSION

The time is right for a reorientation of the prevalent approaches to STD control to meet pressing challenges. The preface to the most recent National Survey of Sexual Health and Behavior called for “communities, practitioners, and policymakers to question long-held beliefs regarding the role and responsibilities of individuals, clinical, and public health services” in order to better address the persistent costs and ravages of STDs.<sup>251</sup> The call for paradigm change, or at least adjustment, was offered in light of the “generational changes resulting from major demographic shifts in sexual attitudes and behaviors, combined with the global expansion of the internet; mobile technology; social networking; novel patterns of sexual mixing; globalization of sex work and technological advances . . . .”<sup>252</sup> This Article’s proposals are offered in the spirit of rethinking the roles and responsibilities of individuals and health providers.

The responsibility for managing STDs cuts across communities and social strata, though marginalized groups have historically borne the greater burdens of surveillance and intervention. The need to brainstorm about and employ broad-based problem-solving strategies is particularly pronounced in a time when the prevalence of casual sex culture and Internet-mediated relationality are changing configurations of risk across communities. As healthcare providers and public health officials search for new ways to manage the burgeoning challenge of STDs amid cultural and technological change, a promising avenue of exploration involves changing the stance of concentrating power and information in the state.

Strategies for devolving information and power can help the STD control regime adapt to the ways people meet and mate today. Public health policies may empower people to make better-informed choices about their sexual health by facilitating more reliable methods of voluntary information sharing, seeding a healthier culture of verification, and providing a safer venue for identification of potentially problematic actors.

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251. Fenton, *supra* note 12, at 250.

252. *Id.*



**Compulsory Vaccination, the Constitution, and the  
Hepatitis B Mandate for Infants and Young Children**

**Mary Holland\***

**INTRODUCTION ..... 41**

**I. PUBLIC HEALTH LAW ..... 42**

    A. JUDICIAL DECISIONS BEFORE JACOBSON V. MASSACHUSETTS ..... 42

    B. JACOBSON V. MASSACHUSETTS ..... 44

        1. CONSTITUTIONAL STANDARDS OF REVIEW ..... 48

        2. JACOBSON’S EARLY LEGACY ..... 49

        3. ZUCHT V. KING: JACOBSON’S LEGACY FOR SCHOOL CHILDREN ..... 50

        4. THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) ..... 54

        5. THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 (NCVIA) . 55

**II. THE SUPREME COURT’S PERSONAL AUTONOMY JURISPRUDENCE ..... 59**

    A. FORCED STERILIZATION, CONTRACEPTION AND ABORTION ..... 59

    B. THE RIGHT TO MAKE MEDICAL TREATMENT DECISIONS ..... 61

    C. THE RIGHT TO AUTONOMY IN SEXUAL RELATIONS ..... 64

**III. A HYPOTHETICAL CHALLENGE TO A HEPATITIS B VACCINATION  
    MANDATE FOR PRESCHOOL CHILDREN ..... 66**

    A. HEPATITIS B DISEASE, FEDERAL POLICY, VACCINATION MANDATES AND  
    PUBLIC RESPONSE ..... 67

        1. THE 1982 AND 1988 ACIP RECOMMENDATIONS ..... 68

        2. THE 1991 ACIP RECOMMENDATION ..... 69

        3. THE 1999 ACIP RECOMMENDATION ..... 72

        4. THE 2005 ACIP RECOMMENDATION ..... 73

    B. FINANCIAL CONSIDERATIONS IN HEPATITIS B VACCINATION MANDATES 76

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C. INFORMED CONSENT, OR LACK THEREOF, TO HEPATITIS B VACCINATION 79

D. A HYPOTHETICAL CHALLENGE TO THE NEW YORK STATE HEPATITIS B  
VACCINE MANDATE FOR PRESCHOOLERS..... 80

    1. PUBLIC HEALTH NECESSITY ..... 80

    2. REASONABLE MEANS ..... 81

    3. PROPORTIONALITY..... 81

    4. HARM AVOIDANCE ..... 82

    5. NON-DISCRIMINATION ..... 82

    6. LIBERTY INTEREST IN DUE PROCESS..... 82

    7. LIBERTY INTEREST IN EQUAL PROTECTION ..... 84

**CONCLUSION ..... 85**

## INTRODUCTION

The federal government today recommends that all children between birth and age eighteen years receive seventy doses of sixteen vaccines.<sup>1</sup> Of these recommended vaccines, the majority of states mandate between thirty and forty-five vaccine doses for children to be able to attend school.<sup>2</sup> Forty-seven states require preschool-age children to receive three doses of the hepatitis B vaccine to attend public school.<sup>3</sup> The federal government recommends that infants receive their first dose of the hepatitis B vaccine shortly after birth, while they are in the hospital.<sup>4</sup>

The disease hepatitis B today affects approximately 730,000 people in the United States.<sup>5</sup> Hepatitis B is usually a chronic disease for which there is no known cure; it can lead to severe liver disease and death.<sup>6</sup> People spread the disease through intimate contact, primarily through sex and shared intravenous drug use.<sup>7</sup> The vaccine has demonstrated efficacy in checking the spread of the disease among the at risk population.<sup>8</sup>

So what is the medical rationale for the hepatitis B vaccination mandate for

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1. *Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States, 2011*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/recs/schedules/downloads/child/0-6yrs-schedule-bw.pdf> (last visited Nov. 9, 2011); *Recommended Immunization Schedule for Persons Aged 7 Through 18 Years—United States, 2011*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/recs/schedules/downloads/child/7-18yrs-schedule-pr.pdf> (last visited Nov. 28, 2011).

2. See *Hepatitis B Prevention Mandates for Daycare and K-12*, IMMUNIZATION ACTION COALITION, <http://www.immunize.org/laws> (last updated May 26, 2011) (showing vaccination mandates by state). While the Coalition is solely responsible for the website, its information is based on government sources, and the website is funded in part by the Centers for Disease Control and Prevention.

3. *Id.* (showing that only Alabama, Montana, and South Dakota have no hepatitis B mandates for daycare or school).

4. Ctrs. for Disease Control & Prevention, *A Comprehensive Immunization Strategy To Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part I: Immunization of Infants, Children and Adolescents*, 54 MORBIDITY & MORTALITY WKLY. REP., Dec. 23, 2005, at 1, 15, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5416a1.htm>.

5. Annemarie Wasley et al., *The Prevalence of Hepatitis B Virus Infection in the United States in the Era of Vaccination*, 202 J. INFECTIOUS DISEASES 192 (2010).

6. *Hepatitis B Information for the Public*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hepatitis/B> (last updated Mar. 12, 2009).

7. Ctrs. for Disease Control & Prevention, *supra* note 4.

8. Ctrs. for Disease Control & Prevention, *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)*, 40 MORBIDITY & MORTALITY WKLY. REP., Nov. 22, 1991, at 1, 2, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>.

very young children? What legal requirements must a state meet to enable it to impose such a mandate? To what extent have the legal requirements for vaccination mandates changed over time? Do states today meet the constitutional requirements for the hepatitis B vaccination mandate for very young children? These are the questions that this Article explores.

The Article highlights the historical requirements for vaccination mandates: necessity, reasonable means, proportionality, non-discrimination, harm avoidance, and fairness. It considers Fourteenth Amendment Due Process and Equal Protection Clause requirements. It shows that the vaccination mandate that the Supreme Court upheld in 1905 was markedly different from today's hepatitis B mandate for preschoolers.<sup>9</sup> The *Jacobson* decision upheld a mandate for the entire population, in the context of an airborne epidemic emergency, with a relatively small monetary fine for non-compliance. Today's hepatitis B mandate is imposed exclusively on children, for preventive purposes, although children are at minimal risk of contracting the disease—a disease that is transmitted exclusively through intimate contact—on penalty of limiting the right to an education.

The Article is divided into three Parts. Part I reviews public health law related to vaccination, including *Jacobson v. Massachusetts*; the public health mechanism to recommend vaccination mandates; and the Congressional statute that created the federal vaccine program. Part II considers more recent Supreme Court precedent on personal autonomy, addressing rights in bodily integrity and medical decision-making. Part III considers a hypothetical challenge to New York State's hepatitis B vaccination mandate for preschool children. Part III also considers the evolution of federal hepatitis B recommendations, financial considerations in mandates, vaccine safety, informed consent, and the manner in which the Supreme Court might review a challenge. The Article concludes that the constitutionality of state vaccination mandates against hepatitis B disease for preschool children is questionable.

## I. PUBLIC HEALTH LAW

### A. *Judicial Decisions Before Jacobson v. Massachusetts*

Infectious diseases were leading causes of death in the United States until the 20th century. During the 19th century, movement from the countryside to cities, with overcrowded housing, inadequate sanitation and impure drinking water, spurred outbreaks of infectious disease.<sup>10</sup> These conditions resulted in repeated epidemics of cholera, typhoid, influenza, and malaria. In 1900, more

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9. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

10. Ctrs. for Disease Control & Prevention, *Achievements in Public Health, 1900-1999: Control of Infectious Diseases*, 48 MORBIDITY & MORTALITY WKLY. REP. 621, 622 (1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4829a1.htm>.

than thirty percent of all deaths occurred among children under five years of age.<sup>11</sup> Although vaccination carried recognized risks, the practice became widespread in Europe and the United States in the 1800s as a preventive health measure against smallpox, a deadly, contagious, airborne disease.<sup>12</sup> In the 19th century, vaccination against smallpox meant introducing a milder form of the disease, cowpox, into individuals and inducing an immune response intended to prevent the recipient from getting smallpox. If a vaccination subject received a sufficiently strong immune response, he would not contract smallpox over several years, even if repeatedly exposed to it.<sup>13</sup> Compulsory smallpox vaccination was introduced in some jurisdictions in the 1800s to ensure “herd immunity.” When a large proportion of a community is vaccinated, these individuals form a barrier which prevents spread of the disease to those not vaccinated and those for whom the vaccine is ineffective. The proportion required for “herd immunity” varies depending on the infectious agent. For polio, the proportion is about eighty percent; for measles, it is above ninety percent.<sup>14</sup>

Vaccination mandates are laws requiring individuals to be vaccinated or face penalties, such as a fine or deprivation of the right to attend school. Before *Jacobson*, state statutes on vaccination varied. In 1905, eleven states had compulsory vaccination mandates for smallpox, but the majority, thirty-four states, did not. No states had, or have, laws that force vaccination on unwilling subjects. In other words, no states physically restrain and vaccinate individuals, although this practice reportedly has occurred.<sup>15</sup>

Judicial decisions interpreting state laws on vaccination before *Jacobson* were similarly diverse. In 1894, the Pennsylvania Supreme Court upheld the right of the state to exclude unvaccinated children from school during a smallpox epidemic, but took pains to point out that the state could not physically force vaccination. It simply upheld the regulation to exclude unvaccinated children to protect the public health during an epidemic.<sup>16</sup> In 1900, the Utah Supreme Court

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11. *Id.* at 621.

12. *Jacobson*, 197 U.S. at 34 (“Smallpox is known of all to be a dangerous and contagious disease.” (quoting *Viemeister v. White*, 72 N.E 97, 99 (N.Y. 1903))).

13. *Id.*

14. LAW IN PUBLIC HEALTH PRACTICE 340 (Richard A. Goodman et al. eds., 2003); see also Steve P. Calandrillo, *Vanishing Vaccinations: Why Are So Many Americans Opting Out of Vaccinating Their Children?*, 37 U. MICH. J.L. REFORM 353, 419-21 (2004) (describing herd immunity); Gail Javitt et al., *Assessing Mandatory HPV Vaccination: Who Should Call the Shots?*, 36 J.L. MED. & ETHICS 384, 388 (2008) (describing the theory of herd immunity, which postulates that, as vaccination rates rise, chains of communicable disease transmission are interrupted and diseases—and the risks they present to the public health—can be eliminated altogether).

15. See e.g., Michael Willrich, “*The Least Vaccinated of Any Civilized Country*”: *Personal Liberty and Public Health in the Progressive Era*, 20 J. POL’Y HIST. 76, 85-86 (2008) (“The local health authorities carried out the orders during a public health emergency, and their impatience with resistance led easily to violence, including many documented cases of physical-force vaccination.”).

16. *Duffield v. Williamsport Sch. Dist.*, 29 A. 742 (Pa. 1894).

similarly upheld an exclusion order for an unvaccinated child, but this majority opinion prompted a strong dissent, noting that the exclusion rule was “an attempt, indirectly, to make vaccination compulsory” and that the medical board had no such authority.<sup>17</sup> In 1902, the Minnesota Supreme Court upheld a school exclusion rule for an unvaccinated child, but made clear that its ruling was narrow and permissible “in cases of emergency only.”<sup>18</sup> In 1900, a California court established that no vaccination mandate could be applied in a racially discriminatory manner because it would violate the equal protection clause of the Fourteenth Amendment to the Constitution.<sup>19</sup>

In 1903, New York’s highest court opined that the state’s mandate for school vaccination and its state constitutional right to a public education were compatible provisions. It construed the state constitution’s language, “[t]he Legislature shall provide for the maintenance and support of a system of free common schools, wherein all the children of this State may be educated,” as a privilege, not a right.<sup>20</sup> It reasoned that because all pupils were subject to the same vaccination obligation, the state met constitutional due process and equal protection guarantees. It further suggested that courts owe great deference to legislatures on such questions. It relied on decisions of several other courts that found that state constitutional guarantees of education did not contradict vaccination mandates, even when there was no imminent threat of disease.<sup>21</sup>

While judicial decisions preceding *Jacobson* never forced vaccination, they often justified existing mandates, whether for adults or children, and upheld exclusion of unvaccinated children from public school during epidemics. Some courts spoke explicitly of the need to show necessity and emergency; others took a more expansive view, leaving broad discretion to the legislatures on matters of public health. In short, there was an emerging judicial consensus to uphold vaccination mandates, but the overwhelming majority of states did not impose them. And, in any event, at issue was always a single vaccine against one disease.

### *B. Jacobson v. Massachusetts*

Today there are school vaccination laws in fifty states<sup>22</sup> and mandates for certain categories of adults, such as military personnel<sup>23</sup> and healthcare

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17. *State ex rel. Cox v. Bd. of Educ.*, 60 P. 1013, 1020 (Utah 1900).

18. *Freeman v. Zimmerman*, 90 N.W. 783, 784 (Minn. 1902).

19. *Wong Wai v. Williamson*, 103 F. 1 (N.D. Cal. 1900).

20. *Viemeister v. White*, 84 N.Y.S. 712, 713 (App. Div. 1903).

21. *Id.* at 718.

22. James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 Ky. L.J. 831, 833 (2002) (“Each state has school vaccination laws which require children of appropriate age to be vaccinated for several communicable diseases.”).

23. Military regulations require U.S. soldiers to be vaccinated against a number of diseases, including hepatitis A, influenza, tetanus, diphtheria, measles, mumps, rubella, polio, and yellow

workers.<sup>24</sup> There are also public health acts for emergencies with vaccination provisions in many states.<sup>25</sup> In 1905, the Supreme Court in *Jacobson* decided that states may impose reasonable regulations to ensure the public health and safety, even if such regulations infringe individuals' personal liberty.

*Jacobson* came to the United States Supreme Court from the Massachusetts Supreme Court, which upheld the validity of a Cambridge, Massachusetts mandate to compel smallpox vaccination for all adults on penalty of a five-dollar fine (the equivalent of about \$110 today).<sup>26</sup> Mr. Jacobson refused to comply with the regulation and would agree neither to be vaccinated nor pay the five-dollar fine. Mr. Jacobson argued that the regulation violated his rights under the Fifth and Fourteenth Amendments.<sup>27</sup> He argued that the state mandate threatened his life, liberty, and property, and deprived him of the due process and equal protection of the law. In essence, he argued that his right to bodily integrity and personal liberty trumped the state's right to impose vaccination in the name of public health.

In upholding the Cambridge regulation, the Supreme Court reasoned that constitutional protection of individuals is not unlimited and that states retain police powers to ensure public health and safety. States retain the right to issue reasonable regulations, it argued, and, in the context of a potential smallpox epidemic, Cambridge's ordinance was not "unreasonable, arbitrary and oppressive."<sup>28</sup> It was the legitimate province of the elected legislature to decide what measures would be best, and the legislature was unquestionably aware of opposing views about vaccination among the medical profession and the

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fever. See PETER J. SCHOOMAKER ET AL., ARMY REGULATION 40-562, IMMUNIZATIONS AND CHEMOPROPHYLAXIS (2006), available at [http://www.vaccines.mil/documents/969r40\\_562.pdf](http://www.vaccines.mil/documents/969r40_562.pdf).

24. The CDC provides information on states' requirements for healthcare workers and patients. *Vaccines & Immunizations: State Immunization Laws for Healthcare Workers and Patients*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www2a.cdc.gov/nip/StateVaccApp/statevaccsApp/default.asp> (last modified Sept. 19, 2011). For instance, in New York, hospital employees must be offered hepatitis B vaccine and are required to be vaccinated against measles, mumps, and rubella. *Vaccines & Immunizations: Immunization Administration Requirements for State: NY*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <http://www2a.cdc.gov/nip/StateVaccApp/statevaccsApp/Administration.asp?statetmp=NY> (last modified Sept. 19, 2011).

25. See JAMES G. HODGE, JR. & LAWRENCE O. GOSTIN, THE MODEL STATE EMERGENCY HEALTH POWERS ACT - A BRIEF COMMENTARY (2002), available at <http://www.publichealthlaw.net/MSEHPA/Center%20MSEHPA%20Commentary.pdf>.

26. The Consumer Price Index was started in 1913 to track changes in prices of consumer goods. A government inflation calculator indicates that \$5 in 1913 would be the same as about \$114.59 in 2011. *CPI Inflation Calculator*, BUREAU LABOR STAT., [http://www.bls.gov/data/inflation\\_calculator.htm](http://www.bls.gov/data/inflation_calculator.htm) (last visited Nov. 9, 2011).

27. See U.S. CONST. amend. XIV, § 1 ("No state shall make or enforce any law which shall abridge the privileges or immunities of citizens of the United States; nor shall any state deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.").

28. *Jacobson v. Massachusetts*, 197 U.S. 11, 26 (1905).

electorate. The regulation required the inhabitants to be vaccinated only when “that was necessary for the public health or the public safety.”<sup>29</sup> The regulation did not violate the Fourteenth Amendment because it was “applicable equally to all in like condition.”<sup>30</sup> The Court analogized the state’s police power to impose a vaccination mandate to its power to enforce quarantines and to the federal government’s right to impose a military draft.<sup>31</sup>

*Jacobson*’s claims arose under the Fourteenth Amendment’s Due Process and Equal Protection clauses, but the decision makes no mention of substantive due process under the Fourteenth Amendment. Only two months later, the Court articulated that doctrine in the *Lochner* decision.<sup>32</sup> Lawrence Gostin, a public health law authority, cited *Jacobson* for the proposition that public health regulations require five elements to be constitutional: (1) public health necessity, (2) reasonable means, (3) proportionality, (4) harm avoidance, and (5) fairness.<sup>33</sup> In trying to square *Jacobson* with *Lochner*, a recent commentator, Dr. Allan Jacobs, argued that “[t]he Court’s proscription of ‘arbitrary and oppressive’ state action may be invoking procedural due process in banning ‘arbitrary’ action, and substantive due process in proscribing ‘oppressive’ action.”<sup>34</sup>

However, the Court did not give states blind deference. It justified the Cambridge regulation as reasonable, recognizing that it imposed one vaccine, on the entire adult population, in the context of a contagious, deadly epidemic, with a relatively small fine for non-compliance. The regulation excluded some children from compliance. The Court’s paradigm was clear: a mandate is permissible in “an emergency,”<sup>35</sup> when there was “imminent danger,”<sup>36</sup> when “an epidemic of disease . . . threatens the safety of [society’s] members,”<sup>37</sup> when there was “the pressure of great dangers,”<sup>38</sup> and for an “epidemic that imperiled an entire population.”<sup>39</sup> The Court’s language—emergency, imminent danger, peril to the entire population—suggests grave risk. While Professor Shapiro in his response downplays this high threshold, I believe Justice Harlan’s words speak for themselves.

Describing the potential abuse of police power, the Court opined:

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29. *Id.* at 27.

30. *Id.* at 30.

31. *Id.* at 29-30.

32. *Lochner v. New York*, 198 U.S. 45 (1905) (striking down a state public health regulation as a restriction on the substantive due process right to freedom of contract).

33. LAWRENCE O. GOSTIN, *PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT* 126-28 (2d ed. 2008).

34. Allan J. Jacobs, *Needles and Notebooks: The Limits of Requiring Immunization for School Attendance*, 33 *HAMLIN L. REV.* 171, 183 (2010) (discussing *Jacobson v. Massachusetts*).

35. *Jacobson*, 197 U.S. at 27.

36. *Id.* at 29.

37. *Id.* at 27.

38. *Id.* at 29.

39. *Id.* at 31.



[A regulation] might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons.<sup>40</sup>

The Court noted cases when state laws “went beyond the necessity of the case, and, under the guise of exerting a police power . . . violated rights secured by the Constitution.”<sup>41</sup> It stated:

There is, of course, a sphere within which the individual may assert the supremacy of his own will, and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution, to interfere with the exercise of that will.<sup>42</sup>

The Court cautioned that if a state statute purported to be for the public health, but “has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of the courts to so adjudge.”<sup>43</sup> The Court anticipated that the police power to vaccinate might include circumstances when regulations could be “so arbitrary and oppressive . . . as to justify the interference of the courts to prevent wrong and oppression.”<sup>44</sup>

The Court expressly created a medical exemption from vaccination, when a person was not a fit subject for vaccination and it “would be cruel and inhuman in the last degree” to vaccinate him.<sup>45</sup> Because of *Jacobson*, medical exemptions exist in all fifty states.<sup>46</sup> Although the *Jacobson* decision did not create them, statutory religious exemptions exist in forty-eight states today,<sup>47</sup> and philosophical or conscientious belief exemptions exist by statute in twenty states.<sup>48</sup>

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40. *Id.* at 28 (citing *Wis. Minn. & Pac. R.R. v. Jacobson*, 179 U.S. 287 (1900)).

41. *Id.*

42. *Id.* at 29.

43. *Id.* at 31.

44. *Id.* at 38.

45. *Id.* at 39.

46. Hodge & Gostin, *supra* note 22, at 874 (“While the statutory provisions vary from state to state, all school immunization laws grant exemptions to children with medical contra-indications to immunization, consistent with the judicial and ethical principles of harm avoidance asserted by the Supreme Court in *Jacobson v. Massachusetts*.”).

47. See *States with Religious and Philosophical Exemptions from School Immunization Requirements*, NAT’L CONF. ST. LEGISLATURES (Mar. 2011), <http://www.ncsl.org/default.aspx?tabid=14376> (only West Virginia and Mississippi do not have religious exemptions).

48. *Id.* Under a philosophical exemption, a person need not specify the basis for her objection to vaccination.

Although the Court was clearly wary of treading on areas of legislative competence, it proclaimed the right, indeed the responsibility, to give sensible construction to any regulation so that it would not lead to “injustice, oppression, or an absurd consequence.”<sup>49</sup> It made clear that no law should be interpreted in practice to be “cruel and inhuman in the last degree.”<sup>50</sup>

### *1. Constitutional Standards of Review*

It is not certain what standard of review the Supreme Court would apply to a state compulsory vaccination mandate today. The Supreme Court decided *Jacobson* before it had adopted explicit standards for review of government authority. In *Jacobson*, the Court required only that Massachusetts’s statute be rationally related to the purpose of eradicating infectious disease. Since the 1940s, however, as Part II explores, the Court has held that a higher standard must apply if a state law impinges on a fundamental liberty interest.<sup>51</sup> For a law to be constitutional under a strict scrutiny test, the highest standard, there must be a compelling governmental interest and the law must be narrowly tailored to achieve its end.<sup>52</sup> In cases where strict scrutiny does not apply, the Supreme Court usually uses the lowest standard, the rational basis test. The rational basis test applies when the rights at stake are not considered fundamental. Under this standard of review, “if a law neither burdens a fundamental right nor targets a suspect class, we will uphold the [law] so long as it bears a rational relation to some legitimate end.”<sup>53</sup>

Between these two extremes of strict scrutiny and rational basis review, the Supreme Court has required an intermediate level of scrutiny or a “pumped-up” rational basis test for liberty interests after *Jacobson*.<sup>54</sup> In these cases, the Supreme Court has struck down questionable state laws on the grounds that the state interest did not outweigh an individual’s liberty interest. Several prominent public health scholars have suggested that a case like *Jacobson* today would require intermediate scrutiny because of the clear liberty interests at stake.<sup>55</sup>

In recent decisions, the Supreme Court has itself read *Jacobson* to support the inference that the Constitution protects a patient’s liberty interest in the right

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49. *Jacobson*, 197 U.S. at 39.

50. *Id.*

51. *See infra* Part II.

52. *Id.*

53. *Romer v. Evans*, 517 U.S. 620, 631 (1996).

54. *City of Cleburne Texas v. Cleburne Living Center*, 473 U.S. 432 (1985).

55. GOSTIN, *supra* note 33, at 141 (“The Court has found a constitutionally protected liberty interest in bodily integrity, but it has yet to hold that such an interest is ‘fundamental.’”); KENNETH R. WING & BENJAMIN GILBERT, *THE LAW AND THE PUBLIC’S HEALTH* 24 (7th ed. 2007) (“[I]f *Lochner* or *Jacobson* were argued today, the analysis in both cases would likely adopt the ‘rational basis/close scrutiny’ rhetoric that modern courts have developed in the last several decades . . .”).

to refuse care, suggesting that it would apply intermediate scrutiny.<sup>56</sup> The Court has found that “[t]he forcible injection of medication into a nonconsenting person’s body represents a substantial interference with that person’s liberty.”<sup>57</sup>

## 2. Jacobson’s *Early Legacy*

Initial interpretation of *Jacobson* was circumspect. From 1907 to 1914, state appellate and supreme courts construed *Jacobson* as permitting single vaccination mandates during smallpox outbreaks.<sup>58</sup> The courts upheld mandates and exclusion of unvaccinated school children during emergencies. These decisions applied an “oppressive or arbitrary” standard and looked for evidence of public necessity, and, particularly, the threat of epidemic.<sup>59</sup> These decisions held that statutes must incorporate medical exemptions.<sup>60</sup> The decisions required that school boards act in good faith and exclude unvaccinated students only as long as the danger of smallpox endured.<sup>61</sup>

Beginning in 1916, however, judicial interpretations of *Jacobson* broadened. The Alabama Supreme Court read *Jacobson* to contain the implied power to prevent epidemics, not simply to respond to existing ones. A father sued the school board for excluding his unvaccinated daughter from school when there was no smallpox epidemic.<sup>62</sup> The court upheld the state’s delegation of authority to the school board and the state’s right to prevent disease. The decision also argued that mandates for children, and not adults, were valid because a group of children “constitutes a condition different, with respect to hygienic circumstances, effects, and results, from that to be found in any other character of assemblage in a municipality.”<sup>63</sup> The court deferred to municipal authorities on public health.<sup>64</sup>

The Kentucky Supreme Court reached a similar conclusion that same year, finding that boards “are not required to wait until an epidemic actually exists before taking action. Indeed, one of the chief purposes of their existence is to adopt and enforce such timely measures as will prevent epidemics.”<sup>65</sup> These decisions interpreted *Jacobson* expansively; in neither situation was there an

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56. *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 278 (1990).

57. *Washington v. Harper*, 494 U.S. 210, 229 (1990).

58. *Hammond v. Town of Hyde Park*, 80 N.E. 650 (Mass. 1907); *State ex rel. O’Bannon v. Cole*, 119 S.W. 424 (Mo. 1909); *People v. Ekerold*, 105 N.E. 670 (N.Y. 1914); *McSween v. Bd. of Sch. Trs.*, 129 S.W. 206 (Tex. Civ. App. 1910); *State ex rel. McFadden v. Shorrock*, 104 P. 214 (Wash. 1909).

59. *O’Bannon*, 119 S.W. at 427.

60. *McFadden*, 104 P. at 216.

61. *Hammond*, 80 N.E. at 651.

62. *Herbert v. Demopolis Sch. Bd. of Educ.*, 73 So. 321 (Ala. 1916).

63. *Id.* at 323.

64. *Id.*

65. *Bd. of Trs. v. McMurtry*, 184 S.W. 390, 394 (Ky. 1916).

imminent danger or necessity for the state to act in self-defense.

### 3. *Zucht v. King*: Jacobson's Legacy for School Children

All states today compel elementary education, whether in public or private schools or at home. States compel education under the police power and under the state's role as *parens patriae*, or protector of the state. The Supreme Court's decision in *Wisconsin v. Yoder* acknowledged that compulsory "education is necessary to prepare citizens to participate effectively and intelligently in our open political system."<sup>66</sup> Since 1943, the Supreme Court has recognized that "the state as *parens patriae* may restrict the parent's control by requiring school attendance."<sup>67</sup>

In 1922, the Supreme Court held in *Zucht v. King* that a smallpox vaccination mandate for school admission was a valid exercise of the police power.<sup>68</sup> In a cursory, unanimous decision, the Court cited *Jacobson* as settling that compulsory vaccination may be a requirement of public school admission.<sup>69</sup> Denying the petitioner's claim of infringement of her Fifth and Fourteenth Amendment rights based on *Jacobson*,<sup>70</sup> the Court did consider that the law might have been administered in a way that violated her rights.<sup>71</sup> Nonetheless, the Court found that the school vaccination mandate had not conferred arbitrary power, but "only that broad discretion required for the protection of the public health."<sup>72</sup> It did not inquire into the circumstances of the epidemic and affirmed substantial deference to the school board, with smallpox as the relevant, but unnamed, backdrop.

*Zucht* did not alter *Jacobson*'s analysis that necessity is required to justify state police powers, but it applied this analysis outside of a mandate for the whole population. Whether the Justices thought that *Jacobson*'s analysis was sufficient or that smallpox posed an obvious risk, the Supreme Court affirmed the mandate without detailed discussion. Indeed, *Zucht* is a three paragraph decision presumably intended to stop judicial challenges to school smallpox vaccination mandates.

*Zucht* did shift *Jacobson*'s paradigm, though, by upholding a mandate exclusively for children, a subpopulation, and by affirming the validity of a preventive mandate for a disease not in circulation. It is notable that the Cambridge regulation in *Jacobson* specifically excluded some children as excessively vulnerable subjects for compulsory vaccination with the smallpox

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66. *Wisconsin v. Yoder*, 406 U.S. 205, 221 (1972).

67. *Prince v. Massachusetts*, 321 U.S. 158, 166 (1943).

68. *Zucht v. King*, 260 U.S. 174, 176 (1922).

69. *Id.* at 176.

70. *Id.*

71. *Id.* at 177.

72. *Id.*

vaccine.<sup>73</sup> *Zucht* did not acknowledge that there might be an equal protection problem if the mandate was imposed selectively on children rather than the population as a whole.<sup>74</sup> Still, *Zucht* did not lessen *Jacobson*'s requirements to compel vaccination.<sup>75</sup>

*Zucht* implicitly acknowledged that school attendance creates unique threats to the health of the children gathered there. Hundreds, or even thousands, of children may be in one building for several hours a day, making transmission of airborne disease likely. As Dr. Allan Jacobs noted:

A public health necessity exists when the disease is serious and vaccination to obtain herd immunity is substantially safer than failure to vaccinate. The reasonable means test is satisfied by the nexus between school attendance and disease transmission. The proportionality test is satisfied by the relative safety of the vaccine. Finally, the principle of harm avoidance is met by allowing exemption for medical conditions that make vaccination detrimental to a child's health.<sup>76</sup>

*Jacobson* requires that decisions to mandate vaccination for school attendance be subject to a balancing test that assesses the severity of the disease, the risks of the vaccine, the amount of overall clinical experience with the vaccine, and alternative methods of prevention. As Dr. Jacobs suggested, "The absence of linkage of a disease to school activities should weigh heavily against a vaccination requirement."<sup>77</sup>

Some commentators reject the view that there must be a close nexus between school and vaccination to warrant a state mandate.<sup>78</sup> Indeed, states do impose vaccines on school children for tetanus, a noncontagious disease, and for relatively mild childhood illnesses, such as rubella, largely to protect pregnant mothers from infection. One expert sees such mandates as instrumental in furthering "society's strong interest in ensuring that people are protected from

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73. *Jacobson v. Massachusetts*, 197 U.S. 11, 30 (1905) ("[T]here are obviously reasons why regulations may be appropriate for adults which could not be safely applied to persons of tender years.").

74. *Id.*

75. *Zucht* raises some procedural problems in interpretation. The writ of error was dismissed because of the lack of a federal question. Justice Brandeis noted at the end of the opinion that some of the issues the case raised would only be appropriate before the Court on a writ of *certiorari*, not a writ of error. This may help to explain why this critically important decision on childhood vaccination is so cursory.

76. Jacobs, *supra* note 34, at 192-93.

77. *Id.* at 193.

78. Scholars favoring the human papilloma virus vaccine mandate hold this view. See, e.g., Cynthia Dailard, *Achieving Universal Vaccination Against Cervical Cancer in the United States: The Need and the Means*, 9 GUTTMACHER POL'Y REV. 12 (2006); Sylvia Law, *Human Papillomavirus Vaccination, Private Choice, and Public Health*, 41 U.C. DAVIS L. REV. 1731 (2008).

disease throughout their lives.”<sup>79</sup> Others suggest that vaccination mandates can realistically only be for children because “no national program exists to support vaccine purchase and infrastructure for vaccine delivery to uninsured and underinsured adults.”<sup>80</sup> As a matter of constitutional law, unresolved questions remain about which criteria are essential for valid vaccination mandates.

By 1934, courts read *Jacobson* to validate preventive smallpox mandates.<sup>81</sup> The Mississippi Supreme Court granted discretion to public health authorities, stating “the presumption is in favor of the reasonableness and propriety of regulations enacted in pursuance of such grant of power.”<sup>82</sup> A 1934 Texas court decided that it could not evaluate whether an emergency existed.<sup>83</sup> It explained, “[W]e cannot attempt to measure how pressing a necessity must be in order to allow the board’s discretion to be exercised.”<sup>84</sup> That court flatly rejected the idea that the court could assess emergency.<sup>85</sup>

Courts increasingly deferred to states’ police powers in the ensuing years. In 1948, the New Jersey Supreme Court, upholding a school vaccination mandate, held that “the question of the desirability or efficacy of compulsory vaccination and whether it is wise or unwise is strictly a legislative and not a judicial question.”<sup>86</sup> The Court seemed to read *Jacobson* to justify all vaccination mandates, disregarding its language to reject unreasonable, arbitrary or oppressive state actions.<sup>87</sup>

A 1951 Arkansas case asked the court to evaluate the validity of a preventive school vaccination mandate, but that court decided that it was not its place to judge the efficacy or safety of vaccinations.<sup>88</sup> The court even suggested that the plaintiffs should lodge objections with the Board of Health rather than the court.<sup>89</sup>

By the mid-1950s, it was arguably settled law that school vaccination mandates were presumptively valid. *Jacobson*’s cautionary language had not figured meaningfully into the case’s application. In 1964, the Arkansas Supreme

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79. Dailard, *supra* note 78, at 14.

80. Eric E. Mast et al., Ctrs. for Disease Control & Prevention, *A Comprehensive Immunization Strategy To Eliminate Transmission of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults*, 55 MORBIDITY & MORTALITY WKLY. REP., Dec. 8, 2006, at 1, 13 (“In contrast to vaccination of children, no national program exists to support vaccine purchase and infrastructure for vaccine delivery to uninsured and underinsured adults.”).

81. Hartman v. May, 151 So. 737 (Miss. 1934).

82. *Id.* at 739.

83. Booth v. Bd. of Educ., 70 S.W.2d 350 (Tex. Civ. App. 1934).

84. *Id.* at 353.

85. *Id.*

86. Sadlock v. Bd. of Educ., 58 A.2d 218, 220 (N.J. 1948).

87. *Id.*

88. Seubold v. Fort Smith Special Sch. Dist., 237 S.W.2d 884, 887 (Ark. 1951).

89. *Id.*

Court held that parents had no legal right to refuse vaccination of their children. The court removed children from the father's custody, placed them with a guardian, and ordered them to be forcibly vaccinated.<sup>90</sup> The Arkansas court did not recognize the validity of the children's religious exemptions, and, in referring to *Jacobson*, reasoned that "it is within the police power of the State to require that school children be vaccinated against smallpox . . . . In fact, this principle is so firmly settled that no extensive discussion is required."<sup>91</sup> The Arkansas Supreme Court upheld the prosecutor's charge of child neglect against the father who refused to vaccinate his children on religious grounds.

Given such extreme deference to police powers for many decades, potential plaintiffs did not challenge *Jacobson* directly. Potential plaintiffs opposing vaccination mandates presumably considered direct challenges futile. Instead, since the 1960s, when states began to compel children to receive six or more vaccines in multiple doses, litigation has centered on exemptions. Forty-eight of the fifty states provide for religious exemption from vaccination mandates.<sup>92</sup> Cases before courts have considered whether membership in an unrecognized faith justifies religious exemption;<sup>93</sup> whether exclusion of unvaccinated children from school following a measles outbreak is justified;<sup>94</sup> whether a parent's religious objections to vaccination are sincerely held;<sup>95</sup> whether religious exemptions violate the First Amendment establishment clause;<sup>96</sup> and whether state laws with no religious exemption violate the First, Fifth, and Fourteenth Amendments.<sup>97</sup> As the Arkansas case above illustrates, states sometimes punish non-compliant parents harshly. Even when religious exemptions exist, courts sometimes find parents liable for child neglect when they refuse to vaccinate their children.<sup>98</sup> Courts have mandated child removal and forced vaccination in families that have asserted religious objections.<sup>99</sup>

Courts have used *Jacobson* to justify results that the original decision did not condone: vaccination mandates exclusively for children with no imminent disease outbreaks and with serious penalties for noncompliance. Punishments include loss of education, social isolation, parents' loss of custodial rights, child-

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90. *Cude v. State*, 377 S.W.2d 816 (Ark. 1964).

91. *Id.* at 819.

92. See Hodge & Gostin, *supra* note 22, at 874 n.233; *States With Religious and Philosophical Exemptions from School Immunization Requirements*, *supra* note 47.

93. *Brown v. Stone*, 378 So.2d 218 (Miss. 1979).

94. *Maricopa Cnty, Health Dep't v. Harmon*, 750 P.2d 1364 (Ariz. Ct. App. 1987).

95. *LePage v. State (In re LePage)*, 18 P.3d 1177 (Wyo. 2001).

96. *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002); *McCarthy v. Boozman*, 212 F. Supp. 2d 945 (E.D. Ark. 2002).

97. *Workman v. Mingo Cnty. Bd. of Educ.*, 419 F. App'x 348 (4th Cir. 2011); *Workman v. Mingo Cnty. Schs.*, 667 F. Supp. 2d 679 (S.D. W. Va. 2009).

98. *In re Christine M.*, 595 N.Y.S.2d 606 (Fam. Ct. 1992); *In re Elwell*, 284 N.Y.S.2d 924 (Fam. Ct. 1967).

99. *Cude v. State*, 377 S.W.2d 816, 821 (Ark. 1964).

neglect sanctions against parents, and, even, forced vaccination. In *Jacobson* and *Zucht*, the Supreme Court upheld mandates for one vaccine during airborne epidemics. Courts have expanded the original *Jacobson* precedent dramatically.

#### 4. *The Advisory Committee on Immunization Practices (ACIP)*

Although *Jacobson* today remains the landmark case on state compulsory vaccination, the federal government began to assume the driving role in immunization policy in the 1960s. Government experts within the Centers for Disease Control and Prevention (CDC) adopted the goal of eradicating infectious disease, establishing an infrastructure for a war against it. In 1964, the Advisory Committee on Immunization Practices (ACIP) met for the first time.<sup>100</sup> This organization, under the Public Health Service Act, was to “assist states . . . in the prevention and control of communicable diseases; to advise states on matters relating to the preservation and improvement of the public’s health; and to make grants to states to assist in meeting the costs of communicable disease control programs.”<sup>101</sup> ACIP remains the key decision-making body within the federal government on childhood immunization policy.

ACIP’s charter requires it to advise the public about vaccines against vaccine-preventable diseases. For children, the charter requires ACIP to create a list of vaccines for federal subsidy. ACIP became the only federal entity to make vaccination recommendations to the states for public health, and for children in particular.<sup>102</sup> States today rely on ACIP’s recommendations for school vaccination mandates. The federal government subsidizes vaccines on the ACIP-recommended list for indigent children, and manufacturers receive liability protection for ACIP-recommended vaccines by statute.<sup>103</sup>

ACIP meets several times each year and consists of fifteen non-governmental expert advisers whom the Secretary of the Department of Health and Human Services (HHS) appoints.<sup>104</sup> In addition to fifteen voting members, ACIP includes eight ex officio members who represent federal agencies with responsibility for immunization programs and twenty-six non-voting

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100. *Vaccines Timeline: 50 Years of Vaccine Progress*, CENTERS FOR DISEASE CONTROL & PREVENTION (Oct. 19, 2006), <http://www.cdc.gov/vaccines/pubs/vacc-timeline.htm>.

101. See 42 U.S.C. § 217a (2006) (“The Secretary may . . . appoint such advisory councils or committees . . . for the purpose of advising him in connection with any of his functions.”); *ACIP Charter: Authority, Objective, and Description, Authority*, CENTERS FOR DISEASE CONTROL & PREVENTION (Apr. 6, 2010), <http://www.cdc.gov/vaccines/recs/acip/download/charter.pdf>.

102. *ACIP Charter: Authority, Objective, and Description, Authority*, *supra* note 101 (ACIP is tasked to “establish . . . and revise a list of vaccines for administration to children and adolescents . . . along with schedules . . .”).

103. See 42 U.S.C. § 300aa-6 (2006) (authorizing appropriations necessary to carry out the statute’s provisions); see also 42 U.S.C. § 300aa-11 (providing liability protection for manufacturers of vaccines).

104. *ACIP Charter: Authority, Objective, and Description, Authority*, *supra* note 101.



representatives of liaison organizations. Under its charter, ACIP must have at least one consumer or community representative—all the rest may be from public health and medical specialties.<sup>105</sup> In other words, of the forty-nine people charged to deliberate on national vaccine policy, only one must represent the public.

From ACIP's inception, *Jacobson's* requirements and the federal government's mission for immunization pointed in two potentially different directions. *Jacobson* justified state and local health officials to mandate vaccines against contagious epidemics that posed an imminent danger to the entire population. By contrast, ACIP, the new driver of national immunization policy, aimed to prevent and control infectious disease and to fund state childhood vaccination programs. ACIP's mission does not reference *Jacobson's* requirements of self-defense, imminent danger, necessity, or local authorities' discretion. Instead, the federal government created in ACIP an infrastructure to prevent and control communicable diseases particularly among children through compulsory vaccination. In 1965, one year after its inception, ACIP urged the creation of a federal program to compensate victims of vaccine injury and to relieve manufacturers of ordinary tort liability.<sup>106</sup> ACIP recommended that this would keep the vaccine market stable, keep vaccines affordable, and ensure compensation to victims. Manufacturers and medical communities joined this recommendation.<sup>107</sup> Later, the American Academy of Pediatrics developed detailed proposals for a compensation scheme that would also relieve doctors of tort liability.<sup>108</sup> Indeed, other developed countries had already adopted governmental compensation schemes for vaccine injury in the 1970s and 1980s.<sup>109</sup> In 1986, the United States Congress would adopt such a program.

### 5. *The National Childhood Vaccine Injury Act of 1986 (NCVIA)*

Congress enacted the National Childhood Vaccine Injury Act of 1986 (NCVIA) almost two decades after the ACIP first recommended a government compensation scheme.<sup>110</sup> In the intervening two decades, vaccine injury litigation had become more commonplace, more costly and, therefore, more problematic to manufacturers and doctors who administered vaccines. Manufacturers threatened to leave the marketplace unless the federal government granted them tort liability protection. Seeking to shield the relatively new childhood immunization program, Congress held hearings, including testimony from the pharmaceutical

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105. *Id.*

106. JAMES COLGROVE, *STATE OF IMMUNITY: THE POLITICS OF VACCINATION IN TWENTIETH-CENTURY AMERICA* 192 (2006).

107. *Id.* at 193.

108. *Id.* at 208.

109. *Id.* at 193.

110. Pub. L. No. 99-660, 100 Stat. 3755.

industry, doctors, and parents of vaccine-injured children. Through the NCVIA, Congress sought to (1) create the infrastructure for a national immunization program,<sup>111</sup> (2) insulate industry and the medical profession from liability,<sup>112</sup> (3) establish a program to compensate the injured,<sup>113</sup> and (4) promote safer vaccines.<sup>114</sup>

The NCVIA outlined an ambitious agenda of research, production, procurement, distribution, promotion and purchase of vaccines.<sup>115</sup> It established the National Vaccine Injury Compensation Program (VICP) for “vaccine-related injury or death.”<sup>116</sup> In its legislative history, Congress made clear that compensation was to be swift, generous, and nonadversarial.<sup>117</sup> Congress enacted the statute to compensate children who were injured while serving the public good.<sup>118</sup>

The Program requires the parents of vaccine-injured children to file first in the VICP before they may file a lawsuit in any ordinary civil court.<sup>119</sup> In other words, the Program has original jurisdiction over all claims of childhood vaccine injury from federally recommended vaccines. The Court of Federal Claims in Washington, D.C. administers it.<sup>120</sup> After filing in the VICP, however, petitioners retain the right to go to civil court after rejecting a VICP decision or waiting a specified period.<sup>121</sup> Congress intended to create an administrative program, where families would establish injuries specified in the Vaccine Injury Table and receive compensation.<sup>122</sup>

When Congress passed the NCVIA, there were many recognized vaccine injuries, including anaphylaxis, encephalopathy, paralytic polio, and other acute complications, including death.<sup>123</sup> Almost all injuries on the Vaccine Injury Table were to have occurred within thirty days of vaccination; most were to have occurred within hours or a couple days of the vaccination.<sup>124</sup> If petitioners met the precise requirements of the specified injuries, then they would have a presumption of compensation.<sup>125</sup> For injuries that were not listed on the Table,

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111. 42 U.S.C. § 300aa-2 (2006).

112. *Id.* § 300aa-11.

113. *Id.* § 300aa-10.

114. *Id.* § 300aa-27.

115. *Id.* § 300aa-2.

116. *Id.* § 300aa-10.

117. H.R. REP. NO. 99-908, at 3 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344.

118. *Id.*

119. *See* 42 U.S.C. §§ 300aa-2, -11(a)(2)(A).

120. *Id.* § 300aa-12.

121. *Id.* § 300aa-21.

122. *Id.* § 300aa-14; *see Vaccine Injury Table*, HEALTH RESOURCES & SERVICES ADMIN., <http://www.hrsa.gov/vaccinecompensation/vaccinetable.html> (last visited Dec. 3, 2011).

123. 42 U.S.C. § 300aa-14.

124. *Id.*

125. *Id.*

however, petitioners would have to prove them based on a preponderance of the evidence.<sup>126</sup>

The VICP requires that petitioners sue HHS; petitioners may not sue manufacturers or healthcare practitioners in the Program.<sup>127</sup> HHS is the respondent for all vaccine injury claims in the VICP. The rationale for this protection of industry was to ensure a stable childhood vaccine supply and to keep vaccine prices affordable.<sup>128</sup> The source of VICP compensation is the Vaccine Injury Trust Fund, a fund now containing more than \$3.3 billion from an excise tax of seventy-five cents on the sale of every vaccine.<sup>129</sup>

Petitioners try cases in the VICP before Special Masters of the Court of Federal Claims. Eight Special Masters act as finders of fact and law. There are no jury trials.<sup>130</sup> The VICP is meant to be informal, without reliance on the federal rules of evidence and civil procedure.<sup>131</sup> Congress intended this informality to benefit the petitioners, and Congress expected that the overwhelming majority of claims would be resolved administratively, where detailed rules of evidence would not be necessary. The statute also requires that the Secretary of HHS “undertake reasonable efforts to inform the public of the availability of the Program.”<sup>132</sup>

Petitioners are entitled to receive \$250,000 in the event of a vaccine-related death and a maximum amount of \$250,000 for pain and suffering.<sup>133</sup> These caps have not changed since 1986. The Act also provides for “reasonable attorney’s fees and costs” for bringing a petition so that petitioners do not have to pay lawyers out of pocket or out of the proceeds of a judgment, as they would have to do in civil court under a contingency fee arrangement.<sup>134</sup>

The NCVIA requires that claimants file petitions no more than “36 months after the . . . first symptom or manifestation of onset or of the significant aggravation of such injury.”<sup>135</sup> This three-year statute of limitations is

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126. *Id.* § 300aa-13(a)(1).

127. *Id.* § 300aa-11(a).

128. *See, e.g.,* Calandrillo, *supra* note 14, at 408 (“Vaccine manufacturers quickly learned their lesson and threatened to halt production unless guaranteed indemnification by the federal government. As a result, vaccine shortages ensued, prices skyrocketed, and Congress was forced into action.” (footnote omitted)).

129. *National Vaccine Injury Compensation Program*, HEALTH RESOURCES & SERVICES ADMIN., <http://www.hrsa.gov/vaccinecompensation/index.html> (last visited Nov. 9, 2011) (“The Trust Fund is funded by a \$0.75 excise tax on each dose of vaccine purchased (i.e., each disease prevented in a dose of vaccine).”).

130. 42 U.S.C. § 300aa-11 (giving jurisdiction to the court of federal claims).

131. FED. CL. R. app. 8(b)(1) (“In receiving evidence, the special master will not be bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence governed by principles of fundamental fairness to both parties.”).

132. 42 U.S.C. § 300aa-10.

133. *Id.* § 300aa-15.

134. *Id.*

135. *Id.* § 300aa-16.

considerably shorter than most state tort statutes for injury to minors.

In perhaps the most significant part of the statute, the NCVIA restricts vaccine manufacturers' liability for those vaccines included on ACIP's recommended childhood schedule. Under its terms, starting in 1988, no vaccine manufacturer was liable for a vaccine-related injury or death from one of the ACIP-recommended vaccines "if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."<sup>136</sup>

In the 1990s, the number of cases of alleged vaccine injury filed with the VICP jumped dramatically. Many families alleged that their children's autism resulted from certain vaccine antigens or from a mercury-containing vaccine preservative, thimerosal, used in multi-dose vaccine vials.<sup>137</sup> Thimerosal is approximately fifty percent mercury by weight.<sup>138</sup> Some of these families successfully litigated in civil court, bypassing the VICP, arguing that the use of thimerosal in infant vaccines was a defective design and outside VICP jurisdiction.<sup>139</sup>

In 2008, the Georgia Supreme Court held that civil courts must decide design defect claims on a case-by-case basis.<sup>140</sup> By contrast, in 2009, the Third Circuit Court of Appeals held that all vaccine injuries allegedly due to design defects of approved vaccines are by definition unavoidable under the NCVIA.<sup>141</sup> In 2011, the U.S. Supreme Court decided *Bruesewitz v. Wyeth*, a case interpreting the VICP's jurisdiction and resolving the split in interpretation between the Supreme Court of Georgia and the Third Circuit Court of Appeals. The Court addressed whether the NCVIA preempts all vaccine design defect lawsuits. In a 6-2 decision, the Supreme Court upheld the Third Circuit's decision to disallow all design defect claims.<sup>142</sup> These claims are thus barred in all courts, as the VICP hears cases of individual injury only and is not equipped to hear design defect claims.

In addition to broad liability protection, the NCVIA provides another important protection to manufacturers.<sup>143</sup> It provides that vaccine manufacturers are not liable for damages if they fail to give direct warnings to patients.<sup>144</sup>

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136. *Id.* § 300aa-22(b)(1).

137. *Autism Decisions and Background*, U.S. CT. FED. CLAIMS, <http://www.uscfc.uscourts.gov/node/5026> (last visited Oct. 17, 2011).

138. *Thimerosal in Vaccines, Thimerosal as a Preservative*, U.S. FOOD & DRUG ADMIN., available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm> (last updated Mar. 31, 2010).

139. *See, e.g.*, *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008).

140. *Id.*

141. *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233 (3d Cir. 2009), *aff'd*, *Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011).

142. *Bruesewitz*, 131 S. Ct. 1068.

143. 42 U.S.C. § 300aa-22(c).

144. *Id.* (explaining that there is no liability "solely due to the manufacturer's failure to

Resting on the “learned intermediary” doctrine, which states that it is sufficient to inform doctors of the risks, manufacturers bear no obligation to provide accurate or complete information to those actually vaccinated.<sup>145</sup>

Complementing manufacturers’ relief from disclosure requirements, another provision exempts doctors from substantial federal disclosure requirements. It tasks the HHS Secretary to “develop and disseminate vaccine information materials.”<sup>146</sup> It states that these materials should outline the benefits and risks of vaccines and the availability of the VICP.<sup>147</sup> Doctors are obliged to provide families with these information materials, but there is no penalty for failing to do so.

*Jacobson*, *Zucht*, the ACIP, and the NCVIA all continue to play critical roles in U.S. vaccine law and policy.

## II. THE SUPREME COURT’S PERSONAL AUTONOMY JURISPRUDENCE

Since *Jacobson*, the Supreme Court has decided several cases about medical intervention, bodily integrity, and sexual autonomy, further articulating what constitutes valid individual liberty interests and the level of scrutiny a court must apply to laws restricting them. These personal autonomy cases contrast starkly with *Jacobson*’s legacy. While none of the cases addressing personal autonomy touch on vaccination, they are relevant to how the Supreme Court would view a challenge under the Fourteenth Amendment to a compulsory vaccination mandate today.

### A. Forced Sterilization, Contraception and Abortion

The first case where the Supreme Court invoked the term “strict scrutiny” was *Skinner v. Oklahoma*, a 1942 case that struck down a state criminal statute on forced sterilization.<sup>148</sup> Having only fifteen years earlier upheld forced sterilization of a woman in a state mental institution in *Buck v. Bell*,<sup>149</sup> the Supreme Court rejected the Oklahoma statute on Fourteenth Amendment Equal Protection grounds. In *Buck v. Bell*, the Court had relied on *Jacobson* to justify the state’s exercise of the police power;<sup>150</sup> in *Skinner*, the Court imposed a heightened standard of review and found the state’s statute lacking.<sup>151</sup>

The Court noted that “[m]arriage and procreation are fundamental to the

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provide direct warnings to the injured party of the potential dangers resulting from the administration of the vaccine”).

145. *Id.*

146. *Id.* § 300aa-26.

147. *Id.*

148. *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

149. *Buck v. Bell*, 274 U.S. 200 (1927).

150. *Id.* at 204.

151. *Skinner*, 316 U.S. at 541.

very existence and survival of the race. The power to sterilize, if exercised, may have subtle, far-reaching and devastating effects.”<sup>152</sup> The Court noted that the individual would be “forever deprived of a basic liberty” and “that strict scrutiny of the classification which a State makes in a sterilization law is essential, lest unwittingly or otherwise invidious discriminations are made against groups or types of individuals in violation of the constitutional guaranty of just and equal laws.”<sup>153</sup> The Court found that the criminal statute was being applied unequally, forcing sterilization on those convicted of theft but not on those convicted of embezzlement—crimes which carried the same penalty.<sup>154</sup> Justice Jackson, in his concurrence, raised due process issues as well as those of equal protection.<sup>155</sup> The case suggests that when “fundamental civil rights” or “basic liberties” are at stake, the Court must use strict scrutiny.

Although *Buck v. Bell* has never been formally overruled, the Colorado Supreme Court summarized the contemporary view that “since *Skinner*, commentators generally have concluded that compulsory sterilization laws, no matter what their rationale, are unconstitutional in the absence of evidence that compulsory sterilization is the only remedy available to further a compelling governmental interest.”<sup>156</sup>

In the 1960s and 1970s, the Court began to recognize liberty interests in contraception and abortion decision-making. In 1961, the Court upheld a state statute prohibiting access to contraception in *Poe v. Ullman*. Justice Harlan in dissent outlined the balancing tests for “fundamental liberties” in the face of state police powers.<sup>157</sup> His reasoning strongly influenced the Court’s later decision in *Griswold v. Connecticut*, which required the state to show that the contraceptive restriction was “necessary, and not merely rationally related to, the accomplishment of a permissible state policy.”<sup>158</sup>

Harlan’s *Poe* dissent reasoned that due process guarantees are the “bulwarks . . . against arbitrary legislation” that cannot be reduced to a simple formula.<sup>159</sup> He suggested that the balance between liberty and the demands of organized society must be “a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, and which also recognizes . . . that certain interests require particularly careful

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152. *Id.*

153. *Id.*

154. *Id.* at 541-42.

155. *Id.* at 546-47 (Jackson, J., concurring).

156. *In re A.W.*, 637 P.2d 366, 368-69 (Colo. 1981).

157. *Poe v. Ullman*, 367 U.S. 497, 523-55 (1961) (Harlan, J., dissenting).

158. *Griswold v. Connecticut*, 381 U.S. 479, 497 (1965) (citing *McLaughlin v. Florida*, 379 U.S. 184 (1964)).

159. *Poe*, 367 U.S. at 541 (Harlan, J., dissenting) (citing *Hurtado v. California*, 110 U.S. 516, 532 (1884)).

scrutiny of the state needs asserted to justify their abridgement.”<sup>160</sup> Justice Harlan asserted that, when one is reviewing something that is a “basic liberty,” such as the ability to procreate, there are limits to what the government may impose. Justice Harlan argued that the contraception statute at issue should be subjected to “strict scrutiny.”<sup>161</sup>

Although the right to personal autonomy in sexual conduct was highlighted in *Griswold*, the decision also concerned the right to protect one’s health through autonomous medical decisions without government interference. The movement for birth control was in part to address the toll on women’s health from pregnancy.<sup>162</sup> The lack of a medical exception in the statute motivated the petitioners as well as liberty interests.

The Court in 1973 applied strict scrutiny to the right to an abortion during the first trimester. *Roe v. Wade* declared that “the right to personal privacy includes the abortion decision, but that this right is not unqualified.”<sup>163</sup> The Court found that a woman’s right to abort outweighed the state’s compelling interest in protection of fetal life in the first trimester of pregnancy. Justice Rehnquist dissented, arguing that the appropriate standard of review should be rational basis and that the right to abortion was not deeply rooted in the country’s history.<sup>164</sup>

### *B. The Right to Make Medical Treatment Decisions*

In the 1990s, the Court decided three cases on the limits of medical autonomy: *Cruzan v. Missouri*, *Washington v. Harper*, and *Glucksberg v. Washington*. While the Court did not adopt a strict scrutiny standard of review in any of them, the majority did adopt intermediate scrutiny. These decisions recognized individuals’ strong liberty interests in the right to make decisions about bodily integrity and medical treatment.

In 1990, the Court directly addressed the right of an individual to refuse unwanted medical intervention. In *Washington v. Harper*, the Court recognized a prisoner’s “significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment.”<sup>165</sup> The Court reversed the Supreme Court of Washington’s application of a strict scrutiny standard and decided “whether the regulation is reasonably related to legitimate penological interests.”<sup>166</sup> It upheld the right of the state to administer the drugs according to the procedures in the statute, but

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160. *Id.* at 543 (citations omitted).

161. *Id.* at 548.

162. B. Jessie Hill, *The Constitutional Right To Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 307 (2007).

163. *Roe v. Wade*, 410 U.S. 113, 154 (1973).

164. *See id.* at 173-76.

165. *Washington v. Harper*, 494 U.S. 210, 221 (1990).

166. *Id.* at 223 (internal quotation mark omitted).

acknowledged that forcible medical intervention was “a substantial interference with that person’s liberty,” including the possibility of “serious, even fatal, side effects.”<sup>167</sup> The Court nonetheless upheld the statute as permissible largely based on the security interest in the prison environment and deference to professional medical judgment in the due process procedures.

Justice Stevens, joined by Justices Marshall and Brennan, dissented from the majority about the liberty interest, the standard of review, and the quality of due process available under the statute.<sup>168</sup> The dissent argued that the Court “undervalued [the] respondent’s liberty interest. . . and has concluded that a mock trial before an institutionally biased tribunal constitutes ‘due process of law.’”<sup>169</sup> It states that “a competent individual’s right to refuse such medication is a fundamental liberty interest deserving the highest order of protection.”<sup>170</sup> It does not agree that the statute takes the inmate’s interests into account, and argues that the policy “sweepingly sacrifices the inmate’s substantive liberty interest to refuse psychotropic drugs, regardless of his medical interests, to institutional and administrative concerns.”<sup>171</sup> Justice Stevens argued that the policy was not narrowly drawn, that the decision makers were biased, and that there was an insufficient showing of the state’s necessity to medicate.<sup>172</sup>

The *Cruzan* decision followed just two months later, recognizing a constitutionally protected liberty interest in refusing unwanted medical treatment for an incapacitated individual in a coma. The Court upheld a state statute that required that the evidence of the individual’s wishes in such circumstances be “clear and convincing.”<sup>173</sup> The Court noted the deep legal roots of the right to refuse medical treatment. It noted that “[a]t common law, even the touching of one person by another without consent and without legal justification was a battery.”<sup>174</sup> It quoted a Supreme Court decision from 1891 stating, “No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.”<sup>175</sup>

Citing Justice Cardozo, the *Cruzan* majority wrote, “Every human being of adult years and sound mind has a right to determine what shall be done with his own body.”<sup>176</sup> The Court noted that “[t]he informed consent doctrine has become

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167. *Id.* at 229.

168. *Id.* at 237 (Stevens, J., dissenting).

169. *Id.*

170. *Id.* at 241.

171. *Id.* at 245-46.

172. *Id.* at 242-57.

173. *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 280-81 (1990).

174. *Id.* at 269.

175. *Union Pac. R.R. Co. v. Botsford*, 141 U.S. 250, 251 (1891).

176. *Cruzan*, 497 U.S. at 269 (quoting *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93



firmly entrenched in American tort law.”<sup>177</sup> It found that the Court’s prior decisions, including *Jacobson*, implied the constitutionally protected liberty interest in refusing unwanted medical treatment.<sup>178</sup>

Justice O’Connor’s concurrence was more emphatic about the liberty interest to refuse unwanted medical treatment. She wrote, “[T]he liberty guaranteed by the Due Process Clause must protect, if it protects anything, an individual’s deeply personal decision to reject medical treatment, including the artificial delivery of food and water.”<sup>179</sup> She argued that “notions of liberty are inextricably entwined with our idea of physical freedom and self-determination” and that “the Court has often deemed state incursions into the body repugnant to the interests protected by the Due Process Clause.”<sup>180</sup>

Justice Scalia’s concurrence emphasized that the best way to address such issues was through the Equal Protection Clause: “Our salvation is the Equal Protection Clause, which requires the democratic majority to accept for themselves and their loved ones what they impose on you and me.”<sup>181</sup>

As in *Washington v. Harper*, Justices Brennan and Marshall dissented, with Justice Blackmun joining them as well. They argued that Nancy Cruzan had a “fundamental right to be free of unwanted medical care,” that her right was “not outweighed by any interests of the state,” and that “improperly biased procedural obstacles imposed by the Missouri Supreme Court impermissibly burden that right.”<sup>182</sup> The dissenters argued that because the Missouri statute impinged on a fundamental right, the state interest had to be narrowly tailored. Fundamental rights are to be protected even from “subtle governmental interference.”<sup>183</sup> They criticized the majority for recognizing a “general liberty interest,” but failed to state explicitly what the “measure of that liberty interest or its application” was.<sup>184</sup> If, as Justice O’Connor conceded, a competent person has a right to refuse medical treatment, then it “must be fundamental,” they argued.<sup>185</sup> “[The] freedom from unwanted medical attention is unquestionably among those principles ‘so rooted in the traditions and conscience of our people as to be ranked as fundamental,’” they concluded.<sup>186</sup> While they acknowledged that the individual’s liberty right is not absolute, Missouri’s general interest in protecting life did not outweigh Cruzan’s parents’ petition to end hydration and nutrition.<sup>187</sup>

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(1914)).

177. *Id.*

178. *Id.* at 278.

179. *Id.* at 289 (O’Connor, J., concurring).

180. *Id.* at 287.

181. *Id.* at 300 (Scalia, J., concurring).

182. *Id.* at 302 (Brennan, J., dissenting).

183. *Id.* at 304.

184. *Id.*

185. *Id.*

186. *Id.* at 305 (quoting *Snyder v. Mass.*, 291 U.S. 97, 105 (1934)).

187. *Id.* at 313.

Justice Stevens wrote a separate, forceful dissent. He characterized the state's interest as an "abstract, undifferentiated interest in the preservation of life," that overwhelms the best interests of Nancy Cruzan.<sup>188</sup> He argued that Cruzan's parents' rights should prevail, and that the state should not substitute its decisions for theirs.<sup>189</sup> He argued that the "sanctity, and individual privacy, of the human body is obviously fundamental to liberty. Every violation of a person's body is an invasion of his or her liberty."<sup>190</sup> He argued that "lives do not exist in abstraction from persons, and to pretend otherwise is not to honor but to desecrate the State's responsibility for protecting life."<sup>191</sup> While the majority did not join his view, the Court's range of opinion had shifted towards greater recognition of the liberty interest.

In 1997, the Court decided *Glucksberg v. Washington*, unanimously holding that there was no right to assisted suicide.<sup>192</sup> Nevertheless, the Court reaffirmed its line of cases finding a liberty interest in the Due Process Clause and requiring heightened protection against government interference. The Court reviewed the interests in marriage, procreation, education, contraception, bodily integrity and abortion.<sup>193</sup> It stated that "we have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment."<sup>194</sup> The Court contrasted its decision in *Cruzan*, holding that the common law had long recognized the right to refuse unwanted medical treatment, with *Glucksberg*, where it found the right to assisted suicide was not deeply rooted.

Justice Stevens in his concurrence wrote that the right to refuse treatment comes not only from the common law, but also from the more fundamental rights to bodily integrity and dignity. He agreed with the Court's conclusion, but would have applied strict scrutiny.<sup>195</sup>

### C. The Right to Autonomy in Sexual Relations

In 2003, the Court affirmed a heightened standard of review for the liberty interest in an individual's sexual autonomy.<sup>196</sup> In *Lawrence v. Texas*, the Court

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188. *Id.* at 331 (Stevens, J., dissenting).

189. *Id.* at 337.

190. *Id.* at 342.

191. *Id.* at 356-57.

192. *Washington v. Glucksberg*, 521 U.S. 702, 705-06 (1997).

193. *Id.* at 719-20 (citing *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992) (abortion); *Loving v. Virginia* 388 U.S. 1 (1967) (marriage); *Griswold v. Connecticut*, 381 U.S. 479 (1965) (marital privacy, contraception); *Rochin v. California*, 342 U.S. 165 (1952) (bodily integrity); *Skinner v. Oklahoma*, 316 U.S. 535 (1942) (having children); *Pierce v. Society of Sisters*, 268 U.S. 510 (1925) (educational choice)).

194. *Id.* at 720.

195. *Id.* at 741-43 (Stevens, J., concurring).

196. *Lawrence v. Texas*, 539 U.S. 558 (2003).

found a Texas statute criminalizing homosexual sodomy unconstitutional. The majority found that individuals enjoy heightened liberty protection from government intrusion in their private dwellings and personal autonomy. The Court overruled its prior decision in *Bowers v. Hardwick*, supporting its reversal with the Court's precedents applying intermediate scrutiny in *Casey v. Planned Parenthood*, an abortion rights case, and in *Romer v. Evans*, a discrimination case on the basis of sexual orientation.<sup>197</sup> The majority argued that Justice Stevens's dissent in *Bowers* should have been the majority decision.<sup>198</sup> By contrast, Justice O'Connor wrote that she found the Texas statute unconstitutional only on equal protection grounds. She cited Justice Jackson on the Equal Protection Clause:

The framers of the Constitution knew, and we should not forget today, that there is no more effective practical guaranty against arbitrary and unreasonable government than to require that the principles of law which officials would impose upon a minority be imposed generally. Conversely, nothing opens the door to arbitrary action so effectively as to allow those officials to pick and choose only a few to whom they will apply legislation and thus to escape the political retribution that might be visited upon them if larger numbers were affected.<sup>199</sup>

Justices Scalia, Rehnquist and Thomas dissented, arguing that the majority applied "an unheard-of form of rational-basis review."<sup>200</sup> The dissent argued that no fundamental right had been impinged; that there was a rational relationship with a legitimate state interest; and that neither due process nor equal protection of the law were violated.<sup>201</sup> Justice Thomas added in a separate dissent that while the Texas statute was "uncommonly silly," there was no constitutional basis for protection of the right to personal autonomy.<sup>202</sup>

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Thus since the 1940s, the Supreme Court has applied intermediate or strict scrutiny to cases about sterilization, abortion, medical treatment, and sexual autonomy. Yet, it has never revisited compulsory vaccination since 1922, and has not treated the issue in any depth since 1905. Based on the review of recent personal autonomy cases, it seems likely that the Supreme Court would apply at least an intermediate level of scrutiny to a state vaccination mandate case, even though *Jacobson* required only a rational basis test.

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197. *Id.* at 573-74.

198. *Id.* at 578.

199. *Id.* at 585 (citing *Ry. Express Agency, Inc. v. New York*, 336 U.S. 106, 112-13 (1949)).

200. *Id.* at 586.

201. *Id.* at 605.

202. *Id.* at 605-06.

The Supreme Court today has two distinct and somewhat contradictory lines of cases that relate to vaccination mandates—one focused on public health and the limits of individual liberty and the other focused on the individual's fundamental claims to bodily integrity and autonomy. Both lines of cases have potential life-and-death implications for individuals and society.

The contours of the vaccine issue have changed fundamentally since the early 1900s. Now at issue are thirty to forty-five preventive vaccinations whose administration start on the day of birth and which are compelled almost exclusively on children. It is possible that the Supreme Court may be called on in the foreseeable future to decide a case about the constitutionality of vaccination mandates.

### III. A HYPOTHETICAL CHALLENGE TO A HEPATITIS B VACCINATION MANDATE FOR PRESCHOOL CHILDREN

Forty-seven states impose hepatitis B vaccination mandates for daycare and school attendance, or both.<sup>203</sup> New York's public health law on school immunizations is representative, stating that a "school" includes "any public, private or parochial child caring center, day nursery, day care agency, nursery school, kindergarten,"<sup>204</sup> and defining "child" as "any person between the age of two months and eighteen years."<sup>205</sup> According to the statute, every child must receive the federally recommended doses of the hepatitis B vaccine, and several other vaccines, for school admission. "No principal, teacher, owner or person in charge of a school shall permit any child to be admitted to such school, or to attend such school, in excess of fourteen days, without the certificate [of immunizations]."<sup>206</sup>

The statute provides for the right of medical exemption if the required immunizations "may be detrimental to the child's health."<sup>207</sup> And it grants the right to religious exemption to parents who object to their child's immunization due to "genuine and sincere religious beliefs which are contrary to the practices herein required."<sup>208</sup> New York State does not afford individuals a philosophical or personal belief exemption to vaccination. It also requires the vaccination of children who do not attend school and have no valid exemptions.<sup>209</sup>

Are hepatitis B vaccination mandates for preschool aged children under the age of six constitutional under the Fourteenth Amendment Due Process and

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203. *Hepatitis B Prevention Mandates for Daycare and K-12*, *supra* note 2 (showing that only Alabama, Montana, and South Dakota have no hepatitis B mandates for daycare or school).

204. N.Y. PUB. HEALTH LAW § 2164(1)(a) (Consol. 2011).

205. *Id.* § 2164(1)(b).

206. *Id.* § 2164(7)(a).

207. *Id.* § 2164(8).

208. *Id.* § 2164(9).

209. *Id.* § 2164(8-a).

Equal Protection Clauses? Consider the hypothetical challenge of parents seeking to place their son in a preschool in New York City that requires compliance with the hepatitis B mandate. Assume that the parents of the three-year-old boy complied with all other vaccination mandates but refused this medical intervention against a disease that poses a negligible risk to their son and his classmates. They also believe that the vaccine itself carries irrational risks without any countervailing necessity.<sup>210</sup> The child is ineligible for a religious exemption because the family does not oppose the mandate on religious grounds. They oppose the mandate because it is unreasonable, arbitrary, oppressive, and against the child's best interests, concerns that *Jacobson* squarely addressed.

Imagine that they challenged the validity of the New York State regulation under the Fourteenth Amendment Due Process and Equal Protection Clauses. The New York State trial and appellate courts upheld the mandate but the New York Court of Appeals, the state's highest court, reversed and held that the hepatitis B vaccination mandate violated the Fourteenth Amendment Due Process Clause following the Supreme Court's precedents in *Jacobson*, *Harper*, *Cruzan*, and *Glucksberg*. New York State petitioned for *certiorari* and the U.S. Supreme Court granted it.

How might the Supreme Court balance the interests of the state and young child? The Court would have to look to *Jacobson*, *Zucht*, and the Court's most recent precedents on personal autonomy. But before turning to how the Court might decide, the Article reviews background about the disease itself, federal policy recommendations, and hepatitis B vaccination mandates that commenced in the 1990s. The Article will then return to the hypothetical challenge.

#### *A. Hepatitis B Disease, Federal Policy, Vaccination Mandates and Public Response*

The CDC provides the following information about hepatitis B disease:

Hepatitis B is a contagious liver disease that results from infection with the hepatitis B virus. It can range in severity from a mild illness lasting a few weeks to a serious, lifelong illness. Hepatitis B is usually spread when blood, semen, or another body fluid from a person infected with the hepatitis B virus enters the body of someone who is not infected. This can happen through sexual contact with an infected person or sharing needles, syringes, or other drug-injection equipment. Hepatitis B can also be passed from an infected mother to her baby at birth.<sup>211</sup>

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210. See *infra* notes 211-258 and accompanying text.

211. *Hepatitis B Information for the Public*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hepatitis/B> (last updated Mar. 12, 2009).

While the ACIP notes that transmission through saliva is possible, it suggests that nonsexual interpersonal contact must occur over an extended period, such as living with a chronic hepatitis B infected person in the same household.<sup>212</sup> Official CDC and ACIP materials do not suggest that transmission between young children through routine contact poses a significant threat.

*1. The 1982 and 1988 ACIP Recommendations*

In 1982, ACIP recommended the hepatitis B virus (HBV) vaccine only for those people “at substantial risk of HBV infection who are demonstrated or judged likely to be susceptible.”<sup>213</sup> ACIP noted that the United States is “an area of low HBV prevalence,” and that “the estimated lifetime risk of HBV . . . [is] approximately 5% for the population as a whole.”<sup>214</sup> ACIP recommended the vaccine only for “higher risk groups”: health-care workers, infants born to mothers infected with hepatitis B, and people likely to be in sexual or “needle stick” contact with those infected with hepatitis B.<sup>215</sup> In other words, ACIP recommended the vaccine to healthcare workers, drug addicts, homosexual and heterosexual adults with multiple sexual partners, and infants of infected mothers.

In 1988, ACIP issued another statement about the vaccine, calling for screening of all pregnant women to identify which mothers were infected—it estimated 16,500 mothers per year—and recommended that their infants be vaccinated. Without vaccination, ACIP estimated that 3500 infants would become chronic hepatitis B carriers.<sup>216</sup> It stated:

Prenatal screening of all pregnant women would identify those who are HBsAg-positive [hepatitis B surface antigen positive] and thus would allow treatment of their newborns with hepatitis B immune globulin (HBIG) and hepatitis B (HB) vaccine, a regimen that is 85%-95% effective in preventing the development of the HBV chronic carrier state.<sup>217</sup>

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212. Mast et al., *supra* note 80, at 5.

213. Ctrs. for Disease Control & Prevention, *Recommendation of the Immunization Practices Advisory Committee (ACIP) Inactivated Hepatitis B Virus Vaccine*, 31 MORBIDITY & MORTALITY WKLY. REP. 317 (1982), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001116.htm>.

214. *Id.*

215. *Id.*

216. Ctrs. for Disease Control & Prevention, *Recommendations of the Immunization Practices Advisory Committee Prevention of Perinatal Transmission of Hepatitis B Virus: Prenatal Screening of All Pregnant Women for Hepatitis B Surface Antigen*, 37 MORBIDITY & MORTALITY WKLY. REP. 342 (1988), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000036.htm>.

217. *Id.*

Thus by 1988, ACIP had proposed a solution to address potential hepatitis B transmission to approximately 3500 infants annually.

## 2. The 1991 ACIP Recommendation

In 1991, after the NCVIA was in effect, ACIP changed its recommendation dramatically. Now, instead of characterizing the United States as “an area of low HBV prevalence”<sup>218</sup> with certain high risk groups, ACIP describes the situation this way: “The acute and chronic consequences of hepatitis B virus infection are major health problems in the United States.”<sup>219</sup> While acknowledging that “most infections occur among adults and adolescents,” ACIP decided “immunization with hepatitis B vaccine is the most effective means of preventing HBV infection and its consequences.”<sup>220</sup> ACIP’s recommendation was a “comprehensive strategy to eliminate transmission of HBV and ultimately reduce the incidence of hepatitis B and hepatitis B-associated chronic liver disease in the United States.”<sup>221</sup>

To achieve this end, ACIP recommended hepatitis vaccination for all infants, regardless of the mother’s infection status. It stated that “[h]epatitis B vaccine should be incorporated into vaccination schedules for children. The first dose can be administered during the newborn period, preferably before the infant is discharged from the hospital, but no later than when the infant is 2 months of age.”<sup>222</sup>

The 1991 recommendation noted two types of licensed hepatitis B vaccines in the United States, Merck’s Recombivax HB and GlaxoSmithKline’s Engerix-B, both produced with new, genetically engineered recombinant DNA technology.<sup>223</sup> As to safety, the report stated that the vaccines “have been shown to be safe,” “over 4 million adults have been vaccinated,” and that “many children have received hepatitis B vaccine worldwide.”<sup>224</sup> It noted however, that “only a small number of children have received recombinant vaccine.”<sup>225</sup> Indeed,

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218. *Recommendation of the Immunization Practices Advisory Committee (ACIP) Inactivated Hepatitis B Virus Vaccine*, *supra* note 213.

219. Ctrs. for Disease Control & Prevention, *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)*, 40 MORBIDITY & MORTALITY WKLY. REP., Nov. 22, 1991, at 1, 2, *available at* <http://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm>; *see also* ADVERSE EVENTS ASSOCIATED WITH CHILDHOOD VACCINES: EVIDENCE BEARING ON CAUSALITY 211-35 (Kathleen R. Stratton et al. eds., 1994), *available at* <http://www.nap.edu/catalog/2138.html> (addressing safety and reported adverse events for hepatitis B vaccine administration).

220. Ctrs. for Disease Control & Prevention, *supra* note 219, at 3.

221. *Id.*

222. *Id.* at 12.

223. *Id.* at 6.

224. *Id.* at 10.

225. *Id.* at 11.

the package inserts for Recombivax HB and Engerix-B indicated that the clinical trials for the vaccines had been done on small groups of children, and gave scant evidence that the trials had been done on newborn infants.<sup>226</sup>

In addition to recombinant DNA, which had not been used previously on a widespread basis, the hepatitis B vaccine administered at birth from 1990 to 2001 included 25 micrograms of the mercury-containing preservative thimerosal,<sup>227</sup> or 12,500 parts per billion (ppb) of ethylmercury (because thimerosal is half mercury by weight).<sup>228</sup> Mercury is a recognized neurotoxin, with an amount as low as 0.5 ppb able to destroy human neuroblastoma cells.<sup>229</sup> The vaccine today continues to contain 0.3 ppb thimerosal, or what the CDC denotes as a “trace” amount.<sup>230</sup> Both approved vaccines also contain aluminum as an adjuvant to

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226. Merck & Co., *Recombivax HB: Hepatitis Vaccine*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110114.pdf> (insert for Recombivax HB). Merck’s Recombivax HB package insert currently provides the following information about clinical trials that occurred before marketing: “In three clinical studies, 434 doses of RECOMBIVAX HB, 5 mcg, were administered to 147 healthy infants and children (up to 10 years of age) who were monitored for 5 days after each dose.” The insert does not state the ages of the children or the proportion of the 147 subjects who were infants. It makes no mention of newborns. See also GlaxoSmithKline, *Engerix-B*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproducts/ucm224503.pdf> (insert for Engerix). GlaxoSmithKline (GSK) Engerix-B package insert provides this information: “In 36 clinical studies, a total of 13,495 doses of ENGERIX-B were administered to 5,071 healthy adults and children who were initially seronegative for hepatitis B markers, and healthy neonates. All subjects were monitored for 4 days post-administration.” While GSK suggests that it did test the vaccine in healthy newborns, it provides no number of them on which the vaccine was tested nor does it clarify how many adults vs. how many children tested the vaccine.

227. See *Thimerosal in Vaccines, Thimerosal as a Preservative*, *supra* note 138.

228. NAT’L RESEARCH COUNCIL, TOXICOLOGICAL EFFECTS OF METHYLMERCURY 11 (2000) (citing the Environmental Protection Agency’s guideline of 0.1 microgram per kilogram per day). Thus a baby weighing approximately five kilograms at two months should not receive more than 0.5 micrograms of mercury on the day of a doctor’s visit. At the two-month visit, infants routinely received 62.5 micrograms of mercury, or 125 times the EPA limit. Later studies suggested that “the accepted reference dose should be lowered to between 0.025 and 0.06 micrograms per kilogram per day,” meaning that the exposure at the two-month visit could be as high as 500, rather than 125, times the recommended level. Steven G. Gilbert & Kimberly S. Grant-Webster, *Neurobehavioral Effects of Developmental Methylmercury Exposure*, 103 ENVTL. HEALTH PERSP. 135 (1995).

229. Michael F. Wagnitz, Comment to Rahul K. Parikh, *Fighting for the Reputation of Vaccines: Lessons from American Politics*, 121 PEDIATRICS 621 (2008), available at [http://pediatrics.aappublications.org/content/121/3/621/reply#pediatrics\\_el\\_36839](http://pediatrics.aappublications.org/content/121/3/621/reply#pediatrics_el_36839).

230. Merck & Co., *supra* note 226; GlaxoSmithKline, *supra* note 226. In its list of excipients, the CDC states: “Where thimerosal is marked with an asterisk (\*) it indicates that the product should be considered equivalent to thimerosal-free products. This vaccine may contain trace amounts (<0.3 mcg) of mercury left after post-production thimerosal removal, but these amounts have no biological effect.” *Vaccine Excipient & Media Summary, Part 2: Excipients Included in U.S. Vaccines*, by Vaccine, CENTERS FOR DISEASE CONTROL & PREVENTION (Oct. 17, 2011), <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf>. The FDA considers Recombivax HB and Engerix-B products thimerosal-free. See *Thimerosal in Vaccines*, U.S. FOOD & DRUG ADMIN., available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm> (last updated Mar. 31, 2010) (“New pediatric



boost immune response.<sup>231</sup> Like mercury, aluminum is also a recognized toxic substance<sup>232</sup> and both metals potentially stimulate autoimmune syndromes.<sup>233</sup>

On mercury's long-time use as a vaccine preservative, Dr. George Lucier, former Director of the National Toxicology Program of the National Institute of Environmental Health Sciences, wrote:

I conclude that the justification for considering thimerosal . . . as safe was inadequate and flawed, information on alternative preservatives was ignored, the vaccine manufacturers ignored a significant body of knowledge on health effects for at least 50 years and that the vaccine manufacturers did not conduct necessary toxicology studies to establish safety.<sup>234</sup>

Besides the mercury safety concern, the Engerix-B and Recombivax HB inserts do not address the safety of simultaneous vaccine administration.<sup>235</sup> This is notable because ACIP recommends that the second and third doses of hepatitis B vaccine be given with the diphtheria, tetanus and pertussis vaccine, the *Haemophilus influenza* type b vaccine, the pneumococcal vaccine and inactivated poliovirus vaccine. Although it recommends simultaneous administration of vaccines, ACIP does not require that childhood vaccines be clinically tested for synergistic effects.

The Association of American Physicians and Surgeons filed a Freedom of Information Act (FOIA) in 1999 to require information on the hepatitis B vaccine preliminary safety data. It requested all safety data the CDC had prior to ACIP's 1991 recommendation and the statistical model ACIP used to assure safety.<sup>236</sup> It

formulations of hepatitis B vaccines have been licensed by the FDA, Recombivax-HB (Merck, thimerosal free) in August 1999 and Engerix-B (GlaxoSmithKline, thimerosal free) in January 2007.”)

231. *Vaccine Excipient & Media Summary, Part 2: Excipients Included in U.S. Vaccines*, by Vaccine, *supra* note 230.

232. For neurotoxic effects of mercury, see *Mercury: Human Health*, ENVTL. PROTECTION AGENCY, <http://www.epa.gov/mercury/health.htm> (last updated Oct. 1, 2010), and for aluminum, see *Division of Toxicology and Environmental Medicine ToxFaq's*, AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY (Sept. 2008), <http://www.atsdr.cdc.gov/tfacts22.pdf>.

233. E. Israel et al., *Adjuvants and Autoimmunity*, 18 LUPUS 1217 (2009); Lucette Pelletier et al., *Autoreactive T Cells in Mercury-Induced Autoimmunity: Ability To Induce the Autoimmune Disease*, 140 J. IMMUNOLOGY 750 (1988); Yehuda Shoenfeld & Nancy Agmon-Levin, 'ASIA' – *Autoimmune/Inflammatory Syndrome Induced by Adjuvants*, 36 J. AUTOIMMUNITY 4 (2010); Ellen K. Silbergeld et al., *Mercury and Autoimmunity: Implications for Occupational and Environmental Health*, 207 TOXICOLOGY & APPLIED PHARMACOLOGY 282 (2005); L. Tomljenovic & C. A. Shaw, *Aluminum Vaccine Adjuvants: Are They Safe?*, 18 CURRENT MEDICINAL CHEMISTRY 2630 (2011).

234. George W. Lucier, *Thimerosal Is a Developmental Neurotoxicant*, VERMONTERS FOR A CLEAN ENV'T, <http://www.vtce.org/mercury/lucier.pdf> (last visited Nov. 9, 2011).

235. Merck & Co., *supra* note 226; GlaxoSmithKline, *supra* note 226.

236. *The Hepatitis B Vaccine: Helping or Hurting Public Health: Hearing Before the Subcomm. on Criminal Justice, Drug Policy, and Human Res. of the H. Comm. on Gov't Reform*, 106th Cong. 260 (1999) [hereinafter *Hepatitis Hearings*] (statement of Barbara Loe Fisher).

has never received a response to its request made more than ten years ago.<sup>237</sup>

By 1999, several scientific studies questioned the merits of the program to vaccinate infants and newborns against hepatitis B. A 1996 article in the *Journal of Autoimmunity* concluded, “[t]here is no doubt that the new recombinant hepatitis B vaccine is different from mumps, measles, and rubella vaccines in its ability to trigger autoimmunity.”<sup>238</sup> A 1999 study in *Epidemiology* found a positive association between hepatitis B vaccination and liver disease in children under age six.<sup>239</sup> The article “question[s] the logic of universal infant HB vaccination in the United States.”<sup>240</sup> It further states, “[t]here is no evidence . . . supporting a protective effect of the HB vaccine against liver problems for the general population of U.S. children.”<sup>241</sup> It concludes that “[e]ven if the HB vaccine is effective for high risk groups, it does not indicate that it is also effective for negligible risk groups.”<sup>242</sup>

Another article reported, “In the case of Sweden, vaccinating over 100,000 children annually to ideally avoid 200 acute cases per year (mainly in drug addicts) is not considered logical from a public health standpoint.”<sup>243</sup> In other words, in their calculus, it was irrational to vaccinate 1000 people to prevent illness in 2. To compare this to the U.S. context, according to ACIP, approximately 3500 infants were considered to be at risk of hepatitis in 1988 and only 15% of them at most, or 525 infants, would not have been successfully treated through hepatitis B immune globulin treatment and vaccination. According to this information, the United States now vaccinates approximately 4 million infants per year to prevent approximately 525 cases of likely infection, or about 10,000 infants to prevent likely illness in one child.

### 3. The 1999 ACIP Recommendation

In January 1999, ACIP expanded its hepatitis B vaccination recommendation to include “all unvaccinated children aged 0-18 years and made hepatitis B vaccine available through the Vaccines for Children program (VFC) for persons

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237. Michael Belkin, *The Vaccine Bubble and the Pharmaceutical Industry*, in VACCINE EPIDEMIC 139 (Louise Kuo Habakus & Mary Holland eds., 2011) (“We are still waiting for a response today. Their failure to respond is damning. The implication is that the at-birth hepatitis B vaccine recommendation was made without conducting proper safety studies in babies beforehand.”).

238. Arnon Dov Cohen & Yehuda Shoenfeld, *Vaccine-Induced Autoimmunity*, 9 J. AUTOIMMUNITY 699, 701 (1996).

239. Monica A. Fisher & Stephen A. Eklund, *Hepatitis B Vaccine and Liver Problems in U.S. Children Less Than 6 years Old, 1993 and 1994*, 10 EPIDEMIOLOGY 337 (1999).

240. *Id.* at 339.

241. *Id.*

242. *Id.*

243. Sten Iwarson, *Why the Scandinavian Countries Have Not Implemented Universal Vaccination Against Hepatitis B*, 16 VACCINE S56 (1998).

aged 0-18 years who are eligible for VFC.”<sup>244</sup> This new policy expanded the recommendation from just infants, covering about 4 million newborn infants per year, to include all children through eighteen years, or approximately 76 million children under age 18 who would each be recommended or required to get three doses of the vaccine, or about 228 million doses. Under the VFC, all children would be eligible for the vaccine; doctors could provide them to families without charge because of federal and state subsidies.<sup>245</sup>

Congress held hearings on the hepatitis B vaccine in May 1999. Doctors, nurses, and parents of children injured by the hepatitis B vaccine testified. The testimonies suggested that the vaccine’s side effects vastly outweighed the threat of the disease to young children.<sup>246</sup> The speakers expressed alarm at the apparent rise in vaccine-related neurological disorders, deaths, and also at the decision-making process that had led to hepatitis B vaccination without representation.<sup>247</sup>

On July 8, 1999, the U.S. Public Health Service and the American Academy of Pediatrics issued a joint statement recommending reduced infant exposure to thimerosal, the mercury-containing preservative then used in the hepatitis B vaccines. It specifically recommended that the birth dose of the vaccine should be postponed in infants whose mothers were not hepatitis B positive until two to six months of age.<sup>248</sup> By mid-September 1999, however, when the hepatitis B vaccines became available without thimerosal as a preservative, although it still contained “trace” amounts, the Public Health Service returned to its prior recommendation to administer the first dose of hepatitis B vaccine to newborns.<sup>249</sup>

#### 4. The 2005 ACIP Recommendation

In 2005, ACIP strengthened its hepatitis B recommendation further, stating that “[a]ll delivery hospitals should implement standing orders for administration of hepatitis B vaccination as part of routine medical care of all medically stable

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244. Ctrs. for Disease Control & Prevention, *Notice to Readers Update: Recommendations To Prevent Hepatitis B Virus Transmission -- United States*, 48 MORBIDITY & MORTALITY WKLY. REP. 33 (1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00056293.htm>.

245. VFC: For Parents, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/programs/vfc/parents/default.htm> (last updated Oct. 19, 2011) (“The Vaccines for Children (VFC) Program offers vaccines at no cost for eligible children through VFC-enrolled doctors.”).

246. *Id.*

247. *Hepatitis Hearings*, supra note 236, at 67 (statement of Michael Belkin).

248. Ctrs. for Disease Control & Prevention, *Notice to Readers: Thimerosal in Vaccines: A Joint Statement of the American Academy of Pediatrics and the Public Health Service*, 48 MORBIDITY & MORTALITY WKLY. REP. 563 (1999), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4826a3.htm>.

249. Ctrs. for Disease Control & Prevention, *Notice to Readers: Availability of Hepatitis B Vaccine That Does Not Contain Thimerosal as a Preservative*, 48 MORBIDITY & MORTALITY WKLY. REP. 780, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4835a3.htm>.

infants weighing greater than or equal to 2000 g at birth.”<sup>250</sup> This 2005 ACIP report also noted that 15-50% of children “have low or undetectable concentrations of anti-HBs (anti-HBs loss) [hepatitis B antibodies] 5-15 years after vaccination.”<sup>251</sup> Although the report asserted that these children would likely develop an antibody response upon exposure to HBV, it stated that the children did not have documented immunity 5-15 years after vaccination. Vaccination decisions are typically made on the basis of documented immunity. In other words, at the age of sexual maturity when the children might themselves benefit from the vaccine’s protection, its efficacy might not exist. This ACIP report also rejected any purported association between the vaccine and multiple sclerosis, chronic fatigue syndrome, neurologic disorders, rheumatoid arthritis, type I diabetes, autoimmune disease, and sudden infant death syndrome that had been described in the scientific literature.<sup>252</sup>

Since 2005, further scientific investigation has suggested severe deleterious health consequences for many children from the hepatitis B vaccine. A 2008 study associates hepatitis B vaccination of male newborns with autism diagnoses from 1997-2002.<sup>253</sup> Boys who received the birth dose of hepatitis B vaccine were three times more likely to have parental report of autism than those who had not received the hepatitis B birth dose.<sup>254</sup> Gallagher and Goodman also found that the three dose series of hepatitis B vaccines were associated with a nine-fold risk for the vaccinated male newborns to have received early intervention or special education services.<sup>255</sup> Data acquired from the CDC’s Vaccine Safety Datalink under a Freedom of Information Act request also show an association between vaccinations given before one month of age and autism and other neurological disorders.<sup>256</sup> A 2011 study of the hepatitis B vaccine on mice demonstrates that it changes gene expression in the liver “which reflected subtoxic/adverse effects of

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250. Ctrs. for Disease Control & Prevention, *supra* note 4, at 14.

251. *Id.* at 10.

252. *Id.* at 11.

253. Carolyn M. Gallagher & Melody S. Goodman, *Hepatitis B Vaccination of Male Neonates and Autism Diagnosis, NHIS 1997-2002*, 73 J. TOXICOLOGY & ENVTL. HEALTH PART A 1665 (2010).

254. *Id.*

255. Carolyn M. Gallagher & Melody S. Goodman, *Hepatitis B Triple Series Vaccine and Developmental Disability in U.S. Children Aged 1-9 Years*, 90 TOXICOLOGICAL & ENVTL. CHEMISTRY 997 (2008).

256. *A Brief Review of Verstraeten’s “Generation Zero” Vaccine Safety Datalink Study Results*, SAFE MINDS (2004), <http://www.safeminds.org/research/library/GenerationZeroNotes.pdf>; *Generation Zero, Thomas Verstraeten’s First Analyses of the Link Between Vaccine Mercury Exposure and the Risk of Diagnosis of Selected Neuro-Developmental Disorders Based on Data from the Vaccine Safety Datalink: November-December 1999*, SAFE MINDS (2004) <http://www.safeminds.org/research/library/GenerationZeroPowerPoint.pdf> (showing significant correlation between early mercury exposures and autism, attention deficit disorder and sleep disorders).

the vaccine, especially in subtle liver injury.”<sup>257</sup> The authors attributed these adverse effects to aluminum included in the vaccine as an adjuvant.<sup>258</sup>

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ACIP’s hepatitis B recommendations remain in effect today, with the first dose recommended before hospital discharge, the second between one and two months, and the third between six and eighteen months.<sup>259</sup> The hepatitis B vaccines continue to contain aluminum and trace amounts of mercury. Forty-seven states make the hepatitis B vaccine mandatory for daycare and preschool.<sup>260</sup>

Critics continue to question the rationality of this vaccination mandate for young children. First, newborns are at almost no risk of hepatitis B. According to one doctor, when the U.S. population was around 248 million in 1991, there were 18,003 reported cases of hepatitis B viral illness in total—a national incidence of 0.007%.<sup>261</sup> The number of cases of hepatitis B in the United States peaked in 1985 and started to decline because of improved precautions. In 1986, five years before the 1991 ACIP Recommendation, only 279 cases of HBV infection were reported nationwide in children under age fourteen.<sup>262</sup> By contrast, as of June 2006, there were 47,198 reports to the Vaccine Adverse Event Reporting System (VAERS) describing complications following the administration of the hepatitis B vaccine alone or with other vaccines. Of these, 23,406 were for children fourteen years of age and younger. There were 909 death reports, of which 795 were under the age of fourteen.<sup>263</sup> Dr. David Kessler, former commissioner of the FDA, wrote in the *Journal of the American Medical Association* that “only about 1% of serious adverse events are reported to the FDA,”<sup>264</sup> suggesting that the number of reported vaccine-related injuries may be underestimated.

In his 1999 testimony before the U.S. Congress, Mr. Belkin stated “only 54 cases of the disease were reported to the CDC in the 0-1 age group.”<sup>265</sup> In the same year, there were 1080 reports of adverse events reported in the 0-1 age group, with 47 deaths. “Total VAERS hepatitis B reports for the 0-1 age group

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257. Heyam Hamza et al., *In Vivo Study of Hepatitis B Vaccine Effects on Inflammation and Metabolism Gene Expression*, MOLECULAR BIOLOGY REP., Mar. 17, 2011.

258. *Id.* at 6.

259. *Recommended Immunization Schedule for Persons Aged 0 Through 6 Years—United States, 2011*, *supra* note 1.

260. *See Hepatitis B Prevention Mandates for Daycare and K-12*, *supra* note 2.

261. F. Edward Yazbak, *The Hepatitis B Vaccine: What Went Wrong?*, VACCINATION NEWS, <http://www.vaccinationnews.com/node/19957> (last visited Dec. 2, 2011).

262. *Id.*

263. *Id.*

264. David Kessler et al., *Introducing MEDWatch: A New Approach to Reporting Medication and Device Adverse Events and Product Problems*, 269 JAMA 2765, 2765 (1993) (“Only about 1% of serious events are reported to the FDA, according to one study.”).

265. *Hepatitis Hearings*, *supra* note 236, at 67 (statement of Michael Belkin).

outnumber reported cases of the disease 20 to 1.”<sup>266</sup> If these reports in fact reflected about 1% of total adverse reactions to the vaccine, as is conceivable, the number of vaccine injuries to disease cases would be closer to 2000 to 1.

Mr. Belkin wrote:

Clearly, the interests of newborn babies were not represented on the original panel that created this vaccination policy in 1991. This vaccine has no benefit whatsoever for newborns, in fact it wears off and they will need booster shots later in life when they actually could get exposed to the disease. This is simply a case of ravenous corporate greed and mindless bureaucracy teaming up to overwhelm common sense.<sup>267</sup>

*B. Financial Considerations in Hepatitis B Vaccination Mandates*

The incidence of the disease was already diminishing when ACIP made its 1991 recommendation for newborns. While public health officials found it challenging to vaccinate the at-risk adult populations, they were already succeeding at vaccinating the at-risk infants of infected mothers. The rationale to vaccinate the whole population of infants and young children in order to avoid later incidence of the disease among the adult population was unproven. Infants have been exposed to unknown risks for decades because of inadequate safety science. The public health rationale for the hepatitis B vaccination of newborns, infants, and young children is weak.

Financial motivation for the recommendation, however, is strong. The vaccination of four million infants per year yields a substantial annual income stream in the hundreds of millions of dollars.<sup>268</sup> After the liability protections for industry and the medical profession were in place under the NCVIA, there were substantial incentives for industry to work with government to introduce new universal childhood vaccination mandates. NCVIA’s liability protection mitigated the risks to industry from new, relatively untested vaccines. Infants in the hospital after birth were available for medical intervention; additional doses could be given at regularly scheduled pediatric visits. Given the way the courts had interpreted *Jacobson*, few in government or industry would have feared a

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266. *Id.*

267. Michael Belkin, *Mindless Vaccination Bureaucracy*, NAT’L VACCINE INFO. CTR., <http://www.nvic.org/vaccines-and-diseases/Hepatitis-B/fatherstory.aspx> (last visited Dec. 2, 2011).

268. *See, e.g.*, BUSINESS INSIGHTS, *THE VACCINE MARKET OUTLOOK: MARKET ANALYSIS OF FUTURE GROWTH AND FUTURE PLAYERS BY SECTOR* 39 tbl. 2.2 (2005). The report indicates that the total U.S. revenue from hepatitis B vaccines in 2002 was \$499.6 million and \$468.1 in 2003. The report does not disaggregate the revenue from infant, childhood, and adult hepatitis B vaccines or from the hepatitis A vaccine, so the information is imprecise. The report does discuss, however, the importance of compulsory vaccination to the vaccine market. “What is evident from th[ese] data is that for a vaccine brand or category to perform well in the US market, it is essential that it is included in the US immunization schedule.” *Id.* at 38.

constitutional challenge. Indeed, two cases challenging the hepatitis B vaccination mandates on religious grounds lost.<sup>269</sup>

Part of *Jacobson's* rationale for deference to state legislatures was their representative nature; legislatures by their nature must take account of differing views. If the legislature makes bad choices, the electorate can reverse those choices and unseat the legislators through popular elections. But ACIP has become the driving force behind vaccination mandates, a federal advisory body with almost no public participation and no direct accountability to voters.<sup>270</sup> Because of this change in the locus of real decision making from legislators to ACIP, there are far greater risks of conflicts of interest. ACIP advisers have strong ties to industry, and financial and professional self-interest may outweigh public health in their decision-making.

In 2000, a Congressional report on *Conflicts of Interest in Vaccine Policy Making* identified notable conflicts of interest in the FDA and CDC advisory bodies that make national vaccine policy.<sup>271</sup> The report looked in detail at the conflict of interests in the decision-making that led the FDA and CDC to approve Merck's Rotashield vaccine against rotavirus, an intestinal disease in infants.<sup>272</sup> Merck voluntarily withdrew Rotashield from the market thirteen months after its launch due to serious adverse reactions.<sup>273</sup> The House Government Reform Committee found numerous problems with Rotashield's approval and vaccine approvals in general:

advisers' financial ties to vaccine manufacturers;  
pervasive conflicts of interest;  
little unbiased public participation;  
advisers' permitted stock ownership in companies affected by their decisions;  
advisers' lack of disclosure of partisan expert witness work;  
advisers who held vaccine patents approving vaccines for the same disease;  
excessively long terms for committee members; and  
liaison members' undisclosed ties to vaccine manufacturers.<sup>274</sup>

There is little evidence that the CDC or FDA implemented any of Congress's recommendations. In 2008, eight years later, a government study of

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269. *Boone v. Boozman*, 217 F. Supp. 2d 938 (E.D. Ark. 2002); *McCarthy v. Boozman*, 212 F. Supp. 2d 945 (E.D. Ark. 2002).

270. *Hepatitis Hearings*, supra note 236, at 67 (statement of Michael Belkin).

271. STAFF OF H. COMM. ON GOV'T REFORM, 106TH CONG., *CONFLICTS OF INTEREST IN VACCINE POLICY MAKING* (Comm. Print 4024), available at <http://www.nvic.org/nvic-archives/conflicts-of-interest.aspx> ("In the interest of public health, Congress should revise existing law to ensure that advisory committees contributing to vaccine policymaking are not unduly affected by individuals with conflicts of interest.").

272. *Id.*

273. *Id.*

274. *Id.*

disclosure and conflict waivers at the CDC found that ninety-seven percent of Special Government Advisers on CDC committees failed to disclose necessary information,<sup>275</sup> prompting criminal investigation of some.<sup>276</sup>

Illustrative of the culture of conflicts of interest is the former Director of the CDC, Dr. Julie Gerberding. One year after she stepped down as CDC Director, she joined Merck as the Director of its Vaccine Group.<sup>277</sup> During her tenure at CDC, ACIP approved Merck's Gardasil vaccine for human papilloma virus (HPV) against cervical cancer.<sup>278</sup> Gardasil is the most expensive childhood vaccine for the least prevalent disease that ACIP has ever approved and recommended for universal use. There were well-documented conflicts of interest in the Gardasil approval process. Since ACIP's approval of the HPV vaccine in 2007, the Vaccine Adverse Event Reporting System (VAERS) has recorded 23,388 adverse events, including 103 deaths and 4777 individuals who have not recovered after HPV vaccination.<sup>279</sup>

The financial motivations in vaccine recommendations and mandates are manifold. Industry offers ACIP members and other regulators career and financial incentives. Industry offers financial inducements to state legislators who make ACIP recommendations mandatory. States receive federal funding for vaccination mandates. Doctors generate revenue from additional pediatric visits

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275. DEP'T OF HEALTH & HUMAN SERVICES, OFFICE OF INSPECTOR GEN., OEI-04-07-00260, CDC'S ETHICS PROGRAM FOR SPECIAL GOVERNMENT EMPLOYEES ON FEDERAL ADVISORY COMMITTEES 16 (2009).

276. *Id.* at 23 n.69 ("The cases were forwarded to the OIG Office of Investigations because the waivers were created pursuant to the criminal conflict-of-interest statute. The OIG Office of Investigations reviewed information regarding these seven SGEs [special government employees] and determined, largely as a result of CDC's systemic lack of oversight of the ethics program for SGEs identified in this report, that the actions of the seven SGEs did not rise to the level of criminal violations of the conflict-of-interest statute.").

277. Dr. Julie Gerberding Named President of Merck Vaccines, MERCK (Dec. 21, 2009), [https://merck.com/newsroom/news-release-archive/corporate/2009\\_1221.html](https://merck.com/newsroom/news-release-archive/corporate/2009_1221.html).

278. Lauri E. Markowitz et al., Ctrs. for Disease Control & Prevention, *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 56 MORBIDITY & MORTALITY WKLY. REP., Mar. 12, 2007, available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr56e312a1.htm>.

279. VAERS Data, VACCINE ADVERSE EVENT REPORTING SYS., <http://vaers.hhs.gov/data/index> (last visited Dec. 2, 2011); see also Mark Blaxill, *A License To Kill? Part 1: How a Public-Private Partnership Made the Government Merck's Gardasil Partner*, AGE OF AUTISM (May 12, 2010, 5:35 AM), <http://www.ageofautism.com/2010/05/a-license-to-kill-part-1-how-a-public-private-partnership-made-the-government-mercks-gardasil-partner.html>; Mark Blaxill, *A License To Kill? Part 2: Who Guards Gardasil's Guardians?*, AGE OF AUTISM (May 12, 2010, 5:37 AM), <http://www.ageofautism.com/2010/05/a-license-to-kill-part-2-who-guards-gardasils-guardians.html>; Mark Blaxill, *A License To Kill? Part 3: After Gardasil's Launch, More Victims, More Bad Safety Analysis and a Revolving Door Culture*, AGE OF AUTISM (May 13, 2010, 5:45 AM), <http://www.ageofautism.com/2010/05/a-license-to-kill-part-3-after-gardasils-launch-more-victims-more-bad-safety-analysis-and-a-revolvin.html>; Online Access to the U.S. Government's VAERS Data, NAT'L VACCINE INFO. CTR., <http://www.medalets.org> (last visited Dec. 2, 2011); SANE VAX, INC., <http://sanevax.org> (last visited Dec. 2, 2011).



and from the vaccinations themselves. A “more is better” vaccination policy has many financial rewards, but does not necessarily lead to optimal or even rational public health outcomes.

While observers have long noted conflicts of interest in vaccination mandates, what is new is the potential scale of such conflicts. Because all school children in the country are now subject to ACIP vaccination recommendations, and state mandates based on them, conflicts of interests have greater impact than when mandates were local affairs. The NCVIA, which centralized national vaccination policy and created its infrastructure, facilitated vastly greater effect, both good and bad.

### *C. Informed Consent, or Lack Thereof, to Hepatitis B Vaccination*

The norm of informed consent in medicine requires doctors to provide extensive information about the known risks of interventions to patients and to allow them to make the ultimate decisions.<sup>280</sup> Similarly, drug manufacturers are required by law to provide accurate and complete information about drug risks with their products. With respect to vaccines, however, these norms are substantially relaxed. The NCVIA does not require doctors or vaccine manufacturers to give complete warnings directly to the person or guardian of the child being vaccinated. It requires that doctors give government-produced information and requires that manufacturers provide proper warnings to doctors only, who are considered to be “learned intermediaries.”<sup>281</sup> Both industry and the medical community lobbied for this lowered standard.<sup>282</sup>

The NCVIA initially required more information than what parents receive today. It specified ten items for CDC-drafted Vaccine Information Materials (VIMs).<sup>283</sup> The initial versions were twelve pages long and required parental signature. But pediatricians found the brochures were scaring parents and took too much time.<sup>284</sup> The American Academy of Pediatrics submitted legislation to shorten the VIMs and Congress enacted the proposed changes in 1993. Instead of ten information items, statements for parents now contained four: the benefits of

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280. See, e.g., 61 AM. JUR. 2D *Physicians, Surgeons, Etc.* § 175 (2010) (“The doctrine of informed consent imposes on a physician the duty to explain the procedure to the patient and to warn him of any material risks or dangers inherent in all collateral therapy, so as to enable the patient to make an intelligent and informed choice about whether or not to undergo the treatment.”).

281. See, e.g., 28 C.J.S. *Drugs and Narcotics* § 128 (2010) (“Under the learned-intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient, consumer or general public of the dangers involved with the product, but instead has a duty to warn the patient’s doctor, who acts as a learned intermediary between the patient and the manufacturer.”).

282. See COLGROVE, *supra* note 106, at 208-17.

283. 42 U.S.C. § 300aa-26(c) (2006).

284. Kristine M. Severyn, *Jacobson v. Massachusetts: Impact on Informed Consent and Vaccine Policy*, 5 J. PHARMACY & L. 249, 270-71 (1996).

the vaccine, the risks, one sentence about the VICP, and a reference to the CDC for further information. Parents' signatures were also eliminated. In an advisory to doctors, the CDC wrote that the new VIMs "provide enough information that anyone reading the materials should be adequately informed."<sup>285</sup> The current statements largely reassure parents that immunizations are safe and effective.

The current Hepatitis B Vaccine Information Statement provides the following information about possible adverse events, claiming, "Hepatitis B is a very safe vaccine. . . . Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses. A vaccine, like any medicine, *could* cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small."<sup>286</sup>

By contrast, the hepatitis B vaccine package inserts provide long lists of adverse events reported since the vaccine entered the market. A partial list of adverse events reported for Engerix-B and Recombivax HB include anaphylaxis, encephalitis, encephalopathy, paralysis, optic neuritis, multiple sclerosis, and vasculitis.<sup>287</sup>

Under the vaccine laws before 1986, these Vaccine Information Statements would not have met minimum requirements for duty to warn. Some parents and caregivers today also find the statements insufficient for rational decision-making and informed consent. In Oregon, for instance, a bill has been introduced in the state legislature to require physicians to give parents the hepatitis B vaccine package insert and to have them consent in writing so that they can better appreciate the risks.<sup>288</sup> The citizen who took this initiative is the grandmother of an infant who suffered a severe stroke after hepatitis B vaccination.

#### *D. A Hypothetical Challenge to the New York State Hepatitis B Vaccine Mandate for Preschoolers*

So how would the Supreme Court today evaluate a challenge to New York State's hepatitis B vaccination mandate for preschoolers? The Court would likely have to address the following issues based on its public health and personal autonomy precedents.

##### *1. Public Health Necessity*

The Court would have to decide if there is a sufficient public health necessity for the state to impose a preschool vaccination mandate. While the

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285. *Id.* at 272.

286. *Hepatitis B Vaccine: What You Need To Know*, CENTERS FOR DISEASE CONTROL & PREVENTION (July 18, 2007), <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-b.pdf>.

287. Merck & Co., *supra* note 226; GlaxoSmithKline, *supra* note 226.

288. H.R. 2635, 76th Leg. Assemb., 2011 Reg. Sess. (Ore. 2011), *available at* <http://gov.oregonlive.com/bill/2011/HB2635>.

Court would be highly deferential, it would not grant a blank check. Although the population as a whole may face the necessity to prevent and reduce the prevalence of hepatitis B, the state would likely have to show that the necessity specifically pertains to preschool children, the population to be burdened with vaccination risks. As Dr. Jacobs has suggested, “The absence of linkage of a disease to school activities should weigh heavily against a vaccination requirement.”<sup>289</sup> As young children are presumably not engaged in high risk transmission activities in preschool, on or off school premises, and there is substantial evidence of potential medical harm to them based on science and adverse vaccine event reporting, the state’s rationale of necessity is questionable.

## 2. Reasonable Means

The Court would have to assess if a vaccination mandate for preschoolers is a reasonable means of addressing the threat of hepatitis B prevalence in the broader society. Assume that the trial record revealed minimal clinical trials of the vaccine on newborn infants and young children, including extremely short monitoring periods.<sup>290</sup> Assume that empirical evidence showed that the adverse effects on this age group were greater than the risks posed by the illness.<sup>291</sup> Assume that the evidence showed that the vaccine’s efficacy wore off before puberty and that preschoolers would require booster shots by age twelve to maintain protection against the disease.<sup>292</sup> While the state would point to the vaccine’s approvals by the FDA and ACIP as evidence of reasonableness, these regulatory affirmations would not end constitutional inquiry. No jurisprudence of which the author is aware suggests a presumption of reasonableness based on agency approval.

## 3. Proportionality

The Court would have to assess whether the New York State vaccination mandate is proportionate to the risk of disease. The state would have to show that the risks of the disease to these children outweigh the risks of the vaccine. Most likely, this would be very difficult to prove since incidence of the disease in the preschool population is exceedingly low, yet the risks of adverse events from the vaccine, including anaphylaxis, encephalopathy, and death, are well-documented.<sup>293</sup> Furthermore, the public health rationale for the preschool mandate was never primarily to reduce disease solely in this age group; rather, it was to prevent risks to the entire population. It is unlikely that a court would be

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289. Jacobs, *supra* note 34, at 193.

290. See *supra* notes 219-226 and accompanying text.

291. See *supra* notes 264-287 and accompanying text.

292. See *supra* notes 249-251 and accompanying text.

293. See *supra* notes 264 - 287 and accompanying text.

willing to see the benefits to preschoolers as proportionate to the risks.

#### 4. *Harm Avoidance*

The state would have to show that it provides for harm avoidance in its hepatitis B mandate. In other words, it would have to demonstrate that it offers a fair process for allowing medical exemptions to those who are at risk of injury or death from the vaccine. A federal policy that recommends newborn vaccination makes harm avoidance almost impossible, despite the fact that this is one of *Jacobson's* core requirements. How parents and doctors can avoid harm to a newborn, who has virtually no medical history at birth, is hard to fathom except by avoiding neonatal medical intervention altogether.

If (1) harm avoidance is an essential element to the state's right to compel vaccination (as *Jacobson* concluded), while (2) the administration of vaccines may prevent any meaningful opportunity for harm avoidance because the infant's health status is unknown, then one may question whether the harm avoidance criterion is met. While day of birth administration is not strictly required for preschool attendance, the federal newborn recommendation tries to ensure that the mandate is followed.<sup>294</sup> In forty-seven states, the mandate is compulsory, and for all infants, day of birth administration is recommended.

#### 5. *Non-discrimination*

The Court would have to assess whether the vaccination mandate is non-discriminatory. The state would argue that because the mandate is imposed on all children in the same way, it is non-discriminatory. The parents would argue that while *Zucht* upholds the right of a school district or state to impose vaccination mandates on school children exclusively, that right is limited. If a vaccination mandate is imposed without any rational relation to an educational purpose and is based on population-wide necessity, its application may be arbitrary. If the mandate is imposed solely on young children not primarily for their benefit, its non-discrimination is questionable.

#### 6. *Liberty Interest in Due Process*

The Court would have to assess whether parents, on behalf of their child,

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294. Even though newborn administration of the hepatitis B vaccine is the standard of care, forty percent of infants do not receive the birth dose. The mothers of these infants have higher levels of income and education. Sean O'Leary, *Risk Factors for Non-Receipt of Hepatitis B Vaccine in the Newborn Nursery*, Centers for Disease Control & Prevention (Mar. 29, 2011, 11:15 AM), <http://cdc.confex.com/cdc/nic2011/webprogram/Paper25335.html> ("64,425 infants were identified in the birth cohort, of whom 39,703 (61.6%) received a birth dose of HBV. . . . Maternal characteristics such as higher income, higher education, and white race are associated with non-receipt of the HBV during the perinatal period.").

have a liberty interest in being able to refuse an unwanted medical intervention. The Court would likely acknowledge that any compulsory medical intervention, including childhood vaccination, is “a substantial interference with that person’s liberty.”<sup>295</sup> Having acknowledged that there are limits to the imposition of unwanted medical treatment on a prisoner in *Harper*, the Court would likely recognize an analogous liberty interest in a young child, which the child’s parents exercise as guardians. The Court has repeatedly acknowledged that the right to bodily integrity and to refuse unwanted medical treatment is deeply rooted in the historical traditions of the United States. To be sure, vaccination against infectious disease raises concerns different from a medical intervention that would affect only the individual. But the deeply rooted interest in bodily integrity exists in both contexts.

*Jacobson* acknowledged that the right to bodily integrity is not absolute but that the state may not impermissibly burden that right. In *Harper*, the Court recognized that the psychotropic drugs administered to a prisoner had to be related to legitimate penological interests.<sup>296</sup> While there is a distinction between forcible injection of a prisoner and compelled injection of a preschooler, the difference may be more theoretical than real. New York does not assert the right to force vaccination on preschoolers, but it does assert the right to withhold education and to require vaccination even if a child is homeschooled. The Court would need to elaborate what constitutes an “impermissible burden” or “undue burden” on the child’s liberty interest if it found that New York’s statute interfered excessively with the child’s liberty interest.

Although courts have interpreted the required nexus between vaccination mandates and education to be slight since *Zucht*, the Court would have to examine whether some connection must exist between the disease and transmission at school. In this case, the parents would argue that there is no nexus, no threatened disruption of attendance, and a better available means, *i.e.* screening mothers and vaccinating only those infants at risk of hepatitis B infection. The state would argue that no nexus is required under expansive interpretations of *Jacobson*.

Some of the Justices who participated in the personal autonomy decisions, notably Justices Stevens, Brennan, Marshall, and Blackmun,<sup>297</sup> would likely have found the right to refuse vaccination to be a “fundamental” right and would have subjected the state’s statute to “strict scrutiny.” These Justices likely would have required that any state statute be narrowly tailored to obtain its compelling state interest. As Justice Stevens concurred in *Glucksberg*, the right to refuse medical treatment stems not just from the common law but also from the rights to bodily

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295. *Washington v. Harper*, 494 U.S. 210, 229 (1990).

296. *Id.* at 223.

297. See *supra* notes 166–193 and accompanying text.

integrity and dignity.<sup>298</sup> Justice Stevens would likely have argued that the right to bodily integrity is fundamental.<sup>299</sup>

Subjected to strict scrutiny, the Court would likely find the vaccination mandate unconstitutional. It is not clear that prevention of hepatitis B in the preschool population is a compelling state interest, particularly when children are at negligible risk, and there is no mandate for the adult population. Similarly, it is not clear that a preschool mandate is narrowly targeted to achieve the state interest of eradicating hepatitis B viral disease. Given poor evidence that children's immunity persists into puberty, it would be difficult for the state to prove its case. Neither the federal government nor states have alleged that disease transmission among preschoolers is a serious threat to public health.

It seems doubtful that there would be much readiness on the Court today to adopt a strict scrutiny standard of review for a state vaccination mandate, however. As Justice Scalia chided the majority in *Lawrence v. Texas*, the Justices in the majority seemed to be more ready to "apply an unheard-of form of rational-basis review" than to declare a new interest "fundamental."<sup>300</sup> Under intermediate scrutiny or even rational basis, though, the state must demonstrate that its mandate is rational. If the petitioner can prove that the vaccine causes more harm than it prevents to this population, the mandate might not meet even the rational basis test.

### 7. Liberty Interest in Equal Protection

A vaccination mandate for hepatitis B exclusively for young children, when none is imposed on the adult population, raises equal protection issues when the state's objective is eradication of hepatitis B viral disease from the population as a whole. While *Zucht* decided that schools may impose mandates for infectious diseases, there are constitutional limits to what a legislative majority may impose on any minority while leaving itself free of such constraints. While the state might argue that children are at risk from the disease and benefit from its compulsion, a child petitioner might argue that the adult population, which is demonstrably at far greater risk, is exempted from a universal mandate in violation of equal protection. Children may be the subject of discrimination if they are selectively vaccinated for a disease from which they are at negligible risk. While the hepatitis B mandate for children raises both due process and equal protection concerns, one could imagine a Justice deciding that the regulation meets a rational basis or intermediate scrutiny test but fails equal protection. Justice O'Connor followed this rationale in *Lawrence v. Texas*.<sup>301</sup>

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298. *Washington v. Glucksberg*, 521 U.S. 702, 741-43 (1997) (Stevens, J., concurring).

299. *Id.*; *Cruzan v. Dir., Mo. Dep't of Health*, 497 U.S. 261, 331-34 (1990) (Stevens, J., dissenting); *Harper*, 494 U.S. at 237-39 (Stevens, J., concurring in part and dissenting in part).

300. *Lawrence v. Texas*, 539 U.S. 558, 586 (2003) (Scalia, J., dissenting).

301. *Id.* at 579-80.

## CONCLUSION

Although courts have interpreted *Jacobson* generously over the last century, the decision itself and subsequent Supreme Court cases place real limits on coercive medical interventions. In 1905, Justice Harlan made clear that unreasonable, arbitrary or oppressive vaccination mandates could violate the Fourteenth Amendment Due Process and Equal Protection Clauses. He foresaw that mandates “might be exercised in particular circumstances and in reference to particular persons in such an arbitrary, unreasonable manner, or might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons.”<sup>302</sup>

The parents in this hypothetical argue that the hepatitis B mandate for preschoolers is precisely such an abuse of the police power, going far beyond what is reasonably required for the safety of the public. Later cases have widened the scope of personal autonomy in medical decision-making. As Justice Stevens warned in his *Washington v. Harper* dissent, a state’s “abstract, undifferentiated interest in the preservation of life may in fact overwhelm real individuals’ best interests.”

The hepatitis B vaccination mandate—not primarily for the benefit of young children, and inadequately tested for their safety—has failed to honor young children’s liberty, equal protection, and health. On the CDC’s record, there was no clear medical rationale for introducing the vaccine for young children. The apparent explanation for the dramatic turnaround in federal vaccination recommendation was financial, not medical.

Professor Shapiro raises many important and interesting points in his response, but his expansive analysis seems to bypass the precise reasons he finds the hepatitis B vaccination mandate necessary for children under age six. What is the basis, according to his constitutional logic, for compelling these children, who are presumably not sexually active, drug using, or at risk of other routes of infection, during early childhood? What important governmental objectives does the mandate serve when these children’s artificial immunity will wane or be nonexistent by the time they are potentially at risk of sexual or IV drug infection? What distinguishes a hepatitis B mandate for preschoolers from the “spectacle of unneeded coercion” that Professor Shapiro warns against?

In concluding, Professor Shapiro suggests that readers comply with vaccination recommendations but be alert to potential conflicts of interest. But this conclusion implies that readers get to make up their own minds—just what the parents of preschoolers in forty-seven states do not get to do for the hepatitis B vaccine.

Justice Jackson wrote in his concurrence in *Skinner*, “There are limits to the

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302. *Jacobson v. Massachusetts*, 197 U.S. 11, 28 (1905) (citing *Wis., Minn. & Pac. R.R. v. Jacobson*, 179 U.S. 287 (1900)).

extent to which a legislatively represented majority may conduct biological experiments at the expense of . . . a minority . . . .”<sup>303</sup> It is time to reconsider hepatitis B vaccination mandates for preschool children. If federal agencies, advisory bodies, and state legislatures will not do so, then, as Justice Harlan wrote in *Jacobson*, it may be time for “the courts to interfere for the protection of such persons.”<sup>304</sup>

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303. *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535, 546 (1942) (Jackson, J., concurring).

<sup>304</sup> *Jacobson*, 197 U.S. at 28.



Updating Constitutional Doctrine: An Extended Response  
to the Critique of Compulsory Vaccination \*

Michael H. Shapiro \*\*

I. INTRODUCTION ..... 89

II. THE OLDER CONSTITUTIONAL CONTEXT—*JACOBSON*: HANDLE WITH  
GREATER CARE..... 91

A. THE CLAIM THAT JACOBSON HAS BEEN EXPANDED..... 93

B. WHAT DID JACOBSON SAY? ..... 101

1. THE CHARACTERIZATION OF THE RIGHT ..... 102

2. THE JACOBSON STANDARD OF REVIEW..... 103

3. THE COURT’S CAVEATS..... 103

III. TODAY’S CONSTITUTIONAL HIERARCHIES, STANDARDS OF REVIEW, AND  
THEIR APPLICATION TO OLD AND NEW BIOMEDICAL CONTEXTS . 104

A. JACOBSON 2.1:KEY QUESTIONS..... 104

B. THE ARTICLE’S ATTEMPTED RECONSTRUCTION ..... 107

C. A NOTE ON CONSTITUTIONAL VALUES AND THEIR ENTAILMENTS:  
STANDARDS OF REVIEW AS INHERENT IN ADJUDICATION AND AS HEURISTICS  
..... 109

D. TECHNICAL DIFFICULTIES WITH THE ARTICLE’S DOCTRINAL ACCOUNT 110

E. AN OUTLINE OF JACOBSON 2.1: WHAT KIND OF RIGHT, OF WHAT VALUE,  
AND BEARING WHICH STANDARD OF REVIEW? ..... 112

1. WHAT IS THE RIGHT AND WHAT DO WE CALL IT? ..... 112

2. WHAT IS THE STANDARD OF REVIEW AND WHAT DO WE CALL IT? .... 113

\* This Response addresses the concerns raised in Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL’Y L. & ETHICS 39 (2012).

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3. PENALTIES VERSUS FORCE: WHICH GOVERNMENT ACTION DOES THE RIGHT PROTECT US AGAINST? .....	115
4. THE CONCEPTUAL INTERACTION BETWEEN THRESHOLD RIGHTS AND COUNTERVAILING INTERESTS .....	116
5. WHAT EXACTLY IS THE OBJECTION TO BEING VACCINATED? .....	117
6. THE ARTICLE'S SHAKY START ON JACOBSON 2.1 .....	119
<b>IV. VACCINATION ANALYTICS: WHAT DO WE PLACE INTO THE CONSTITUTIONAL ARGUMENT STRUCTURES?.....</b>	<b>122</b>
A. BASIC QUESTIONS ABOUT THE HEPATITIS B VACCINE ISSUE: HARMS AND THEIR CAUSES .....	122
1. FACTUAL AND CONCEPTUAL BACKGROUND.....	122
2. ADVERSE EVENTS, STUDY FINDINGS, AND CAUSATION .....	126
B. WHAT IF WE CONCEDE CAUSATION? .....	130
C. EFFICACY, SAFETY, AND NEED .....	131
D. EDUCATION AND VACCINATION: A NOTE ON THE "PUNISHMENT" OF CHILDREN AND PIGGYBACKING PUBLIC HEALTH MEASURES ONTO GOVERNMENT FUNCTIONS .....	138
E. JACOBSON 2.1 APPLIED: THE PINPOINT ISSUES.....	141
1. SOME ASSUMPTIONS.....	141
2. THE VACCINATION-RESISTER'S CLAIMS .....	144
3. HOW FAR TO GO WITHIN A STANDARD OF REVIEW .....	146
4. ADDITIONAL MORAL ANALYTICS, SOME OF WHICH SHOULD BE ABSORBED INTO CONSTITUTIONAL ADJUDICATION. ....	155
<b>V. ADDITIONAL CRITICISMS. ....</b>	<b>160</b>
A. CONFLICTS OF INTEREST: THE VACCINE MANUFACTURERS (AND OTHERS) WANT TO MAKE MONEY.....	160
B. IMPAIRED INFORMED CONSENT PROCESSES.....	162
C. UNREPRESENTATIVE DECISION-MAKING .....	164
D. COMMUNICABLE VERSUS NONCOMMUNICABLE DISORDERS; SELF-PROTECTION AGAINST THE UNVACCINATED .....	167
<b>CONCLUSION .....</b>	<b>168</b>

## I. INTRODUCTION

Science is not supposed to tout certainty for its findings.<sup>1</sup> It leaves absolute truth to other fields, such as mathematics, logic, and religion. There are, of course, well-confirmed theories and “laws” that do warrant the loose use of “certain.” The bare theoretical possibility that the oxidation theory of combustion will fall and the phlogiston theory will be restored to its rightful place does not move the research establishment. And scientists (like many others) are certain that scientific methodology is a powerful tool for illuminating the world, if not everything about every aspect of existence.

So, within this very stance, scientists themselves should be skeptical of critiques of what is thought to be already established. Moderate conservatism of this sort is rational and often inevitable.<sup>2</sup> The burden of proof, at the start, is rightly on the critics of accepted scientific claims unless those claims are absurd (which is rarely the case). And, for their part, scientists like Semmelweis, Marshall, and Warren were also right not to take established matters as certain.

Calls for skepticism in the face of scientific claims generally, and vaccination claims in particular, are, thus, welcome among the rational. Professor Holland’s article (the “Article”) calls attention to important medical, scientific, and constitutional issues, but has flaws requiring attention. Skepticism of medical or scientific claims may be a rational necessity, but her Article is an uneven and incomplete expression of that skepticism, for the reasons that follow in this Response’s Parts II-V. The Article relies, at various points, on flawed modes of inference and questionable sources of opinion and information; it fails to specify underlying value and policy assumptions; and its analysis of constitutional precedents and doctrine does not confirm her claims that compulsory vaccination programs are constitutionally suspect within current or preexisting doctrine.

One should ask what incites Professor Holland’s complaints about current

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1. See PHILIP KITCHER, SCIENCE, TRUTH, AND DEMOCRACY 13 (2001) (“To claim the truth of a statement is not to declare the certainty of our knowledge. Whatever hopes our predecessors may have had, contemporary views about human knowledge are saturated by the conviction that our beliefs about nature are fallible, that absolute certainty is not an option for us. When someone maintains the truth of the thesis about the composition of the atmosphere, he can consistently acknowledge the possibility that further inquiry might reveal it to be false. Indeed, we spend our lives proclaiming true, and acting upon, beliefs we recognize as vulnerable to the course of future experience. There is no snapping shut of our minds, no insulation against critical scrutiny, when we move from saying what we believe to declaring its truth.”).

2. Of course, critics should not have treated Marshall and Warren (bacteria cause many ulcers) and Semmelweis (germ theory of disease) as badly as they did, but much of the initial skepticism of received wisdom is sound. See Polyxeni Potter, *About the Cover: Ignaz Philipp Semmelweis (1818-65)*, 7 EMERGING INFECTIOUS DISEASES 368 (2001), available at [http://wwwnc.cdc.gov/eid/article/7/2/ac-0702\\_article.htm](http://wwwnc.cdc.gov/eid/article/7/2/ac-0702_article.htm); Kathryn Schulz, *Stress Doesn’t Cause Ulcers! Or, How To Win a Nobel Prize in One Easy Lesson: Barry Marshall on Being... Right*, SLATE, Sept. 9, 2010, [http://www.slate.com/blogs/thewrongstuff/2010/09/09/stress\\_doesn\\_t\\_cause\\_ulcers\\_or\\_how\\_to\\_win\\_a\\_nobel\\_prize\\_in\\_one\\_easy\\_lesson\\_barry\\_marshall\\_on\\_being\\_right.html](http://www.slate.com/blogs/thewrongstuff/2010/09/09/stress_doesn_t_cause_ulcers_or_how_to_win_a_nobel_prize_in_one_easy_lesson_barry_marshall_on_being_right.html).

immunization practices and policies—at least as applied to hepatitis B vaccination, which is the Article’s prime target. Here are some possibilities, starting with the least likely, but nonetheless important:

- It is in pursuit of loyal opposition to science in application—a way of keeping scientists honest and promoting due care in formulating, confirming, and disclosing hypotheses and findings. We are all from Missouri, after all.<sup>3</sup> And, no more than with any other institution, we probably should not rely on science to police its own domain.

- It is meant to vindicate autonomy and the rule of law, regularly scorned by overbearing governments and greedy pharmaceutical companies.

- Some think that there have been serious injuries from vaccinations, including those for hepatitis B; these pressing facts require ventilation and calls for reducing or terminating some programs.

I doubt that the Article is simply meant to keep science on its toes. It seems likelier to be a reaction to a sense of autonomy under assault by at least some vaccination projects, and a push toward deemphasizing them. True enough, autonomy is always under assault. Give the government or immense private interests an inch, and they will take a light year. (Sometimes little private interests do that too.) The Article does not claim there is a pattern (systematic or otherwise) of putting down individual liberty of certain sorts, but its critique of supposed conflicts of interest and “financial distortions” suggests a governmental and commercial indifference to claims against personal intrusions.

As for the view that there are facts showing that the risk of vaccine-related injury is unacceptable, I do not think that is made out here, although the author is right to reject arrogant dismissals about such injuries by persons who seem to *know* that nothing can go wrong. A central distinction to stress is that between *vaccine-caused* injury—whether it occurs and at what rate—and what constitutes “acceptable losses.” Other critical distinctions concern the attribution of injuries to vaccines. Such distinctions include the differences between (1) associational links *simpliciter* and causation and (2) injuries caused by the active components of the vaccine and those caused by additives (e.g., thimerosal). I do not recall encountering any calls for halting hepatitis B vaccinations because of the one-in-1.1 million risk of anaphylactic shock concededly created by the vaccine.<sup>4</sup> The author does not insist on a zero incidence of vaccine-related injuries (never mind a zero incidence of adverse events correlated with vaccination), but her tolerance is not great. Not unexpectedly, her tolerance for “low benefit” is also limited.

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3. Missouri is known as the “Show-Me” state. See *Missouri History: Why Is Missouri Called the “Show-Me” State?*, MO. SECRETARY ST. ROBIN CARNAHAN, <http://www.sos.mo.gov/archives/history/slogan.asp> (last visited Dec. 2, 2011).

4. See, e.g., Eric E. Mast et al., Ctrs. for Disease Control & Prevention, *A Comprehensive Immunization Strategy To Eliminate Transmission of Hepatitis B Virus Infection in the United States; Recommendations of the Advisory Committee on Immunization Practices (ACIP) Part II: Immunization of Adults*, 55 MORBIDITY & MORTALITY WKLY. REP., Dec. 8, 2006, at 1, 13.

“According to this information [from the U.S. Advisory Committee on Immunization Practices (ACIP)], the United States now vaccinates approximately 4 million infants per year to prevent approximately 525 cases of likely infection, or about 10,000 infants to prevent likely illness in one child.”<sup>5</sup>

But this description does not constitute an argument for any legal or policy conclusion and, in this sense, cannot stand alone. Without applying the asserted facts and factual hypotheses to accepted value premises, this description imports no value conclusions whatever. In fact, privately, and as a matter of public policy, we often bear harms that seem, monetarily, to outweigh the benefits. Moreover, little is said about the seriousness of hepatitis B infections; only the number 525 is recorded. Still more, the very idea of “prevent[ing] 525 cases of likely infection” is sought to be trivialized by saying that the benefit is to one in 10,000. (On the figures presented, it’s actually about one in 7600.) Something more is needed to explain the insistent call to arms.

What follows is not a point-by-point account and evaluation of the Article, and is not meant to be a comprehensive freestanding article either. I am addressing ideas that are worth further illumination. More specifically, I assess the Article’s analysis of constitutional precedent and doctrine, criticize how it addresses the evidence of vaccination harm and benefit, and question its very framework for determining what constitutes harm and benefit on an individual and social scale. In the course of doing this, I try to probe the value premises underlying supposed collisions of personal autonomy with social claims and how these have been, and are likely to be, managed within a constitutional framework. In short, I try to address conceptual, doctrinal, and empirical flaws in the Article.<sup>6</sup>

## II. THE OLDER CONSTITUTIONAL CONTEXT—*JACOBSON*: HANDLE WITH GREATER CARE

Much of Professor Holland’s Article is about constitutional law. The threshold reason for this is obvious: If there are objections to compulsory vaccination, basic issues of the integrity of the person are openly contested, and rights will be invoked against government action. These are constitutional issues, and, if the constitution is to be obeyed, they are rule of law issues. Another

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5. Mary Holland, *Compulsory Vaccination, the Constitution, and the Hepatitis B Mandate for Infants and Young Children*, 12 YALE J. HEALTH POL’Y L. & ETHICS 39 (2012). For statutory sources and history, see *ACIP Charter: Authority, Objective, and Description*, Authority, CENTERS FOR DISEASE CONTROL & PREVENTION (Apr. 6, 2010), <http://www.cdc.gov/vaccines/recs/acip/download/charter.pdf>.

6. Because many issues derive from efforts to assess and compare advantages and disadvantages of vaccination programs, I note, for clarity, that references to “costs” should be broadly understood to include at least all direct adverse harms and disadvantages from vaccinations and their programs: the financial burden and physical and mental harms of adverse incidents attributable to the vaccine or the way in which the program is administered; attenuation of autonomy norms; even Heckler’s Veto problems in objecting, rationally or not, to vaccination.

reason is that the constitutional matrix is a heuristic that drives us to probe the idea and practice of vaccination, or, indeed, any policy that finds itself embedded within a constitutional dispute. The constitutional framework, rightly used, illuminates the moral and policy issues and draws out analytical strands that might be overlooked within a looser framework for analysis. Rightly used, it skews nothing. (I do not address arguments against “over legalization,” many of which are hugely flawed.)<sup>7</sup>

A third reason, amplifying the first two, is that adjudication involving technology generally, and vaccination in particular, may provide special challenges to constitutional interpretation and argumentation.<sup>8</sup> In this light, the constitution and vaccination need each other. The conceptual tools we use in constitutional theory and adjudication reflect the hierarchy of values embedded in the constitution; its text is not value free—a point quite independent of jurisprudential debates about meaning, interpretation, and authority. The rights, interests, and political structures embedded in the constitution are, to greater or lesser degree, aspects of American identity (a sprawling, but not meaningless, idea) and its vaunted exceptional status. What these rights, interests, and structures mean in theory and operation are tested constantly, but real-world developments—often technological innovations—push us to unpack and develop meanings that had been comfortably dormant. *Jacobson v. Massachusetts*<sup>9</sup>—that old, old case—represented a major medical innovation that had been introduced over a century earlier and pointedly required constitutional explication in a science-infused controversy.

Technological developments, from *Jacobson* through *Roe v. Wade* through future artificial gestation and cloning cases, require us to rethink our threshold values and, thus, necessarily how we implement them through tools for sorting and comparing constitutional claims. These tools are our standards of review. The competing views about and within science mentioned by Justice Harlan are with us now with increasing frequency and complexity.<sup>10</sup> *Jacobson* itself is, thus, a continuing presence. In a contemporary compulsory vaccination case applying today’s doctrine,<sup>11</sup> the Court will be pressed to be more precise about its

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7. See Michael H. Shapiro, *Is Bioethics Broke?: On the Idea of Ethics and Law “Catching Up” with Technology*, 33 IND. L. REV. 17, 87-103 (1999).

8. Michael H. Shapiro, *Constitutional Adjudication and Standards of Review Under Pressure from Biological Technologies*, 11 HEALTH MATRIX: CASE W. RES. J.L. & MED. 351, 486 (2001) (referring to the goal of “learn[ing] more about constitutional adjudication by watching it when it is pressed by biomedical technology”).

9. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

10. “The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases.” *Jacobson*, 197 U.S. at 35 (quoting *Viemeister v. White*, 72 N.Y. 97, 99 (1904)).

11. See *infra* text accompanying notes 50-81, 86-92, where I refer to such a case as *Jacobson 2.1* and differentiate it from a literal application of *Jacobson*’s original tenets today (*Jacobson 2.0*).

conceptual template than it was in saying, “According to settled principles, the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety.”<sup>12</sup> This opaque formulation will not do today, although it seems as explicit as standards of review were at the time and was similar to the standard expressed in that exemplar of judicial aggressiveness, *Lochner v. New York*, which struck down the state’s regulation of the working hours of bakers. Unless we view both courts and legislatures as black boxes, something more penetrable than “reasonableness” is required.<sup>13</sup>

Within *Jacobson*’s standard of review (which I construe as far from fully deferential to government), how does the Court address conflicting scientific claims (if at all), their legislative assessment and use, and the legislative valuations of means and ends? If a single study supports a given finding (confirming or disconfirming some hypothesis), does the strictest scrutiny entail deference to the accuracy of the raw data, or to the methodologies for generating and drawing inferences from them? With strict or other heightened scrutiny, flat references to the need to defer to the legislature simply do not work, as they do within minimal scrutiny.<sup>14</sup> Unlimited deference even to factual conclusions makes no sense under strict scrutiny, a point rightly mandated by the framework of the Article. But the idea of lay judges vetting the complexities of scientific claims does not inspire confidence either. So, there is much more to come beyond *Jacobson*.

#### *A. The Claim that Jacobson Has Been Expanded*

In *Jacobson v. Massachusetts*, the Supreme Court upheld the conviction and five-dollar fine<sup>15</sup> imposed on the defendant for refusing to be vaccinated against smallpox. The Rev. Jacobson was a Lutheran clergyman who had emigrated from Sweden, but the exact nature of his objection to vaccination was not made clear in the opinion. At least one historical commentary suggests he believed that vaccination was counter to God’s preference that we follow nature. The same source says that he ultimately paid the fine, under threat of confinement.<sup>16</sup> The

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12. *Jacobson*, 197 U.S. at 25.

13. *Lochner v. New York*, 198 U.S. 45 (1905).

14. *E.g.*, *City of New Orleans v. Dukes*, 427 U.S. 297, 303 (1976).

15. Five dollars was a much bigger deal at the time of *Jacobson*. The average factory worker in America in 1905 earned around thirteen dollars per week. MICHAEL WILLRICH, *POX: AN AMERICAN HISTORY* 285 (2011).

16. *Who Is Reverend Henning Jacobson?*, SUBURBAN EMERGENCY MGMT. PROJECT (Oct. 7, 2009), [http://www.semp.us/publications/biot\\_reader.php?BiotID=653](http://www.semp.us/publications/biot_reader.php?BiotID=653). Rev. Jacobson and his lawyers had vigorously pressed what we would now call the fundamental rights/liberty interest perspective. “Pickering and Ballard [Rev. Jacobson’s counsel] claimed before the Supreme Judicial Court of Massachusetts that the Cambridge ordinance violated the 14th Amendment of the Constitution. Their briefs were filled with colorful language and religious allusions. They claimed that compulsory vaccination was a ‘greater outrage than the scalping of a living victim by an Indian

case itself is rightly used to address autonomy issues and countervailing state interests, and it serves well within a tutorial on the nature and evolution of standards of review in constitutional theory and adjudication.

Justice Harlan's majority opinion is regularly invoked both to support and attack "compulsory" vaccination statutes. (As Professor Holland notes, there is little statutory or decisional law authorizing actual forced vaccination. Whether forced vaccination is worse than being fined—or worse than being imprisoned for refusal to pay up—is interesting, but not pertinent here.) Although law-trained persons regularly invoke the same cases to further opposing sides, *Jacobson* in particular has something for everyone. Professor Holland argues that *Jacobson*, as both the offspring of its time and as still-good (if uncertain) law, should be read as affording strong protection for individual claims against required vaccination, particularly when it is a condition for school attendance. She contends that the case has been "expanded" by including children-in-school within the scope of mandatory vaccination, and also by loosening the supposed constraints of "necessity," "emergency," and threats to an "entire population."<sup>17</sup>

*Jacobson* is an old case, and it is difficult to place ourselves within its historical and contextual framework. It is also opaque, not simply in the sense that it inevitably uses partially indeterminate concepts, but in the sense that its formulations differ from ours and require a kind of translation into contemporary terms. Even when we try to do this, it is hard to sort out whether the opinion "always meant *X*" or has been "expanded (or contracted)" to mean *X*.

It is, then, a challenge to answer sensibly the question, "How would *Jacobson* apply today?" It may be both that connotation and denotation of its key terms have shifted. The operational language has certainly changed. So what does this question mean? To note a simple real-world shift, the current and recent incidence of smallpox is zero. The smallpox virus is said to exist in laboratories only (unlike the polio virus); if not, it is now fully quiescent. The last U.S. smallpox case was in 1949, and the last anywhere was in Somalia in 1977.<sup>18</sup> There would be hardly any point in a compulsory vaccination program.<sup>19</sup>

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savage or the tattooing of a captive of a South Sea Islander.' They ended their brief by proclaiming that, 'here—in Massachusetts . . . a law compels a man to offer up his body to pollution and filth and disease; that compels him to submit to the barbarous ceremonial of blood-poisoning and virtually to say to the sick calf, 'Thou art my saviour: in thee do I trust,' and to bear ever after on his defiled body literally and truly the MARK OF THE BEAST.'" (alteration in original; internal quotation mark omitted). Rev. Jacobson also said that he had experienced an adverse reaction to a prior smallpox vaccination, as did one of his sons.

17. Holland, *supra* note 5, at 46-48.

18. See *Smallpox Disease Overview*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.bt.cdc.gov/agent/smallpox/overview/disease-facts.asp> (last updated Dec. 30, 2004).

19. *Smallpox: Symptoms, Diagnosis and Treatment*, N.Y. TIMES HEALTH INFO., <http://health.nytimes.com/health/guides/disease/smallpox/overview.html> (last reviewed June 23, 2011). ("[T]he United States stopped giving the smallpox vaccine in 1972. In 1980, the World Health Organization (WHO) recommended that all countries stop vaccinating for smallpox. . . . Many people were



We, thus, need to ask a particular set of doctrinal questions, including: What is the proper interpretation of *Jacobson* concerning the nature and strength of the individual rights it recognized and—closely connected—concerning the burden of justification placed on the state? How does this interpretation compare to our current understanding of these rights and the burdens of justifying their impairment? How would this current understanding be expressed in contemporary articulations of standards of review? I address all of these questions.

I think that *Jacobson* should be understood to protect (as we would now put it) at least a “liberty interest.” Although the Court’s usage (and that of others) is not entirely consistent, that term generally designates a right that does not draw strict scrutiny (as do most “fundamental rights”),<sup>20</sup> but nevertheless receives far more protection than that afforded by the minimal rational basis test as used in substantive due process cases.<sup>21</sup> The operational standard of review for liberty interests has been, in many cases, a form of intermediate scrutiny. This view of *Jacobson* is not universal, and some accounts place the standard of review at or near minimal scrutiny, although the issue is not always clearly put.<sup>22</sup> One may complain about discontinuous tiers and the inappropriateness of giving names to standards of review (thus improperly reifying them, so the argument goes), but it is one effective way of recognizing hierarchies of constitutional interests and (perforce) of standards of review *in some form*. Some burdens of justification placed on the state are maximal, some are minimal, and some are “intermediate,”

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vaccinated against smallpox in the past. The vaccine is no longer given to the general public because the virus has been wiped out. The possible complications and costs of the vaccine outweigh the benefits of taking it. If the vaccine needs to be given to control an outbreak, it can have a small risk of complications. Some complications are mild, such as rashes. Others are more serious. Only military personnel, health care workers, and emergency responders may receive the vaccine today. Smallpox vaccination policies and practices are currently being reviewed.”).

20. The right to bear arms may be an exception. *See infra* note 60. Note also that “liberty interests” are not always called “fundamental liberty interests,” and it is unclear how the latter differ, if at all, from fundamental rights. As I said, usage is not consistent. As for designating what sort of individual interest the rational basis test “protects” in substantive due process, there seems to be no official terminology; it is simply a claim of liberty that does not rise to “liberty-interest” or fundamental rights status.

21. The rational basis test is sometimes used as a form of intermediate scrutiny in equal protection cases. *See infra* text accompanying note 57.

22. Kenneth Wing, for example, stresses the strong degree of deference accorded the legislature in *Jacobson*. KENNETH R. WING, *THE LAW AND THE PUBLIC’S HEALTH* 25 (2007). All-but-total deference is characteristic of minimal scrutiny, but even the strictest scrutiny requires (in theory) serious attention to government justifications, and this will include important strands of deference. (Courts are not going to rerun laboratory experiments.) Strict scrutiny is sometimes satisfied, which is what one would expect—indeed, demand—of a non-per se rule. *See, e.g.,* *Burson v. Freeman*, 504 U.S. 191 (1992) (plurality upholding electioneering restrictions). *See generally* Adam Winkler, *Fatal in Theory and Strict in Fact: An Empirical Analysis of Strict Scrutiny in the Federal Courts*, 59 *VAND. L. REV.* 793 (2006). With intermediate scrutiny, one would expect intermediate degrees of deference.

reflecting the status of the right. We cannot do without such orderings to tell us the general direction of our analysis and where we are within it.

*Jacobson's* (operational) liberty interest was not watered down to cover children, in school or out. Nor were its references to "necessity" and "emergency" attenuated, further weakening the individual interests (somewhat inexplicitly) recognized in the case. Professor Holland thinks otherwise (bracketed remarks are mine):

Initial interpretation of *Jacobson* was circumspect. From 1907 to 1914, state appellate and supreme courts construed *Jacobson* as permitting single vaccination mandates during smallpox outbreaks. The courts upheld mandates and exclusion of unvaccinated school children during emergencies. These decisions applied an "oppressive or arbitrary" standard and looked for evidence of public necessity, and, particularly, the threat of epidemic. These decisions held that statutes must incorporate medical exemptions. The decisions required that school boards act in good faith and exclude unvaccinated students only as long as the danger of smallpox endured.

Beginning in 1916, however, judicial interpretations of *Jacobson* broadened. The Alabama Supreme Court read *Jacobson* to contain the implied power to prevent epidemics, not simply to respond to existing ones. [*Is the author objecting to this, either as an interpretive or policy matter?*] A father sued the school board for excluding his unvaccinated daughter from school when there was no smallpox epidemic. [*Doesn't vaccination help to prevent epidemics? Do we always have to wait until the sword is loosed?*] The court upheld the state's delegation of authority to the school board and the state's right to prevent disease. The decision also argued that mandates for children, and not adults, were valid because a group of children "constitutes a condition different, with respect to hygienic circumstances, effects, and results, from that to be found in any other character of assemblage in a municipality." The court deferred to municipal authorities on public health.

. . . These decisions interpreted *Jacobson* expansively; in neither situation was there an imminent danger or necessity for the state to act in self-defense.<sup>23</sup>

Elsewhere, she argues:

The regulation [in *Jacobson*] excluded all children from

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23. Holland, *supra* note 5, at 49-50.

compliance. The Court's paradigm [*This term is tendentious; it is not at all clear what the "paradigm" was; if it were clear, we would be much clearer on the holding, but that is part of what is at issue*] was clear: a mandate is permissible in "an emergency," when there was "imminent danger," when "an epidemic of disease . . . threatens the safety of [society's] members," when there was "the pressure of great dangers," and for an "epidemic that imperiled an entire population."<sup>24</sup>

Professor Holland also contends that "*Zucht* [*v. King*, another smallpox vaccination case] did shift *Jacobson*'s paradigm, though, by upholding a mandate exclusively for children, a subpopulation, and by affirming the validity of a preventive mandate for a disease not in circulation."<sup>25</sup>

But Justice Harlan used the term "emergency" only once, referring to what was "necessary for the public health or the public safety,"<sup>26</sup>—a not-very-illuminating phrase. As for the departure from "necessity," there is no clear explanation in the Article about what "necessity" or any "shift" from its use as a standard mean. In interpreting the opinion, one should not invoke the language referring to an "epidemic that imperiled an entire population" without also noting that *there was no such situation in Cambridge at the time*, at least by the Court's own description. The context of the quoted remark is this: "The state legislature proceeded upon the theory which recognized vaccination as at least an effective, if not the best-known, way in which to meet and suppress the evils of a smallpox epidemic that imperiled an entire population."<sup>27</sup> This is less a finding than a statement about the legislature's theory of vaccination in setting up a general program and did not address the specific situation in Cambridge.

As for conditions in Cambridge, Justice Harlan quoted Cambridge's board of health, which had adopted a regulation under the aegis of state law:

Whereas, smallpox has been *prevalent to some extent* in the city of Cambridge, and still continues to increase; and whereas, it is necessary for the speedy extermination of the disease that all

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24. *Id.* at 8 (alternations in original) (footnotes omitted).

25. *Id.* at 12. The case reference is to *Zucht v. King*, 260 U.S. 174 (1922). There, a child was excluded from a public school because she had no certificate of vaccination and refused to be vaccinated. She argued that she had been deprived of liberty without due process and deprived of the equal protection of the laws, all under the Fourteenth Amendment. The Court, per Justice Brandeis, dismissed the writ of error because it found "in the record no question as to the validity of the ordinance sufficiently substantial to support the writ of error." *Id.* at 177. The Court, nevertheless, referred favorably to *Jacobson*, stating that it had "settled that it is within the police power of a state to provide for compulsory vaccination." *Id.* at 176. The opinion does not state what diseases were included within the vaccination program, but the lower court's opinion indicates that smallpox was the target. *Zucht v. King*, 225 S.W. 267 (Tex. Civ. App. 1920). Because of the procedural posture of the case, it is not clear what it held substantively, if anything.

26. *Jacobson*, 197 U.S. at 27.

27. *Id.* at 30-31.

persons not protected by vaccination should be vaccinated; and whereas, in the opinion of the board, the public health and safety require the vaccination or revaccination of all the inhabitants of Cambridge; be it ordered, that all the inhabitants habitants of the city who have not been successfully vaccinated since March 1st, 1897, be vaccinated or revaccinated.<sup>28</sup>

There is nothing in *Jacobson* to indicate either that there was in fact an ongoing catastrophe or that the city or the Court thought there was. The italicized language simply recognizes the following: smallpox was present; it was contagious and harmful if contracted; *and a much worse situation could develop and could and should be prevented*. This is what “necessary” means here. It clearly includes the idea of reasonably believing that something *more serious may develop* out of current conditions. The idea that there has been some departure from a *sine qua non* of disaster, or complete failure of a means toward a goal, echoes the debate on the meaning of “necessity”—efficient or useful versus absolutely physically necessary—underlying *McCulloch v. Maryland*.<sup>29</sup>

Moreover, “necessity” is systematically equivocal. It might refer to those aspects of a situation that justify *some* liberty-impairing action. In *Jacobson*, Justice Harlan ruled that it was not necessary to exclude all other useful methods—a point doing double service for us by also telling us that a strict no-less-intrusive-alternative standard was not in use.<sup>30</sup> This softer “narrowing” requirement of his reasonableness standard of course is perfectly consistent with the functional status of Rev. Jacobson’s claim as reflecting an important liberty interest, though not with its possible status as an A-1 fundamental right drawing the strictest scrutiny.

As for the claimed expansion to cover school children: first, children were presumptively included within the mandate, and, second, this was not facially limited to school attendance. “An exception is made in favor of ‘children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination.’”<sup>31</sup>

When *Jacobson* was decided, the safety-benefit profile of smallpox vaccination was not as well understood as it is today, and relatively few children today would be considered unfit for vaccination—although it would not be recommended for children under twelve months, or for persons under eighteen under nonemergency circumstances, or for anyone with certain specified

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28. *Id.* at 12-13 (emphasis added).

29. *McCulloch v. Maryland*, 17 U.S. 316, 408-09, 413-14 (1819).

30. *Jacobson*, 197 U.S. at 35 (“Since, then, vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that *particular method was—perhaps, or possibly—not the best* either for children or adults.” (emphasis added)).

31. *Id.* at 12 (citation omitted).

conditions.<sup>32</sup> After all, we do not have smallpox anymore so there is nothing imminent or even possible (barring accidental release or, say, a monkey pox breakout into something like an old-style smallpox threat).<sup>33</sup> In any case, the issue of extensive coverage of children was not at issue in *Jacobson*, and there is nothing in the opinion to indicate that children—even children exclusively—cannot properly be the subjects of a vaccination program.<sup>34</sup>

In this light, it is too loose to describe *Jacobson*’s “paradigm” as involving “emergency,” “imminent danger” (in any restricted sense), or epidemics threatening “entire populations.” It is not entirely clear *what* the paradigm is.<sup>35</sup> It is, thus, uncertain what would constitute a “shift” of a paradigm. The *Zucht* children/school context does not clearly constitute an augmentation of a clear set of defining (necessary and sufficient) conditions or even of a specific cluster of criteria that might justify compulsory vaccination. In any case, as I suggested, to refer to shifts in paradigms requires specifying what the paradigm is and there is a difference between applying the selfsame paradigm to a new situation as opposed to “shifting” it. This is the main difference between *Jacobson* and *Zucht*.

Thus, there is a major three-way distinction to be drawn between *correctly* applying a precedent to new situations; *incorrectly* applying it to those situations; and changing the rules, standards, or principles involved to cover something *unjustifiably* covered under that precedent because of the incorrect application. True, it is often difficult to distinguish between an incorrect application and an expanded application—in some cases, impossible. But the distinction remains, and lawyers are accustomed to distinguishing—sometimes successfully—between a mistaken use of a prior case and its alteration, whether by reasonable extension or by overruling. We will, however, never be rid of having to choose between saying “these earlier cases have always meant *X*” and “these earlier cases are being utterly misread by my colleagues.” Still, it is precisely because *Jacobson* is unclear that we cannot definitively say that it has not swollen beyond

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32. *Emergency Preparedness and Response—Vaccine Overview: The Smallpox Vaccine*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.bt.cdc.gov/agent/smallpox/vaccination/facts.asp> (last reviewed Feb. 7, 2007).

33. Wendy Orent, *Will Monkeypox Be the Next Smallpox? The Thought of a New Human Poxvirus Evolving Under Our Noses Is Unsettling*, L.A. TIMES, Sept. 26, 2010, <http://www.latimes.com/news/opinion/commentary/la-oe-orent-pox-20100926,0,6800911.story>. According to the Centers for Disease Control and Prevention, monkeypox, also a serious infection, is preventable via the smallpox vaccine. *Smallpox Vaccine and Monkeypox, Monkeypox Fact Sheet*, CENTERS FOR DISEASE CONTROL & PREVENTION, [http://www.cdc.gov/ncidod/monkeypox/smallpoxvaccine\\_mpx.htm](http://www.cdc.gov/ncidod/monkeypox/smallpoxvaccine_mpx.htm) (last updated Sept. 5, 2008).

34. It seems pretty well agreed today that some vaccination programs really do save lives and resources. I suppose smallpox is the gold standard. “The eradication of smallpox in the 1970s, by targeted use of smallpox vaccine, has not only prevented many thousands of deaths, but is estimated to have saved US \$1.2 billion annually in the 25 years since the last case was reported.” D. Isaacs et al., *Should Routine Childhood Immunizations Be Compulsory?*, 40 J. PAEDIATRICS & CHILD HEALTH 392 (2004).

35. See *infra* Part III.

its boundaries.

More generally, many, perhaps most, claims about the expansion, contraction, or distortion of a precedent are normatively ambiguous—that is, they might be interpreted as empirical claims, value claims, or both, and it may be difficult to untangle these strands. One would expect, for example, that those opposed to a particular new *application* of a concept or standard will view it as an *expansion* of what seems to have been in force. But here we have the familiar problem of distinguishing expansion of *denotation* by virtue of change of facts and expansion of *meaning*.<sup>36</sup>

To illustrate, consider Professor Wing's observation: "Today, we do not demand the threat of a pending epidemic to require childhood immunizations for school, suggesting perhaps that the standard for 'necessity' has relaxed considerably as the benefits and general safety of immunizations have become better established."<sup>37</sup>

But it is not clear that *Jacobson* ever required such a threat. In any case, we have to distinguish conceptual change from conceptual application-to-new-circumstances. It may be that precisely the same standards with the same conceptual meanings are in play in a new situation, pitting several variables against each other that may resolve differently from prior interplay in a different case. A high-risk vaccine requires a high-risk disease in order to justify even voluntary vaccination. But if newly developed vaccines for the same malady are far safer, the balance is different and compulsion may be more justifiable. Perhaps some malady has-been later found to be either more dangerous—or less so, or both, in different ways; this too would change the balance. Facts may change while meaning may not. There is *much* more commerce among the states these days, so there are *many* more situations covered by the commerce clause,<sup>38</sup> even if the conceptual meaning of the clause remained unchanged (which it probably did not). Of course, if the conceptual meaning becomes more expansive, coverage is even more amplified, as all constitutional lawyers know. Both augmentations have been at work in the commerce clause.<sup>39</sup>

So, it is no simple matter to sort out the meanings of *Jacobson*, given all the variations in facts, possible changes in public values, and the continuing reformulations of standards of review. But I think that the case is clear enough for us to say that Professor Holland's conclusion is overstated (italicized comments in brackets are mine):

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36. See Melvin Fitting, *Intensional Logic*, 2006; rev. 2011, STAN. ENCYCLOPEDIA OF PHIL., <http://plato.stanford.edu/entries/logic-intensional> (last updated Jan. 27, 2011).

37. WING, *supra* note 22, at 63.

38. U.S. CONST. art. I, § 8, cl. 3.

39. On shifts in denotation resulting from both empirical changes and changes of meaning, see Michael H. Shapiro, *Argument Selection in Constitutional Law: Choosing and Reconstructing Conceptual Systems*, 18 S. CAL. REV. L. & SOC. JUST. 209, 225 n.36, 256 (2009).

Courts have used *Jacobson* to justify results that the original decision did not condone: vaccination mandates exclusively for children, with no imminent disease outbreaks, and with serious penalties for noncompliance. *[There is a big difference between saying Jacobson did not directly deal with some variable and saying that it would not have “justified” or could not have applied to the current result. Nothing in Jacobson foreclosed, for example, vaccinations exclusively for children. At most, it was simply beyond the issue presented at that time, but not excluded by anything said in the case. Indeed, the Court acknowledges the application to children, subject to exclusions. Jacobson’s language does not justify a conclusion that the results about which the author complains were unjustifiable under its terms.]* Punishments include loss of education, social isolation, parents’ loss of custodial rights, child neglect sanctions against parents, and, even, forced vaccination. In *Jacobson* and *Zucht*, the Supreme Court upheld mandates for one vaccine during airborne epidemics. *[The Court did not uphold much on the merits in Zucht because it declined to rule on them and dismissed the writ of error. It nevertheless referred with favor to Jacobson.]* Courts have expanded the original *Jacobson* precedent dramatically. *[There are cases described by the author in which courts have indeed been too deferential. But this does not necessarily mean that Jacobson had been “expanded” rather than misapplied. Over deference is not justified by Jacobson and is arguably inconsistent with it.]*<sup>40</sup>

### B. What did Jacobson say?

It is hard to understand *Jacobson*—but not *that* hard. It helps to check both what it said and what it did. Here are some major questions about *Jacobson*, and any reconstructions of it in contemporary language.

■ What is the proper characterization of the right as recognized in *Jacobson*? How does it connect to plausible current characterizations?

■ What is the *operational* standard of review? (There are *always* implicit or explicit standards of review in any valid constitutional argument that has to resolve competing constitutional claims.)

■ What did the Court think the material facts and public values were?

■ What caveats did the Court itself issue about its ruling? These could serve as interpretive guides.

■ How would *Jacobson* be decided today?

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40. Holland, *supra* note 5, at 53-54.

*1. The Characterization of the Right*

The best source on this is Justice Harlan himself:

There is, of course, a sphere within which the individual may assert the supremacy of his own will, and rightfully dispute the authority of any human government,—especially of any free government existing under a written constitution, to interfere with the exercise of that will. But it is equally true that in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.<sup>41</sup>

This is not wholly unlike what we read today in major opinions of the Supreme Court. The second Justice Harlan said, dissenting in *Poe v. Ullman* and quoted in *Planned Parenthood v. Casey*:

It [the liberty guaranteed by the Fourteenth Amendment's Due Process Clause] is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints, . . . and which also recognizes, what a reasonable and sensitive judgment must, that certain interests require particularly careful scrutiny of the state needs asserted to justify their abridgment.<sup>42</sup>

But the first Justice Harlan's account does not tell us as much as we need to know, then or now. There is no precise description of the right. It is not couched as a matter of bodily integrity or personal security or "the right to define one's own concept of existence."<sup>43</sup> Moreover, there is no way to tell, however flowery the language, the "constitutional value" of the right until we see how it is pitted against the state's claim that its coercion is justified. We need to probe for the standard of review and how it is used.

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41. *Jacobson*, 197 U.S. at 29.

42. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 848 (1992) (quoting *Poe v. Ullman*, 367 U.S. 497, 543 (1961) (Harlan, J., dissenting from dismissal on jurisdictional grounds)); see also *Lawrence v. Texas*, 539 U.S. 558, 578 (2003) ("The Texas statute furthers no legitimate state interest which can justify its intrusion into the personal and private life of the individual."). Evidently somewhat out of control, the Court in *Casey* said: "At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life." *Casey*, 505 U.S. at 851. I suppose I would rather have liberty described too expansively than too narrowly, but without knowing more about the meaning of "liberty" at issue, this account is too boundless even for a constitutional standard. In any case, the quoted remark can't be taken as a rigorous expression of current doctrine.

43. See *Casey*, 505 U.S. 838.



## 2. *The Jacobson Standard of Review*

The loosely stated standard of review is contained within the same passage that extolled the claimant's liberty. One asks whether the regulation is "reasonable . . . as the safety of the general public may demand."<sup>44</sup> The language is not unlike that in *McCulloch v. Maryland* and, a bit later, in *Lochner v. New York*.<sup>45</sup> But this does not tell us much either. In *McCulloch*, Chief Justice Marshall inquired into the national bank's functions even less carefully than Justice Harlan examined Cambridge's findings and valuations. *McCulloch* was, in modern terms, closer to the nominal rational basis test than to strict scrutiny—despite the warnings about "pretextual" government action that evades constitutional limitations. In *Lochner*, it seems fairly clear that the "reasonableness" language served as a form of strict scrutiny for Justice Peckham. Under pressure from the majority, Justice Harlan's dissent was far more elaborate in its scrutiny of New York's law than was his examination of Cambridge's action, but in the end it seems his standard of review was similar to the one he used in *Jacobson* the year before.

I do not think that *Jacobson* is a case of minimal scrutiny and maximal or automatic deference. There is no reason not to take Justice Harlan's warnings about governmental abuse seriously. But there is not much of a case to be made for strict scrutiny. The proper level of scrutiny is somewhere in the middle.

## 3. *The Court's Caveats*

The Court's caveats about the limits of its ruling do not reveal anything different from the preceding account; they simply reinforce it. Against the claim of government power, the opinion insists, "[I]f a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of the courts to so adjudge, and thereby give effect to the Constitution."<sup>46</sup> And, addressing the needs of vulnerable persons, the Court conceded that government "might go so far beyond what was reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons."<sup>47</sup> The Court elaborated the last point a bit later:

It is easy . . . to suppose the case of an adult who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health or body would be cruel and

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44. *Jacobson*, 197 U.S. at 29.

45. *Lochner v. New York*, 198 U.S. 45 (1905).

46. *Jacobson*, 197 U.S. at 31.

47. *Id.* at 28.

inhuman in the last degree. We are not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned.<sup>48</sup>

But against more general claims of right, Justice Harlan said:

It is not . . . true that the power of the public to guard itself against imminent danger depends in every case involving the control of one's body upon his willingness to submit to reasonable regulations established by the constituted authorities, under the sanction of the state, for the purpose of protecting the public collectively against such danger.<sup>49</sup>

Once again, I see neither strict scrutiny nor the nothingness of the substantive due process rational basis test.

### III. TODAY'S CONSTITUTIONAL HIERARCHIES, STANDARDS OF REVIEW, AND THEIR APPLICATION TO OLD AND NEW BIOMEDICAL CONTEXTS

#### A. Jacobson 2.1: *Key Questions*

We should distinguish between *Jacobson 2.0* and *Jacobson 2.1*. The former would ask how the same Court at the same time would decide the case under present day epidemiological, vaccinological, and medical treatment conditions concerning smallpox.<sup>50</sup> (A literal *Jacobson 2.0* should not uphold compulsory vaccination, given the apparent demise of smallpox.) I think it more instructive, however, to ask a different set of questions. *Jacobson 2.1*, on the other hand, is a thoroughly modern case involving someone making the same claim (without any religious aspects, to keep things simpler) under current conditions and doctrines.

First, the broad question, "How would *Jacobson* be decided today by a contemporary Court?," is too unfocused for any clear answer. It could mean any of several things:

- How would the case be decided today *on the exact same epidemiological and medical facts* that existed in Cambridge in 1902?
- How would it be decided given the *current status of smallpox threats*?

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48. *Id.* at 38-39.

49. *Id.* at 29-30.

50. Medical treatment of smallpox may benefit from modern antivirals, but evidently there is no specific medicine or other treatment accepted for smallpox treatment. *Smallpox | Description | Prevention | Causes and Symptoms | Treatment*, MODERN MED. GUIDE, <http://www.modernmedicalguide.com/smallpox-description-prevention-causes-and-symptoms-treatment> (last visited July 27, 2011).

■ How would it be decided in any given case *involving a given disorder; a particular kind of vaccine indicated for it; manufactured and distributed in a particular way; and given specific local, regional, national, and international facts about the disorder and the surrounding situation?*

■ In particular (given the Article's focus): How would it be decided when applied to hepatitis B vaccine programs as applied to children as a condition for entry into (pre)school?

The overarching question is, "What argument structure would the Court use?" This involves many constituent questions: What rights characterization would it use to identify the right and its constitutional value? What would be the standard of review, given the right's constitutional value and the nature of its impairment? How would that standard be used to vet matters of technical scientific dispute and the government's value judgments, implicit or explicit? An important linked question in the vaccination context, more pertinent now than in 1905 is whether there is a constitutional, moral, or policy problem with "piggybacking" vaccination and other public health programs onto society's educational missions?

There are parallel inquiries that suggest additional shades of important meaning:

■ If we translate into modern terms *Jacobson's* argument structure, which embraces constitutional values *as recognized in the 1905 decision*, what do we get? In the century-plus since then, we have not transmogrified into a world so different and bearing such a locked-in perspective that the comparison involves "incommensurable" values.<sup>51</sup>

■ Would *Jacobson's* argument structure be revised to explicitly recognize different constitutional valuations by characterizing a set of related but nonidentical rights? For example, might the Court recognize a top-level fundamental right of personal security, comprehending the integrities of body, mind, and identity, and generating strict scrutiny? (This may be what Professor Holland prefers.) Would it instead run away with maximal deference (retaining some special scrutiny for highly vulnerable persons—those who might die of an allergic reaction to a vaccine or its additives, for example)? This would treat the "right" as a liberty claim (i.e., invoking the liberty clause of the Fifth Amendment, Fourteenth Amendment, or both) with no special status, meriting only minimal scrutiny. Would it instead recognize a "liberty interest" in the current sense, drawing intermediate scrutiny? Would it borrow from equal protection jurisprudence and ramp up the rational basis test without acknowledging it to be intermediate scrutiny?

There is no reason to think that *Jacobson 2.1*, decided on the same medical or epidemiological facts acknowledged for Cambridge in 1905, would be decided

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51. Nien-hêHsieh, *Incommensurable Values*, STAN. ENCYCLOPEDIA OF PHIL. (July 23, 2007), <http://plato.stanford.edu/entries/value-incommensurable>.

differently today. (I will not discuss the argument formulation, in current terms, if *Rev. Jacobson* 2.1 made an explicit claim under the free exercise clause, except to say that it would probably fail under *Employment Div., Dept. of Human Res. v. Smith*<sup>52</sup> and even under pre-*Smith* doctrine.)

However, there is ambiguity here. What does it mean to ask whether *Jacobson* would be decided “the same way” today? One could have in mind either the same facts prevailing in Cambridge when the case was brought or facts involving other health threats that are at least equally serious.<sup>53</sup> Moreover,

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52. *Employment Div. v. Smith*, 494 U.S. 872 (1990) (ruling that with laws of general application—i.e., not targeting the protected interest in question, which in this case is free exercise of religion—there is no heightened scrutiny of claimed burdens on free exercise).

53. See, e.g., Lawrence O. Gostin, *Jacobson v. Massachusetts at 100 Years: Police Power and Civil Liberties in Tension*, 95 AM. J. PUB. HEALTH 576 (2005) (“If the Court today were to decide *Jacobson* once again, the analysis would likely differ—to account for developments in constitutional law—but the outcome would certainly reaffirm the basic power of government to safeguard the public’s health . . . . Supreme Court jurisprudence has progressed markedly from the deferential tone of *Jacobson* and its progressive-era embrace of the social compact. The Warren Court, within the context of the civil rights movement, transformed constitutional law. The Court developed its “tiered” approach to due process and equal protection that placed a constitutional premium on the protection of liberty interests. Thus, the question arises: Would *Jacobson* be decided the same way if it were presented to the Court today? The answer is indisputably yes, even if the style and the reasoning would differ.” *Id.* at 576, 580. I think that when mapped against the questions I unpacked in the text, this account is consistent with my own parallel answers. But the concept of “being decided the same way” is quite ambiguous. Separating the possibilities is important for the present analysis. It is possible that the Court would be somewhat less deferential in both tone and action, but there is a wide range of deferential stances between the strictest and the loosest scrutinies, and even strict scrutiny involves deference to legislative empirical findings and value preferences. The exact content of this deference will have to be specified through a variety of cases that test the operational meaning of all levels of scrutiny.) See *infra* Part III; see also Wendy K. Mariner et al., *Jacobson v. Massachusetts: It’s Not Your Great-Great-Grandfather’s Public Health Law*, 95 AM. J. PUB. HEALTH 581, 586 (2005) (“A law that authorizes mandatory vaccination to prevent dangerous contagious diseases in the absence of an epidemic, such as the school immunization requirement summarily upheld in 1922, also would probably be upheld as long as (1) the disease still exists in the population where it can spread and cause serious injury to those infected, and (2) a safe and effective vaccine could prevent transmission to others.”). See generally Arnold J. Rosoff with Shana Siegel, *Treatment Without Express Consent*, in TREATISE ON HEALTH CARE LAW § 17.05 (Matthew Bender/LexisNexis, 2010) (“In recent years, some courts have shown a greater skepticism toward claims of necessity for public health measures and an increasing sensitivity toward preservation of individual rights. Thus, if the *Jacobson* case were to arise today, probing questions might be asked about the seriousness of the health threat being addressed, the safety and efficacy of the inoculations, and the weight of the personal burdens and risks, if any, upon the citizens affected. While inoculations to combat smallpox would likely withstand such scrutiny—as have mandatory vaccination of school children, 56 mandatory blood tests for persons applying for a marriage license, mandatory examination, treatment, and/or quarantine of persons suspected of transmitting communicable diseases, 57 the fluoridation of public water supplies, etc.—other public health measures, particularly such controversial measures as mandatory testing for HIV infection, very well might not.”). See generally Wendy E. Parmet, POPULATIONS, PUBLIC HEALTH, AND THE LAW 38-42 (2009) (“As the dreaded epidemics of previous centuries began to fade from memory, the necessity of public health interventions became less obvious and the limitation of individual liberty in the name of public health became less readily

deciding “the same way” does not necessarily mean that the same argument structure or underlying values would be applied. That is, “the same way” could refer to a similar (perhaps identical) adjudicatory outcome, or to the outcome as informed by the argument structure leading to it. The same adjudicatory outcome may result from differing argument structures and values.<sup>54</sup> This is a good time to make the transition to an explicit question: “How would the modern Court (or the Court of the moment, writing here in 2011) frame the substantive issues (assumed to be properly presented within the current limits of the judicial power) in cases of vaccination generally and vaccination of school children in particular?” The facts are, of course, highly variable, but not so ineffable that this question is meaningless. The question is not just about *Jacobson* or *Jacobson 2.0*, but about *Jacobson 2.1* (and beyond).

### B. The Article’s Attempted Reconstruction

There are reconstructions and reconstructions. The target here is *Jacobson 2.1*—a contemporary vaccination case using contemporary articulations of constitutional values. One can also try to reconstruct the case in the sense of simply clarifying it in its own terms. Although both Justice Harlans are noted for their lucidity, *Jacobson* could be easier to follow. Professor Holland seems to combine both tasks here: clarifying the case as it stands, and presenting an account of what would or should happen now in at least some public health and vaccination cases. She suggests that some latter-day Justices would have recognized a right against vaccination as fundamental, but the case for this is shaky.<sup>55</sup> In any case, in pursuing the reconstruction of *Jacobson*, she follows in

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accepted. At the same time, with less fear of contagious diseases, public health became less salient to both the culture and the law. Indeed, following *Jacobson*, the Supreme Court would not again face a question so starkly and directly related to a community’s response to an imminent epidemic.”) Question: Do these apparent attitude shifts reflect a value change or the application of constant values to changing facts? If the former, did the changing facts influence a rethinking of our values?

54. See Shapiro, *supra* note 39, at 216-21, 241-49.

55. Holland, *supra* note 5, at 83. Professor Holland also believes that some Justices would have recognized a right against vaccination as fundamental. “Some of the Justices who participated in the personal autonomy decisions, notably Justices Stevens, Brennan, Marshall, and Blackmun, would likely have found the right to refuse vaccination a ‘fundamental’ right and would have subjected the state’s regulation to ‘strict scrutiny.’” *Id.* I doubt this, but for some Justices, the claim is not outlandish. Still, it is not clear whether resisting vaccination involves one of “the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, [which] are central to the liberty protected by the Fourteenth Amendment.” *Planned Parenthood Of Se. Pa. v. Casey*, 505 U.S. 833 (1992). Indeed, broad as this formulation is, vaccination fits uncertainly within it. “At the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe and of the mystery of human life. Beliefs about these matters could not define the attributes of personhood were they formed under compulsion of the State.” *Id.* at 851. Does fear of remote though serious adversities fall within this? Perhaps vaccination represents too trivial a threat to the sanctity of personhood to merit status within the

part the analysis of Professor Gostin. Neither seems to be suggesting that the matrix of variables presented should be understood simply as a reconstruction of *Jacobson* in modern terms. Rather, it is a preferred set of factors for any rational decision.

The proposed matrix contains the factors of “necessity,” “reasonable means,” “proportionality,” and “harm avoidance” as a way to both illuminate *Jacobson* and inform current public policy. As Professor Gostin puts it:

*Jacobson’s* social-compact theory was in tension with its theory of limited government. Beyond its passive acceptance of state discretion in matters of public health was the Court’s first systematic statement of the constitutional limitations imposed on government. *Jacobson* established a floor of constitutional protection that consists of 4 overlapping standards: necessity, reasonable means, proportionality, and harm avoidance. These standards, while permissive of public health intervention, nevertheless required a deliberative governmental process to safeguard liberty.<sup>56</sup>

As a reconstruction of *Jacobson*, this seems both useful and harmless; it does not take any liberties with the opinion.

Professor Holland, however, later invokes a significantly enlarged matrix as a clarification of *Jacobson*. She asks, in her hepatitis B hypothetical:

How might the Supreme Court balance the interests of the state and the child? The Court would have to look to *Jacobson* and *Zucht* for a balancing test on vaccination for school attendance and to the Court’s more recent precedents on personal autonomy to decide this case. The Court would have to review the following factors [public health necessity; reasonable means; proportionality; harm avoidance; non-discrimination; liberty interest in due process; and liberty interest in equal protection].<sup>57</sup>

This list of things the Court would consider in compelled vaccination cases certainly contains considerations that would be *relevant* in most cases. But the author asks, “How might the Court balance the interests of the state and child,” without *first* characterizing the right(s) at stake and specifying the entailed

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mantle of a fundamental right or liberty interest.

56. Gostin, *supra* note 53, at 579.

57. Holland, *supra* note 5, at 67. I do not know to what “liberty interest in equal protection” refers. It is not an impossible or incoherent concept, but the term “liberty” is not, in constitutional law, ordinarily used to refer to our interest in being treated equally. However, it may refer to those fundamental rights (indeed construed as liberties), that are thought (by some) to be derived only or largely from the equal protection clause, e.g., the right to vote in state elections. See *Harper v. Va. State Bd. of Elections*, 383 U.S. 663, 665 (1966).

standard(s) of review. Instead, she jumps the threshold stage, and straightaway starts parsing the factors that specify the constitutional metric. This is backwards. I do not mention this as a point of literary criticism or esthetic preference or technical nitpicking. This is a matter of basic constitutional logic. Describing the “liberty interest” at stake is not something one simply throws into the “balance”; it is—in constitutional adjudication—an issue that is a starting point for substantive analysis. (The matter, to be sure, is complicated by the fact that there is bound to be some bounce-back between threshold valuation, analysis of government justifications, re-valuation of threshold matters, and so on.)

The elements of the matrix also include some anomalous and/or hard to understand entries. The references to a “liberty interest in equal protection” and to “proportionality” are especially problematic, as I will explain. There are also some technical problems with her account of current doctrine concerning the characterization of rights/liberty interests and the set of available standards of review. I discuss this in Section III.C, below.

*C. A Note on Constitutional Values and Their Entailments: Standards of Review as Inherent in Adjudication and as Heuristics*

I make a few points briefly.<sup>58</sup> I said in one article:

The Constitution, at least as currently interpreted, embeds or encodes a hierarchy (or perhaps an ascending continuum) of values, and different standards of review are meant to track differences in constitutional value by placing very different burdens on government to justify its actions in different situations. In this sense, the constitution is both a repository and an engine for executing basic values.<sup>59</sup>

The Constitution embeds values, sorts them, and operationally *commits* us (if we take it as authoritatively calling for implementation) to things we now call “standards of review.” To dwell on these standards is not a case of the tail wagging the dog; they are the dog. They are different aspects of the concept of

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58. I have explained these points at greater length elsewhere. See Shapiro, *supra* note 39, at 269-71, 295-97; Shapiro, *supra* note 8, at 356-64.

59. See Shapiro, *supra* note 39, at 269-70; see also Shapiro, *supra* note 8 (“If constitutional hierarchies are recognized by converging interpretive theories and are taken seriously, they must be operationally reflected in standards of review of one sort or another. If they are not, then there are no hierarchies in the first place. To put it crisply, if constitutional hierarchy (among legal relations and their associated constitutional values) is accepted, to implement the hierarchy is to select and apply a standard of review. Doing so is embedded in realizing the hierarchy. Put otherwise, implementing a constitutional hierarchy amounts to the application of a standard of review.”) (emphasis omitted). *Id.* at 366. As I noted in that article, some “hierarchies” are so simple one may be inclined to say that they are not hierarchies at all, as in “the President always wins.”) But that is not how we operate, at least in theory, and probably not in fact. *Id.* at 359-60; see also *id.* at 354.

rights-as-authoritatively-implemented. They are not egregious artifacts that mask circularity, although they—along with many conceptual devices—can be used tendentiously to do so. But there is nothing in this account that dictates their exact formulation, or that they are to be ordered into tiers or step-functions separated by thresholds of constitutional value and of their impairments, as opposed to “spectra.”

Still, standards of review, as the logical entailments of interpreting the constitution to find value hierarchies have taken certain crystallized forms. Both high theory and everyday adjudication have to take account of this, as the next few points about *Jacobson* show.

#### *D. Technical Difficulties with the Article’s Doctrinal Account*

The Article to which I am responding presents itself as much more than a commentary on policy. It is a call for implementing constitutional values via adjudication and legislation. So, marking out the doctrine precisely is both a practical necessity and integral to theory.

Here is a passage from Professor Holland’s article; again, the italicized, bracketed remarks are mine, as are footnotes.

It is not certain what standard of review the Supreme Court would apply to a state compulsory vaccination mandate today.*[If constitutional valuations have changed since Jacobson, the question should be, “What standard of review is required, given the (new) rights valuation, for modern vaccination and various other public health/coercion cases?”]* The Supreme Court decided *Jacobson* before it had adopted explicit standards for review of government authority. In *Jacobson*, the Court required only that Massachusetts’s statute be rationally related to the purpose of eradicating infectious disease. Since the 1940s, however, as Part II explores, the Court has held that a higher standard must apply if a state law impinges on a fundamental liberty interest. For a law to be constitutional under a strict scrutiny test, the highest standard, there must be a compelling governmental interest and the law must be narrowly tailored to achieve its end. *[Although the formal and informal terminologies are somewhat inconsistent, fundamental rights usually (not always)]*<sup>60</sup> draw stricter scrutiny than mere “liberty interests.”

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60. Cf. *Dist. of Columbia v. Heller*, 554 U.S. 570, 593-94 (2008) (referring to the right to bear arms as having become fundamental to Englishmen). For Fourteenth Amendment purposes, the characterization is clearer in *McDonald v. City of Chi.*, 561 U.S. 3025 (2010) (holding that under the Fourteenth Amendment the right to bear arms is fundamental and applies to the states). Neither case applied strict scrutiny, as far as I can tell—certainly not in express terms. Both cases may be counterexamples to the once-usual practice of assigning strict scrutiny to fundamental rights. But compare *Troxel v. Granville*, 530 U.S. 57, 65-66 (2000), where Justice O’Connor’s plurality



*(Justice Scalia seems to use “fundamental rights” and “fundamental liberty interests” synonymously.)<sup>61</sup> The liberty interests recognized in Casey and Cruzan<sup>62</sup> did not draw strict scrutiny. Each case must be examined on its own, to some extent, and sweeping accounts of Court terminology are, even after all this time, still premature in this arena.] In cases where strict scrutiny does not apply, the Supreme Court usually uses the lowest standard, the rational basis test. The rational basis test applies when the rights at stake are not considered fundamental. [This is incomplete. It ignores, to this point at least, intermediate scrutiny—the middle tier. Note again Casey, Cruzan, Romeo, and Harper—all liberty interest cases, but no strict scrutiny.<sup>63</sup> The author’s later comment on souped-up rational basis is only one form of intermediate scrutiny, and it seems, so far, to apply only in equal protection. Admittedly, the Court has been very loose about describing the standards of review attached to liberty interests, usually eschewing even the term “intermediate scrutiny.” But whatever these standards are called, it remains that strict scrutiny is greater than intermediate-scrutiny-for-liberty-interests, which is greater than rational-basis-for-due-process.] Under this standard of review, “if a law neither burdens a fundamental right nor targets a suspect class, we will uphold the [law] so long as it bears a rational relation to some legitimate end.” [The Court itself in Romer v. Evans was unfortunately speaking loosely here, and left out its middle tier. Whatever the Justices say in their looser moments, the doctrinal reality is more complex.]*

Between these two extremes of strict scrutiny and rational basis

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opinion used the terms “liberty interest,” “fundamental liberty interest,” and “fundamental right”—all on the same page—in describing a parent’s right to control the care and upbringing of her child. The Court clearly acted with heightened scrutiny, but the standard of review was not specifically described.

61. “Our opinions applying the doctrine known as ‘substantive due process’ hold that the Due Process Clause prohibits States from infringing *fundamental* liberty interests, unless the infringement is narrowly tailored to serve a compelling state interest.” *Lawrence v. Texas*, 539 U.S. 558, 558 (2003) (Scalia, J., dissenting) (citing *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997)). To some extent, this compounds the confusion among these terms.

62. *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261 (1990) (recognizing—not assuming *arguendo*—a liberty interest in refusing lifesaving medical treatment; the assumption *arguendo* was limited to viewing artificial nutrition and hydration as medical treatment); see also *Youngberg v. Romeo*, 457 U.S. 307 (1982) (holding that a mentally impaired inmate in civil institution had a liberty interest in personal security); *Washington v. Harper*, 494 U.S. 210 (1990) (ruling that a prisoner had a liberty interest in refusing antipsychotic drugs).

63. In *Harper*, the claimant was a convicted, incarcerated prisoner and thus his claim received intermediate scrutiny under *Turner v. Safley*; if the interest protected is less than a *fundamental* right, it would probably draw less-than-strict scrutiny whatever the setting. But recall that the fundamental rights found in *Heller* and *McDonald* apparently *didn’t* generate strict scrutiny.

review, the Supreme Court has required an intermediate level of scrutiny or a “pumped-up” rational basis test for liberty interests after *Jacobson*. [*In the first place, the only domain of pumped-up rationality seems to be equal protection, not substantive due process, although some claim Lawrence v. Texas to be an exception. In the second place, the equal protection rational basis test on steroids is not the only form of intermediate scrutiny.*] In these cases, the Supreme Court has struck down questionable state laws on the grounds that the state interest did not outweigh an individual’s liberty interest. [*This is primarily, perhaps exclusively, a matter of equal protection. The account again leaves out intermediate scrutiny for liberty interests as framed within substantive due process. There may be a liberty interest branch, as well as a fundamental rights branch to equal protection, the former drawing intermediate scrutiny.*]<sup>64</sup>

*E. An Outline of Jacobson 2.1: What Kind of Right, of What Value, and Bearing Which Standard of Review?*

*1. What Is the Right and What Do We Call It?*

The difficulty in predicting general constitutional development (as opposed to outcomes in particular cases) is overestimated. It all depends on how one characterizes the asserted outcome or development. Accurate predictions—admittedly with low informational content—are easy to come by, and the information is not entirely empty. If the late columnist Drew Pearson could be eighty-four percent accurate, so can constitutional lawyers.<sup>65</sup> Prediction: the Court is not going to dismantle all fundamental rights all at once. We know this. Perhaps we can, then, predict a meaningful range of responses for *Jacobson 2.1*.

How would the right be described? And what considerations do we draw on when answering this? One characterization immediately comes to mind. The right not to be vaccinated could be called, “The right not to be vaccinated (whether with a stick, a pill, a scratch, etc.).” After all, it is all a form of battery (speaking loosely), even if administered with a Star Trekian hypospray.<sup>66</sup> This

64. Holland, *supra* note 5, at 48. (alteration in original) (footnotes omitted) (quoting *Romer v. Evans*, 517 U.S. 620, 631 (1996)) (citing *City of Cleburne v. Cleburne Living Center*, 473 U.S. 432 (1985)).

65. You have to have to been around a while to remember this; Pearson (the columnist, not the football player) died in 1969. Jim Heintze, *Books and Articles by and About Drew Pearson: A Selective Bibliography of Print Materials* (last visited Nov. 10, 2011), <http://www.library.american.edu/pearson/bibliography.html>.

66. For a general formulation (not specifically keyed to hyposprays), see *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 269 (1990) (“At common law, even the touching of one person by another without consent and without legal justification was a battery. Before the turn of the century, this Court observed that ‘[n]o right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person,

designation, however, seems oddly particular and unilluminating. What happened to integrity of mind, body, identity, and personhood generally?<sup>67</sup> Still, the Court in *Harper* spoke of the prisoner's right to refuse antipsychotic drugs, holding that it is a liberty interest.<sup>68</sup> This, too, was oddly restricted. Does the liberty interest include antidepressant drugs also? Or did the Court think its description covered that and all medical-psychotropics? Why not "personal security," as in *Youngberg v. Romeo*,<sup>69</sup> or "bodily integrity," as mentioned in passing in *Washington v. Glucksberg*?<sup>70</sup> Are these descriptions curiously broad? Probably not. Personal security generally, and the integrity of body, mind and identity more particularly may be as good as we can get now, although technology (among other things) will press us to be more precise on what we mean operationally by our constitutional valuations and the standards of review they entail.<sup>71</sup>

The freestanding terms "autonomy" and "privacy" are too fat and too equivocal to rely on in precisely describing the right. If this is not already clear, it should become so as we move on.

## 2. What Is the Standard of Review and What Do We Call It?

The last time the Court newly characterized something as a fundamental right—the right to bear arms, in *McDonald v. City of Chicago*<sup>72</sup>—it declined to assign any *named* standard of review. But we know standards of review are not elective: the constitutional value of an interest and its standard of review are not

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free from all restraint or interference of others, unless by clear and unquestionable authority of law.' This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment." (quoting *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891)).

67. One who resists vaccination might object that the procedure does not cohere with "who she is"—her identity. Of course, vaccination in itself poses no direct threat to literal physical/mental identity.

68. *Washington v. Harper*, 494 U.S. 210, 222 (1990) (ruling that "respondent possesses a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment.").

69. *Youngberg v. Romeo*, 457 U.S. 307, 314, 315, 319 (1982) (grouping it among "fundamental liberties" and referring to it as a "liberty interest"; also holding that "Romeo retains liberty interests in safety and freedom from bodily restraint").

70. *Washington v. Glucksberg*, 521 U.S. 702, 720 (1997).

71. As we saw, the Court does speak of bodily integrity from time to time. Planned Parenthood of Se. Pa. v. *Casey*, 505 U.S. 833, at 896; *Cruzan*, 497 U.S. at 269, and of personal security, *Youngberg*, 457 U.S. 307 at 315. I do not try to explicate rigorously the overlapping ideas of the integrity of body, mind, and identity, and do not address issues of reducing any of these categories to any of the others.

72. *McDonald v. City of Chi.*, 561 U.S. 3025 (2010). Its direct antecedent, *Dist. of Columbia v. Heller*, 554 U.S. 570 (2008) alluded to the fundamental rights of Englishmen but did not actually say the right to bear arms was a fundamental right under the American constitution. *McDonald*, however, said fairly clearly that both the pure Second Amendment right and the parallel Fourteenth Amendment right are fundamental.

simply entangled: they are interdefinable.<sup>73</sup> They derive from the same overarching and authoritative conceptual structure. Whatever standard of review is linked to the right to bear arms under the Fourteenth Amendment, it led to the remand in *McDonald*. Although this litigation did not survive the repeal of the Chicago and Oak Park ordinances,<sup>74</sup> the standard used would clearly have been some form of heightened scrutiny, even if not so described. Strict scrutiny itself has not been officially foreclosed.<sup>75</sup> After all, the value of a right is reflected largely through its standard of review. If one is confused about the correct standard of review, one is *necessarily* confused about the constitutional value of the interests in contention.

*Jacobson 2.1*, then, will be characterized ultimately by the standard of review used, implicitly or explicitly, however the opinion describes the right in question.<sup>76</sup> Perhaps neither the right nor the review standard will be clearly stated. To some degree, this is inevitable: the Court might formulate a right, but not be sure how to rank it. Moreover, there are tactical and political reasons for obscuring even the logical entailments of what one says. It may thus wish to be circumspect about how to describe the standard, given that it is supposed to implement a right of still-uncertain constitutional value.

But the doctrinal/logical fact remains: to characterize a right and decline—perhaps openly—to specify its standard of review suggests that *something* has provoked a departure from what might be considered basic judicial transparency.<sup>77</sup> The Court's grasp of what it was doing is askew, its confidence

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73. See STEPHEN DARWALL, *THE SECOND-PERSON STANDPOINT: MORALITY, RESPECT, AND ACCOUNTABILITY* 12 (2006).

74. Afterwards, Chicago and Oak Park repealed their respective ordinances, rendering the case moot. *National Rifle Ass'n v. City of Chi.*, 393 Fed.Appx. 390 (7th Cir. 2010).

75. Justice Breyer complained that Justice Scalia had not specified a standard of review. Justice Scalia complained about the complaint. *Dist. of Columbia v. Heller*, 554 U.S. 570, 634 (2008).

76. In *Youngberg*, 457 U.S. 307, the right to personal security was implemented, after a fashion, through the professional judgment standard, which involved very substantial deference to government. The relative absence of clear professional standards for treating severely mentally impaired persons was thought to require this, although one could argue that such impenetrability cuts the other way: the Court is simply deferring to a black box. See generally MICHAEL H. SHAPIRO ET AL., *BIOETHICS AND LAW: CASES, MATERIALS AND PROBLEMS* 408-412 (2003). One might well ask whether and when such deference vindicates the rule of law or weakens it.

77. It is not uncommon for courts to use standards of review (which they must) without identifying or explaining them, but in most cases it's clear enough what they are doing. Even in *Heller*, for example, the standard of review is clearly heightened, although one may well argue, as did Justice Breyer, that greater precision was called for. See *Heller*, 554 U.S. 570. Still, full disclosure was not jurisprudentially imperative. In *Cohen v. California*, 403 U.S. 15, 26 (1971), Justice Harlan did not use any words of art to signal his use of strict scrutiny until nearly the end of the opinion (state needed a "particularized and compelling reason" for criminalizing the use of an offensive word). There is no need to canvass the various reasons and explanations for circling around the designation of a standard of review, but confusion and rhetorical impact loom large, one would think.

that it is correct is weak, or some rhetorical maneuver is needed for value reinforcement or political accommodation. When matters become more sorted out, however, it will be quite irrational to characterize the right but to decline to specify the standard of review. It is like trying to withhold one side of a plane surface when delivering the other.

The chance that the Court will recognize a top-grade fundamental-right-with-strict-scrutiny is pretty low for the vaccination field,<sup>78</sup> simply based on past performance. Recall that although *Harper* involved a prisoner, subject to the middling *Turner v. Safley* standard of review, the Court nowhere hinted that the liberty interest in refusing antipsychotic drugs would generate strict scrutiny outside of a prison (or other confinement?) context.

On the other hand, however loose (in some eyes) the *Jacobson* decision was in allowing personal interests to be invaded by government, it did not apply minimal scrutiny, and the modern Court is also unlikely to do so. True, the *Jacobson* Court did seem to apply the “reasonableness” standard (not to be confused with the “rationality” standard) rather more loosely there than it did the following year in *Lochner v. New York*. (*Lochner*’s majority opinion was written by Justice Peckham, who dissented without opinion in *Jacobson*.) There, the standard, whatever it was called, was pretty high on the strictness scale. Whatever we call the right at stake in compulsory vaccination cases, its value will almost certainly draw well-above-zero scrutiny. It will not be as if one is insisting on a right not to be prevented from storing nuclear waste on one’s property.

So far, so easy. I excluded the very top niche and the very bottom niche of constitutional value sites. As I said, prediction can be easy. Just don’t be too precise.

### 3. Penalties Versus Force: Which Government Action Does the Right Protect Us Against?

To ask, “What is the right *against*?,” is another way of asking what the right

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78. *Saenz v. Roe*, 526 U.S. 489 (1999), doesn’t establish otherwise. There, the Court, per Justice Stevens, seemed to assign strict scrutiny to a claimed impairment of the right to travel. “Neither mere rationality nor some intermediate standard of review should be used to judge the constitutionality of a state rule that discriminates against some of its citizens because they have been domiciled in the State for less than a year. The appropriate standard may be more categorical than that articulated in *Shapiro v. Thompson*, 394 U.S. 618 (1969)], but it is surely no less strict.” *Id.* at 504. The source of law was the Fourteenth Amendment’s Privileges and Immunities Clause. Some version of the right to travel had already been recognized as fundamental, deriving (I’m not clear how) from the equal protection clause. *Shapiro v. Thompson*, 394 U.S. 618, 638 (1969). The Court, however, did not clearly characterize the right as fundamental or as a liberty interest, though it assigned strict scrutiny, suggesting a fundamental right was at stake. (There was a passing reference to fundamental rights covered by Article IV’s Privileges and Immunities clause, 526 U.S. at 502 n.14.) Operationally, it’s a fundamental right because of the strict standard used.

is, and then one closes in on asking how much it is worth and what its associated standard of review is. Rights talk propels cascades. It is well known that neither *Jacobson* nor the law it applied authorizes vaccination by force. It authorizes fines and imprisonment, not holding someone in a headlock while assailing their bodies. This seems to be a pretty firm tradition, although I assume that some persons have been vaccinated by force.<sup>79</sup>

Suppose, however, we were inclined to endorse actual force in order to maximize public safety. Consider the question, “What could possibly be so wrong with forcing on you an only slightly painful needle stick that administers an effective vaccine bearing no risks?” Then, you raise the point, “It’s not a matter of what you find right or wrong or even what some moral theory says is right or wrong. It’s my body, my mind, my identity, my *person*, and you cannot mess with it directly at all; you can only provide incentives (comply or you pay or get locked up).”

The force of the distinction between penalty and force is clear here: We, in fact, do not force people to be stuck (or to swallow or be scratched). This is because of the value that we assign to the integrity of one’s person. No one has to be vaccinated. To be sure, the penalties imposed may not be trivial, and one can well argue that suffering steep fines (perhaps any fine) and imprisonment is a serious breach of personhood, even if no one’s physical person or mind is directly intruded upon. (Most people probably would prefer getting vaccinated to having to pay a thousand-dollar fine. Even the Rev. Jacobson seems to have complied.) One might make a parallel point about extended exclusion of children from school, given the critical importance of education.

It is not clear how much to make of the fact that we do not exercise force. The physical loss and risk attributable to the act of force are, by hypothesis, low to nonexistent. Yet we are inclined to admire those who refuse to sign loyalty oaths or to bow to the regent, even though the action required is, in itself, trivial. We do sanction arrests, shackles, and the death penalty. We have adopted a kind of clumsy compromise in upholding physical compulsion of certain sorts and not others, and physical compulsion in some but not all forms. But the fact that we simply do not by law force vaccination is a telling point going to the strength of the liberty interest, however described.

#### *4. The Conceptual Interaction Between Threshold Rights and Countervailing Interests*

Despite the abstract distinction between saying that *X* is a right, but that government can qualify it for reasons *R*, we often formulate the right (or no-right) by partially absorbing into it the countervailing reasons against describing

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79. I have not canvassed vaccination law and practice through time and region to see to what extent force has been authorized.

or valuing it in certain ways. Indeed, we may deny that there is a right or liberty interest at all; we pack the government interest into the rights claim, and collapse it into a no-right (or at least a weak one). This is in many ways politically and even jurisprudentially efficient, if not entirely neat. We do not say that the right to gratuitously inflict pain on others is qualified by the harm it causes. We simply say there is no such right. We do the same with the right to injure ourselves in some ways. True, we could say there is a presumptive right to do what we want, qualified by harms imposed—the classic libertarian position.<sup>80</sup> But we simply do not talk this way in every case. We fragment human conduct into subsets, and, within these differing domains, there are arenas in which the overwhelming needs of society dictate a no-right (or even a who-would-ever-think-we-have-a-right-to-*X*?) stance. We inquire into “the point” of the right, of the harms done to others and to oneself, and say there is no right to mutilate oneself or others (beyond tattooing and affixing nose rings). Who demonstrates for recognizing such rights?

Let us apply this idea of interaction between rights and their countervails to vaccination and, for comparison, to the prisoner in *Washington v. Harper* who was administered Mellaril and other medicines over his objection.

#### 5. *What Exactly Is the Objection to Being Vaccinated?*

The question here is not about the objection to being vaccinated over one’s objection. It is about the vaccination itself, even if presented as a voluntary choice. Of course, one can question the moral propriety of forcing anyone to do anything over her objection, even if the thing done bears no risks at all. As I said, most exercises of fundamental rights do not have to be explained to others (not to oneself either). If there is a serious right against compulsory vaccination, “I just don’t feel like it” is presumptively good enough. If your friends tell you they are trying to procreate and you press for rational reasons for doing so, the friendships may be impaired.

Still, one rightly wonders why a rational person would object to vaccination, either generally or in particular situations, or object to it more than to other medical procedures. Pressing this question makes a lot more sense than asking why someone or some couple living in reasonably normal circumstances would want children. Sometimes we need to ask what good are rights, right? We can speak grandly about the integrity of body, mind, and identity, but how are they even at stake with a (perhaps not-yet-existent) generation of drugs that are maximally effective and minimally intrusive?

Is pain avoidance the reason for objecting? The risk of adverse effects? Which adverse effects? If getting vaccinated makes the world look very purple for three seconds, and this is it—no further effects, no permanent damage, no

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80. JOHN STUART MILL, ON LIBERTY 68 (1859).

porphyrophobia involved—are there any rational grounds for refusal? Perhaps, instead, the idea is that it is unnatural (not *necessarily* a religious objection) or interferes with God’s will? (Recall that we are not at the moment concerned with the familiar idea that autonomous persons should not be forced to do anything, risky or benign, on behalf of anyone else at all, ever, except for duties we incur by having children or entering into contracts or statuses of certain sorts.)

The force of the question put to the vaccination objector is enhanced when we recall a basic observation about human behavior: not every unsought impingement on our persons is viewed as an incursion on our personal nature or identity or an interference with the order of things. Sometimes we decline to characterize something as an impingement on our integrity because it is just totally unimportant. For example, although we do not like crowding, most of us do not go to unusual lengths to arrange things so that no one ever brushes against anyone else.

Turn now to Justice Harlan’s impassioned call for limiting government action where the right is explicitly invoked as sounding (at least in part) as *harm-avoidance*:

It is easy, for instance, to suppose the case of an adult who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health or body would be cruel and inhuman in the last degree. We are not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned . . . . Until otherwise informed by the highest court of Massachusetts, we are not inclined to hold that the statute establishes the absolute rule that an adult must be vaccinated if it be apparent or can be shown with reasonable certainty that he is not at the time a fit subject of vaccination, or that vaccination, by reason of his then condition, would seriously impair his health, or probably cause his death.<sup>81</sup>

What if the procedure is painless (a transdermal patch or small pill)? Suppose the risks of adverse effects, whether of vaccination, or of Mellaril and other medicines administered to Harper, were nil. To restate a familiar utilitarian “paradox,” assume that administering the medicine by force will save the world. Surely a rational non-psychopath would accept the vaccination or medicine (religious authority aside). Would forced administration shock the conscience?<sup>82</sup> It is not as shattering as, say, torturing a child to death to preserve

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81. *Jacobson*, 197 U.S. at 38-39.

82. See *Rochin v. California*, 342 U.S. 165, 172 (1952) (holding that use of swallowed morphine obtained by forcing an emetic into defendant’s stomach through a tube violated the Due Process Clause of the Fourteenth Amendment, it being “conduct that shocks the conscience”).



humanity. When there are no external risks, however, we can resist even modest interference with our persons for no reason at all. But when there are risks, we do say that some reasons for objecting are not good enough. In *Jacobson*, Justice Harlan made a point of quoting the Massachusetts Supreme Judicial Court in ruling on Rev. Jacobson's objection: "[W]hile they [the medical profession] have recognized the possibility of injury to an individual from carelessness in the performance of it [vaccination], or even, in a conceivable case, without carelessness, they generally have considered the risk of such an injury too small to be seriously weighed as against the benefits coming from the discreet and proper use of the preventive . . . ."<sup>83</sup>

#### 6. *The Article's Shaky Start on Jacobson 2.1*

A word on the matrix of criteria suggested by Professor Holland in her account of what would have to be done in a *Jacobson 2.1* situation. As noted, they include "(1) public health necessity, (2) reasonable means, (3) proportionality, (4) harm avoidance, and (5) fairness."<sup>84</sup>

Here, the theoretical question and the practical adjudicative advocacy question coincide: What is this list supposed to do for us? Where do its elements go in the argument structure of a vaccination case? The concepts listed are her suggested criteria for assessing a rights claim against government assertions that serious interests are being promoted. "Necessity," in its clumsy way, is about both assessing the strength of the government interest in the situation at hand and appraising the means. Although it bears significant (if highly competitive) meanings, it is too opaque to be retained as a critical term in constitutional analysis unless it is carefully specified, as when used as a tool for evaluating mechanisms toward reaching a conceded significant objective. It reduces the scope of "necessity" to prefix it with "public health," but does not add much to its precision.

Moreover, it stands uneasily with "reasonable means." Is this concept meant to be a weaker standard than "necessary means"? A reasonable means criterion goes into every non-minimal standard of review. (Recall that the minimal rational basis test in substantive due process is not a true reasonableness requirement with any teeth.) An even harder question—and more important for our purposes—concerns the paired analytic operations a court should pursue in examining government choice of means. The court must examine the efficiency of mechanisms *with respect to the identified goals*, and it must also *evaluate* whether, in light of the value of the goals, the mechanisms are constitutionally adequate. Constitutional adequacy of means requires determining whether they "sufficiently" advance the goal, considering its value, and do so without undue

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83. *Commonwealth v. Pear*, 66 N.E. 719, 721 (Mass. 1903).

84. Holland, *supra* note 5, at 46.

(disproportionate?) intrusion on protected interests. The intensity with which the courts perform these tasks varies with (among other things) the burden of justification defined by the standard of review. What is “reasonable” (in either the constitutional or everyday sense) may in some cases amount to a least restrictive alternative requirement, while in others a looser “narrowing” requirement may do for liberty interests not treated as major league fundamental rights. What is the difference? There are differences in how hard a court (and the legislature when it acts) looks for alternatives; in how the court addresses the data (if any) and the inferences drawn from them; and so on. This is exactly the sort of increasingly rigorous specification of review operations that courts will be pushed to perform under the pressure of technological innovation, although such pressures have always existed.<sup>85</sup>

Although it is hard to be certain about their meanings, the other elements of the proposed matrix—proportionality, harm avoidance, and fairness—seem to be miscategorized as independent aspects of analysis. Harm avoidance straddles both the goal-evaluation dimension (“necessity”) and the efficiency of the mechanisms in moving toward the goal at relatively low cost (where “cost” refers primarily, but not exclusively, to burdened constitutional interests). Although “proportionality” is used (controversially) in Eighth Amendment jurisprudence,<sup>86</sup> the term is used differently here. This concept is often used in constitutional adjudication outside the United States, but is occasionally mentioned here also. I do not think that, as used so far, it significantly alters the content of what is already contained within our doctrines, expressly or impliedly. Importing the concept of proportionality is of questionable benefit, partly because it *seems* as if it is doing some work. Proportionality concerns the comparative analysis required identifying and evaluating goals, pitting them against interests impaired by moving toward the goals, and examining the relative efficiency of the means for so moving. Efficiency itself is value laden in any proportionality or balancing process. For example, whether a given means advances a goal efficiently in a constitutional sense depends in part on the value of the goal, which determines the value of moving any given distance toward it. So proportionality covers at least some forms of “balancing,” as used in American constitutional jurisprudence. However, there might be some theoretical and functional differences between the two conceptual systems. For example, some proportionality formulations might suggest standards of review more akin to a continuous “sliding scale” than to a “step-function” with built-in tiers—i.e., thresholds that define where heightened scrutiny bursts onto the scene.<sup>87</sup> Yet it

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85. For an account of the narrow tailoring requirement and its limits, see *Grutter v. Bollinger*, 539 U.S. 306, 339-40 (2003).

86. *E.g.*, *Roper v. Simmons*, 543 U.S. 551, 575 (2005) (ruling that execution of juveniles who were under eighteen when their crimes were committed is disproportionate and thus violates the Eighth Amendment).

87. I discuss this contrast in formulations of standards of review in Shapiro, *supra* note 39, at

does not seem that this is the reason for its inclusion within the Article's matrix. In any case, the claim that the "proportionality" argument structure is extensionally equivalent to what we already have—either adding some contained inference, or rhetorical flavor, or just cluttering things up—cannot be examined extensively here.<sup>88</sup> I simply note that Justice Breyer, rather obliquely, suggests this equivalence. (How this might affect outcomes is not clear.) He said, dissenting in *United States v. Playboy Entertainment Group, Inc.*,

Consequently § 505's restriction [on access by juveniles to sexually oriented cable TV programming], viewed in light of the proposed alternative, is proportionate to need. *That is to say*, it restricts speech no more than necessary to further that compelling need. Taken together, these considerations lead to the conclusion that § 505 is lawful.<sup>89</sup>

So, I see little reason that the idea of proportionality adds to the constitutional and policy analysis of vaccination. I stress that I am not saying it has *no* incremental meaning—a point I turn to in Subsection III.E.6. The term helps to understand the meanings of "balancing" by directing attention to some aspects of use—and, in the other direction, the idea of balancing itself helps to illuminate that of proportionality: they are entangled concepts.

Much the same applies to the overlapping idea of "fairness," which concerns proportionality (among other things, such as justice, equality, and utility), which in turn concerns evaluating the burdens imposed by the government's means in light of the goals supposedly advanced. But this is what our standards of review already do. Rendering these already-contained aspects of judicial review explicit is not objectionable, but serious reconstruction of current doctrine is only

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269 n.136. The differing structures may yield different results, although this is far from inevitable, and often unlikely.

88. By "extensionally equivalent," I mean that the compared terms denote the same things but have a different meaning (or sense or intension). Cf. Ruth Barcan Marcus, *Extensionality*, OXFORD REFERENCE ONLINE THE OXFORD COMPANION TO PHILOSOPHY (2011), <http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry=t116.e851> (last visited July 29, 2011).

89. *U.S. v. Playboy Entm't Grp., Inc.*, 529 U.S. 803, 846 (2000) (emphasis added) (Breyer, J., dissenting). Justice Breyer evidently thought that proportionality language was fully translatable—at least in that context—into prevailing American terminology. The Court, however, ruled that a cable TV regulation meant to shield children from sexually oriented programming failed the least restrictive alternative standard. For more extensive comparative discussions of proportionality, see Dieter Grimm, *Proportionality in Canadian and German Constitutional Jurisprudence*, 57 U. TORONTO L.J. 383, 386 (2007) (noting that the test, in the jurisdictions analyzed, "requires a means-ends comparison"); Moshe Cohen-Eliya & Iddo Porat, *American Balancing And German Proportionality: The Historical Origins*, 8 INT'L J. CONST. L. 263, 265 (2010) ("One can, of course, deny that balancing and proportionality are similar and argue that, despite superficial similarities, they are analytically distinct. However, . . . we believe that the analytical differences between the two concepts are not substantial enough to account for the differences in attitudes toward them. Other, more promising explanations for the differences in attitudes between the U.S. and Europe may be found in aspects of legal and political culture.").

marginally advanced, if at all, by the Article's matrix. Although its elements bear significant meaning, what was needed was a mapping of the sort tried here, linking those terms to current constitutional doctrine, to see if they add anything. If they do, it does not seem to be much.

#### IV. VACCINATION ANALYTICS: WHAT DO WE PLACE INTO THE CONSTITUTIONAL ARGUMENT STRUCTURES?

Here, I apply the abstractions of the constitutional argument structures just discussed to some of the specific aspects of the hepatitis B vaccine issue, and vaccination issues generally.

##### *A. Basic Questions About the Hepatitis B Vaccine Issue: Harms and Their Causes*

###### *1. Factual and Conceptual Background*

No case has been made against any form of hepatitis B vaccine in general, nor as a condition of school attendance, nor as a routine accompaniment of birth. I think Professor Holland has made a case for asking vaccinologists, allied biomedical professionals, and public health experts to answer some specific questions (e.g., whether the vaccine is thimerosal free), but her conclusion that the vaccine has caused widespread harm to children is not scientifically confirmed, and the anecdotes—in light of the research to date—are not persuasive as clues that the dangers of vaccination are significant. True, anyone is free to argue that science is not everything, and—here is an issue to pinpoint—one may believe that parents and individuals generally should be free to decide whether to allow personal invasions *even if their objections have no scientific warrant*. If the right not to be vaccinated is a liberty interest, then I suppose the claim is presumptively to be recognized—but it can be overcome under heightened scrutiny.

Professor Holland's Article also calls attention to the fact that there are varying degrees of need<sup>90</sup> in different regions of the world. "Need," here, is a

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90. Indeed, in some places, the vaccine program arguably should be broader—given at birth, not just as a condition of school entry. See Koen Van Herck & Pierre Van Damme, *Benefits of Early Hepatitis B Immunization Programs for Newborns and Infants*, 27 PEDIATRIC INFECTIOUS DISEASE J. 861, 862 (2008) (stating that "In highly endemic countries, HBV is predominantly transmitted among young children through perinatal or child-to-child transmission. It makes sense, therefore, to vaccinate infants for early protection."). Even in the United States, infant vaccination might be justified across the board. See *id.* at 862-64 ("An effective vaccination strategy must focus on preventing HBV chronic carriage. Those infected at an early age are far more likely to become chronic carriers. For example, in the United States, children younger than 5 years of age represent only 1-3% of cases of acute HBV infections, but the risk of HBV infection to become chronic in children younger than age 5 is 30-90%. As a result, 30-36% of cases of chronic HBV infection in the United States contracted the infection during childhood. It is therefore important to have large-

function both of the incidence of infection and of the local health care system. For example, an effective voluntary system that generates high compliance may make compulsion unnecessary.

I do not see major issues about long-term efficacy. Most sources concur that booster shots are not necessary for at least fifteen years in most cases.<sup>91</sup> There is little support in the biomedical community for any claims of serious vaccine-caused complications, save for anaphylactic shock (about one-in-1.1 million). It does seem confirmed, however, that there is a nontrivial incidence of some minor adversities, all transient: fever, soreness, and a sense of discomfort or ill-being.

There is some support for the idea that *some* causal connection for *some* adverse events in *some* vaccination subjects cannot be entirely excluded, unless a causal link is simply inconsistent with well confirmed scientific findings about how things work (findings that of course are themselves corrigible). The Article should have highlighted this more clearly because it is at least consistent with its skeptical stance on vaccination. As things stand, however, existing evidence does not support a finding of any causal link between hepatitis B vaccine and any serious disorders (very rare anaphylactic shock aside), including neurological diseases such as multiple sclerosis. Science being what it is, one should assume a window of possibility for showing otherwise, but this “revision space” is not, in this case, a rational foundation for objecting to hepatitis B vaccination, compelled or otherwise.

Recent attention has been given to the possibility that vaccination with a hepatitis B vaccine increases the risk for developing multiple sclerosis (MS). *While we cannot say with absolute certainty that the vaccine has never caused a case of MS*, some temporal associations are expected because hepatitis B vaccine is administered to the same age groups where symptoms of MS first occur. Since 1990, VAERS [Vaccine Adverse Event Reporting System] has received 76 U.S. reports of MS following vaccination with hepatitis B vaccine. These reports are spread fairly evenly over the years. CDC has undertaken a further prospective study of the possible association between demyelinating disease (neurological diseases) and the hepatitis B vaccine.<sup>92</sup>

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scale routine vaccination as early as in infancy to allow a maximum impact on reduction of HBV transmission.”). Targeting only those at high risk because of their behavior (drug use, sex) is thought to allow too many victims to fall through the holes. “The main limitation of that selective [high risk targeting] strategy was the fact that no risk factor for HBV infection can be identified in over 30% of infected persons. Hence, a substantial proportion of HBV cases are missed by the ‘at-risk’ vaccination strategy.” *Id.* at 861.

91. *See id.* at 684 (It may be, however, that several administrations are required at the outset.).

92. *See* Susan S. Ellenberg, *Vaccine Adverse Event Reporting System (VAERS)*, U.S. FOOD & DRUG ADMIN. (last visited July 15, 2011), <http://www.fda.gov/NewsEvents/Testimony/ucm115058>.

So, “no causal relationship has been found” *does not yield* “there is no causal relationship.”<sup>93</sup> (Again, one would need to add premises about the inconsistency of a causal hypothesis with confirmed scientific accounts.)

There are several distinct questions about how to respond rationally to a scientific consensus-with-qualifications (no causal relationship established, but not-a-cause is not confirmed either). One is whether it is rational to *believe* that there is, in fact, a causal link between the vaccine and some serious adverse events, other than anaphylaxis, even in the face of existing data. (Adverse events caused in part because of certain contraindicating vulnerabilities are another matter.) It’s hard to see how it can be rigorously rational, despite the impact of anecdotal reports, which certainly can have colossal impact, and indeed may provide *clues for further investigation*.<sup>94</sup> I am not sure that there is a consensus

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htm (emphasis added). (“With virtually universal childhood immunization, beginning at birth or shortly thereafter, any adverse medical event in a child will ‘follow’ vaccination, and some of these will coincidentally follow within a few days of a vaccination. Thus, even if a vaccine is not the cause of certain rare medical problems, it is a certainty that some number of these events will occur within a short interval following a vaccination. For this reason, the fact that an event—even a very serious event such as a death—occurs shortly after a vaccine has been administered cannot by itself lead to the conclusion that the event was caused by the vaccine. . . . A determination that the vaccine caused the post-vaccination event usually cannot be made on the basis of information acquired from individual VAERS reports.”); *see also* Mast, *supra* note 4, at 15 (“A causal association has been established between receipt of hepatitis B vaccine and anaphylaxis. On the basis of VSD data, the estimated incidence of anaphylaxis among children and adolescents who received hepatitis B vaccine is one case per 1.1 million vaccine doses distributed (95% confidence interval = 0.1–3.9). Early post licensure surveillance of adverse events suggested a possible association between Guillain-Barré syndrome (GBS) and receipt of the first dose of plasma-derived hepatitis B vaccine among U.S. adults (181). However, in a subsequent analysis of GBS cases reported to CDC, FDA, and vaccine manufacturers, among an estimated 2.5 million adults who received >1 dose of recombinant hepatitis B vaccine during 1986–1990, the rate of GBS that occurred after hepatitis B vaccination did not exceed the background rate among unvaccinated persons. *An Institute of Medicine review concluded that evidence was insufficient to reject or accept a causal association between GBS and hepatitis B vaccination.*”(emphasis added) (citations omitted)).

93. Suppose the background incidence of some disorder is one per million persons (perhaps limited some way according to certain traits, such as age or gender). Suppose also the incidence of that disorder among every million persons given a particular vaccine is the same. No causal pathway between the vaccine and the disorder is known, but no scientific knowledge excludes it. No study finds a statistically significant result for a causal hypothesis—i.e., that the adverse event is not the result of chance. Of course, even if a finding of causality were statistically significant, this doesn’t mean it couldn’t have been the result of chance. Nor does failure of a result to be statistically significant mean, standing alone, that there is in reality no causal relationship. Does this entail that there can be no causal relationship between a given occurrence of the disorder and the vaccine? No, but this isn’t saying much, and it’s certainly not saying that there is a good reason to avoid the vaccine. What would it take to show causation? One would have to probe the possibility of predisposing individual conditions that set up the rare individual for the adverse event.

94. *See* Alison M. Stuebe, *Becoming a Physician: Level IV Evidence — Adverse Anecdote and Clinical Practice*, 365 NEW ENG. J. MED. 8, 8 (2011) (noting that adverse personal experience will create compelling memories and can transform clinical practice). But there has to be more involved than the occurrence of an event, *simpliciter*. Otherwise, the transformation in clinical practice may

that there is in fact no causal connection (rather than “none shown”) between the hepatitis B vaccine and various adverse events cited by the vaccine’s critics. Even if there is, it could be the result of loose conflation of “no cause shown” and “causation flatly excluded”; there are consensuses and consensuses.

Moreover, because of the *contested* nature of causation—cause-in-fact as well as proximate cause—some causal attributions may be value laden, or linked to one’s personal preferences. Proximate cause is of course famous for its normative ambiguity, but the supposedly factual notion of cause-in-fact might also be, at least on occasion.<sup>95</sup>

Another question about rational causal belief concerns what one ought to do about these beliefs in various situations. Suppose everyone agrees that there is a causal link between the vaccine and an extremely rare, very serious disorder (how serious is of course critical). The obvious example is the accepted belief in anaphylaxis. Should one avoid vaccination, for oneself or one’s child, because of this risk? Anaphylaxis can be fatal, especially if immediate medical help is unavailable. Hepatitis B is a serious disorder, but not necessarily life threatening.<sup>96</sup> One can ask the same thing concerning, say, multiple sclerosis and other serious neurological disorder: even conceding a causal link, is it rational to avoid vaccination, given the seriousness of the disorder and the probability and gravity of the described risk?

Here is another consideration. Suppose neither causation nor no-causation is established. If causation is not empirically excluded, then it must be considered at least possible. Assume that there are adverse event reports indicating a certain incidence of occurrence of a serious adverse effect. Since it is, by hypothesis, *possible* for there to be a causal link, is it rational to decline vaccination? (One can then proceed as above.)

One can understand being leery of any medical procedure, including vaccinations that are *generally known* to be safe, because of the expected disutility (roughly, the product of an event’s probability and its gravity). If the risk of getting polio is one in a million and the risk of getting it from a vaccination is one in a million, what is the point—within the individual’s decision framework—of taking it? From a collective standpoint, there may be an epidemiological reason to vaccinate on a large scale—to maintain the low level

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not be for the better.

95. See Taofikat Agbabiaka et al., *Methods for Causality Assessment of Adverse Drug Reactions: A Systematic Review*, 31 DRUG SAFETY 21, 22 (2008) (discussing the abundance of causal algorithms).

96. Hepatitis B is a liver disorder caused by viral infection. *Hepatitis B*, PUBMED HEALTH, <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0001324> (last reviewed Nov. 23, 2010) (“Early symptoms may include: Appetite loss; Fatigue; Fever, low-grade; Muscle and joint aches; Nausea and vomiting; Yellow skin and dark urine due to jaundice. People with chronic hepatitis may have no symptoms, even though gradual liver damage may be occurring. Over time, some people may develop symptoms of chronic liver damage and cirrhosis of the liver.”).

of polio infection, depending on the risks of resurgence of the disease.

But it is difficult to understand why any of the data presented in the Article or its sources justifies a serious opposition to the hepatitis B vaccine. The author principally cites writings that support her position, and one can raise questions about the biomedical credentials of some of her principal sources.<sup>97</sup> The strongest material in her favor, presented by biomedical researchers, simply states that causation cannot be excluded, and there is not much of it cited in her Article.

We are, thus, left with a value/preference issue, but one with a constitutional dimension: Are we bound to leave such *decisions about small but nonzero degrees of risk* to individuals because of the importance of their liberty interests in the integrity of body, mind, and identity—of personal security in a comprehensive sense?

## 2. Adverse Events, Study Findings, and Causation

“Adverse event” reporting is, of course, critical to assessing the safety of medical mechanisms. Bare association of an adverse event with medical treatments *is* scientifically relevant. But there is relevance and *relevance*. Relying on such “anecdotal” information is a critical part of the scientific process and cannot rationally be dismissed out of hand. To do so reflects a basic misunderstanding of scientific research and advancement.

But such association generally cannot, at the start and standing alone, establish causation. Bare reports of adverse events, however awful, cannot justify opposition to a vaccination program, voluntary or otherwise, unless the scale of the events indicates the strong possibility of causation. If one person out of five hundred eating food from the same source suffers major digestive upset, there is no cause for general alarm (although it may happen anyway). If several dozen get sick, it is time to prosecute the food.

Moreover, the criteria for addressing whether linked events are causally related are not settled. “Currently, there is no universally accepted method for assessing causality of ADRs [(adverse drug reactions)]. No up-to-date review of the existing causality assessment methods is available.”<sup>98</sup> Simply referring to adverse event reports does not provide sufficient warrant for avoiding or suspending vaccination, unless particular circumstances concerning scale and indicia of causation are satisfied. It, thus, will not do to state, without far more support than is offered, that “Since 2005, further scientific investigation has suggested severe deleterious health consequences for many young children from the hepatitis B vaccine. A 2008 study *associates* hepatitis B vaccination of male

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97. See *infra* note 104.

98. See Agbabiaka et al., *supra* note 95, at 22 (2008). The article is an extensive literature review of the methods for assessing causation.



newborns with autism diagnoses from 1997-2002.”<sup>99</sup>

But, as the Vaccine Adverse Event Reporting System (VAERS) states:

VAERS data contains coincidental events and those truly caused by vaccines. More than 10 million vaccines per year are given to children less than 1 year old, usually between 2 and 6 months of age. At this age, infants are at greatest risk for certain medical adverse events, including high fevers, seizures, and sudden infant death syndrome. Some infants will experience these medical events shortly after a vaccination by coincidence. These coincidences make it difficult to know whether a particular adverse event resulted from a medical condition or from a vaccination. Therefore, vaccine providers are encouraged to report all adverse events following vaccination, whether or not they believe the vaccination was the cause.<sup>100</sup>

In any case, *even if a confirmed percentage of adverse events is considered caused by the vaccine*, this is not sufficient to withhold support for the vaccine program. It depends not only on incidence, but also on the seriousness of the events, the seriousness of the disorder being prevented, whether the disorder is in fact being prevented, and whether it is possible to stratify patients into high and low vulnerability groups. A one hundred percent probability of a mild fever with no adverse sequelae does not warrant suspending an otherwise justifiable preventive program.

As for causation itself, what is needed to support Professor Holland’s reservations about hepatitis B vaccinations is an application of the various methods and algorithms of causation analysis. There is no cited reference in her Article that does this for hepatitis B, using any method of causation analysis. There is nothing referred to that provides a basis for accepting any causal hypotheses that adverse events—including multiple sclerosis—derive from the hepatitis B vaccine, except (most seriously) for fever and (very rarely) anaphylactic shock.<sup>101</sup>

99. Holland, *supra* note 5, at 74 (emphasis added.).

100. VAERS Data, VACCINE ADVERSE EVENT REPORTING SYS., <http://vaers.hhs.gov/data/index> (last visited July 15, 2011).

101. See, e.g., Annemarie L. Broderick & Maureen M. Jonas, *Hepatitis B In Children*, 23 SEMINARS LIVER DISEASE 59, 66 (2003) (“Hepatitis B vaccines have been shown to be safe for both adults and children. Pain at the injection site (3 to 29 %) and a temperature greater than 37.7°C (1 to 6 %) have been the most frequently reported side effects, but these side effects were reported no more frequently among vaccinees than among persons receiving a placebo. Anaphylaxis is the only serious adverse event; this rare event occurs at a rate of approximately 1 per 600,000 vaccine doses. [Editorial note: I cannot account for the variation in reported incidence.] Reports of multiple sclerosis (MS) developing after HBV vaccination led to concern that the vaccine might cause MS in previously healthy subjects. This was refuted in a nested control study of two large cohorts of nurses in the United States. No association was found. In a case crossover study using the European MS database, recent vaccination against HBV, tetanus, or influenza did not appear to increase the

If so, both the individual patient's decision and the overarching moral and public policy issues concern the proper responses to conditions of uncertainty, given personal and societal risk preference patterns. However, given the risks of hepatitis B, the literature reports suggest that avoiding hepatitis B vaccinations given present knowledge may not be entirely a matter of risk aversion patterns. I note some possible alternative subtexts below.

The difficulties with marking out the nature of causation—whether we are speaking of cause-in-fact, proximate cause, or related ideas—are well known. Proximate cause, as suggested, is a standard example of normative ambiguity because it embraces both the empirical links among events and policy judgments. But even cause-in-fact has value components. We have to choose among competing notions of causality, and, in some fields at least, there is no overarching concept that unifies differing modes of analysis. The analysis of adverse drug reactions is a clear example:

Numerous methods for causality assessment of adverse drug reactions . . . have been published. The aim of this review is to provide an overview of these methods and discuss their strengths and weaknesses. . . . We conducted electronic searches in MEDLINE (via PubMed), EMBASE and the Cochrane databases to find all assessment methods. Thirty-four different methods were found, falling into three broad categories: expert judgement/global [sic] introspection, algorithms and probabilistic methods (Bayesian approaches). . . . As a result of problems of reproducibility and validity, no single method is universally accepted. Different causality categories are adopted in each method, and the categories are assessed using different criteria. Because assessment methods are also not entirely devoid of individual judgements [sic], inter-rater reliability can be low. In conclusion, there is still no method universally accepted for causality assessment of ADRs.<sup>102</sup>

It is hard to see how American courts pursuing heightened scrutiny can do

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short-term risk of relapse in MS. Vaccines were commonly prepared with thimerosal, sodium ethylmercurithiosalicylate, to prevent bacterial and fungal contamination. This preservative has aroused great public concern regarding mercury toxicity. Infants were considered at greater risk for mercury poisoning from thimerosal-containing vaccines. No adverse outcomes have been clearly associated with thimerosal use; nevertheless, in 1999, a joint statement was issued by the AAP, the American Academy of Family Physicians, the Advisory Committee on Immunization Practices, and the U.S. Public Health Service. These four bodies called for the national goal of removal of thimerosal from vaccines and the performance of studies to establish any relationship between thimerosal exposure and health effects. HBV vaccination in newborns was temporarily suspended in 1999 until thimerosal-free vaccines became available, unless the mother was infected with HBV. There are now two thimerosal-free HBV vaccines available in the United States for use in infants. Hence, parents can be reassured about the lack of exposure to mercury in HBV vaccines.”).

102. Agbabiaka et al., *supra* note95, at 21.

more than inquire into the views of persons credentialed in empirical analysis (assuming credentials can even be agreed upon) and screen for conflicts of interest and other factors that may compromise adequate neutrality. This sort of inquiry would seem required by heightened scrutiny, but it obviously must operate within resource, knowledge, and ability constraints that limit judicial inquiry and decision.<sup>103</sup>

These difficulties are not extensively addressed in the Article, and there seems to be excessive reliance on the reporting of adverse events, *simpliciter*, as well as reliance on certain sources whose background and training are not directly in vaccine or epidemiological research, although they may have practiced medicine or acquired expertise in statistics.<sup>104</sup> There are no grounds for completely dismissing what they say, even though they have not yet made a case for “equal time.” Credentials (training and experience, at the least) are hardly perfect proxies for sound opinions, never mind accurate results. But they are not nothing, and non-experts—including courts—have to pay serious attention to them. It is easy to say that one should avoid over-reliance on expert judgment, but it is hard to say just what counts as “over-reliance.” Even if experts are often wrong, it is not clear what the threshold alternative is to according some authority to their views and to await better grounded informed opinion. The best that the laity can do is to inquire about rational foundations for judgment, including the investigation of conflicts of interest that are widely accessible outside of the experts’ domain. This is especially important in light of the almost inevitable normative dimensions of expert conclusions. “These girders are strong enough” is not a simple factual judgment,” any more than is “This vaccine is quite safe.” Experts are wrong *often*. See Aristotle, Ptolemy, and the opponents of Semmelweis, Marshall, and Warren, and, more recently, Dan Shechtman, the winner of the 2011 Nobel Prize in Chemistry, who was expelled from his research group for “disgracing” it with his work on quasicrystals.<sup>105</sup> His results were considered “impossible.” But the errors of experts are generally established by *other* experts running scientific studies and experiments, not simply reporting sequences of salient events!

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103. See *infra* notes 175, 193.

104. Michael Belkin describes himself as a statistician. Geoff Metcalf, *Vaccines That Kill Children? Geoff Metcalf Interviews Mandated-Immunization Opponent Michael Belkin*, WORLDNETDAILY.COM (Dec. 3, 2010), <http://www.whale.to/m/belkin1.html>. Dr. F. Edward Yazbak, M.D., is described as having practiced pediatrics for many decades. *Dr. F. Edward Yazbak, MD*, HEALTHGRADES, <http://www.healthgrades.com/physician/dr-f-edward-yazbak-32ff3/> (last visited July 24, 2011).

105. Interview with Dan Shechtman, Distinguished Professor of Materials Science at Technion (Oct. 10, 2011), available at [http://pubs.acs.org/cen/news/89/i41/8941notw1.html?from\\_TRM\\_site=Ytterbium](http://pubs.acs.org/cen/news/89/i41/8941notw1.html?from_TRM_site=Ytterbium).

### B. What If We Concede Causation?

I raised this possibility in the preceding section and add a few points. Completeness requires that we indulge such assumptions *arguendo*. The point of the question is this: Even where causality is conceded (or credibly posited), the risks, as understood so far, are extremely low. The risk of causing anaphylactic shock is about one-in-1.1 million, as noted.<sup>106</sup> Suppose one also accepts, as some do, that hepatitis B vaccine may cause serious autoimmune disorders in a group (fairly small) of susceptible subjects. What policy outcome? What constitutional rationale and outcome when someone refuses compelled vaccination and is fined or imprisoned?<sup>107</sup> Apply these questions to the points made by Geier and Geier:

One would have to consider that there is [a] causal relationship between HBV and serious autoimmune disorders among certain susceptible vaccine recipients in a defined temporal period following immunization. In immunizing adults, the patient, with the help of their physician, should make an informed consent decision as to whether to be immunized or not, weighing the small risks of the adverse effects of HBV with the risk of exposure to deadly hepatitis B virus.<sup>108</sup>

But what exactly are they saying has been found? The “causal relationship” is not (necessarily) between *the vaccine* and the adverse event, but between *circumstances of administration of the vaccine* and the results. Part or all of the problem may be that the “inactive” substances included in the vaccination package are risky, e.g., thimerosal, a preservative (which has been significantly phased out).<sup>109</sup> Geier et al. state:

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106. See *supra* note 4.

107. See the discussion of possible constitutional argument structures for a latter-day Jacobson, *infra* Section III.E.

108. Mark R. Geier & David A. Geier, *A Case-Series of Adverse Events, Positive Re-Challenge of Symptoms, and Events in Identical Twins Following Hepatitis B Vaccination: Analysis of The Vaccine Adverse Event Reporting System (VAERS) Database and Literature Review*, 22 CLINICAL EXPERIMENTAL RHEUMATOLOGY 749 (2004); see also Arnon Dov Cohen & Yehuda Shoenfeld, *Vaccine-Induced Autoimmunity*, 9 J. AUTOIMMUNITY 699, 701 (1996) (“The data summarized here suggest that some vaccines may in rare cases induce autoimmune disorders. The subject of the vaccine-autoimmunity relationship is still obscure; reports have been rare, no laboratory experimentation on this topic has been undertaken, and there are few animal models. For the time being no conclusions can be drawn. Since vaccines are an important prophylactic intervention, the risk-benefit ratio clearly leans towards the advantages of infectious disease prevention. Vaccination routines should not be changed in the healthy population or for patients with known autoimmune disorders.”).

109. See Broderick & Jonas, *supra* note 101. This does not mean there is no contaminant danger. See Katherine Hobson, *Charred Shrink Wrap in Merck Vaccines: Read the FDA Inspection Reports*, WALL ST. J.: HEALTH BLOG, July 29, 2011, <http://blogs.wsj.com/health/2011/07/29/charred-shrink-wrap-in-merck-vaccines-read-the-fda-inspection-reports>. Recall that some deny that the vaccine additive thimerosal causes adverse events.

Hepatitis B is one of the most important infectious causes of acute and chronic liver disease both in the US and worldwide. In order to combat the life-threatening effects of hepatitis B infection, recombinant hepatitis B vaccines have been developed. The medical and scientific communities have generally accepted that recombinant hepatitis B vaccine—a highly purified, genetically engineered, single antigen vaccine—is a safe vaccine. *Information is presented showing that hepatitis B vaccine contains yeast, aluminium, thimerosal and hepatitis B surface antigen epitopes, which may result in hepatitis B vaccine being associated with autoimmune diseases among susceptible adult vaccine recipients. There is little doubt that the benefits of this vaccine overall far outweigh its risks.*<sup>110</sup>

Very young children are in no position to provide informed consent, to be sure, so their parents must make the choice. But I think that in the case of hepatitis B, this does not alter the conclusion that vaccination risks may be imposed within the legislature's discretion, even when heightened scrutiny is imposed. For other vaccination programs, the result may be different.

### *C. Efficacy, Safety, and Need*

"I need this "ambiguously embeds matters of fact, value, and personal preference. There is a lot of information about hepatitis B carrier rates and the incidence of infection, but some disagreement about its significance. In the United States, we are rarely overwhelmed by epidemics, but we are far from home free: the smallpox-is-dead story is only about smallpox. Nevertheless, a pressing question concerns what levels of safety and prevention are morally and constitutionally "enough" to sustain compelled vaccination in various situations, *conceding* a certain set of facts. Here is a pinpoint illustration: Suppose one says (Professor Holland does not do so directly) "*only* persons will be protected from X through this vaccination program." This formulation is significantly begging the question, and its circularity does not seem universally recognized. It is circular because the "only" presupposes an unstated value premise: it is just not *worth* other costs and risks to prevent ("merely") *n* persons from getting X. This is sometimes put in a remarkably blunt way: "[V]accinating over 100,000 children annually to ideally avoid 200 acute cases per year (mainly in drug addicts) is not considered logical from a public health standpoint [in Sweden]."<sup>111</sup>

This sort of buried premise on what is worth doing to save lives and preserve

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110. Mark R. Geier et al., *A Review of Hepatitis B Vaccination*, 2 EXPERT OPINION ON DRUG SAFETY 113 (2003) (emphasis added).

111. Sten Ivarson, *Why the Scandinavian Countries Have Not Implemented Universal Vaccination Against Hepatitis B*, 16 VACCINE S56 (1998).

health requires ventilation—certainly far more than appears in some of the cited literature.<sup>112</sup> It is a plain moral and logical truth that, for all  $n$ , where  $n$  is any number,  $n$  lacks *independent moral* significance, whatever its import in number theory.)

How, then, should we characterize the degree of success or failure of the hepatitis B vaccine? To be sure, claims of “success” may be as normatively ambiguous and possibly question begging as claims of failure and uselessness, but the following account seems reasonably neutral. It suggests, among other things, some issues in causal attribution, noting that behavioral changes among adults—not children—may explain some of the decline in the incidence of the disease.

In the United States of America, the impact of hepatitis B immunisation has been impressive. From 1990 to 2001, the overall incidence of acute hepatitis B declined by 66%, from 8.1 to 2.8 cases per 100,000. The decline was most dramatic among children 0–11 years old, with an 89% decline, from 1.1 to 0.12 per 100,000. Among adults, the reasons for the decline in incidence include vaccination, as well as safer sex and injection practices. However, among children the decline in incidence can be attributed to vaccination, which has been routinely recommended for all infants since 1991.<sup>113</sup>

On the other hand, the hepatitis B situation is not such a big deal, right?

In 1996, fifty-four cases were reported to the Center for Disease Control in the birth-to-1 age group. There were 3.9 million babies born that year so the incidence of hepatitis B is 0.001%. [0.00138%] *Does that sound like enough cases to warrant a vaccine?* 90 to 95% of all hepatitis B cases recover completely after 3 to 4 weeks of nausea, fatigue, headache, arthritis, jaundice and tender liver. Approximately 50% of patients who contract Hepatitis B develop no symptoms after exposure. However, the exposure ensures that they will have life-time immunity.<sup>114</sup>

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112. *Id.* at S56-S57. No effort was made to unpack any material premises to demonstrate the conclusion.

113. David FitzSimons et al., *Long-Term Efficacy of Hepatitis B Vaccine, Booster Policy, and Impact of Hepatitis B Virus Mutants*, 23 *VACCINE* 4158, 4163 (2005). See also Broderick & Jonas, *supra* note 101, at 60 (“Although HBV infection is not highly endemic in the United States, similar effects have been noted. Due to both immunization strategies and changes in risk behaviors, the annual incidence of HBV infection has declined from about 200,000 cases to 79,000 over the last decade or so. From 1986 to 2000, the rate of acute hepatitis B among children 1 to 9 years of age declined more than 80%.”).

114. *Hepatitis B*, *VACCINE TRUTH*, [http://www.vaccinetruth.org/page\\_11.htm](http://www.vaccinetruth.org/page_11.htm) (last visited July 18, 2011) (emphasis added).

If numbers can be morally freighted and the moral weight of these particular numbers is known, then one can just *see* that the recommended vaccination program is unwarranted, right? Would the number would have to be, say, 762? Fifty-four babies with these symptoms is not worth it?<sup>115</sup>

The opposing side, which soft-pedals adversities rather than life-protection, is occasionally no better formulated. According to the Centers for Disease Control:

Severe problems are extremely rare. Severe allergic reactions are believed to occur about once in 1.1 million doses. A vaccine, like any medicine, could cause a serious reaction. But the risk of a vaccine causing serious harm, or death, is extremely small. More than 100 million people have gotten hepatitis B vaccine in the United States.<sup>116</sup>

On these figures, there were over ninety severe allergic reactions. This is not enough either. Is 762 the right number when adversities are played down?

It is sometimes denied that the vaccination program even serves to reduce the incidence of hepatitis B, although it is hard to distinguish these claims from “it doesn’t reduce it (enough)” and “the program wasn’t administered very well so it failed.” The weight of authority, however, is that the programs have significantly reduced the incidence of hepatitis B—although there are no magic moral numbers here either—and some emphasize factors other than the vaccine to account for the low incidence of the infection.<sup>117</sup>

One might argue that the highest risk behaviors—drug use and sex—are simply not pursued by the younger school age children. There are some ready responses to this. First, even if few of the younger children pursue illicit conduct, those few should be protected, particularly since they are generally judged to be below the age of fully responsible behavior. In any case, getting hepatitis B is

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115. Note that vaccinating babies is a way of reducing the risks of contracting hepatitis B in later childhood or in adulthood. See Mast, *supra* note 4. See also Ctrs. for Disease Control & Prevention, *Recommendations of the Immunization Practices Advisory Committee Prevention of Perinatal Transmission of Hepatitis B Virus: Prenatal Screening of all Pregnant Women for Hepatitis B Surface Antigen*, 37 MORBIDITY & MORTALITY WKLY. REP. 341 (1988) available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000036.htm>.

116. *Hepatitis B Vaccine: What You Need To Know*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/vaccines/pubs/vis/downloads/vis-hep-b.pdf> (last visited July 18, 2011).

117. See F. Edward Yazbak, *The Hepatitis B Vaccine: What Went Wrong?*, VACCINATION NEWS, available at <http://www.vaccinationnews.com/node/19957> (last visited July 15, 2011). But see R. S. Koff, *Review Article: Vaccination And Viral Hepatitis – Current Status And Future Prospects*, 26 ALIMENTARY PHARMACOLOGY & THERAPEUTICS, 1285, 1289 (2007) (“By 2005, a 98% decline in HBV infection was reported for children 13 years of age or younger since 1990 and a 97% decline among adolescents aged 12–19 years, a result of the national programme of childhood immunization. The decline in hepatitis B among adults was less striking at 76%. Sexual transmission and injection drug use remained important risk factors in this group.”).

disproportionate to whatever responsibility they bear. Second, there is a risk of horizontal transmission from students—including older students—who do contract hepatitis B, from whatever source. Third, once acute, a patient is at significant risk for developing chronic hepatitis B, which, though treatable, remains a serious condition.<sup>118</sup>

In pursuing her questions about whether the hepatitis B vaccine is, in fact and in value, needed, Professor Holland invokes the experience of some Scandinavian countries having a low incidence of hepatitis B.<sup>119</sup> In Denmark, for example:

The report concluded that the effect of introducing hepatitis B vaccine into the childhood vaccination programme would begin to manifest itself in 15-20 years. After 40-50 years the immunisation programme would save an estimated 10 lives per year as a result of fewer cases of chronic liver disease. In the short term, a universal vaccination programme would mean that targeted vaccination children [sic] in daycare centres where there are children with chronic hepatitis B would be unnecessary, and children in the daycare centres with chronic hepatitis B would run a smaller risk of stigmatisation. The net costs would be substantial if hepatitis B was to be implemented as a stand alone vaccine. On the basis of the conclusions from the medical technology assessment report, the National Board of Health has recommended that hepatitis B is not introduced into the childhood vaccination programme, and has instead suggested optimising the current risk group vaccination strategy [....]<sup>120</sup>

Some points to consider: First, the carrier rate of hepatitis B surface antigen A is higher in the United States than in Denmark. This may suggest a stronger need for a given vaccination program. The Danish experience may be instructive, but is not decisive for the United States. Second, why is saving ten lives over a half century not worth the effort—or is that not what was meant in the Danish report and in the Cowan article? What *is* the effort? Does the conclusion presuppose that we are to assess the program via a *simple* cost-benefit analysis, in

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118. Broderick & Jonas, *supra* note 101, at 61 (“Children not infected at birth remain at risk from infected household and community contacts, especially in subpopulations in which HBV infection is prevalent. This is called horizontal transmission. The exact mechanisms are unknown, but transmission by shared toiletry items, such as toothbrushes, and even by activities such as sharing chewing gum has been postulated. Transmission by sexual contact and shared injection drug equipment represents risk factors for adolescents as well as adults.”) Also, “Infants who acquire HBV perinatally have up to 90% risk of developing chronic HBV infection.” *Id.* at 59.

119. Holland, *supra* note 5, at 72.

120. Susan A Cowan, *Denmark Decides Not To Introduce Hepatitis B into the Childhood Vaccination Programme*, 10 EURO SURVEILLANCE 2827 (2005). This article also stressed that much of the increased incidence was attributable to immigrants.



which harms and benefits are monetized? If so, this presupposition requires a fuller articulation and defense. To some extent, public policy operates within a cost-benefit framework, but often it does not, at least in the usual senses of that concept. Most parents do not cost out the expected value of a child when deciding to use all their resources to fund an organ transplant. Third, the Danish policy was not based on the probability and gravity of adverse effects, but on cost per life saved.<sup>121</sup> This is not a sufficiently complete way of assessing a policy's advantages and disadvantages. Fourth, hepatitis B vaccine policies do not pretend to be pitched on saving enormous numbers of lives that would be snuffed out by liver disease. It does save lives, but for each death, there are many more cases of illness and dysfunctionality; no one aspires to contract this disorder. Assessing the number of deaths prevented is focusing on a relevant variable, but far from the only one; *morbidity* is a central issue in formulating a rational hepatitis B policy.

Moving north in Scandinavia, Sweden's policy, as described in an article (somewhat dated) cited by Professor Holland, states:

Northern and Western Europe are low-prevalence areas for hepatitis B, with HBsAg [hepatitis B surface antigen, indicating infection]<sup>122</sup> carriage rates below 0.05%. [Some regions are at 20%.] Even among low-prevalence areas, however, great differences are seen. In Scandinavia, carrier rates are approximately 0.05% as compared with France, for instance, which has a carrier rate of approximately 0.5%. [The U.S. carrier rate is reported in at least one source to be 0.27%.]<sup>123</sup> .... The limited spread of the hepatitis B virus in Scandinavia can be demonstrated by the low number of officially reported acute hepatitis B cases occurring annually in Sweden. Despite the low number of reported acute cases of hepatitis B, a substantial number of Sweden's immigrant population is HbsAg positive. These carriers, however, do not seem to have a major impact on the number of acute hepatitis B cases in Sweden. Over the past ten years increasing numbers of immigrants have entered the country, but acute cases of hepatitis B continue to be seen mainly among drug addicts and their contacts and to a certain extent, among male homosexuals with multiple partners.

Countries in Scandinavia have chosen not to introduce universal infant immunization against hepatitis B because the problem is

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121. *Id.*

122. See Mast, *supra* note 4.

123. Annemarie Wasley et al., *The Prevalence Of Hepatitis B Virus Infection in the United States in the Era of Vaccination*, 202 J. INFECTIOUS DISEASES 192 (2010). ("During the period 1999-2006, age-adjusted prevalences of anti-HBc (4.7%) and HBsAg (0.27%) were not statistically different from what they were during 1988-1994 (5.4% and 0.38%, respectively).").

considered to be a very limited one. In the case of Sweden, *vaccinating over 100,000 children annually to avoid 200 acute cases per year (mainly in drug addicts) is not considered logical from a public health standpoint.*<sup>124</sup>

Without specifying other premises, including certain assumptions about what social preferences are in place, there is nothing “illogical” or irrational about vaccinating one hundred thousand children to prevent two hundred cases of a serious disorder—at least until we know what the criteria of “illogicality” are in this context. Which moral metric tells us that it is not worth it to do X to get Y? Comparison of the monetary valuation of bodily intrusions to lives and health? Which opportunity costs (the costs of foregone benefits) are at stake? If the Swedish approach to the logic (or illogic) of public health is part of the foundation for working out a rational American vaccination policy, this should be disclosed and explained more clearly. Cost-benefit analytics may be powerful tools of public policy, but, as they are usually pursued, such metrics are not always decisive—neither in fact or as a matter of value analysis.<sup>125</sup> Why, for example, do we have an orphan disease research policy in the United States? If a dollar spent on disease X would save one life and a dollar spend on disease Y would save one hundred lives . . . the drill here is obvious. Perhaps the policy is ill-considered, but we have it, and it is partly based on close assessments of the seriousness, as well as the incidence, of the disorder.<sup>126</sup> Consideration of opportunity costs looms large here.

To be sure, to say that in some cases we do not use cost-benefit analysis is not to deny that we consider advantages and disadvantages. The former process is often a more particularized and quantified version of the process of comparing advantages and disadvantages.<sup>127</sup> This cluster of issues concerning the moral aspects of harm and benefit analysis seem insufficiently addressed in any of the accounts about Scandinavian practice cited in Professor Holland’s Article or this Reply. This is not made up for in other ways in the Article.

Moreover, there is a rather obvious subtext, although I make no claims about

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124. Iwarson, *supra* note 111, at S56-S57 (emphasis added).

125. See generally Steven Kelman, *Cost-Benefit Analysis: An Ethical Critique*, in FOUNDATIONS OF ENVIRONMENTAL LAW AND POLICY 93 (Richard L. Revesz ed., 1997).

126. Orphan Drug Act of 1983, Pub. L. No. 97-414, 96 Stat. 2049 (codified as amended in scattered sections of 15 U.S.C., 21 U.S.C., 26 U.S.C., 35 U.S.C., & 42 U.S.C.).

127. Even this general remark may be controversial. Definitions of “cost benefit analysis” are varied. For example: “The quantification of the total social costs and benefits of a policy or a project, usually in money terms.” John Black et al., *Cost-Benefit Analysis*, OXFORD REFERENCE ONLINE, <http://www.oxfordreference.com/views/ENTRY.html?subview=Main&entry=t19.e611> (last visited Oct. 12, 2011). This formulation is consistent both with a quantification-only approach and a more general comparison of advantages and disadvantages. The latter formulation, however, may expand the meaning of the term beyond its more technical uses.

what motivates public policy in Scandinavia or anywhere else. The quoted article emphasizes the role of immigrants, gay persons, and addicts in maintaining the incidence hepatitis B. Its reference to “vaccinating over 100,000 children annually to avoid 200 acute cases per year (*mainly in drug addicts*)” (emphasis added) offers a rather pointed suggestion about values that affect vaccination policy. One might add that some children do grow up to be drug addicts, so why protect them from the inevitable? (I am not at all ascribing this view to Professor Holland.)

The hepatitis B literature does contain some indirect critiques of the Scandinavian policy.

Although the proportion of young children infected by HBV in countries with low endemicity is small, this population largely contributes to HBV morbidity and transmission because of more frequent progression to chronic carriage when HBV is contracted early in childhood. Therefore, only newborn/infant universal vaccination could lead to efficient prevention of chronic carrier state and finally elimination of the disease. Of particular importance for countries with low endemicity is the element of HBV import through migration of HBV chronic carriers born in regions with high HBV endemicity, subsequently spreading HBV infection. As population movements increase, for example mobility into Europe, control of infectious diseases needs to be supported by appropriate strategies, such as infant immunization programs.<sup>128</sup>

Of course, the need for a particular vaccination program rests on the efficacy of the vaccination as well as the gravity and epidemiology of the disease. (It also rests on the adequacy of the administrative set up of the program.) The scientific sources indicate fairly clearly the substantial effectiveness and a long period during which boosters are not required; no one claims perfection.<sup>129</sup>

Finally, here is a note on thimerosal. This is vaccine preservative containing mercury, and it is being phased out of use. Whatever harms it causes are not intrinsic to hepatitis B vaccine. Whether it causes harms is contested, but I do not think that the studies suggesting risk can be ignored.<sup>130</sup> I note particularly the

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128. Van Herck & Van Damme, *supra* note 90, at 865-866.

129. *See supra* note 91; *see also* Fitz Simons et al., *supra* note 113, at 4159 (“Each new study extends the known duration of efficacy of hepatitis B immunisation; several published reports document long-term efficacy lasting for 15 years and other studies will probably push this figure up to 20 years and longer.”). The vaccine, however, is not one hundred percent effective. *See, e.g.,* Chuanfang Lee et al., *Research Effect of Hepatitis B Immunisation in Newborn Infants of Mothers Positive for Hepatitis B Surface Antigen: Systematic Review And Meta-Analysis*, 332 BRIT. MED. J. 328, 335 (2006) (“Repeated vaccination over months is required to mount an effective antibody response.”).

130. Carolyn Gallagher & Melody Goodman, *Hepatitis B Triple Series Vaccine and*

quoted remarks by Geier, Geier & Zahalsky, attributing some autoimmune adversities to thimerosal additives in hepatitis B vaccines.

For future reference, here are other matters to consider: Suppose the law (federal or non-preempted state law, if any) prohibited the use of a vaccine, and that the enactment was based solely or primarily on adverse event reports and some rare but serious harms concededly caused by the vaccine itself. What then? Could the hepatitis B vaccine properly be banned? Although important, I will not discuss such issues here, except to say that for every right-against-X, one could (in theory) mount a right-to-X claim.

*D. Education and Vaccination: A Note on the “Punishment” of Children and Piggybacking Public Health Measures onto Government Functions*

Although the Article’s title stresses vaccination of pre-school children, there is an implicit criticism of the use of compulsory schooling programs as a hook to latch onto children in order to vaccinate them. Professor Holland, for example, notes critically, that “[s]ome commentators reject the view that there must be a close nexus between school and vaccination to warrant a state mandate.”<sup>131</sup> The result of this improper piggybacking is thought to work an injustice to the child excluded for lack of a required vaccination. Professor Holland states: “Punishments include loss of education, social isolation, parents’ loss of custodial rights, child neglect sanctions against parents, and even forced vaccination.”<sup>132</sup> Here, the term “punishment” is tendentiously pejorative—a weak

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*Developmental Disability in US Children Aged 1-9 Years*, 90 TOXICOLOGICAL & ENVTL. CHEMISTRY 997, 997 (2008) (“This study found statistically significant evidence to suggest that boys in United States who were vaccinated with the triple series Hepatitis B vaccine, during the time period in which vaccines were manufactured with thimerosal, were more susceptible to developmental disability than were unvaccinated boys.”). Different forms of mercury compound may pose different risks. In any case, the Public Health Service in 1999 urged manufacturers to reduce or eliminate the preservative, and “[m]uch progress has been made to date in removing or reducing thimerosal in vaccines. New pediatric formulations of hepatitis B vaccines have been licensed by the FDA, Recombivax-HB (Merck, thimerosal free) in August 1999 and Engerix-B (Glaxo SmithKline, thimerosal free) in January 2007.” *Thimerosal in Vaccines*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228#tox> (last updated Mar. 31, 2010). But note that not all researchers concur on the thimerosal risk. See Osman David Mansoor & Peter Salama, *Should Hepatitis B Vaccine Be Used for Infants?*, 6 EXPERT REV. VACCINES 29 (2007) (“Concerns have been raised regarding the mercury preservative in vaccines leading to potential toxicity. But the evidence to date does not support any association of hepatitis B vaccine with serious adverse consequences. Protecting infants through immunization is the most effective control strategy. By 2005, over 80% of countries had implemented routine infant immunization. In countries with relatively low rates of hepatitis B virus infection, some have argued to defer immunization until later life. However, these arguments focus on the more visible acute infection. *The possible future cost from a single infant infection argues for universal infant hepatitis B immunization—given the very high costs of treating its consequences (e.g., liver transplant) and the very low price of the vaccine.*” (emphasis added)).

131. Holland, *supra* note 5, at 51.

132. *Id.* at 15.

rhetorical device complaining about school exclusion; the fact that it is a disadvantage not to be schooled does not render it a “punishment,” and the exclusion, if adequately justified, is preferable under the circumstances to inclusion. The so-called punishment is a mechanism to protect the student’s health and educational potential.

Although the argument is not explicit, the embedded view that schools should not be used as a device to implement vaccination requires some comment. One cannot assess the situation by focusing on any given student. The vaccination system is workable only in the large.<sup>133</sup> What is needed, then, is attention to the possible consequences of not having a vaccination program: there will be more students unable to study because of illness, however contracted. It is possible, of course, that a given school vaccination program is not justified. A smallpox vaccination program would not now be in order. But the lack of justification for any given program cannot rest on the considerations presented in this passage. The social isolation is not for nothing. As for more drastic measures, such as sanctions for neglect—there is not just one tray in the scale.

This view that compulsory school attendance programs can be used to further goals other than education is common, although one could not properly argue that schools are a kind of medium into which anything can be poured. (The goal—e.g., preventing sickness—is not always “other than education”: it is hard to educate sick students.) But we have long used schools for more than standard educational purposes. (Don’t ask me to list the purposes—many are sharply contested. For example, we also rely on schools to develop professional cadres of athletes and soldiers: think athletic teams, ROTC, and the armed services academies.) There is nothing illogical, contradictory, or otherwise irrational about this *in general*. Using the educational system as a device to insure at least one good meal a day for students is controversial and not well implemented, but it does not *necessarily* contradict educational goals, and may promote them. This is why education is (at least) a two-way deal: the supposedly peripheral objectives (promoting student health and well-being via vaccination, food

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133. As to this last point, which contrasts the individual rationality and collective rationality frameworks, see James G. Hodge, Jr. & Lawrence O. Gostin, *School Vaccination Requirements: Historical, Social, and Legal Perspectives*, 90 KY. L.J. 831, 876-877 (2002). (“[P]erceptions differ sharply depending on whether the risk of vaccination is viewed from an individualistic or societal perspective. From the perspective of a single child, there may be greater risk if she is vaccinated than if she remains unvaccinated. For example, during the past two decades, the only cases of polio reported in the United States are caused by the vaccine; an unvaccinated child’s risk of contracting wild polio virus is very small. State-imposed vaccination should be understood in this light. The state is explicitly asking parents to forego their right to decide the welfare of their children not necessarily for the child’s benefit but for the wider public good. From a societal perspective, the choice not to immunize may be optimal to the individual if there is herd immunity, but in the aggregate, this choice could lead to failure of that herd immunity. Affording individuals the right of informed consent to vaccination, then, may not be for the greatest good of the community. Rather, informed consent can contribute to a ‘tragedy of the commons’ if too many people make the decision not to immunize.”).

programs, etc.) not only enhance education, but may make it possible in the first place for some students. The Article's objections implicate serious disputes between competing political philosophies. From some of those moral and political vantage points, it is wrong for the state to displace parental or private responsibility generally.<sup>134</sup> Some of these objections are also informed by a more general opposition to paternalism in various forms, although the subject is not directly addressed in the Article. But these premises are not fully articulated or defended.

Piggybacking vaccination and other public health measures onto the educational system is meant to serve several overlapping (and usually nonconflicting) purposes: to further educational goals, to protect the children themselves (this includes both unvaccinated and vaccinated children—immunity is rarely complete),<sup>135</sup> and to promote public health *generally*. Using the school is simply one way to get at certain members of the public—children—who happen to be in particular places at particular times, thus ameliorating a serious logistical problem. There is no *inherent* policy or constitutional problem with this. Vaccinating the entire population outside any independent programs that gathers them together in groups would be hugely inefficient and possibly ineffective. As a byproduct rather than a primary goal, such programs may also reinforce notions of community responsibility by selective overriding of personal autonomy in certain matters. On the other hand, they may also erode the lofty normative status of autonomy. Impairing autonomy (in one way) in order to promote it (in another way) is a two-edged blade, bearing mixed social learning messages. Much depends on the conditions of public perception and debate. To be sure, public health is furthered by measures not linked to schools, and has improved significantly for reasons not limited to successful vaccination programs. But this does not damage the case for compulsory school vaccination.

Leaving aside the religious issues (which I do not cover here), does the combinatorial aspect of these functions—education and public health—raise federal constitutional issues? I denied this earlier. A standard form of individual rights claim is that the right is impaired and heightened scrutiny triggered when certain conditions are imposed on their exercise.

For example, suppose “The State of Anomie hereby establishes the Agency for Promoting Safety in Extreme Sports. No one who has ever had an abortion or performed, assisted, procured, aided, abetted, or encouraged an abortion need apply.” I assume for the sake of argument that there is no fundamental right or liberty interest in a particular job, trade or profession (leave aside procedural due

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134. For example, *Jesse Helms*, ANSWERS.COM, <http://www.answers.com/topic/jesse-helms> (last visited July 18, 2011) (“He believed it was the role of the private individual to help others, as he and his wife, Dorothy Helms, had done by adopting a nine-year-old orphan with cerebral palsy. In Congress he voted against federal aid to disabled people and against school lunch programs.”).

135. See *infra* note 209.

process issues) or even in having a job. But canceling a job prospect as a sanction for having or performing an abortion is clearly an undue burden on a woman's rights under *Casey*. Similarly, if delivering a speech in a public forum is a fundamental right (subject to reasonable time, place and manner rules), it cannot be conditioned on paying prohibitive fees in advance.<sup>136</sup>

One might, then, argue that the interest in attending school is compromised by requiring vaccination. This will not work for various reasons. For better or worse, there is no fundamental right to education as such.<sup>137</sup> Moreover, if there is no independent constitutional infirmity in compelled vaccination, then conditioning school admittance on compliance is not itself unconstitutional.

### *E. Jacobson 2.1 Applied: the Pinpoint Issues*

#### *1. Some Assumptions*

We are now in a position to work on some related reconstructions of *Jacobson*. I try to make the questions relatively precise, but the varying doctrinal possibilities and sharply different social situations make this difficult.

I start with a brief but instructive (if hard to penetrate) remark about comparing medical and epidemiological situations in different places: "Mandatory immunization may not be needed or appropriate for all societies, particularly those with health care systems that cover the entire population and stress prevention."<sup>138</sup>

There is of course some irony here. Many vaccination opponents are inspired by the same autonomy concerns that stir opposition to government-regulated health care systems, but it is precisely the latter systems in which there seems to be a lesser need for compulsory vaccination because most persons get vaccinated, more or less voluntarily, through the existing health care establishment.<sup>139</sup>

136. *Forsyth Cnty. v. Nationalist Movement*, 505 U.S. 123 (1992).

137. *San Antonio Sch. Dist. v. Rodriguez*, 411 U.S. 1 (1973); see also *Viemeister v. White*, 72 N.E. 97 (N.Y. 1904) (decided under the New York constitution and cited in *Jacobson*).

138. Walter A. Orenstein & Alan R. Hinman, *The Immunization System in the United States-The Role Of School Immunization Laws*, 17 VACCINE S19, S23 (1999).

139. Gail Horlick et al., *Delivering New Vaccines to Adolescents: The Role of School-Entry Laws*, 121 PEDIATRICS S79, S81 (2008) ("Many countries around the world rely on other factors rather than law to increase vaccination coverage. For example, the United Kingdom relies on the individual's sense of responsibility to society to seek vaccination. However, comparisons between the United States and other countries have been complicated by differences in cultural context; what works in one society may not work in another. The United States has a historical tradition of individualism and freedom from government influence. Also, immunization programs in the United States and the United Kingdom differ in some key respects, which may impact implementation of new vaccines; for example, in the United Kingdom, vaccines are available at no charge." (footnotes omitted)); see also Cowan, *supra* note 120 ("In the Scandinavian countries, as well as in the Netherlands and the UK, Universal childhood vaccination has not been implemented because the incidence of the infection in the general population is very low."). It is not clear whether the low incidence is the result of the health care system, other factors, or some combination of these causes.

Most argument structures in constitutional law are not so rigid that major differences in situation cannot yield different outcomes. Suppose the hepatitis B situation in Scandinavian nations or the United Kingdom prevailed in the United States. This is, of course, a quite heroic supposition, because the “situation” in the United States might include sharp differences in social and legal values as well as in disease demographics. In any event, the American constitutional argument framework would still be applied to this limited Scandinavia-to-America social and medical transplant, but it might play out very differently. For example, the analysis of tradition might, on the one hand, reveal lesser concern for individuality across wide swaths of behavior, but greater concern in discrete fields such as vaccination. Europe, considered by many to be a lesser bastion of rigorous individuality than America, arguably has, in some locales, a greater tradition of voluntariness in vaccination. Traditions, depending on how described, differ from region to region.

But this is getting a bit ahead of the game. Assume that the U.S. Supreme Court says that a right to refuse vaccination is a serious liberty interest that instantiates an overarching right to personal security. Assume also that this right comprehends the integrity of body, mind and identity, but draws mid-level scrutiny.

There are many ways to pursue and describe the next series of analytic steps, and I avoid further comment on whether “balancing,” “proportionality” and “fairness” are (in this context) extensionally equivalent. We would proceed *roughly* as the Supreme Court did in working out the logic of liberty interests in *Cruzan*, *Romeo*, *Casey*, *Harper*, and *Lawrence*. All these cases, rightly mentioned by Professor Holland, involved some form of “liberty of the person,”<sup>140</sup> so designated, and drew on nontrivial standards of review (not always designated), all derived from the due process clause of the Fourteenth Amendment. So we can discuss these cases as a doctrinal set and use them to analyze the constitutional properties of compulsory vaccination.

To overcome the presumption favoring a person’s exercise of a given right against vaccination, the government can offer the justifications of promoting the health of children, adults, and society, and of reinforcing certain communitarian norms. In turn, such value reinforcement may feed back into promoting right actions and good results. (Normative systems are not simply dangling

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The author states: “During the past 10 years, the number of notified cases infected through injecting drug use (IDU) has declined. It is not known if this decline is due to vaccination among IDUs or to the success of needle exchange programmes. Although heterosexual transmission has remained low, it is now the leading route of infection. . . . Prevalence studies in Denmark over the past 20 years have shown a decline in the prevalence of HBsAg carriers from 0.15 % to 0.03 % in the indigenous population. During the same period there has been a considerable influx of people from high endemic countries. Studies of HBsAg prevalence in immigrants to Denmark in 1998 and 2002 have demonstrated a prevalence of 0.6% among children and 2.6% among pregnant women.” *Id.*

140. *E.g.*, *Lawrence v. Texas*, 539 U.S. 558, 562 (2003) (protecting sexual practice liberties).



abstractions; they inform and often govern behavior in massive ways.)

This is not the place to write an entire hypothetical opinion, so I jump to the nub of the next stage of analysis. Here are the primary points that drive the constitutional argument in this not-so-imaginary *Jacobson 2.1*:

First, vaccinations work for hepatitis B and many other disorders, but they are not *perfectly* effective.

Second, vaccination is not a walk in the park: they all pose a risk of adverse effects, from trivial (quite common) to fatal (extremely rare).

Third, the scientific literature supports a causal connection between vaccination and adverse effects only for a small proportion of all the adverse effects that have occurred “within the curtilage” (or *res gestae*?) of vaccination. It takes far more than the bare occurrence of an adverse effect to establish causation.

Fourth, for most adverse events, the research can support a strong finding of “no causal link shown within accepted templates for causal analysis, therefore no rational reason to believe it for any given case.”

Fifth, unless well-confirmed science forecloses a causal association, a “no cause shown” conclusion does not yield “causation is excluded; there is not and cannot be any causal link.” If in fact some vaccination caused a single case of autism because of a one-in-billion vulnerability, no research study yet designed would be able to discern this (absent specific scientific causal path discoveries).<sup>141</sup> Although it would be an interesting exercise to imagine a clinical study capable of confirming such causation, I leave this to quantitative empiricists.

Sixth, many persons do not have a realistic understanding of the meaning of probability and assign greater danger or disvalue to highly improbable outcomes than is warranted. This seems to be consistent with general human predispositions toward certain forms of cognitive error (some of which may be “wired in” through evolutionary adaptation).<sup>142</sup>

Seventh, the impact of specific events (even when reported anecdotally)—especially when in one’s face—can be enormous. This has advantages (it rationally spurs investigation) and disadvantages (we are prone to make causal attribution errors).<sup>143</sup>

Eighth, the pressing need for social protection for any given disorder varies

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141. There is apparently some evidence that *preexisting* autism is a predisposing factor for adverse vaccine reactions. Maria Dorota Majewska et al., *Age-Dependent Lower or Higher Levels of Hair Mercury in Autistic Children than in Healthy Controls*, 70 ACTA NEUROBIOL. EXP. (Pol.) 196 (2010). So far, the only example of serious caused adversity for hepatitis B vaccine seems to be anaphylactic shock, but here, biomedical specialists need to be consulted; I haven’t run across anything else shown.

142. See generally 2 HANDBOOK OF SOCIAL PSYCHOLOGY 763 (Susan T. Fiske et al. eds., 5th ed., 2010).

143. See *supra* note 94 and accompanying text.

over time and place. The conditions that drive smallpox and polio are now totally different: there is no smallpox. Yet, although the incidence of polio is low (though variable), polio could re-emerge at any time if vaccination programs are not continued.<sup>144</sup>

## 2. *The Vaccination-Resister's Claims*

So, here I stand, the resister: I'm risk averse, and *very* risk averse when it comes to my kids. I say where there's smoke, there's fire. I'm also more averse to what might be immediate (vaccination injury) rather than remote and unlikely (getting hepatitis B). You tell me that my reasoning is skewed, that I am overawed by mere salience, and I tell you that the exercise of important rights does not rest on the rationality of my decision, and anyway I don't think it's irrational. Rationality is normatively ambiguous. If I am unwilling to take a one in a million chance of anaphylactic shock (*scientifically confirmed*), it's my right to refuse, *either* for myself *or* my child. I think that "no cause shown between X and Y" doesn't mean "it has been shown that X *doesn't* cause Y," and that the bare possibility (*not refuted*) that the vaccine causes autism or MS is enough to justify refusing the vaccination. Still more, I don't care if there is some social benefit: I am not a mere means to an end and don't want to be injected with or forced to otherwise ingest something I don't want in my body, possibly impinging on my mind. In constitutional terms, here are my pinpoint claims ("pinpoint" compared to other formulations):

I invoke my liberty interest (including parental liberty interest in child raising)<sup>145</sup> to follow my preference to avoid risk. I concede that I am overawed by anecdote, but hey, that's me, and I *know* that I'm right, and Kahneman & Tversky<sup>146</sup> and their ilk are rightly ignorable. Yes, I am aware that my personal security and dignity interests and those of my family can be compared with and weighed against social interests, but those interests don't outweigh my claim. Why should I take a chance of fatal

144. Horlick et al., *supra* note 139, at S79; *see supra* note 139.

145. *See* *Troxel v. Granville*, 530 U.S. 57, 65 (2000) (recognizing a liberty interest in making decisions about the care, custody and control of one's children) (plurality opinion). As mentioned, the Court obviously used a form of heightened scrutiny, but did not say where it fell within the available range of standards. Somewhat confusingly, the Court spoke both of liberty interests and fundamental rights, referring to the "fundamental right to make decisions concerning the rearing of her two daughters." *Id.* at 68.

146. I'm referring here to the now vast literature on human proneness to cognitive error. *See, e.g.*, RICHARD NISBETT & LEE ROSS, *HUMAN INFERENCE: STRATEGIES AND SHORTCOMINGS OF SOCIAL JUDGMENT* (1980); Amos Tversky & Daniel Kahneman, *The Framing of Decisions and the Psychology of Choice*, 211 *SCIENCE* 453 (1981).

anaphylactic shock in order to prevent a disease that is generally nonfatal and treatable, and, in the United States, has an incidence far lower than what prevails in high endemic areas.

For that matter, why should I take a very high risk that I or my child will suffer even mild, transient fever and malaise under these non-urgent conditions?

And just in case you think, foolishly, that the risk of adverse effects is functionally zero (Who gets hit with the one-in-million catastrophe? Barely one in a million!), I say this: I invoke my liberty interest to maintain the integrity of my person whether there is danger or not. Even if the medical risk is zero, even if there is no psychological apprehension on anyone's part (and even if they experience positive pleasure from the needle stick), I don't want my body invaded by anything I don't want in me, whether this preference is idiotic or not. If I'm competent, I'm free to be irrational in that way, assuming it's irrational, which it isn't. (Don't ask me why it makes a difference whether I'm competent if I'm free to be as irrational as I want when competent.)

Yes, I understand that although the risk to me or mine may be zero, asserting my rights entails that certain risks are run by others (although I don't think those risk are that serious). Why are their preferences to be preferred to mine when mine are directly and immediately under threat? *Maybe* others will come down with something. But it's *certain* I'll get stuck or have to pay for it if I continue to refuse. Where rights are at stake, you can't just count up and compare utiles and declare that I don't have enough of them. As Nozick said, "Individuals have rights, and there are things no person or group may do to them (without violating their rights). So strong and far-reaching are these rights that they raise the question of what, if anything, the state and its officials may do."<sup>147</sup> So I don't owe nothin' to nobody—at least most of the time. I concede that if there is an overwhelming risk of really bad things going down—like one of those alien infections that perennially afflict *The Enterprise* and really mess everyone up—that forcing me to comply would be both morally and constitutionally justifiable. But that's not true with hepatitis B. Whether it's true for any disease going around, I don't have to say.

Finally, I don't even believe a lot of the claims about vaccine safety, efficacy, disease incidence, and disease treatment. The

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147. ROBERT NOZICK, *ANARCHY, STATE, AND UTOPIA* IX (1974).

people making these claims are operating under a conflict of interest: they want money. So, in many senses, I have a “divergent risk perception[,]” and a “different [and nondelusional!] perception of reality”<sup>148</sup> compared to the mainstream.

One more thing. You can’t put a definitional stop on me by saying that my choices are stupid or insufficiently reflective and therefore violate some definitional rationality constraint on autonomy, and so I and my choices are not autonomous.<sup>149</sup> I don’t see autonomy that way, but I’m not just claiming an autonomy right (bearing possible conceptual limitations)—I’m claiming a *liberty* right. I say I’m perfectly rational, but I don’t have to make sense to you. Even if my decisions don’t satisfy your (restricted) notions of “autonomous choice,” they are within my constitutional liberty interests.

As a general matter, this set of claims is too broad to be sustained within current doctrine, although I would guess there is no shortage of persons who would support them. Buthow are courts to address this array of entangled empirical and value questions (including value questions associated with both risk and uncertainty)<sup>150</sup> under any given standard of review?

### 3. *How Far To Go Within a Standard of Review*

#### a. *In General: Craig v. Boren*

I start with an example that is far afield in subject matter, but not in constitutional relevance. In *Craig v. Boren*,<sup>151</sup> the Court invalidated a law that prohibited sales of 3.2% beer to males under age 21, but allowed sales to females 18 or over. Persons from 18 through 20 were thus treated differently because of their gender. *Craig* was the first case formally to apply intermediate scrutiny to gender-based classifications.<sup>152</sup> The standard was that “classifications by gender

148. Lotte Asveld, *Mass-Vaccination Programmes and the Value of Respect for Autonomy*, 22 *BIOETHICS* 245, 253 (2008).

149. *Id.* at 248 (“Internal autonomy or positive freedom as such involves reflection on one’s actions, the outcome of which effectively determines those actions. When one acts on a whim, this is not an autonomous action.”). There seems to be a normative/conceptual rationality plank to autonomy, but the point may go too far.

150. “Risk” refers to measurable probabilities of defined harms, and “uncertainty” applies when we cannot calculate the probabilities (and possibly when we cannot even tell if an outcome would be a harm or a benefit). See generally FRANK H. KNIGHT, *RISK, UNCERTAINTY, AND PROFIT*, at ix (Signalman Publishing 2009) (1921).

151. *Craig v. Boren*, 429 U.S. 190 (1976) (invalidating gender-based age requirements for purchasing 3.2% beer).

152. *Craig* was preceded by (for example), *Reed v. Reed*, 404 U.S. 71 (1971), which applied heightened, but non-strict, scrutiny to gender-based rules governing appointment of administrators

must serve important governmental objectives and must be substantially related to achievement of those objectives.”<sup>153</sup>

What was the point of the government’s gender classification? Was it to put down adolescent males and glorify the traditional image of female innocence? The main rationale—not well explained by Oklahoma—was to save lives and protect against injury to persons and property. The bare outline of the state’s reasoning was simple—and clumsy: ingesting alcohol leads to driver impairment, which leads to more vehicle crashes, which in turn leads to more injuries and damages, which leads to more deaths. Preventing death and injury seem compelling, not just important, to invoke a freighted term from strict scrutiny.

In using its review standard, the Court did not second-guess the legislature’s implicit view of the moral value of saving life or ask when life might properly be sacrificed for the greater good. As Justice Powell said in his concurrence, “No one questions the legitimacy or importance of the asserted governmental objective: the promotion of highway safety. The decision of the case turns on whether the state legislature, by the classification it has chosen, had adopted a means that bears a “fair and substantial relation” to this objective.”<sup>154</sup>

Of course, the Court was not confronted by some clear and present risk of death, whether to specific persons or “statistical” ones. Still, death and injury were at stake. Yet the Court did not stress the prospect of death and injury despite the obvious accident risks. It glossed over the government’s probable purpose, focusing instead on reviewing the “legislative facts”:

We accept for purposes of discussion the District Court’s identification of the objective underlying [the law at issue] as the enhancement of traffic safety. Clearly, the protection of public health and safety represents an important function of state and local governments. However, appellees’ statistics in our view cannot support the conclusion that the gender-based distinction closely serves to achieve that objective and therefore the distinction cannot under *Reed* withstand equal protection challenge.<sup>155</sup>

The Court attacked the means chosen to implement this goal—a gender classification based on taking arrests as gender-differentiated proxies for

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of decedents’ estates. The Court described its task as determining whether a gender classification “bears a rational relationship to a state objective that is sought to be advanced.” *Id.* at 76.

153. *Craig*, 429 U.S. at 197.

154. *Id.* at 211 (Powell, J., concurring).

155. *Id.* at 200 (majority opinion). The Court found the issue of actual purpose to be slippery, and such problems may arise more pointedly in other cases. By “legislative facts,” I mean the general empirical findings that (supposedly) underlie a legislative action. See Kenneth L. Karst, *Legislative Facts in Constitutional Litigation*, 75 S. CT. REV. 75 (1960) (defining and distinguishing the overlapping categories of legislative and adjudicative facts).

dangerousness. The Court attacked the very quality of the data presenting these comparative arrest records. It was that the arrest count itself was thought to be wrong (although it could have been); it was that biases might have affected the very decision to arrest one person as opposed to another, based on gender. The differing arrest rates of males and females might have been partly attributable to such biases. Thus, inferences about comparative dangerousness drawn from the differential arrest of boys and girls are likely to have been flawed. On this view, we cannot view the higher arrest rate for males as signaling that they are, as drivers, more dangerous than females. Of course, not everyone who drives under the influence is arrested, so the arrest rates may understate whatever danger there is, but this does not affect the overall analysis on either side. As Justice Brennan put it (in a footnote, oddly enough, considering the importance of the point): “The very social stereotypes that find reflection in age-differential laws... are likely substantially to distort the accuracy of these comparative statistics. Hence ‘reckless’ young men who drink and drive are transformed into arrest statistics, whereas their female counterparts are chivalrously escorted home.”<sup>156</sup>

How did Justice Brennan know this? Of course, he did not. He, in effect, judicially noticed the omnipresence of male (and police) stereotyping of gender behaviors and implicitly argued: “This stereotype-induced distortion is so likely that we must consider its constitutional impact—and when we do, we see that the arrest data are tainted and unreliable. Without assurance that the arrest criteria in operation were sound, the data are an uncertain basis for inferences about much of anything.” As a matter of constitutional analysis, one might well compare Justice Brennan’s critique with the conflict-of-interest “financial distortion” attack on medical/vaccination claims made by pharmaceutical companies and allied health care practitioners.<sup>157</sup> (I am not necessarily endorsing either one as a winning constitutional argument or even as sound policy.)

The Court displaced not only the legislature’s presentation of the *facts* of drunk driving arrest differentials, but its *valuation* of the significance of its “findings”:

Viewed in terms of the correlation between sex and the actual activity that Oklahoma seeks to regulate—driving while under the influence of alcohol—the statistics broadly establish that .18% of females and 2% of males in that age group were arrested for that offense. While such a disparity is not trivial in a statistical sense, it hardly can form the basis for employment of a gender line as a classifying device. Certainly if maleness is to serve as a proxy for drinking and driving, a correlation of 2% must be considered an unduly tenuous “fit.” Indeed, prior cases have consistently rejected the use of sex as a decision-making

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156. *Craig*, 429 U.S. at 202 n.14.

157. See *infra* notes 191–194 and accompanying text.

factor even though the statutes in question certainly rested on far more predictive empirical relationships than this.<sup>158</sup>

Justice Brennan grudgingly conceded that the “disparity is not trivial in a statistical sense.” Indeed, it’s an *order of magnitude* difference, as noted by then-Justice Rehnquist.<sup>159</sup> But that concession was of no moment: Justice Brennan’s attitude was, in effect, ‘order-of-magnitude, shmorder-of-magnitude: *both* figures are too low to justify impairing gender-equality interests.’ The risks and losses are acceptable in light of the need to reinforce the gender equality norm. This “acceptable losses” stance is one major crux of the vaccination dispute: at several points, the Article suggests, by way of recounting Scandinavian practices, that compulsory hepatitis B vaccinations simply are not *worth* it as far as lives saved are concerned.<sup>160</sup>

For our purposes, Justice Brennan’s key phrase is this: “Certainly if maleness is to serve as a proxy for drinking and driving, a correlation of 2% must be considered an unduly tenuous ‘fit.’”<sup>161</sup>

Consider the premises embedded within Justice Brennan’s dismissive statement. Note first what he is *not* saying. The claim that two percent of males are arrested over a given period is obviously not a claim that that specific group of males is, over a given period, involved in fatal or otherwise serious accidents. If that were the showing, and we could also show that females never caused accidents, the constitutional argument should play out quite differently. Moreover, the claim is not even that two percent represents an accident rate, with or without injury or damage. It is just arrests that are taken as an index for other rates: accidents, injuries, deaths, and property damage. What is the evidence for the link between drinking (of some sort, in some amount, with some measured

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158. *Craig*, 429 U.S. at 201-02.

159. *Id.* at 226 (Rehnquist, J., dissenting).

160. See *supra* notes 111-112 and accompanying text.

161. *Craig*, 429 U.S. at 201-02 & n.14; Justice Powell offered a similar observation, particularly stressing the lack of a ban on possession. *Id.* at 211 (Powell, J., concurring) (“It seems to me that the statistics offered by appellees and relied upon by the District Court do tend generally to support the view that young men drive more, possibly are inclined to drink more, and for various reasons are involved in more accidents than young women. Even so, I am not persuaded that these facts and the inferences fairly drawn from them justify this classification based on a three-year age differential between the sexes, and especially one that it so easily circumvented as to be virtually meaningless. Putting it differently, this gender-based classification does not bear a fair and substantial relation to the object of the legislation.”). Justice Stevens also entered the fray, complaining of the “slight benefit” of Oklahoma’s classification. *Id.* at 214 (Stevens, J., concurring) (“The legislation imposes a restraint on 100% of the males in the class allegedly because about 2% of them have probably violated one or more laws relating to the consumption of alcoholic beverages. It is unlikely that this law will have a significant deterrent effect either on that 2% or on the law-abiding 98%. But even assuming some such slight benefit, it does not seem to me that an insult to all of the young men of the State can be justified by visiting the sins of the 2% on the 98%.”). Why, exactly, isn’t burdening ninety-eight percent for the sins of the two percent justified if (some of) those sins have fatal or other serious effects?

physiological impact) and road accidents? There are reams of material on the impairment worked by alcoholic intoxication and the consequences of driving under the influence. Let us assume that this scientific showing is sound: drunk driving increases the risk and actual incidence of road wrecks. (However, this is not to concede that drinking 3.2% beer in particular has any effect on accident rates. Justice Brennan, in fact, cast doubt on this.)<sup>162</sup>

But suppose the data show a very high probability that implementing the classification will prevent some deaths or severely disabling injuries, but no more than a few. Compare this to: “Administering one million doses of vaccine *V* will prevent *only* twenty deaths.” How is this an “only”?<sup>163</sup> If we prevent just one death or crippling injury, isn’t it worth it?—even if life is not a pearl beyond price? If that were what had been starkly presented in the record, and a striking gender differential had been soundly shown, what would we say—as citizens, legislators—and constitutional judges?

Of course, it was not starkly presented in the record, and, as we saw, the Court did not go out of its way to point out that averting death and injury was the dominating goal. Of course, it did indicate that even if it were the goal, the legislature picked a very poor way to promote it. Nevertheless, whatever one might say about the legislature’s inept effort to reduce harm by restricting only one gender’s activities instead of everyone’s, *Craig* is still about the *death* of girls and boys and men and women as much as it is about gender discrimination. What costs and irritants are we willing to endure to save a life?

### *b. Judicial Review of Valuing Lives*

We are attracted to questions like this in the way we are attracted to the sight—and site—of disasters. How many lives need to be saved to justify interfering with a basic right? How would we weigh art murder against people murder? (“I will destroy the Mona Lisa unless you kill a child as a sacrifice to me.”) Isn’t the ten-to-one ratio for how many criminals are to be let go to protect an innocent person seriously skewed? This is *way* too many innocents convicted. Even one in a 100 or one thousand is too many. (Or is it way too many guilty persons let go?) Why is it permissible (even for God) to save as few as ten good people, but not fewer? And why did Abraham stop at ten, in trying to save Sodom and Gomorrah?<sup>164</sup> Why not just one? Why does even a single innocent

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162. *Id.* at 203 (majority opinion) (“None purports to measure the use and dangerousness of 3.2% beer as opposed to alcohol generally, a detail that is of particular importance since, in light of its low alcohol level, Oklahoma apparently considers the 3.2% beverage to be ‘nonintoxicating.’”) (citing OKLA. STAT., tit. 37, § 163.1 (1958)).

163. Cf. Mary F. McNaughton-Collins & Michael J. Barry, *Perspective: One Man at a Time — Resolving the PSA Controversy*, NEW ENG. J. MED. (2011) (asking “who is to decide what constitutes a “small” benefit and whether it outweighs the potential harms?”).

164. *Genesis* 18:23-32.



resident have to die because of the evil of his neighbors? Remember the Trolley Problem (saving five by switching the tracks, thus targeting one victim) and the Fat Man problem (pushing the man onto the tracks to save five)? And the problem of deciding who gets the last kidney or dialysis machine? What about letting the violinist directly attached to your kidney die in order to vindicate a major, but temporary, intrusion on your personal integrity?<sup>165</sup> Suppose that we know that media presentations about suicide cause a small number of persons to kill themselves who otherwise would not, or causes them to do so earlier, thus reducing rescue opportunities. It is pretty clear that neither a statutory or administrative ban nor an injunction or damages are permissible under current constitutional doctrine. Why not? One death is not compelling enough? (Of course, it is “only” a statistical death.)<sup>166</sup> Are causal lines too thin—too many intervening causes—so that legal restrictions on speech cannot be considered necessary to promote the government’s interests? Are less restrictive alternatives available so that necessity is again not satisfied?<sup>167</sup>

One of Justice Rehnquist’s complaints about the majority opinion in *Craig* highlights the problem of judicial review of valuing life. He said:

[T]he present equal protection challenge to this gender-based discrimination poses only the question whether the incidence of drunk driving among young men is sufficiently greater than among young women to justify differential treatment. Notwithstanding the Court’s critique of the statistical evidence, that evidence suggests clear differences between the drinking and driving habits of young men and women. Those differences are grounds enough for the State reasonably to conclude that young males pose by far the greater drunk-driving hazard, both in terms of sheer numbers and in terms of hazard on a per-driver basis. The gender-based difference in treatment in this case is therefore not irrational.<sup>168</sup>

Again, there is no direct question of the form, “Is the interest in avoiding gender classification so strong that we cannot prevent the  $x$  deaths attributable to

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165. WILLIAM STYRON, *SOPHIE’S CHOICE* (1979); Judith Jarvis Thomson, *A Defense of Abortion*, 1 PHIL. & PUBLIC AFF. 47 (1971); Judith Jarvis Thomson, *Turning the Trolley*, 36 PHIL. & PUBLIC AFF. 359 (2008).

166. *Cf.* GUIDO CALABRESI & PHILIP BOBBITT, *TRAGIC CHOICES* 38-41, 137-41 (1978) (discussing the gains from saving known lives at the cost of losing a greater number of unknown lives).

167. *See* *McCollum v. CBS*, 249 Cal.Rptr. 187 (Cal.App. 3d. 1988), where parents sued rock musician Ozzy Osbourne and other parties because their son committed suicide after hearing music extolling it. The appellate court held that no cause of action had been made out for incitement or for intentional or negligent invasion of the parents’ rights. The court did not discuss the use of a clear and present danger standard as an alternative to the incitement theory.

168. *Craig v. Boren*, 429 U.S. 190, 226 (1976) (Rehnquist, J., dissenting).

males being more dangerous than females”? But the suggestion is that, in this context at least, the Court should not displace the legislative judgment. (True, Justice Rehnquist applied a standard of review different from the majority’s: the rational basis test, rather than intermediate scrutiny.)<sup>169</sup>

Justice Rehnquist’s point might be reformulated this way. We ask why the interest in avoiding gender classification *in this case* is so monolithically important, and why so little attention is paid to lifesaving *where an order of magnitude difference in gender performance* is claimed?<sup>170</sup> Lifesaving is *really* important. Recall the claim that “[t]he possible future cost from a single infant infection argues for universal infant hepatitis B immunization—given the very high costs of treating its consequences (e.g., liver transplant) and the very low price of the vaccine.”<sup>171</sup> Moreover, the more important the interest, the weaker should be the least-restrictive-alternative burden (a rigorous efficiency standard). There should be some functional relationship between degrees of importance and the search for better alternatives so that government is less burdened when it is trying to vindicate a massively important interest. Constitutional doctrine does not quite read in this finely calibrated way, but if there are degrees of compellingness and importance (there must be), there are degrees of weakening of the narrowing requirement for means-end connections, within standards of review and between them.

To be sure, Oklahoma cast doubt on the seriousness of its lifesaving rationale by banning sales only, not possession or consumption. One could well say that it offends important constitutional interests, whether about liberty or avoiding adverse classifications, to impair them with such ineffective mechanisms *when much more effective ones were available* (such as barring all drinking from eighteen through twenty years of age). But the showings were not *that* thin. Justice Powell, concurring, sided more with Justice Rehnquist than with the majority when he said that that state’s data supported the claim that young men drive and drink and get into more accidents than young women. One wants to say, to the majority, “Well...?”<sup>172</sup>

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169. *Craig*, 429 U.S. at 220. Intermediate scrutiny was put down as having “come[] out of thin air.” *Id.*

170. The issue has to be carefully framed. Justice Rehnquist raised a basic issue of why the legislature couldn’t conclude that certain risks *were* indeed sufficient to justify intruding on constitutional interests, but he did not describe the interest in the most accurate way: “The personal interest harmed here is very minor—the present legislation implicates only the right to purchase 3.2% beer . . . .” *Id.* at 226-27 (Rehnquist, J., dissenting). This is incomplete. The interest also concerns the *reasons* for rights limitation—for interfering with personal autonomy— and the reason in this case was gender and what was thought to be linked to it.

171. See Mansoor & Salama, *supra* note 130.

172. Justice Powell’s concurring conclusion is thus unsettling, even if ultimately correct because the legislature didn’t ban consumption, thus casting great doubt on both the very point and the effectiveness of its gender classification. But he made a lot of telling concessions, usefully applied to the vaccination context. *Craig*, 429 U.S. at 211 (“It seems to me that the statistics offered by appellees and relied upon by the District Court do tend generally to support the view that young

*c. Narrowing*

A final comment on “narrowing”—the search for lower-cost alternatives to the chosen legislative means. This is not some questionable doctrinal artifact: the requirement is a basic rationality constraint, although its form and rigor vary significantly across contexts. If there is another way to accomplish more or less the same thing at a lower cost in rights impairment, then the chosen maneuver is constitutionally questionable. To travel efficiently from San Francisco to Los Angeles, one does not normally take the Polar route. This constraint is, by definition, supposed to be weakened when applying less than strict scrutiny—the alternatives probably do not have to be *equally* effective, the costs imposed do not have to be the lowest possible, the legislature does not have to look as hard for them, and the courts do not have to second-guess the underlying empirical data as rigorously.

One could argue, for example, that with hepatitis B, the most efficient—least restrictive—alternative is simply to target those engaged in the highest risk behaviors: drug use and unsafe sexual practices. Of course, this would be less effective in reducing hepatitis B because not all cases are caused by these ill-famed risky behaviors. But some observers have also suggested that where such high-risk targeting has been attempted, it has not worked well.<sup>173</sup> I have not pursued this issue, but it seems of marginal relevance to the protection of children.

These, then, are the sorts of constitutional adjudication issues raised with increasing frequency by technological innovations, old and new, as well as by the increasing (or simply better noticed) complexity of things generally. Think again of *Craig* and how the Justices managed their bout with intermediate scrutiny. Justice Powell highlighted the issue of how the Court should delve into empirical data and inferences by referring to “the facts and the inferences fairly drawn from them.”<sup>174</sup> (He might also have asked how the Court was to approach legislative conclusions of value, but having accepted the legislative description and valuation of its goal, it was not at issue.) In the vaccination context, how should the Court apply Justice Powell’s advice? For example, how is the Court to address the *data and evidence collection process*? Compare investigating the comparative incidence of arrests with determining the incidence of a

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men drive more, possibly are inclined to drink more, and for various reasons are involved in more accidents than young women. Even so, I am not persuaded that these facts and the inferences fairly drawn from them justify this classification based on a three-year age differential between the sexes, and especially one that it so easily circumvented as to be virtually meaningless. Putting it differently, this gender-based classification does not bear a fair and substantial relation to the object of the legislation.”).

173. “It has become evident that HBV transmission cannot be prevented with a strategy for vaccinating only the groups considered at highest risk.” Broderick & Jonas, *supra* note 101, at 65.

174. *Craig*, 429 U.S. at 211 (Powell, J., concurring).

communicable disease.

Compare next the inferential processes in *Craig* with those in cases asserting a right against compelled vaccination. On promoting traffic safety: If males and females are arrested at different rates, does this reflect differing degrees of “gender-risk”? With respect to reducing disease, does the local epidemiological situation indicate that the infection rate is about to increase sharply?

Finally, examine the legislative valuations. Is the level of traffic risk enough to justify the gender classification? (Compare this question with that of separating race-based gangs in prisons to reduce violence.) Does saving the lives or promoting the health and functionality of fifty people justify a million vaccinations (compulsory? voluntary?) that bear risks  $Y$  and  $Z$  with probabilities  $P_Y$  and  $P_Z$ ? Is there some constitutionally legitimate way for a Court to address stark legislative valuation problems without simply punting—deferring completely to the legislature?

This account, to be sure, barely scratches the surface in outlining material questions about how courts are to *use* a standard of review.<sup>175</sup> (And in pursuing this, one can push the comparison between *Craig* and vaccination cases too far.) Still, it is instructive to ask if we really know the incidence of hepatitis B carrier status (any more than we know the actual incidence of male and female drunk driving). How many cases would be avoided with a given vaccination program? How many lives would be saved? Can the vaccine-induced fever threaten long-term damage? How effective are the treatments for hepatitis B? Do the likeliest victims in fact have access to treatment? (Vaccination programs are likely to be less expensive than treatment.)<sup>176</sup> Can voluntary programs accomplish the same goals? (Compare the United States with the United Kingdom, Denmark and Sweden, as suggested earlier.) Suppose that they do so only a fraction as well? If we can only show “cause not shown” and not “causation is excluded,” can we rightly punish persons for refusing to (in their view) risk autism or multiple sclerosis? Even if rare outcomes are assumed to be vaccine caused, should we still be able to compel?

Where specially protected interests are concerned, questions of this sort cannot be a matter of across-the-board judicial deference. This would be flatly inconsistent with acknowledging a fundamental right or a liberty interest (or, in

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175. The difficulties in specifying plausible operational meanings for standards of review are vividly illustrated in a recent bout between the demands of First Amendment strict scrutiny and the need to defer to expertise even within that realm. See *Holder v. Humanitarian Law Project*, 130 S.Ct. 2705, 2727 (2010), upholding a statute banning “material support or resources” to foreign terrorist organizations. One infers that strict scrutiny was used because the Court stated that the intermediate standard in *United States v. O’Brien*, 391 U.S. 367 (1968), was insufficient; absent a spectrum approach to standards of review, the next threshold up is strict scrutiny. 130 S.Ct. at 2723.

176. See, e.g., Peter A. Muennig & Kamran Khan, *Cost-Effectiveness of Vaccination Versus Treatment of Influenza in Healthy Adolescents and Adults*, 33 CLINICAL INFECTIOUS DISEASES 1879 (2001).

other contexts, a suspect or semi-suspect classification). It is likely that the Court will kick such questions to the legislative black box as often as it can, but every quantum of deference raises the question about whether we are taking our constitutional value rankings seriously.

*4. Additional Moral Analytics, Some of Which Should be Absorbed Into Constitutional Adjudication.*

There are some additional moral issues to discuss here, and they raise in turn the question of how courts are to address them within constitutional law. Would it be sound constitutional jurisprudence for the Court, say, to address Judith Jarvis Thompson's discussion of why a woman can dislodge the famous violinist stuck to her (for nine months) so her kidneys could help his own to recover?<sup>177</sup> Is "independent judicial moral analysis" the only way to address this thought experiment? For present purposes, however, I leave the issue aside and note only a few points.

■ *Reinforcing a culture of coercion.* I have suggested the need to analyze any cluster of rights dealing with the integrity of the self, a phrase I use to refer to the personal boundary problems of insulating body, mind, and identity from unwanted intrusion. (It may also extend to their (re)construction and the adjustment of their boundaries.) One analytic variable concerns the risk that any form of government compulsion will reinforce a culture of coercion. Of course, putting it this way risks a "this proves too much" response: all government is morally unsound within this framework. The point can be cabined (to a degree) by noting that the main risk occurs when we move beyond some standard, ineradicable baseline—e.g., we are all subject to tax and traffic law enforcement, even in a minimal state. Coercion by government (and in certain private interpersonal situations) is often essential, but it ought, in a liberal society, to be confined to furthering significant purposes. Vaccination does seem important in this sense, but the example of large-scale voluntary vaccination in places other than the United States is impressive.<sup>178</sup> So is the absence of physical force in U.S. vaccination programs. Why is coercion through the threat of penal or civil sanctions needed to achieve high vaccination compliance levels, and on what standard of need? The spectacle of unneeded coercion reinforces authoritarian behavior and our preferences for it. This is a human inclination that does not need to be beefed up; we are already overly inured to it.

This focus on norm and behavior change is not only a relevant moral approach (despite its gossamer nature), it also appears in judicial defenses of fundamental rights, sometimes in fairly simple form.<sup>179</sup> Consider these linked

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177. See *supra* note 165 and accompanying text.

178. See, e.g., *supra* note 139.

179. *N.Y. Times Co. v. Sullivan*, 376 U.S. 254, 270 (1964) ("Thus we consider this case [defamation of a public official] against the background of a profound national commitment to the

claims:

The state already applies coercion to many of our daily activities. Do we want to live in the sort of society that extends coercion to routine immunization? At present, many industrialized countries achieve high levels of immunization without the need for compulsion. If such high levels can be maintained through encouragement and incentives, this effectively achieves the aims of the moderate communitarian, without the need for legislation. Compulsory immunization would be certain to inflame those who already believe that their Government interferes too much with their freedom. What is more, coercion may alter perception of risk. People who are coerced into an action may be more likely to perceive the action as being risky than if they are persuaded into it. Recent examples, albeit adult rather than child, have been the mandatory immunization of military personnel against anthrax and smallpox, which led to many protests and loss of confidence. Most parents trust the assurances of health care professionals that the benefits of immunizing their child outweigh the risks. Making immunizations compulsory renders trust redundant. If State coercion can be avoided in the area of routine childhood immunization, so much the better. . . . [I]n order to respect autonomy, State coercion should be kept to a minimum. We believe that, in general, children should not be compulsorily immunized when similar results can be achieved by education and inducements. Australia is in the happy position of having achieved very high rates of routine childhood immunization, over 90%, without the need for compulsion.<sup>180</sup>

Perhaps this is an occasion for what is now sometimes called “empirical philosophy,” which seems also to be a branch of psychology.<sup>181</sup> How would we test the risk that a given program of government coercion would adversely shift felt moral values and resulting behavior? If there is such a risk, how does it

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principle that debate on public issues should be uninhibited, robust, and wide-open, and that it may well include vehement, caustic, and sometimes unpleasantly sharp attacks on government and public officials.”). The Court invalidated common law and statutory provisions allowing defamation recoveries against public officials without a showing of malice. *See also* *Minneapolis Star & Tribune Co. v. Minn. Comm’r of Revenue*, 460 U.S. 575, 585, 592 (1983) (striking down a tax that appeared to the Court to “single out” the press, thus “undercutting the basic assumption of our political system that the press will often serve as an important restraint on government”). There had been no showing of any legislative motives impermissible under the First Amendment. *Id.*

180. Isaacs et al., *supra* note 34, at 395; *see also* P. Bradley, *Should Childhood Immunisation Be Compulsory?*, 25 J. MED. ETHICS 330 (1999) (“Compulsory vaccination cannot, with very few exceptions, be justified in the UK, in view of the high levels of population immunity which currently exist.”).

181. *See generally* John Doris & Stephen Stich, *Moral Psychology: Empirical Approaches*, STAN. ENCYCLOPEDIA OF PHIL. (Apr. 19, 2006), <http://plato.stanford.edu/entries/moral-psych-emp>.

compare with the risk that in the United States, voluntary vaccination programs may not be adequate to the task of securing high compliance?<sup>182</sup> Does requiring parents to submit their children for vaccination erode our culture of familial autonomy—a culture that is of constitutional status? Many vaccination controversies concern the rights of parents to control the nurture and upbringing of their children.<sup>183</sup>

■ *The entanglement of individual rights assertion and community and government interests.*<sup>184</sup> I said earlier (Section III.E.4) that that rights-assertion stage and the government-societal interests stage flow into each other, but the point now is somewhat different. The “ping pong” I referred to concerns the continuing revaluation and possible recharacterization of something as an interest or right, or as one bearing a certain strength. The idea here, however, is that (on the one side) there are communitarian interests in preserving individual rights, as well as in preventing disease, and that (on the other) individual assertions of right are not asserted in a social vacuum: they are asserted against others, who have their own rights and interests, and their very description implicates concerns that may or may not be opposing.<sup>185</sup>

■ *Paternalism.* There is no call to review the mounds of commentary on paternalism generally and medical paternalism in particular. Claims of authority (government or private) to override individual choice are often based, not on harms likely to be inflicted on others, but solely on benefits to the person coerced or influenced (often through preventing harm to her). It is sometimes hard to disentangle such paternalism from coercion taken to avoid “externalities,” but the motivations are in theory distinct.<sup>186</sup> Parallel difficulties are sometimes encountered in vaccination policy. Compelling adults to be vaccinated, for example, might be considered paternalistic because those who want to avoid infection can simply arrange for their own vaccination. This is not a fully

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182. See the discussion of the limits of persuasion in James Colgrove & Ronald Bayer, *Manifold Restraints: Liberty, Public Health, and the Legacy of Jacobson v Massachusetts*, 95 AM. J. PUB. HEALTH 571, 573-74 (2005).

183. Bradley, *supra* note 180, at 331-32.

184. I do not mean to conflate society and government or their interests. However, in constitutional adjudication, the government is generally the voice of the community, despite the fact that individual rights claims *may be* communitarian claims of a sort within a liberal society. See *infra* note 186 and accompanying text.

185. See generally John Tomasi, *Individual Rights and Community Virtues*, 101 ETHICS 521 (1991) (“Rights are conflict notions.”).

186. Crash helmet laws illustrate the point. Those who oppose these laws usually ignore the costs (monetary and otherwise) imposed on others who feel constrained by morality and social norms to rescue them, or deny that these costs can rightly be viewed as significant harms to others (especially if the cyclist is willing to die untreated). Cf. Ruth Faden & Sirine Shebaya, *Public Health Ethics*, STAN. ENCYCLOPEDIA OF PHIL. (Apr. 12, 2010), <http://plato.stanford.edu/entries/public-health-ethics/> (“Defenders of compulsory motorcycle helmet laws, for example, argued that the serious head injuries sustained by unprotected cyclists diverted emergency room personnel and resources, thus harming other patients.”).

effective response because of incomplete vaccine effectiveness and uncertain access to vaccination services, and because of the need to protect children, most of whom cannot just hop in the car and go to the nearest vaccination site. In any case, “this is paternalism” is not necessarily a decisive objection in all contexts, even when understood to be confined to the competent and fully informed (or at least to those who had a fair opportunity to be fully informed).

Antipaternalism is not an explicit theme in Professor Holland’s Article, but it surely is implicit in some of the accounts it refers to. No classical liberal is entirely comfortable with paternalism, but it seems quite clear that sometimes others *do* know better than you what is in your best interests, however competent you are. Friends do not let friends do really stupid things. And we are not supposed to let children run amok. (Protecting children is, etymologically, the archetype of “paternalistic” action.) But here we are talking about government or community paternalism, and even if government often is a force for good, it is not generally your close personal friend. A *practice* of government paternalism may easily do more harm than good, especially if there is a slippery slope nearby.

A plausible if not entirely convincing case of justifiable paternalistic compulsion rests on a rough distinction between short and long run autonomy. The imposition of coercion now, by avoiding future compromises of one’s health and thus impairments of one range of opportunities, thus helps assure greater autonomy over a far more extended time. Compulsory vaccination is then defended on this ground, possibly padded by reference to familiar human frailties such as limited time horizons and “it can’t happen to me” attitudes.

But whatever the merits of paternalistic approaches, we need to consider its application to vaccination. Not all aspects of compulsory vaccination reflect paternalistic reasons, but I do not try to untangle these strands here. I simply note that some unvaccinated persons *will* come down with avoidable sickness, and there *will* be costs not only to individual autonomy, but also to social interests. So paternalism and protection of society are conceptually and empirically intertwined.<sup>187</sup>

There is, however, a major benefit to antipaternalistic movements, even if they go too far. They act as a check on excessive power by government and by health care personnel.<sup>188</sup> Constraints on government that might seem foolish in particular instances might be justified as an institutionalized check on government—particularly its expansion in areas of important rights.<sup>189</sup>

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187. One could maintain that they are intertwined even when each individual act contemplated is purely paternalistic because the practice and the scale of paternalism affect the nature of society and thus human interaction.

188. See, e.g., Matthew McCoy, *Autonomy, Consent, and Medical Paternalism: Legal Issues in Medical Intervention*, 14 J. ALTERNATIVE & COMPLEMENTARY MED. 785, 786 (2008) (stating that there has been a shift from paternalism and that one effect has been the development of patient-centered informed consent doctrine).

189. See generally Vincent Blasi, *The Checking Value in First Amendment Theory*, 2 AM. B.



The relevance of analysis of paternalism to constitutional argumentation is clear enough, although the applicable doctrine may not be explicit. At the Supreme Court level, at least in modern times, the idea that paternalism is entirely illegitimate has not been vindicated. It does not work, as a *constitutional* argument, to say that some *weak* forms of paternalism motivations cannot properly underlie intrusions on specially protected rights.<sup>190</sup> As a matter of moral

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FOUND. RES. J. 521 (1977).

190. On “weak” paternalism (e.g., short-term interference to promote longer term goals), see Gerald Dworkin, *Paternalism*, STAN. ENCYCLOPEDIA OF PHIL., <http://plato.stanford.edu/entries/paternalism> (last updated June 1, 2010). There seems no straightforward rejection of all claims to all forms of paternalism as a legitimate interest under the rational basis test. Under heightened scrutiny, the situation is more complex: certain forms of weak paternalism may be permissible under such review, but strong paternalism is not a strong candidate for a compelling or important interest, even if it is legitimate. For example, in *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 846 (1992), the Court ruled that “[b]efore viability, the State’s interests are not strong enough to support a prohibition of abortion or the imposition of a substantial obstacle to the woman’s effective right to elect the procedure.” The principal state interest identified by the Court was potential life—which clearly does not sound in paternalism: “On the other side of the equation is the interest of the State in the protection of potential life.” *Id.* at 871. But some measures to protect the woman against her own decisions may be permissible as long as she retains the right to make “the ultimate decision.” *Id.* at 877. Thus: “In attempting to ensure that a woman apprehend the full consequences of her decision, the State furthers the legitimate purpose of reducing the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed.” *Id.* at 882. It remains, as Justice Holmes suggested in his *Lochner* dissent, that the Fourteenth Amendment does not implement Herbert Spencer’s Social Statics. *Lochner v. New York*, 198 U.S. 45, 75 (1905). See generally 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 507 (1996) (invalidating a ban on price advertising of liquor, and stating that “[s]uch speculation [on whether price advertising increases liquor consumption] certainly does not suffice when the State takes aim at accurate commercial information for paternalistic ends”). The standard of review was “the less than strict standard that generally applies in commercial speech cases.” *Id.* at 507. Rigorous constitutional scrutiny does seem to embrace the antipaternalistic “shibboleth” Justice Holmes complained about in *Lochner*. But it is not excluded as a legitimate interest under minimal scrutiny, and some weak forms seem permissible under heightened review, as *Casey* indicates. In *Walters v. National Ass’n of Radiation Survivors*, 473 U.S. 305 (1985), a case upholding a limitation on the fee that veterans may pay to attorneys or agents representing them in trying to obtain certain benefits from the Veterans’ Administration, the Court stated the following:

It is not for the District Court or any other federal court to invalidate a federal statute by so cavalierly dismissing a long-asserted congressional purpose. If “paternalism” is an insignificant Government interest, then Congress first went astray in 1792, when by its Act of March 23 of that year it prohibited the “sale, transfer or mortgage . . . of the pension . . . [of a] soldier . . . before the same shall become due.” Acts of Congress long on the books, such as the Fair Labor Standards Act, might similarly be described as “paternalistic” . . . [*Lochner*’s] day is fortunately long gone, and with it the condemnation of rational paternalism as a legitimate legislative goal.

*Id.* at 323 (first four alterations in original) (citation omitted). This was not a heightened scrutiny case. Justice Stevens dissented (joined by Justices Brennan and Marshall, dissented, arguing that the Court had undervalued individual liberty and (operationally) implementing more rigorous scrutiny than did the Court, and criticizing the paternalistic justification as—in this case—irrational. *Id.* at 367.

analysis, one might conclude differently.

## V. ADDITIONAL CRITICISMS.

### *A. Conflicts of Interest: the Vaccine Manufacturers (and Others) Want to Make Money.*

I say people are no damn good. Human motivation is not always to do right by others, or (perhaps) even oneself. Some may even think it wrong to try to do right by others. I do not name names. But if we say all human action labors under a conflict of interest then we fail to mark out those special conflicts warranting legal (or other special) attention. Removing a judge or disbaring a lawyer on conflict-of-interest grounds requires more than claiming that they were (say) simply trying to advance their careers even when rendering the soundest decisions. Every judge is under an incentive to write praiseworthy opinions for personal advancement, not solely to serve society. There is a baseline of individual “aggrandizement” that is largely ineradicable and does not count as legally indictable, though it poses ongoing moral risks.

So, we should, *of course*, be skeptical about most vendor claims of perfection and safety. But how does this skepticism play out operationally? Physicians want business. They want you to consult them—we still have direct fee for service transactions, which reinforces this incentive. And if patients avoid Dr. K. at the local HMO, where there may be no direct pay for service, they might not last long there. Patients have to keep coming, so physicians will say what they need to say to keep and gain customers. Therefore, do not believe anything physicians say, right? As for pharmaceutical companies—do not take any analgesics, even over the counter: their developers and sellers just want to make money, whatever the risks to you.

Of course, this is hyper-hyperbolic. The Article was far from simply dismissing vaccines as lethal and ineffective. Their value and safety, however, are called into question, less pointedly, but nonetheless clearly. Professor Holland, for example, speaks of the “culture of conflicts of interest” and discusses at some length the “Financial Distortions in the Hepatitis B Mandates.” She states, “The vaccination of four million infants per year yields a substantial annual income stream in the hundreds of millions of dollars,” and she lists among the distorting factors “advisers’ financial ties to vaccine manufacturers.”<sup>191</sup>

Although I would not align vaccine manufacturers with those offering to sell the Brooklyn Bridge, the skeptical stance about vaccine quality is well taken as a *part* of a rational process of evaluating vaccination programs. This is no small task, since most of us cannot run biomedical research projects and there is a problem of evaluating qualified evaluators: they too would like to earn a good

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191. Holland, *supra* note 5, at 77.

living. Nor is the conflict of interest problem confined to decentralized economic systems. But we are not about to dismantle capitalism, its markets, and government, so there will *always* be a basis for skepticism about many claims by many contracting parties. What do we do as consumers, then? We try to reduce any incremental, over-the-baseline risks to the public interest arising from incentives for individual or institutional aggrandizement, and we try to do it without unduly impairing the productive enterprise. It is pretty hard to do both, and the risks are largely non-eliminable. The list of standard public-protective measures is not that hard to formulate, but most of them bear internal tensions. We can say that vaccine evaluators should have minimal ties, if any, to vaccine manufacturers and distributors; but such evaluators were not trained in a vacuum: any competent researcher will know others in the field, and many of the best work for or with Pharma. Disallowing ties means losing able consultants, some of whom may in fact be sufficiently objective to render a reliable judgment, regardless of appearances.

How do we implant conflict of interest considerations into vaccine policy and constitutional analysis? The Article is not entirely clear on this. It does not call for shutting anything down. But, if we do not do so, how do we reduce risks and exercise due care? And what do we do about the hepatitis B vaccine in this light? If we cannot rely on need, efficacy, and safety claims, because of commercial (or other) incentives to lie, withhold, or distort information, why should we even permit voluntary vaccination?

The constitutional analysis is fairly straightforward, if imprecise. Conflicts of interest within the vaccination and other healthcare establishments pose risks to persons who are being compelled to accept treatment. If safety and efficacy conclusions are tainted by improper motivations and techniques, government justifications for coercion are correspondingly weakened or fail altogether. This is an analytic line one would expect (and sometimes demand) under heightened scrutiny. The parallel to Justice Brennan's attack on Oklahoma's methodology in *Craig* is clear. He raised the possibility of skewed motivations of the police in arresting more males than females: "[R]eckless young men who drink and drive are transformed into arrest statistics, whereas their female counterparts are chivalrously escorted home."<sup>192</sup> This did not establish that Oklahoma's conclusions were false and that the gender classification had no adequate foundation, but the asserted methodological flaws were taken to foreclose the government from confidently drawing its inferences about differential risks. Those inferences were not thought, in *Craig*, to warrant strong deference, if any. The surveys, as presented to the Court, did not, in Justice Brennan's view, *facially* exclude *nontrivial risks of impaired methodology*. Whether Justice Brennan's analysis was done well is arguable, but I think he was constitutionally obliged to pursue this general line of inquiry into the methodologies for gathering

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192. *Craig v. Boren*, 429 U.S. 190, 203 n.14(1976).

data and drawing inferences from them, *given the elevated status of the individual constitutional interest involved*.

Still, skewed and conflicted motivations are intrinsic problems in every study *and every marketing effort*. This is why clinical trials generally require (where practicable) double-blind studies, and why pharmaceutical salespersons are not always taken at their word. And, this is why we are *always* at risk, whether we take a dose of ibuprofen or hepatitis B vaccine. Although they are obviously not the only source of risk, “baseline” conflicts of interest are inherent in human action and cannot be shut down. There is, then, no reason for automatic deference to the label or the package insert or to a physician’s claim.

Nevertheless, in pursuing heightened scrutiny of empirical claims that inform risk assessment, courts should inquire into the presence of serious, ameliorable risks that exist *atop* the baseline incidence of mixed incentives that may compromise the public interest. When operating within such scrutiny, total reliance on legislative and administrative findings and inferences is inappropriate.<sup>193</sup> “The primary problem with legal conflict-of-interest doctrine is that it fails to recognize conflict of interest as a type of risk analysis aimed at setting *acceptable risk levels* regarding perverse incentives.”<sup>194</sup> The point is as applicable in vaccinology as it is in regulation of the legal profession.

### *B. Impaired Informed Consent Processes*

Professor Holland’s central point here is that legislative and administrative law and practice has impaired the informed consent process in the administration of vaccines. If this process is compromised, then the government compulsion system is not effectively narrowed to reduce the costs to the assumed liberty interest at stake. Securing informed consent is at the core of protecting the integrity of the self, which is in turn the substance of the liberty interest.

Few claim that lack of perfect information means forecloses informed consent. Nor does confusion about one’s preferences or the moral requirements of caring for oneself, one’s family, and others render informed consent impossible. The few who say otherwise are using the concept of informed consent unsoundly. Such excess does not appear in the Article. But, the claim that informed consent—and, thus, autonomy and constitutional liberty—have been unduly burdened in the vaccine area is not clearly shown. The author argues:

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193. Cf. *Holder v. Humanitarian Law Project*, *supra* note 176, 130 S. Ct. at 2727-28 (addressing the tension between heightened scrutiny and deference to government findings).

194. Kevin C. McMunigal, *Conflict of Interest as Risk Analysis*, in CONFLICT OF INTEREST IN THE PROFESSIONS 61, 62 (Michael Davis & Andrew Stark eds., 2001) (emphasis added); see generally CONFLICTS OF INTEREST IN CLINICAL PRACTICE AND RESEARCH (Roy G. Spece, Jr. et al., eds., 1996).

The norm of informed consent in medicine requires doctors to provide extensive information about the known risks of interventions to patients and to allow the patients to make the ultimate decisions. Similarly, drug manufacturers are required by law to provide accurate and complete information about drug risks with their products. In vaccination law, however, these norms are substantially relaxed. The NCVIA does not require doctors or vaccine manufacturers to give complete warnings directly to the person or guardian of the child being vaccinated. It requires that doctors give government-produced information and requires that manufacturers provide proper warnings to doctors only, who are considered to be “learned intermediaries.” Both industry and the medical community lobbied for this lowered standard.<sup>195</sup>

A legally imposed impairment of informed consent surely threatens our posited constitutional liberty interest in resisting vaccination. A law forbidding transmission of significant efficacy and safety information to prospective vaccinees would be unconstitutional under any version of heightened scrutiny, and possibly even under the rational basis test.<sup>196</sup> What about a law forbidding disclosures about claimed adverse events because they would be prejudicial and result in some persons losing needed vaccination protection? Same result. Suppose there was a law requiring that *all* adverse event reports be made available to vaccinees. Such a law would probably not be unconstitutional because of the marginal relevance of the undifferentiated mass of such reports.

But, the Article’s claim that informed consent requirements have been seriously compromised by the law seems overstated. What does “complete” (“complete warnings” are not required) mean? No legal regime of informed consent requires disclosure of every conceivable risk. And, exactly why is the manufacturer required to directly inform the vaccinee? Could this be via package insert? Or manufacturers’ representatives at the vaccination site? Does the law displace existing state doctrine concerning physicians’ duties to disclose? Neither the National Childhood Vaccine Injury Act of 1986 nor the Court’s opinion applying portions of it in *Bruesewitz v. Wyeth* seem to preempt state-imposed duties (whatever they are) on physicians; they only address the matter of design defects and duties to warn by manufacturers.<sup>197</sup>

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195. *Holland* at 79.

196. Some may think otherwise in special settings, e.g. the military or health professions. See, e.g., George J. Annas, Opinion: *Don’t Force Medical Pros to Get H1N1 Vaccine*, *NEWSDAY*, Oct. 3, 2009, <http://www.newsday.com/opinion/opinion-don-t-force-medical-pros-to-get-h1n1-vaccine-1.1496620>.

197. *Holland* states (*id.* at 59) (my remarks are in bracketed italics): “Complementing manufacturers’ relief from disclosure requirements [*As argued, this seems quite overstated*] another provision exempts doctors from substantial federal disclosure requirements. [*Not clear what this means.*] It tasks the HHS Secretary to ‘develop and disseminate vaccine information materials.’ It

The federal law probably should have been more explicit, as the author suggests, but I do not think the Article shows that informed consent and therefore a constitutional liberty interest in personal security is compromised under the 1986 law. It is not clear exactly what the author wants done by manufacturers or physicians, although she refers to proposed state legislation requiring physicians to provide the package insert.

### *C. Unrepresentative Decision-making*

This framework of criticism of vaccine policy is closely related to the concerns about conflicts of interest. Professor Holland states:

Part of *Jacobson's* rationale for deference to state legislatures was their representative nature; legislatures by their nature must take account of differing views in the population. If the legislature makes bad choices, the electorate can reverse those choices and unseat the legislators through popular elections. But ACIP [Advisory Committee on Immunization Practices]<sup>198</sup> has become the driving force behind vaccination mandates, a federal advisory body with almost no public participation and no direct accountability to voters. Because of this change in the locus of true decision-making from legislators to ACIP, there are far greater risks of conflicts of interest. ACIP advisors have strong ties to industry, and financial and professional self-interest may outweigh public health in their decision-making.<sup>199</sup>

I do not know what theory of democratic representation is presupposed here. It seems to be assumed that if someone is not simply part of the lay citizenry, she

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states that these materials should outline the benefits and risks of vaccines and the availability of the VICP. Doctors are obliged to provide families with these information materials." I don't fully follow this. From which disclosure requirements are physicians exempted? If the idea is that the federal provisions preempt basic aspects of state informed consent laws, the point needs to be argued more clearly. *Bruesewitz v. Wyeth*, 131 S. Ct. 1068 (2011), doesn't seem to address this. It held that National Childhood Vaccine Injury Act preempted *design-defect* actions brought against vaccine manufacturers. The Court noted: "Manufacturers are generally immunized from liability for failure to warn if they have complied with all regulatory requirements (including but not limited to warning requirements) and have given the warning either to the claimant or the claimant's physician." *Id.* at 1074. True, this portion of the Act doesn't refer precisely to physicians, but it doesn't purport to relieve them of any liability either. The Act provides: "Except as provided in subsections (b), (c), and (e) of this section State law shall apply to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C.A. § 300aa-22(a)(West 2011). There is an expressly labeled preemption section: "No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part." *Id.* §300aa-22(e).

198. See 42 U.S.C.S. § 217a (West 2011), concerning the creation of advisory councils and committees for the Secretary of Health and Human Services.

199. Holland, at 77.

cannot “represent” it, despite the fact that members of government advisory committees are expected to act for the public interest, and not *just* some distinct constituency.<sup>200</sup> But, depending on their function, they can be aligned with particular groups. Indeed, why else would government seek to appoint members of *particular* groups in its quest for “representative” bodies? Members of government agencies and advisory groups are understood to be linked to a variety of frameworks, while at the same time operating under a public interest ideal. If this seems paradoxical, so do democracy and the very idea of objectivity. I do not think that Professor Holland would deny any of this, but, given her critique, one needs to recall that the duty to promote the public interest does not lie in having no definable perspective, but in being able to enter in some way into the perspective of others. As Thomas Nagel put it, “As in metaphysics, so in the realm of practical reason the truth is sometimes best understood from a detached standpoint; but sometimes it will be fully comprehensible only from a particular perspective within the world.”<sup>201</sup>

It is thus not inconsistent with either democracy or the pursuit of sound public policy for persons exercising certain forms of government power to represent particular constituencies; it depends on the nature of the enterprise and what “representation” means in a given context. It is neither possible nor desirable for people to escape or elude all frameworks of interest, include some frameworks that are in tension with others. We do not and cannot function outside all value frameworks. To try to wrench ourselves from this reality *would* impair the public interest.<sup>202</sup>

To be sure, political representation, even if meant to provide a voice to certain interests, is supposed to be exercised with a degree of objectivity that avoids blind fanaticism. Certainly, not everyone can be trusted to work with appropriate objectivity or detachment all the time, but it seems unreasonable to impose, across the board, either some sort of proportional representation requirement (which presupposes *interest* representation) or a populist template

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200. Although the law setting up the National Vaccine Advisory Committee doesn’t use the term “public interest,” the mandate of the Committee is inconsistent with simple representation of discrete partisan interests. See National Vaccine Program, 42 U.S.C.A. § 300aa-5 (West 2011). The Administrative Procedure Act is strewn with references to promoting the public interest. 5 U.S.C.A. § 551 (West 2011). In any case, as I argue in the text, an administrative committee member who acts (at least not blindly or reflexively) for a particular constituency or interest is not *necessarily* opposed to the public interest. In fact it is undemocratic and may damage the public interest systematically to *prevent* specialized or partisan representation across the board, in all forms. Context is critical.

201. Cf. THOMAS NAGEL, *THE VIEW FROM NOWHERE* 140 (1986). Nagel also urges that “the detachment that objectivity requires is bound to leave something behind.” *Id.* at 87.

202. Suzanne Dovi, *Political Representation*, STAN. ENCYCLOPEDIA OF PHIL., <http://plato.stanford.edu/entries/political-representation/#DeIVsTru> (last updated Oct. 17, 2011)(discussing, among other things, “interest-group pluralism, which [Melissa] Williams describes as the ‘theory of the organization of shared social interests with the purpose of securing the equitable representation . . . of those groups in public policies’”).

(undifferentiated peoplehood, no “elites”)<sup>203</sup> onto all administrative advisory committees. In any case, “public members” are likely to have crystallized views on one side or another of many programs, whether concerning vaccine policy or sewer construction. Some administrators “representing the public” will be partisans or activists for some distinct position: there is no univocal mass public viewpoint.

Of course, I do not all claim that, for administrative representation, “it’s all good.” I concur with many seriously misanthropic views and assume that many agencies are often embarked on mischief. But much more is required than is shown in the Article before any case is made out that vaccine policy is so “distorted” that it needs to be upended in order to save it (if it is to be saved at all). Indeed, it is hard to state what the baseline for nondistortion might be. Members of the ACIP will, in the aggregate, hold many preexisting and competing points of view, and this does not automatically make that body “unrepresentative” or render their respective interests “conflicted,” or keep them from trying in good faith to promote the public interest.

A particular complaint about unrepresentativeness is (quoting Belkin) that “the interests of newborn babies were not represented on the original panel that created this vaccination policy in 1991.”<sup>204</sup> But the bare objection that newborns (and perhaps those unconceived when the vaccination policy was adopted) are not “represented” is a nonstarter in almost every argument.<sup>205</sup> What would it mean to “represent” them? Who could do so? Persons trained to imagine themselves in “the original position” behind “the veil of ignorance” made famous by John Rawls?<sup>206</sup> People who expect to be newborns once again? Whether one should be attentive to the interests of future persons, whatever their designation—contingent, certain, possible, potential—is one thing, but vaccine policy does not demonstrate a representational failure for failing to do the impossible. (True, someone can simply be designated as an official “representative” for the unconceived, but it is hard to see how this renders him or her a true representative in any plausible sense.)

Perhaps the argument from nonrepresentativeness is meant as the beginning of a critique of modern American administrative law generally, or at least in the health care area. If so, much more is required to make out a case.

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203. Cf. Margaret Canovan, *Trust the People! Populism and the Two Faces of Democracy*, 47 POL. STUDIES 2, 3 (1999) (explaining it as “an appeal to the ‘people’”).

204. *Holland* at 76.

205. Compare this to the issue of obligations to future or possible persons. See generally DAVID HEYD, *GENETHICS: MORAL ISSUES IN THE CREATION OF PEOPLE* 13, 24 (1992).

206. JOHN RAWLS, *A THEORY OF JUSTICE* 11 (Revised ed. 1999).



*D. Communicable Versus Noncommunicable Disorders; Self-Protection Against the Unvaccinated*

The prime target of vaccination policy is communicable disease (e.g., smallpox). But if one is really worried about getting such a disease, one need only get a vaccination, right? So, protect yourself; you do not need to try to compel others to do things that threaten you when you can easily blunt the threat. Moreover, for those disorders often caused by avoidable behaviors—drug use, sex—one can seriously reduce or eliminate the risk by in fact not pursuing the dangerous conduct.

If all this is so, what could justify the invasion of the liberty interest—even if the liberty interest were not *that* valuable? If coercion is either useless or unnecessary given the possibility of behavior change, invasions of even minor liberty interests are not justified.

Moreover, some diseases with corresponding vaccines are not communicable or contagious.<sup>207</sup> One rationale for compelled vaccination against such noncommunicable diseases is the protection of pregnant women whose children may become infected, as noted by Professor Holland.<sup>208</sup> But the simplest justification is just that it secures children against a genuine risk of physical harm and of interference with their education. This justification withstands a paternalism objection where children are concerned, although the parental autonomy objection has not withered away. For adults, however, the argument would be that, with no parents egging them on, they would simply delay, even though their rational selves would know that this is unduly risky.<sup>209</sup> This weakness-of-will framework is a standard criterion in efforts to justify forms of weak paternalism.<sup>210</sup>

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207. At least one source suggests that contagious diseases are simply highly communicable diseases. Communicable diseases are infectious diseases that can be transmitted from one person to another. Infectious diseases are those caused by microorganisms. *Controlling the Spread of Contagious Diseases: Quarantine and Isolation*, AM. RED CROSS, [http://www.redcross.org/preparedness/cdc\\_english/IsoQuar.asp](http://www.redcross.org/preparedness/cdc_english/IsoQuar.asp) (last updated Feb. 23, 2006).

208. See Holland, *supra* note 5, at 51.

209. See generally Horlick et al., *supra* note 139, at S80 (“Laws are also used to require vaccinations against diseases for which herd immunity and free-riding do not play a role ([e.g., tetanus, because there is no human-to-human transmission]). The principal justification for a law in this setting is not to build herd immunity or prevent free-riding but simply to protect the child against an infection. Also, an argument can be made that these non-herd-immunity vaccines prevent harm to others by reducing the burden of health care costs caused by the diseases prevented. However, the principal rationale for the laws is simply the determination by society that the beneficence (avoidance of disease in the individual vaccine recipient) represented by a legal requirement outweighs the infringement on individual autonomy. Society has made the same determination for many other public health interventions, including, for example, motorcycle and bicycle helmet laws.”).

210. Cf. Danny Scoccia, *In Defense of Hard Paternalism*, 27 L. & PHIL. 351 (2008); Gerald Dworkin, *Paternalism*, STAN. ENCYCLOPEDIA OF PHIL., <http://plato.stanford.edu/entries/paternalism> (last updated June 1, 2010)(explaining that a weak paternalist holds it permissible to interfere with

The argument based on voluntary self-protection against communicable diseases implicates some connected points. Although it varies with age, children are generally far less capable of securing healthcare on their own than are adults. Moreover—a point that comprehends both adults and children—vaccination is not one hundred percent effective, so that one's risks of infection go up when the proportion of vaccinees in the population goes down. The greater the herd immunity, the safer one is.

Still, those who do not get vaccinated at all—saving some money and time—are free riding, relying on the immunity of others, and this is (as with most free-riding) often unfair, inequalitarian, and disutilitarian.<sup>211</sup> This framework for judgment is not much addressed in the Article. To be sure, free riding may seem more or less rational from the individual's perspective.

Finally, the avoidance of behaviors generally disdained—drug use and certain forms of risky sex—remains, at least in the background, as a reason for attacking the compulsory means chosen to further government interests.<sup>212</sup> But not all cases of hepatitis B come directly from such behaviors.

## CONCLUSION

Professor Holland's Article provides an occasion for considering how far we should push our notion of rights within American traditions, constitutional and otherwise. True, many things provide such an occasion, but this is the only one that I have been asked to respond to on this occasion.

If Professor Holland wanted to add to the skeptical view of vaccination generally and hepatitis B vaccination in particular, then she has made a contribution. Responding to her arguments requires probing the complex ideas of integrity of body, mind, and identity, their place in constitutional and moral theory, and determining what government must show in order to override claims of right. And she has provided some indication that all is not what we would like it to be in the field of vaccinology and its practice. But her analysis is questionable in certain respects. Here are some points to consider. They reflect

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choice of means that may defeat one's goals).

211. In some regions, vaccinations are free of charge. See Horlick, *supra* note 139, at S81 (referring to the United Kingdom).

212. See Horlick, *supra* note 139, at S80 ("Some parents may see school-entry laws as displacing their traditional authority to decide what medical treatments their children should receive. These parents assert that they are in a better position to judge the medical needs of their children than the state. The hepatitis B vaccine is a case in point. Since the enactment of hepatitis B vaccine school-entry laws in the early 1990s, concerns have been raised that vaccination mandates are not justified if they are meant to prevent diseases that can be avoided primarily by behavior, such as abstinence from illegal drug use and certain sexual behaviors. The HPV vaccine may be considered by some to fall in the category of diseases that may be avoided by behavior. Concerns have also been raised that vaccination against sexually transmitted diseases in adolescents can increase premarital sexual activity.").

two dimensions of my response: a critique of her arguments as they were presented, and a description of frameworks and arguments that might have been invoked to further her analysis.

The nature of the right against vaccination, and the larger set of rights in which it resides, is not sufficiently made out. Sometimes it seems as if the analysis of risks is the only thing that counts; sometimes it seems as if personal preference, exercised as purely autonomous action, is the only thing that counts. Most of us want to do the right thing, but we do not want to be *made* to do it, even if the invasion of our interests seems minor from a detached perspective. But it is often right—even obligatory—for the community to make us do things over our objections.

The value premises that inform and drive the Article are not clear. These premises concern autonomy and personal integrity, the nature of harms to these interests and to individual and aggregate health, and *the terms in which we consider when it is worth it to inflict or allow certain kinds of harm on some persons in order to benefit them and others*. We need more transparency for the process of determining whether and when we should run the risks imposed by  $x$  thousand vaccinations in order to save the lives or protect against serious health threats of “only”  $n$  persons. Once again, how do we get to the conclusion that this is an “only,” not worth the harms and injuries to personal integrity?

The operational meaning of standards of review—how they are applied and why—need greater specification, justification, and elaboration. This is necessary because the very logic of those standards implement our constitutional hierarchies. Because of this, I suggested ways of understanding their nature, structure, and use, and in particular the operational upshot of applying them in given cases.

The argument based on vaccination risk is not made out in the Article. Very few causal links between hepatitis B vaccination and adverse events are established. The Article does not sufficiently acknowledge the difficulties—far beyond recording adverse effects—in establishing causation. Even if causality of rare occurrences is conceded, the argument against compulsion is not made out. Nevertheless, in order to further the analysis, I observed that one can raise rights claims *even where causation of harm is not scientifically made out*, and suggested some arguments in defense of doing so (though I do not find them persuasive).

The Article’s constitutional analysis suffers from a hyperextension of *Jacobson v. Massachusetts* and from various technical problems in articulating prior, existing, and projected doctrine. *Jacobson* is not sufficiently “translated” into contemporary doctrine. To that end, I offered an additional parsing of *Jacobson* and analyzed a hypothetical *Jacobson 2.1*.

The constitutional analysis is also burdened by an incomplete analysis of decision-making supposedly compromised by conflicts of interest and inadequate

public representation. Here, I tried to make the nature of the gaps in the Article more precise, but without offering any theories of representation or conflict of interest.

Still, the Article did enough to make us pause before automatically following our physicians' advice to vaccinate. Rarely, one suffers much more than a fever or redness or a sore behind, and most of the time we do not know why (anaphylaxis excepted), although in most cases research and theory strongly suggest no link between vaccination and serious adversities occurring within its *res gestae*. Vaccination advice comes from sources that may be burdened by more than everyday conflicted motivations, thus risking decisions that might work against the interest of some persons and against the public's interest generally. Perhaps the rational thing to do is to keep getting vaccinated (in most cases) and to keep complaining about it (in some cases)—a bit of a clumsy practice, but it is in order.

# Reshaping the American Concept of Consumer Interest in the Food Policy Debate

Lang Liu\*

INTRODUCTION .....	173
I. RHETORICAL FRAMEWORKS OF THE SAN FRANCISCO ORDINANCE DEBATE .....	176
A. OPPONENTS OF THE ORDINANCE .....	177
B. SUPPORTERS OF THE ORDINANCE .....	179
II. THE ORDINANCE DEBATE THROUGH THE LENS OF CULTURAL COGNITION THEORY .....	180
A. INDIVIDUALISTIC VERSUS SOLIDARISTIC CULTURAL WORLDVIEWS.....	180
B. BIASED ASSIMILATION: HOW CULTURAL WORLDVIEWS MEDIATE INFORMATION PROCESSING.....	182
III. CAUSES, EFFECTS AND RESPONSES TO AN INDIVIDUALISTIC WORLDVIEW .....	186
A. CONSEQUENCES OF AN INDIVIDUALISTIC WORLDVIEW: CAUSAL MISATTRIBUTION AND WEIGHT BIAS.....	186
B. POSSIBLE CAUSES OF AN INDIVIDUALISTIC WORLDVIEW .....	189
C. SUPPORTERS' RESPONSES TO AN INDIVIDUALISTIC WORLDVIEW: THE NEED FOR CHANGE.....	191
IV. EXPRESS STRATEGIES TO BE EMPLOYED BY SUPPORTERS OF THE ORDINANCE .....	193

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A. CHALLENGING THE INHERENT ASSUMPTIONS OF AN INDIVIDUALISTIC  
WORLDVIEW..... 193

1. THE GENERAL PUBLIC LACKS HEALTH LITERACY ..... 193

2. MARKETERS CONFUSE DECISIONMAKING AND CONSTRAIN PARENTAL  
AUTHORITY ..... 194

3. QUALITY VERSUS QUANTITY OF CHOICE..... 196

4. POLICY PRIORITIES THAT JUSTIFY LIMITING INDIVIDUAL CHOICES ..... 197

B. RESHAPING CONSUMER INTERESTS FROM ECONOMIC TO PROTECTIONIST  
..... 198

1. POTENTIAL CHALLENGES TO ESTABLISHING THE CONSUMER  
PROTECTION INTEREST FRAMEWORK ..... 200

2. FACTORS INDICATING LIKELIHOOD OF ESTABLISHING THE CONSUMER  
PROTECTION INTEREST ..... 201

**CONCLUSION AND NEXT STEPS—RECRUITING PHYSICIANS AS POLICY  
ENTREPRENEURS..... 206**

## INTRODUCTION

On November 24, 2010,<sup>1</sup> San Francisco's Board of Supervisors (hereinafter "the Board") enacted an ordinance banning the bundling of toys with children's meals that do not meet specific nutritional requirements.<sup>2</sup> The Board faced strong public and political opposition to the passage of the ordinance, even from those that typically support anti-obesity and other public health initiatives. San Francisco Mayor Gavin Newsom vetoed the ordinance, for "[d]espite [the ordinance's] good intentions, [he could not] support this unwise and unprecedented governmental intrusion into parental responsibilities and private choices."<sup>3</sup> Ultimately, there was sufficient support on the Board to override Newsom's veto, and the ordinance passed. Though the Board won the political fight over enacting the ordinance, the success of the regulation in the domain of public opinion is much less certain.

Since the ordinance was first proposed, it has drawn intensive public criticism. Its opponents perceive the regulation as an unwelcome intrusion of governmental authority into the private realms of personal responsibility and individual choice. Most vividly, the California Restaurant Association opposed the legislation through images, depicting a child with a toy in handcuffs with the headline, "Who Made Politicians the Toy Police?"<sup>4</sup> This public outcry against the invasion of the "nanny state" is nothing new, yet the divisiveness over this ordinance is quite puzzling in light of its relatively narrow impact on actual consumer choices. Even with the ordinance, consumers can choose the exact same combination of food items as they would have before. The only difference is that now, if a consumer chooses an unhealthy combination meal, he or she will have to buy the toy separately. Therefore, the ordinance is more accurately characterized as creating an incentive to provide healthy children's meals, not as a ban against unhealthy children's meals, as these options are still available.

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1. The Board of Supervisors first passed the ordinance on November 2, 2010. See Eric Mar, *Opposing View on Child Obesity: Put Kids' Health First*, USA TODAY, Nov. 8, 2010, [http://www.usatoday.com/news/opinion/editorials/2010-11-09-editorial09\\_ST1\\_N.htm](http://www.usatoday.com/news/opinion/editorials/2010-11-09-editorial09_ST1_N.htm). (San Francisco Mayor Gavin Newsom vetoed the ordinance on Friday, November 12; see Michael Martinez, *Mayor Vetoes San Francisco Ban on Happy Meals with Toys*, CNN (Nov. 12, 2010, 8:33 PM), <http://www.cnn.com/2010/US/11/12/california.fast.food.ban/index.html>. The Board of Supervisors voted on November 23 to override the veto 8 to 3. Rachel Gordon & Heather Knight, *Supes Override Meal-Toy Veto*, S.F. CHRON., Nov. 24, 2011, [http://articles.sfgate.com/2010-11-24/bay-area/24943611\\_1\\_veto-meal-toy-drug-companies](http://articles.sfgate.com/2010-11-24/bay-area/24943611_1_veto-meal-toy-drug-companies). The ordinance took effect in December 2011. *Id.*

2. See S.F., CAL., HEALTH CODE art. 8, §§ 471.1-.9 (2010), available at <http://www.sfbos.org/ftp/uploadedfiles/bdsupvrs/ordinances10/o0290-10.pdf>.

3. Martinez, *supra* note 1.

4. Poster, Cal. Rest. Ass'n, *Tough on Crime?*, available at <http://www.calrest.org/go/CRA/?LinkServID=2300091B-C688-4663-BAC00E1F7351F460&showMeta=0> (last visited Nov. 27, 2011).

In this Note, I argue that the debate over the San Francisco ordinance is not about the actual effects of the law, but instead is about the law's expressive value and how this symbolic meaning affirms or challenges the values of different groups in society. Supporters of the ordinance primarily have a solidaristic worldview, meaning that they look to governmental and other societal-level remedies to address problems. Opponents of the ordinance, however, have primarily an individualistic worldview, meaning that they prioritize individual choice and personal responsibility in problem solving. I argue that because of this dichotomy in ideologies, supporters of the San Francisco ordinance cannot rely on the traditional method of persuasion in the public health context—the approach of simply relying on the dissemination of positive scientific evidence to shape public opinion. This traditional approach will further polarize, not persuade, the ordinance's opponents, who prioritize individual autonomy over systematic governmental interventions. Rather, to be successful the ordinance's supporters need to respond to their critics by directly addressing the expressive nature of the ordinance debate. Such an approach requires two steps. First, ordinance supporters should challenge their individualistic opponents' assumption that the children's meal ordinance limits individual choice. Second, rather than fighting their opponents' claim that the ordinance is destroying consumer *economic* interests in having the maximum number of consumer choices, the supporters need to reframe the debate's discourse to show how the ordinance promotes consumer *protection* interests in health and safety. The purpose of this reframing is not to ignore the legitimacy of consumer economic interests but to bring attention to consumer protection interests. Though consumer protection interests are critical, as of yet, they have not been at the forefront of the ordinance debate.

In Part I, I begin to develop this argument by laying out the discursive frameworks used by the opponents and supporters of the children's meal ordinance. Section I.A demonstrates how critics focus on the symbolic meaning of the ordinance, while Section I.B shows how supporters focus on the actual impacts of the ordinance.

In Part II, I utilize cultural cognition theory to demonstrate how cultural worldviews shape public responses to the arguments of both supporters and opponents of the ordinance. Section II.A defines the individualistic and solidaristic cultural worldviews in more detail and shows how these worldviews parallel the different ideologies on both sides of the ordinance debate. Section II.B argues that individuals will evaluate the persuasiveness of information presented by each side based on the information's conformity to their cultural worldviews. Furthermore, the perceived cultural identity of the supporters and opponents of the ordinance themselves plays a key role in the debate, and San Francisco's highly salient liberal identity critically limits the city's proposals from being accepted by those with an individualistic cultural worldview.



In Part III, I sharpen and extend my focus on the individualistic cultural worldview, which presents a key challenge for the supporters of the ordinance. Specifically, Section III.A examines causal misattribution and weight bias, both of which are generated by an individualistic cultural worldview and bar the arguments of the ordinance supporters from gaining traction. Section III.B briefly explores some causes for the prevalence of an individualistic worldview in American society. Having developed an understanding of the individualistic worldview through this prior analysis of its causes and effects, I then, in Section III.C, turn to the strategic response that supporters of the ordinance should adopt. This Section argues that supporters should move beyond the traditional public education approach and directly address the expressive nature of the law. I draw from the history of tobacco regulation to show that reversing even deeply entrenched cultural values is possible.

In Part IV, I lay out two principal ways that supporters of the ordinance should directly engage the expressive nature of the debate. Section IV.A challenges the assumption that the ordinance necessarily reduces informed decisionmaking. Instead, independent, informed decisionmaking is already limited by consumers' lack of understanding of basic nutritional sciences and food marketers' attempts to mislead consumers and usurp parental authority. Moreover, I contend that the ordinance actually increases the number of meaningful consumer choices and that, even if it did limit individual choice, there are three countervailing policy considerations that would still justify passing of the ordinance. Section IV.B argues that supporters of the ordinance should reframe consumer interest to prioritize consumer protection interests in health and safety, and considers some of the possible challenges that the United States faces in making this shift. Reframing the debate may be particularly difficult because the debate implicates other highly sensitive cultural issues in American society, such as the possible contribution of working mothers to the obesity crisis and the correlation of unhealthy diets with specific racial groups. Despite these challenges, numerous historical examples demonstrate that it is possible to shift to different conceptions of consumerism through careful, deliberative advocacy. Focusing on the Progressive Era, I analyze both the general shift from producerism to the rise of American consumerism and the specific shift within the producerist sphere from a *laissez-faire* individualism to a more bureaucratic state that prioritizes the dignity of laborers as a class. Just as the Progressive Era's changes were a necessary response to the rapidly shifting class relationships triggered by industrialism, changes today are necessary to adapt to shifts in our relationship with food driven by technological "advancements" in food production. Accordingly, additional government action, such as the ordinance, is necessary to enable us to make meaningful, informed choices as consumers.

Section IV.C then addresses a possible criticism to my central proposal—

namely, the criticism that calling for supporters to directly address the expressive values of the ordinance is illiberal and undemocratic. Critics may argue that supporters should still favor the traditional public education strategy, since statistical and scientific explanations are more rational and legitimate than debating the cultural values of different societal groups. However, I argue that the opponents of the ordinance are already engaged in public moralizing, and, more importantly, I apply Max Weber's theory of knowledge formation to show that addressing the expressive moral values of the ordinance does not necessitate either illiberal or biased decisionmaking.

After addressing this primary concern, I conclude by arguing that physicians are the stakeholders who should lead the efforts in reframing the expressive value of the ordinance debate. While San Francisco is limited by its ultra-partisan cultural identity, physicians are uniquely situated in that they have the professional authority, legitimacy, and broad acceptability to lead this policy campaign. To convince the public that the overconsumption of fast food is a public, rather than individual, crisis, advocates need to go beyond public education and focus on the expressive moral values of their claims. Physicians are in the prime position to lead this charge.

#### I. RHETORICAL FRAMEWORKS OF THE SAN FRANCISCO ORDINANCE DEBATE

To an outsider, the controversy over the San Francisco ordinance may seem disproportionate to the ordinance's relatively limited impact on consumers' actual consumption choices. Specifically, while the ordinance prevents a fast food chain from bundling the sale of an unhealthy children's meal together with a toy as a single menu item, the ordinance does not ban the sale of either the toy or the unhealthy meal alone. Consequently, customers can still choose to purchase both items simultaneously, they just need to order them separately.<sup>5</sup> Functionally, the ordinance is not so much a *ban*, but rather a change in the *default* children's meal from an unhealthy to a healthy option. In other words, the healthy meal combination is the standard default option, but the unhealthy meal combination is

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5. Note that there is the need to worry about whether the ordinance will effectively narrow consumer choice if in fact the future price of buying the two items separately is much higher than the current bundled cost. While it is impossible to predict exactly how fast food restaurants will change their pricing options in response to the ordinance, as it does not become effective until December 2011, it is unlikely that the cost of the unhealthy meal and toy separately will be much greater than the bundle, as fast food restaurants are not principally trying to profit from the sale of the toy, but instead wish to use the toy as an incentive to attract children to purchase the rest of the bundle. See e.g., Tom Stewart, *The Negative Effects of Child-Centered Marketing for Fast Food*, HELIUM, <http://www.helium.com/items/1483355-fast-food-ads-fast-food-marketing-fast-food-and-children-fast-food-health> (last updated Jan. 7, 2010) (stating that toys in children's meals are a key part of the advertising and marketing schemes created by fast food restaurants to attract children to their unhealthy products).

still available if customers take the initiative to purchase the toy separately.<sup>6</sup> The effects of the ordinance can be further circumvented not only by consumers, but also by the fast food restaurants themselves. Fast food restaurants can effectively nullify any cost barriers to purchasing the toys separately by selling them for only a nominal fee.<sup>7</sup> Given the relative ease with which restaurants can structure their purchasing options around the law and customers can purchase the unhealthy meal and toy as separate items, the ordinance effectively cannot force change in consumers' resulting meal choices.

In spite of its minimal impact, the ordinance has generated extensive controversy. In this Part, I describe the discursive frameworks surrounding this debate. The first Section of this Part argues that critics of the ordinance are opposed to the expressive value of the ordinance, not its actual impact. Oppositely, the second Section argues that the supporters of the ordinance are primarily focused on the ordinance's actual impact on childhood obesity rather than on the ordinance's symbolic meaning.

### *A. Opponents of the Ordinance*

Opponents of the children's meal ordinance object to the fact that the law supposedly limits individual choice.<sup>8</sup> However, in this Section, I show that their criticism focuses not on the actual *effects* of the law on actual consumer choices, but on what they perceive the law to be *expressing* about individual choice. For example, Restaurant Association spokesman Daniel Conway framed his objections to the ordinance in explicitly expressive terms, claiming that San Francisco's ordinance was "sending the message that parents are making the wrong choices, and therefore, they should no longer have that choice."<sup>9</sup> In addition to consumer choices, others recognize that the impact on producers is similarly of a symbolic nature: "The fallout from San Francisco won't be

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6. Trevor Hunnicutt, *Happy Meal Ban Passed: San Francisco Says No to Toys*, CHRISTIAN SCI. MONITOR, Nov. 3, 2010, <http://www.csmonitor.com/Business/Latest-News-Wires/2010/1103/Happy-Meal-ban-passed-San-Francisco-says-no-to-toys> ("If the kids want the toys, they can still get the toys.").

7. *See id.* (arguing that while it is impossible at this point to predict exactly how fast food restaurants will respond to the ordinance, they are unlikely to charge a large separate fee for the toys, which are mostly used as a promotional item to incentivize children to purchase the children's meals).

8. *See, e.g.,* Liz Robbins, *If the Meal Is Too Fatty and Salty, a City Council Proposal Would Take the Toy Away*, N.Y. TIMES, Apr. 6, 2011, <http://query.nytimes.com/gst/fullpage.html?res=9504E0D61F3CF935A35757C0A9679D8B63> ("This proposal robs parents of choice.").

9. Byron Ginsburg, *Mixed Message from Mar(s)*, FREETOCHOOSEOURMEALS.COM (Oct. 1, 2010), <http://www.freetochooseourmeals.com/tag/san-francisco-toy-ban>; *see also* Frank Miele, *Freedom of Choice: Just Another Thing We've Lost?*, DAILY INTER LAKE, Nov. 21, 2010, [http://www.dailyinterlake.com/opinion/columns/frank/article\\_48c11e9c-f50f-11df-b52b-001cc4c002e0.html](http://www.dailyinterlake.com/opinion/columns/frank/article_48c11e9c-f50f-11df-b52b-001cc4c002e0.html) (framing the McDonald's ordinance as a loss of liberty and freedom of choice).

financial -- there are just 19 McDonald's in the city. Instead, it's symbolic."<sup>10</sup> In fact, for some opponents, that the law lacks actual impact and is just "legislation that pushes the boundaries of government for purely symbolic reasons," renders the law even more offensive.<sup>11</sup>

Critics have explicitly noted that the actual impact of the ordinance is relatively narrow in that it does not force consumers to change their fast food consumption preferences. For example, critics have argued that the ordinance is simply a case of "liberals unleash[ing] their coercive urges" that "will probably have no effect on the health of San Franciscans."<sup>12</sup> Other critics have argued that focusing on fast food restaurants is misguided in general, as it is simply an expressive "sideshow" from the actual arenas where the childhood obesity battle should be fought—in schools<sup>13</sup> and in homes.<sup>14</sup> Specifically, critics of the ordinance have also recognized the ease with which customers can circumvent the law, by arguing the following:

The anti-Happy Meal campaign is a silly, self-congratulatory exercise; removing the toy is not going to send consumers flocking to Whole Foods. They will still go to McDonald's, buy a burger and fries without the box, and perhaps ask the cashier for whatever movie-themed promotional trinket lies behind the counter.<sup>15</sup>

Similarly, other critics have noted that customers can also avoid the law by simply going to one of the many fast food restaurants that lies just beyond the

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10. Melanie Warner, *San Francisco's New Ordinance: The Beginning of the End for Happy Meal Toys*, BNET (Nov. 3, 2010, 5:37 PM), <http://www.bnet.com/blog/food-industry/san-francisco-8217s-new-ordinance-the-beginning-of-the-end-for-happy-meal-toys/1935>.

11. Benjamin Wachs & Joe Eskenazi, *How the Happy Meal Ban Explains San Francisco*, S.F. WEEKLY, Jan. 19, 2011, <http://www.sfweekly.com/content/printVersion/2330057>; see also Matthew Bastian, *Sad Tale of the Happy Meal*, TIMES (Trenton, N.J.), Dec. 20, 2010, <http://www.nj.com/opinion/times/oped/index.ssf?/base/news-1/1292827538253910.xml&coll=5> ("The anti-Happy Meal campaign is a silly, self-congratulatory exercise; removing the toy is not going to send consumers flocking to Whole Foods.").

12. Mona Charen, *The Happy Meal Banners and Their Ilk*, NAT'L REV. ONLINE (Nov. 16, 2010, 12:00 AM), <http://www.nationalreview.com/articles/253332/happy-meal-banners-and-their-ilk-mona-charen>.

13. *Unhappy Meal*, BLADEN J. (Elizabethtown, N.C.), Nov. 22, 2010, [http://www.bladenjournal.com/pages/full\\_story/push?articleUnhappy+meal%20&id=10407558&instance=secondary\\_opinion\\_left\\_column](http://www.bladenjournal.com/pages/full_story/push?articleUnhappy+meal%20&id=10407558&instance=secondary_opinion_left_column).

14. Michael O'Connor, *Toying With Kids' Health*, OMAHA WORLD-HERALD, Jan. 30, 2011, <http://www.omaha.com/article/20110130/LIVEWELL02/701309882/1161> ("Jim Partington of the Nebraska Restaurant Association likened the toy debate to a 'sideshow.' Kids eat most of their meals at home, he said, so improving nutrition there is key to combating obesity.").

15. Matthew Bastian, *supra* note 11, at A9.

perimeter of San Francisco and is not subject to the ordinance.<sup>16</sup>

### *B. Supporters of the Ordinance*

In contrast to the critics of the San Francisco ordinance, most supporters primarily focus not on the expressive value of the ordinance, but rather on its actual impact on obesity. To support this non-partisan public health position, proponents of the ordinance base their claims on the results of scientific studies and other forms of empirical evidence that highlight the severity of the childhood obesity crisis and the ordinance's potential to be an effective solution. For example, in the "Findings" section of the San Francisco ordinance, the text cites numerous studies and surveys detailing the growth of the children obesity epidemic in San Francisco, the impact of eating at fast food restaurants on childhood obesity, and the effect of toy marketing on children's consumption choices.<sup>17</sup> In other words, the language of the ordinance focuses on the effects of toy marketing on the childhood obesity crisis in San Francisco and the potential *impact* of the ordinance in addressing this localized problem. Beyond the text itself, supporters of the ordinance often refer to studies showing (1) that the rates of childhood obesity have tripled over the last three decades<sup>18</sup> and (2) that there exists a causal relationship between childhood obesity and fast food consumption.<sup>19</sup> Supporters of the ordinance primarily frame the law in terms of how it impacts the childhood obesity crisis rather than how it champions liberal values.<sup>20</sup>

While primarily focusing on the law's potential impact, some supporters do address the law's expressive and symbolic elements. Ross Mirkarimi, one of the San Francisco supervisors who voted for the ordinance, said that "he is proud of the board for 'pushing the envelope' with the legislation, which he said has spurred discussion nationwide on the issue of healthy fast-food options and what role local governments should have."<sup>21</sup> Likewise, other supporters have stated that the law "will send a strong message to companies and force them [to] change

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16. Meredith Jessup, *San Francisco Takes the "Happy" Out of Happy Meals*, BLAZE (Nov. 11, 2010, 6:01 PM), <http://www.theblaze.com/stories/san-francisco-takes-the-happy-out-of-happy-meals> (noting "that anyone could circumvent the law easily: 'Someone doesn't have to travel very far – a mile outside San Francisco – to get the traditional McDonald's Happy Meals experience'").

17. See S.F., CAL., HEALTH CODE art. 8 § 471.1 (2010), available at <http://www.sfbos.org/ftp/uploadedfiles/bdsupvrs/ordinances10/o0290-10.pdf>.

18. See, e.g., *Overweight in Children*, AM. HEART ASS'N (Mar. 29, 2011, 1:24 PM), [http://www.heart.org/HEARTORG/GettingHealthy/Overweight-in-Children\\_UCM\\_304054\\_Article.jsp](http://www.heart.org/HEARTORG/GettingHealthy/Overweight-in-Children_UCM_304054_Article.jsp).

19. Sarah Parsons, *Unhappy Meals: San Francisco May Ban Toys with Kids' Fast Food*, CHANGE.ORG (Sept. 28, 2010, 12:53 AM), <http://news.change.org/stories/unhappy-meals-san-francisco-may-ban-toys-with-kids-fast-food>.

20. See, e.g., *id.* (focusing on the effect of unhealthy children's meals on health).

21. Dan McMenamin, *Supes Override Veto of Fast Food Toy Ban, Should Go into Effect Next Year*, SF APPEAL (Nov. 23, 2010, 4:03 PM), <http://sfappeal.com/news/2010/11/supes-override-veto-of-fast-food-toy-ban-should-go-into-effect-next-year.php>.

the way they do business.”<sup>22</sup> However, many other supporters are sensitive to the fact that framing the law in expressive terms could actually create more resistance than support. These supporters are wary of highlighting that San Francisco is intentionally pushing the boundaries, as it could trigger a push for the city’s outlier liberal tendencies to be resisted and reigned in.<sup>23</sup> For example, Eric Mar, the San Francisco supervisor who first introduced the ordinance, was careful to explicitly describe the law not as a dramatic shift in policymaking, but as a small, incremental step that is part and parcel of a broader package of food policy proposals—such as menu labeling laws and improvements to school lunches—that local governments had been enacting over the last decade.<sup>24</sup>

The arguments adopted by both sides uncover the discursive frameworks underlying the ordinance controversy, which in spite of their importance have seldom been at the forefront of the debate.

## II. THE ORDINANCE DEBATE THROUGH THE LENS OF CULTURAL COGNITION THEORY

In this Part, I utilize cultural cognition theory to uncover the moral and cultural beliefs underlying the ordinance debate. Fundamentally, the heart of the debate is over which set of cultural worldviews the ordinance prioritizes, not about the actual consequences of the ordinance. Cultural cognition theory also reveals that individuals evaluate the persuasiveness of information based on the information’s conformity to their cultural worldviews, and San Francisco’s liberal identity could prevent its proposals from gaining widespread acceptance. I develop this argument by first laying out the key provisions of cultural cognition theory and then applying these provisions to the ordinance debate.

### *A. Individualistic Versus Solidaristic Cultural Worldviews*

Cultural cognition theory refers to a number of social and psychological mechanisms that collectively operate to ensure that our cultural beliefs are the lens through which we perceive and make sense of objective information.<sup>25</sup> Even when presented with the same facts, individuals with different cultural

22. David Orr, *San Francisco Delays Vote on Controversial Toy Ban*, CHANGE.ORG (Oct. 20, 2010), <http://news.change.org/stories/san-francisco-delays-vote-on-controversial-toy-ban>.

23. Eric Mar, *Creating Access to Healthier Meal Options*, YALE RUDD CENTER (Feb. 23, 2011), [http://streaming.yale.edu/cmi2/opa/podcasts/health\\_and\\_medicine/mar\\_toy\\_022211.mp3](http://streaming.yale.edu/cmi2/opa/podcasts/health_and_medicine/mar_toy_022211.mp3); see also Dan M. Kahan, *The Cognitively Illiberal State*, 60 STAN. L. REV. 115, 117-18 (2007) (demonstrating with a number of historical examples that the more that a policy reflects relatively extreme, outlier beliefs, the more danger there is that the supporters explicitly touting these beliefs could polarize rather than convince their opponents).

24. Mar, *supra* note 23 (“This is a simple and modest policy that holds fast food accountable.”).

25. Dan M. Kahan & Donald Braman, *Cultural Cognition and Public Policy*, 24 YALE L. & POL’Y REV. 149, 150 (2006).

worldviews will understand and process this information differently. However, this is not a deliberate process; individuals are not consciously shaping their responses to information to conform to their existing cultural worldviews. Rather, individuals believe that they are “objectively” responding to information, but their existing values affect how this process occurs. From the viewpoint of cultural cognition theory, culture is not a bias consciously driving decisionmaking, but instead it is an implicit and unconscious filter through which individuals engage in rational information processing.<sup>26</sup> Numerous disciplines use the term “culture” to reference a wide breadth of concepts, but cultural cognition theory uses the term “culture” to refer specifically to the different types of cultural worldviews, developed by Mary Douglas and Aaron Wildavsky, that frame how information is understood.<sup>27</sup> Douglas and Wildavsky developed multiple dimensions for classifying of cultural worldviews, but for the purposes of this Note only the solidaristic versus individualistic dimension is relevant.<sup>28</sup>

People with an individualistic worldview “believe that individuals are expected to secure their own needs without collective assistance” and “individual interests enjoy immunity from regulation aimed at securing collective interests.”<sup>29</sup> Therefore, the opponents of the ordinance can be classified broadly as having an individualistic worldview, for most believe that the ordinance is an unnecessary governmental intrusion into the realms of personal responsibility and individual choice.<sup>30</sup> Oppositely, those with a solidaristic worldview believe “collective needs trump individual initiative” and “society is expected to secure the conditions of individual flourishing.”<sup>31</sup> Therefore, supporters of the ordinance can be broadly classified as having a solidaristic worldview, as most believe that governmental intervention is necessary to address the problem of childhood obesity.

The solidaristic versus individualistic distinction extends beyond the specific context of the San Francisco debate. It also reflects the division in opinions between the two sides of the broader debate on fast food regulations.<sup>32</sup> Specifically, a survey of media reporting on fast food regulatory issues shows

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26. *Id.*

27. *Id.* at 153 (citing MARY DOUGLAS & AARON WILDAVSKY, *RISK AND CULTURE* (1982)).

28. *Id.*

29. *Id.* at 151.

30. Of course, this Note does not claim that every opponent to the ordinance has an individualistic worldview. Rather, generally classifying opponents as having an individualistic worldview and supporters as having a solidaristic worldview allows for the argument to illuminate some of the key differences in the discursive elements of the debate. For examples of criticism that the ordinance infringes on individual choice, see *supra* Section I.A of this Note.

31. Kahan & Braman, *supra* note 25, at 151.

32. It is beyond the scope of this Note to apply cultural cognition theory to the broader regulatory debate. However, it is important to introduce this application of the theory to a new field, as the well-developed body of research and analysis underlying cultural cognition theory can substantially contribute to and inform the broader debate on fast food regulation.

that local governments, consumer groups, nutrition and public health academics, and medical lobby groups tend to favor an individualistic worldview that assigns “responsibility to government, business and larger social forces” for regulating the fast food industry.<sup>33</sup> On the other hand, food and advertising industries favor an individualistic frame that focuses on individual parental responsibility for monitoring and regulating the consumption of fast food.<sup>34</sup>

In sum, the views of the supporters and opponents do not just reflect differences on the issues specific to the ordinance debate, but also much more fundamental cultural worldviews over the proper delegation of responsibility between individuals and society in general.

*B. Biased Assimilation: How Cultural Worldviews Mediate Information Processing*

Clearly, the interests of the San Francisco Board align with a solidaristic worldview, while the interests of the fast food restaurants align with an individualistic worldview. The key issue, however, is how the general public responds to the claims made by each side. Not surprisingly, cultural cognition facilitates this process.

According to cultural cognition theory, people’s responses to the facts and arguments presented by both the supporters and opponents of the ordinance do not depend solely on the substance of presented information. Rather, responses also are predicated both on the source of information and on beliefs about that source.<sup>35</sup> In other words, a person is more likely to react positively to a given piece of information if it comes from a source that the person perceives as having a worldview in alignment with his or her own. This process, in which cultural worldviews mediate how people process information, is known as “biased assimilation.”<sup>36</sup> Biased assimilation recognizes that individuals are not often in positions to investigate personally a wide range of risks, and, therefore, individuals have to rely on those whom they trust for risk assessment. Douglas and Wildavsky note that people naturally trust those who share their values.<sup>37</sup> Since the experts that people tend to trust generally share their cultural commitments, the biased assimilation process often results in a reaffirmation of one’s own cultural worldviews.<sup>38</sup>

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33. Regina G. Lawrence, *Framing Obesity: The Evolution of News Discourse on a Public Health Issue*, 9 HARV. INT’L J. PRESS/POL. 56, 57 (2004).

34. *Id.* at 64.

35. Kahan & Braman, *supra* note 25, at 151, 155-56.

36. *See id.* at 163-64 (citing Charles G. Lord et al., *Biased Assimilation and Attitude Polarization: The Effects of Prior Theories on Subsequently Considered Evidence*, 37 J. PERSONALITY & SOC. PSYCHOL. 2098 (1979)).

37. *Id.* at 151.

38. Beyond Kahan’s cultural cognition theory, this phenomenon has been widely studied and is also described as “confirmation bias,” the tendency to seek out information that bolsters pre-



Furthermore, the link between cultural worldviews and credibility “is not severed by disconfirming empirical information.”<sup>39</sup> “[R]ather than update their prior beliefs based on new information, [individuals] tend to evaluate the persuasiveness of new information based on its conformity to their experience.”<sup>40</sup> Individuals tend to dismiss claims as unreliable if they view them as originating from a source that does not share their cultural commitments.<sup>41</sup> In the ordinance debate, San Francisco’s salience as a “public communicator[] unmistakably associated with particular cultural outlooks or styles”<sup>42</sup> plays a critical role in the public acceptability of the city’s proposals, regardless of the substance of the empirical information underlying its policies. To the extent that San Francisco is viewed as a uniquely liberal entity largely unrepresentative of the rest of the country, rather than as a “neutral” policymaking entity that reflects a range of worldviews, the city’s enactment of the ordinance is less easily acceptable to those with a cultural worldview.

Indeed, other examples of the rhetoric used by the critics of the ordinance demonstrates just how much biased assimilation plays a role in the San Francisco ordinance debate. Specifically, many opponents have ignored the substance of the law itself and have focused on the fact that it originated from San Francisco, which they view as a bastion of unleashed liberalism with residents whose beliefs are misaligned with mainstream American political values.<sup>43</sup> “The Happy Meal ordinance is not at all surprising given San Francisco’s famously liberal leanings.”<sup>44</sup> As one commentator wrote, “The uber-bohemians of San Francisco love this sort of thing; others, maybe not so much.”<sup>45</sup> More importantly, other

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existing views and to ignore data that contradicts those views. The term confirmation bias was first developed by Peter C. Watson. See P.C. Watson, *On the Failure To Eliminate Hypothesis in a Conceptual Task*, 12 Q.J. EXPERIMENTAL PSYCHOL. 129 (1960).

39. See Carl I. Hovland & Walter Weiss, *The Influence of Source Credibility on Communication Effectiveness*, 15 PUB. OPINION Q. 635 (1951); Kahan, *supra* note 23, at 121; Irving Lorge, *Prestige, Suggestion, and Attitudes*, 7 J. SOC. PSYCHOL. 386 (1936).

40. Kahan, *supra* note 23, at 121.

41. *Id.* (citing Jonathan J. Koehler, *The Influence of Prior Beliefs on Scientific Judgments of Evidence Quality*, 56 ORGANIZATIONAL BEHAV. & HUM. DECISION PROCESSES 28 (1993), which demonstrates this effect experimentally with a sample of trained statisticians).

42. Dan M. Kahan, *Fixing the Communications Failure*, 463 NATURE 296, 297 (2010).

43. See, e.g., Charen, *supra* note 12, (citing the ban as an example of “[w]hen liberals unleash their coercive urges”); Laurence D. Cohen & Gina Barreca, *Life, Liberty and the Pursuit of Happy Meals*, HARTFORD COURANT (Conn.), Jan. 30, 2011, [http://articles.courant.com/2011-01-30/news/hc-op-cohen-barreca-happy-0130-20110130\\_1\\_cheeseburger-column-tonka-trucks](http://articles.courant.com/2011-01-30/news/hc-op-cohen-barreca-happy-0130-20110130_1_cheeseburger-column-tonka-trucks) (describing the creators of the ordinance as “[t]he California nutballs”); Ronald V. Miller, Jr., *McDonald’s Happy Meal Lawsuit*, MD. INJURY L. BLOG (Dec. 16, 2010), [http://www.marylandinjurylawyerblog.com/2010/12/mcdonalds\\_happy\\_meal\\_lawsuit.html](http://www.marylandinjurylawyerblog.com/2010/12/mcdonalds_happy_meal_lawsuit.html) (referencing “the liberal bastion of San Francisco”).

44. Trevor Hunnicutt, *Happy Meal Toy Ban Under Consideration in San Francisco*, HUFFINGTON POST (Oct. 2, 2010 4:16 PM), [http://www.huffingtonpost.com/2010/10/03/happy-meal-toy-san-francisco-possible-ban\\_n\\_748456.html](http://www.huffingtonpost.com/2010/10/03/happy-meal-toy-san-francisco-possible-ban_n_748456.html).

45. Charlotte Allen, Editorial, *Stick a Fork in It, We’re Done*, L.A. TIMES, Feb. 13, 2011,

opponents have worried that San Francisco's law could infect other parts of the country.<sup>46</sup> In response to the passage of the ordinance, "restaurant associations in other states started lobbying lawmakers to ensure [that] the wicked nanny government of San Francisco wouldn't spill over into their states."<sup>47</sup> As evidenced by these quotes, opponents of the ordinance have not only objected to the message of what the ordinance expresses, but also to the legitimacy of its source.

Biased assimilation theory also suggests that the facts presented by more "neutral" sources are more easily accepted. This is evidenced by comparing the experience of San Francisco to that of Santa Clara County, California. Santa Clara County passed an ordinance that banned the bundling of unhealthy children's meals with toys six months before San Francisco passed its ordinance.<sup>48</sup> Though the Santa Clara ordinance was controversial, it generated

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<http://articles.latimes.com/2011/feb/13/opinion/la-oe-allen-congress-green-20110213>.

46. Warner, *supra* note 10. The perception that San Francisco, and California more generally, is a tipping point for regulatory "epidemics," see MALCOLM GLADWELL, *THE TIPPING POINT: HOW LITTLE THINGS CAN MAKE A BIG DIFFERENCE* 7 (2000) (likening the birth of new trends and phenomena to "epidemics"), is partially based on the fact that California has on multiple occasions served as the nation's regulatory bellwether, see Ellen Fried & Michele Simon, *The Competitive Food Conundrum: Can Government Regulations Improve School Food?*, 56 DUKE L.J. 1491, 1520 (2007) (describing California as a "policy bellwether"), and repeatedly so in food policy, see Baylen J. Linnekin, *The "California Effect" & The Future of American Food: How California's Growing Crackdown on Food & Agriculture Harms the State & the Nation*, 13 CHAPMAN L. REV. 357, 373 (2010). For example, soon after San Francisco passed its menu labeling ordinance, see *San Francisco Moves Forward on Menu Labeling*, NATION'S RESTAURANT NEWS (Mar. 11, 2008), <http://www.nrm.com/article/san-francisco-moves-forward-menu-labeling>, California became the first state to enact its own menu labeling requirements, see Press Release, Ctr. for Sci. in the Pub. Interest, *California First State in Nation to Pass Menu Labeling Law* (Sept. 30, 2008), available at <http://www.cspinet.org/new/200809301.html>. Other local and state governments soon followed suit. See, e.g., Press Release, Ctr. for Sci. in the Pub. Interest, *Philadelphia Passes Strongest Nutrition Labeling Requirements for Chain Restaurant Menus* (Nov. 6, 2008), available at <http://cspinet.org/new/200811061.html>. This eventually led to the adoption of the Federal Menu Labeling Law in 2010. See Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, § 4205, 124 Stat. 119, 573 (to be codified at 21 U.S.C. § 343(q)(5)). David Vogel of Berkeley's Haas School of Business has documented the "critical role of powerful and wealthy 'green' political jurisdictions in promoting a 'regulatory race to the top,'" generally known as the "California Effect," in a number of regulatory arenas. See Linnekin, *supra*, at 373 (citing DAVID VOGEL, *TRADING UP: CONSUMER AND ENVIRONMENTAL REGULATION IN A GLOBAL ECONOMY* 6 (1995)).

47. Erin Sherbert, *Other States Trying To Dodge Happy Meal Ban Humiliation*, SF WEEKLY: BLOGS (May 10, 2011 12:42 PM), [http://blogs.sfweekly.com/thesnitch/2011/05/happy\\_meal\\_ban.php](http://blogs.sfweekly.com/thesnitch/2011/05/happy_meal_ban.php); see also Thomas Pardee, *States of the Nation: Where To Watch and Why*, ADVERTISING AGE, Mar. 7, 2011, <http://adage.coverleaf.com/advertisingage/20110307/?pg=2> ("If a bad idea bubbles up in one state, you'll see it in other states."); Wachs & Eskenazi, *supra* note 11 ("But when you put San Francisco's laundry list of bans alongside New York City's fatwa against trans fats, Chicago's slavery disclosure ordinance . . . , or Seattle's mandatory composting laws . . . , it becomes clear that a left-leaning pack of cities is fundamentally changing the role—and pushing the limits—of local government.").

48. Santa Clara enacted the ordinance on April 28, 2010. See SANTA CLARA COUNTY, CAL., tit.

nowhere near the level of nationwide interest that San Francisco's later ordinance stirred up. From a consequentialist perspective, this imbalance is quite puzzling, given that Santa Clara was the first to introduce this type of law. Moreover, Santa Clara's law affects a much larger population—there are 805,235 people in San Francisco<sup>49</sup> and 1,781,642 people in Santa Clara County.<sup>50</sup> The contrast between the public reactions to San Francisco's ordinance and Santa Clara County's can be partially explained by the fact that with San Francisco, "[t]he actions of the city's tiny population . . . often have an outsized impact on our national consciousness and the political landscape."<sup>51</sup> In other words, while Santa Clara also is a part of outlying liberal California, it has less salience in the national public imagination than San Francisco.

Finally, biased assimilation theory predicts that an individual will perceive the depth of relevant subject-matter expertise to be secondary to a source's perceived cultural commitments.<sup>52</sup> Soon after San Francisco enacted its ordinance, a mother of two from Sacramento, Monet Parham, filed a class action lawsuit against McDonald's, claiming that the restaurant violated consumer protection laws by using deceptive advertising tactics to target children.<sup>53</sup> Many critics of the lawsuit viewed Parham's case as proof that San Francisco's children's meal ordinance triggered a wave of consumers blaming fast food restaurants for their own personal responsibility failures.<sup>54</sup> Much of the criticism of the case also focused on the fact that Parham was a regional program manager for child nutrition matters and therefore not a "typical" California mother.<sup>55</sup> Despite these attacks, as someone working directly in child nutrition, Parham presumably had more knowledge about the causes and effects of childhood obesity than a "typical" mother. However, Parham's expertise did not lead to her being perceived as a more credible and legitimate litigant against McDonald's; rather, the public perceived Parham as an agent of the radical California regulatory regime, which tarnished her credibility as a "legitimate" plaintiff. The reaction to Parham's lawsuit highlights the primacy of political partisanship over scientific knowledge; individuals simply do not always operate in accordance

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A, div. A18, ch. 22 (2010), available at <http://www.sccgov.org/keyboard/attachments/BOS%20Agenda/2010/April%2027,%202010/202926863/TMPKeyboard203040014.pdf>.

49. *State & County Quickfacts: San Francisco (City), California*, U.S. CENSUS BUREAU, <http://quickfacts.census.gov/qfd/states/06/0667000.html> (last updated Oct. 18, 2011).

50. *State & County QuickFacts: Santa Clara County, California*, U.S. CENSUS BUREAU, <http://quickfacts.census.gov/qfd/states/06/06085.html> (last updated Oct. 13, 2011).

51. Warner, *supra* note 10.

52. See Kahan, *supra* note 23.

53. Complaint, *Parham v. McDonald's Corp.*, No. CGC-10-506178 (Cal. App. Dep't Super. Ct., Jan. 5, 2011), available at [http://cspinet.org/new/pdf/mcdonald\\_scomplaint.pdf](http://cspinet.org/new/pdf/mcdonald_scomplaint.pdf).

54. See, e.g., Walter Olson, *McDonald's Suit over Happy Meal Toys by California Mom Monet Parham New Low in Responsible Parenting*, N.Y. DAILY NEWS, Dec. 15, 2010, [http://articles.nydailynews.com/2010-12-15/news/27084481\\_1\\_french-fries-happy-meals-kids](http://articles.nydailynews.com/2010-12-15/news/27084481_1_french-fries-happy-meals-kids).

55. *Id.*

with the principle that those who know the most about a subject matter should be the ones who inform policy on it.

In sum, this Part reveals the primacy of cultural values to the ordinance debate. The perception of the facts and arguments presented by supporters of the ordinance is ultimately determined by the interaction of the cultural worldviews of the public and the supporters' own perceived cultural identities.

### III. CAUSES, EFFECTS AND RESPONSES TO AN INDIVIDUALISTIC WORLDVIEW<sup>56</sup>

This Part enumerates the challenges that an individualistic worldview presents to proponents of the San Francisco ordinance. An individualistic ideology prioritizes individual control and personal responsibility, greatly emphasizing the role that individual action can have in determining weight outcomes. Section III.A first explores two consequences of such beliefs, namely, causal misattribution and weight bias, and Section III.B then examines some potential causes for the prevalence of an individualistic worldview in American society. Lastly, Part C introduces the strategy that supporters of the ordinance should adopt to respond most effectively to those with an individualistic worldview.

#### *A. Consequences of an Individualistic Worldview: Causal Misattribution and Weight Bias*

There is widespread scientific consensus that personal responsibility is *not* the predominant determinant of body weight.<sup>57</sup> Determining causality for weight outcomes is very complex; weight is driven by a multitude of interacting factors, including biology, genetics, personal responsibility and environment.<sup>58</sup> Moreover, the precise nature of these interactions still is largely unknown.<sup>59</sup> That said, scientists have concluded that genetic factors play a primary causal role,

56. See Lucy Wang, *Weight Discrimination: One Size Fits All Remedy?*, 117 YALE L.J. 1900, 1904-06 (2008), for a more comprehensive and in-depth analysis of the obesity studies cited in this Section.

57. See, e.g., GINA KOLATA, *RETHINKING THIN: THE NEW SCIENCE OF WEIGHT LOSS—AND THE MYTHS AND REALITIES OF DIETING* 69-70 (2007) (quoting obesity researcher Mickey Stunkard as saying that people assume that the overweight “really could lose weight if [they] settled down and stopped being such . . . fat slob[s]”); Catharine Wang & Elliot J. Coups, *Causal Beliefs about Obesity and Associated Health Behaviors: Results from a Population-based Survey*, 7 INT’L J. BEHAV. NUTRITION & PHYSICAL ACTIVITY 19 (2010) (finding that “72% of respondents endorsed the belief that lifestyle behaviors have ‘a lot’ to do with causing obesity, whereas 19% indicated that inheritance has ‘a lot’ to do with causing obesity”).

58. Boyd A. Swinburn et al., *The Global Obesity Pandemic: Shaped by Global Drivers and Local Environments*, 378 LANCET 804 (2011); Walker S. Carlos Poston II & John P. Foreyt, *Obesity Is an Environmental Issue*, 146 ATHEROSCLEROSIS 201 (1999); Steven L. Gortmaker et al., *Increasing Pediatric Obesity in the United States*, 141 AM J. DISEASES CHILD. 535 (1987).

59. See Wang, *supra* note 56, at 1096-1208, for a more thorough discussion of the causalities of obesity.

explaining approximately seventy percent of individual variation in BMI.<sup>60</sup> Accordingly, although important, individual choice is not the predominant determinant of weight.

In spite of the substantial scientific consensus on the factors leading to obesity, personal responsibility is disproportionately cited in public discourse as the primary cause of obesity.<sup>61</sup> This can be explained by cultural cognition theory discussed above. When multiple causal factors exist for a given phenomenon, people are likely to prioritize the cause most consistent with their cultural worldviews, irrespective of scientific research.<sup>62</sup> Consequently, the belief that personal responsibility primarily causes obesity is particularly prevalent because it is consistent with an individualistic cultural worldview, which prioritizes individual choice and control.

Discrimination due to weight bias is another consequence of the belief that being overweight largely is a failure of personal responsibility. Though an individualistic worldview embraces the positive idea that an individual has the power to shape one's own life, the darker corollary is that personal failures are one's own fault. The more that individuals believe that body weight is entirely within one's personal control, the more likely they are to negatively evaluate others against on the basis of weight.<sup>63</sup> As a result of this weight bias, overweight<sup>64</sup> people openly are stereotyped as "mean, stupid, ugly, unhappy, less competent, sloppy, lazy, socially isolated, and lacking in self-discipline, motivation, and personal control."<sup>65</sup>

Indeed, these stereotypes of overweight people are primarily judgments about personal flaws and *moral* failings. Weight bias, unlike other forms of discrimination, such as gender or race, cloaks its discriminatory nature by framing weight gain as being within an individual's control. Framing weight as simply a behavioral choice hides the true discriminatory nature of weight bias

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60. Hermine H.M. Maes et al., *Genetic and Environmental Factors in Relative Body Weight and Human Adiposity*, 27 BEHAV. GENETICS 325, 325 (1997) (analyzing various methodologies and finding that an integrated model estimates a genetic contribution of sixty-seven percent).

61. Rebecca M. Puhl & Kelly D. Brownell, *Psychosocial Origins of Obesity Stigma: Toward Changing a Powerful and Pervasive Bias*, 4 OBESITY REVS. 213, 215-16 (2003).

62. See, e.g., Kahan, *supra* note 23, at 131-42 (finding that this phenomenon occurs in multiple fields and citing examples such as sodomy; drugs, guns, and smoking; and nuclear energy and global warming).

63. Christian S. Crandall & April Horstman Reser, *Attributions and Weight-Based Prejudice*, in WEIGHT BIAS: NATURE, CONSEQUENCES, & REMEDIES 83, 83 (Kelly D. Brownell et al. eds., 2005).

64. The Centers for Disease Control and Prevention (CDC) identifies as overweight an adult whose body-mass index (BMI)—defined as weight in kilograms divided by the height in meters squared—is between 25 and 29.9. See *Overweight and Obesity: Defining Overweight and Obesity*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/obesity/defining.html> (last updated June 21, 2010). The CDC identifies as obese an adult whose BMI is thirty or above. See *id.*

65. Rebecca M. Puhl & Kelly D. Brownell, *Confronting and Coping with Weight Stigma: An Investigation of Overweight and Obese Adults*, 14 OBESITY 1802, 1802 (2006).

and makes it more difficult to eliminate.

Another challenge in generating support for the ordinance is that even those with expert knowledge and personal experience about obesity's actual primary causes are still susceptible to causal misattribution and weight bias. According to a recent study, healthcare professionals share the same prejudices against overweight people as the general public.<sup>66</sup> Therefore, even though healthcare professionals presumably have more access to, and a better ability to understand, information about the causalities of obesity, these professionals' worldviews still primarily drive their behavior and beliefs. Likewise, overweight individuals, who presumably have more personal experience and understanding of the difficulties of controlling weight through individual behavior, are also susceptible to weight bias.<sup>67</sup> Individuals' beliefs that weight is largely controllable may "help[] protect against negative effects of stigma by making self-blame and negative attributions less likely."<sup>68</sup> The idea that personal choice is the key determinant of weight outcomes, which is consistent with an individualistic worldview, can trump both scientific knowledge and personal experience.

This myth of weight controllability also explains the apparent contradictions in several obesity and obesity-related rate trends. Over the last three decades, the obesity rate has risen consistently; "[t]he prevalence of obesity and overweight among US children and adults has more than doubled since the 1970s, and the rate continues to rise."<sup>69</sup> During this time, however, there has been no research showing a concomitant decrease in personal responsibility values.<sup>70</sup>

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66. *Id.* at 1806, 1808 (ranking "[i]nappropriate comments from doctors" as the fourth most common type of stigmatizing situation and finding that physicians are the second most common source of discrimination next to family members: among overweight survey respondents, sixty-nine percent reported discrimination from a physician, and fifty-two percent reported experiencing such discrimination multiple times).

67. Phebe Cramer & Tiffany Steinwert, *Thin Is Good, Fat Is Bad: How Early Does It Begin?*, 19 J. APPLIED DEVELOPMENTAL PSYCHOL. 429, 447 (1998) (finding that overweight children can be just as likely to stigmatize overweight children as non-overweight children). This phenomenon has also been shown to exist with gun ownership. See Dan M. Kahan, *The Secret Ambition of Deterrence*, 113 HARV. L. REV. 413, 452 (1999) ("Survey data show no significant correlation between prior victimization or fear of victimization and positions on gun control. Nor can variation in opinions about gun control be fully explained by variations in violent crime rates across space or time or by variations in the perception of such crime rates. Whatever they say in public, those involved in the gun control debate are not really motivated by beliefs about guns and crime.").

68. Puhl & Brownell, *supra* note 65, at 1813.

69. Youfa Wang & May A. Beydoun, *The Obesity Epidemic in the United States—Gender, Age, Socioeconomic, Racial/Ethnic, and Geographic Characteristics: A Systematic Meta-Regression Analysis*, 29 EPIDEMIOLOGIC REV. 6, 22 (2007).

70. To the best knowledge of the author, there are no published studies showing that, over the same period of time that U.S. obesity rates have increased, Americans value personal responsibility any less. Rather, there do exist studies demonstrating that the United States places greater emphasis on personal responsibility as compared with other countries, such as France. See, e.g., Abigail C. Saguy et al., *Social Problem Construction and National Context: News Reporting on "Overweight" and "Obesity" in the United States and France*, 57 SOC. PROBLEMS 586, 593 (2010).

Simultaneously, there has been a rise in expenditures at fast food restaurants,<sup>71</sup> and multiple studies have shown a causal association among frequency of fast food consumption and excess energy intake, weight gain, and obesity.<sup>72</sup> In spite of these trends, public opinion has shifted in the opposite direction, with the prevalence of weight bias increasing, not decreasing.<sup>73</sup> The psychological mechanisms of cultural cognition explain this apparent contradiction. Consistent with an individualistic worldview, people blame rising obesity rates as a failure of personal responsibility. When overweight individualistic people turn to analyzing themselves, however, their own personal experiences with weight management may challenge this “myth of controllability.” The fact that they are themselves overweight, and yet presumably without major deficiencies in personal responsibility, directly challenges their individualistic belief that weight gain is a personal responsibility problem. This discomfort, which individuals experience when they are presented with evidence contradicting their beliefs, is known as “cognitive dissonance.”<sup>74</sup> To prevent cognitive dissonance, individuals may infer an alternative interpretation of the facts that does not conflict with their individualistic cultural worldview. In this case, individuals may implicitly shift their perceptions of what constitutes obesity downwards to conclude that they themselves are not overweight, since they are not personally irresponsible. Although admittedly speculative, this explanation provides a plausible account of the rising prevalence of obesity and weight bias concomitant with a decrease in individuals’ propensity to self-identify as overweight. It also highlights how strongly cultural worldviews can dominate in the face of directly contradicting information.

### *B. Possible Causes of an Individualistic Worldview*

Historically, Americans consistently have held a more individualistic

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71. Eric Schlosser, *FAST FOOD NATION: THE DARK SIDE OF THE ALL-AMERICAN MEAL* 3 (2004) (“In 1970, Americans spent about \$6 billion on fast food; in 2001, they spent more than \$110 billion.”).

72. See, e.g., J. K. Binkley et al., *The Relation Between Dietary Change and Rising US Obesity*, 24 INT’L J. OBESITY 1032, 1037 (2000) (finding a significant, positive relationship between BMI and one’s consumption of food at fast food outlets for both men and women); Biing-Hwan Lin et al., *Nutrient Contribution of Food Away from Home*, in AMERICAN’S EATING HABITS: CHANGES AND CONSEQUENCES 213, 236 (Frazão ed., 1999), available at <http://www.ers.usda.gov/publications/aib750/aib750l.pdf> (finding little nutritional improvement in foods consumed away from home between 1977-78 and 1994-95); Megan A. McCrory et al., *Overeating in America: Association Between Restaurant Food Consumption and Body Fatness in Healthy Adult Men and Women Ages 19 to 80*, 7 OBESITY RES. 564, 570 (1999) (finding “a positive association between restaurant food consumption frequency and body fatness”).

73. Rebecca M. Puhl & Chelsea A. Heuer, *The Stigma of Obesity: A Review and Update*, 17 OBESITY 941, 941 (2009) (finding that “[t]he prevalence of weight discrimination in the United States has increased by 66% over the past decade”).

74. Cognitive dissonance theory was first developed in LEON FESTINGER, *A THEORY OF COGNITIVE DISSONANCE* (1957).

cultural worldview than citizens of other countries. This Note does not detail the circumstances of this history, as legal comparativists and historians have extensively developed this analysis in other writings.<sup>75</sup> Rather, this Section focuses on more recent developments—how the concept of obesity expressed through media and advertising reflects and then further entrenches an individualistic worldview. These causal factors are important to detail, with respect to both identifying avenues for future study and understanding how supporters of the ordinance can most effectively frame their arguments.

How the media frames obesity likely has contributed to both the rising prevalence of weight bias and the perpetuation of the belief that personal responsibility is the primary cause of obesity. One study of the U.S. media's depiction of the obesity crisis concluded that there was a fivefold increase in media attention to obesity from 1992 to 2003.<sup>76</sup> This news coverage commonly framed obesity as a problem caused by a lack of personal responsibility as opposed to societal level factors.<sup>77</sup> Similarly, the media predominately focused on individually versus socially (or environmentally) based solutions for solving the crisis.<sup>78</sup>

An individualistic worldview is perpetuated not just by “objective” informational sources, such as news agencies, but also by numerous stakeholders with direct financial interests in strengthening the dominance of an individualistic worldview. Restaurants and food manufacturers commonly deflect their own responsibility for contributing to the obesity crisis by emphasizing the need for individuals to take ownership over their health by engaging in more physical activity.<sup>79</sup> The fast growing diet industry, whose annual revenues increased from \$33.3 billion in 1995<sup>80</sup> to over \$55 billion in 2006,<sup>81</sup> also has fueled the personal responsibility discourse. Emphasizing that weight gain is a matter of personal choice and responsibility is essential to the diet industry, which is premised on the idea that individuals can take full control of their weight by buying the “right” products and procedures. Therefore, both “objective” news media and advertisers have contributed to a rise in public exposure to obesity issues and the personal responsibility narrative. Moreover, because of its increased public salience, it appears that more members of society share an individualistic

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75. See, e.g., Saguy et al., *supra* note 70, at 591-92.

76. Lawrence, *supra* note 33, at 64 (examining a sample consisting of numerous network evening news programs and national newspapers, including the *New York Times*).

77. See *id.*; Tatiana Andreyeva et al., *Changes in Perceived Weight Discrimination Among Americans 1995-1996 Through 2004-2006*, 16 *OBESITY* 1129, 1133 (2008).

78. Andreyeva et al., *supra* note 77, at 1133.

79. Jeffrey P. Koplan & Kelly D. Brownell, *Response of the Food and Beverage Industry to the Obesity Threat*, 304 *JAMA* 1487, 1487 (2010).

80. Andreyeva et al., *supra* note 77, at 1133 (citing MARKETDATA ENTERPRISES, *THE U.S. WEIGHT LOSS AND DIET CONTROL MARKET* (4th ed. 1996)).

81. *Id.* (citing MARKETDATA ENTERPRISES, *THE U.S. WEIGHT LOSS AND DIET CONTROL MARKET* (9th ed. 2007)).



worldview than is actually the case.<sup>82</sup> The “availability heuristic”—the phenomenon of individuals being more likely to conform to cultural worldviews that they perceive to be dominant despite their original convictions—has further entrenched the prevalence of an individualistic worldview.<sup>83</sup>

In sum, there are numerous, powerful stakeholders whose actions and interests directly align with the individualistic worldview held by opponents of the ordinance. To effectively advocate for the continued existence of the ordinance, its supporters cannot focus solely on disseminating neutral scientific information.

### *C. Supporters’ Responses to an Individualistic Worldview: The Need for Change*

In the San Francisco ordinance debate, supporters did not sufficiently address the expressive nature of the debate. Rather, the supporters primarily employed “the obvious strategy for dispelling disagreement, and for promoting enlightened democratic decisionmaking, [which was] to produce and disseminate sound information as widely as possible.”<sup>84</sup> In doing so, the supporters hoped that the “truth” would eventually drown out their competitors. Such an emphasis on public education has been the long-standing approach of public health organizations.<sup>85</sup> However, this strategy is misguided because it ignores that the core of the obesity debate is over competing cultural worldviews, rather than the dissemination of key facts. If “the truth carries implications that threaten people’s cultural values, then holding their heads underwater is likely to harden their resistance and increase their willingness to support alternative arguments, no matter how lacking in evidence.”<sup>86</sup> Therefore, supporters of the ordinance need to change course and directly address the expressive elements of the ordinance debate.

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82. Dan M. Kahan et al., *Cultural Cognition of Scientific Consensus*, 14 J. RISK RES. 147, 149-50 (2011) (“Individuals more readily impute expert knowledge and trustworthiness to information sources whom they perceive as sharing their worldviews and deny the same to those whose worldviews they perceive as different from theirs. As a result, information sources that share their worldviews will be overrepresented in individuals’ mental inventories of experts. If individuals observe that a view they are predisposed to believe is in fact espoused by a disproportionate share of the information sources whom individuals recognize to be ‘experts’ by virtue of such a cultural affinity – as could happen if these putative experts are also subject to forces of cultural cognition – individuals of opposing outlooks will end up with different impressions of what ‘most’ credible experts believe.” (footnote omitted)).

83. *Id.* at 149.

84. Kahan & Braman, *supra* note 25, at 151.

85. See generally Peter Barton Hutt, Assistant Gen. Counsel, Food, Drugs, and Prod. Safety Dep’t of Health, Educ., and Welfare, Remarks at the Annual Conference of the Association on Food and Drug Officials of the United States (June 21, 1972), in *Public Information and Public Participation in the Food and Drug Administration*, 36 Q. BULL. ASS’N FOOD & DRUG OFFICIALS 212 (1972) (advocating for greater public education and disclosure in relation to the Food and Drug Administration).

86. Kahan, *supra* note 42, at 297 (2010).

While an individualistic worldview is deeply entrenched in American culture, even deeply entrenched worldviews can change. Specifically, the history of tobacco regulation illustrates how advocates may use awareness and direct engagement of expressive values to change public opinion and enact policy.<sup>87</sup> In 1964, the Surgeon General issued a report strongly warning of the dangers of smoking and condemning the practice.<sup>88</sup> In response, public health officials decided to use public education as their key strategy to combat smoking, specifically focusing their efforts on disseminating the information from the Surgeon General's report.<sup>89</sup> However, the discovery and dissemination of information on the harms of smoking did not spark much change; rather, cigarette usage rates actually continued to rise through the end of the 1970s.<sup>90</sup> Similarly, consumer lawsuits against tobacco companies and efforts to regulate smoking beyond warning requirements and television advertising bans all stalled.<sup>91</sup> Accordingly, scientific discovery of smoking's harms and the subsequent dissemination of this information was a critical, but insufficient, step in decreasing smoking rates and passing antismoking regulations.

Actual changes in consumer behavior did not occur until the symbolic, cultural, and moral connotations of smoking also changed.<sup>92</sup> Eventually, public health advocates shifted their strategy away from educating the public about the harmful effects of smoking to directly challenging the stereotypes of the typical smoker's identity.<sup>93</sup> Rather than focusing on the harmful effects of the *act* of smoking, advocates reframed the *identities* of smokers from being cool and desirable (e.g., the masculinity Marlboro Man) to morally and socially deviant.<sup>94</sup> Only after the expressive and normative value of smoking changed did the activity become socially unpopular, and real progress started to develop with respect to both regulatory reform and changes in consumer behavior. Usage rates dropped dramatically, and the U.S. government pushed through a wave of antismoking regulations.<sup>95</sup> A later Surgeon General acknowledged in retrospect that "the diffusion of new knowledge [embodied in the 1964 Surgeon General's Report] was impeded by the entrenched norm of smoking."<sup>96</sup> The smoking

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87. The following treatment of tobacco regulation is based on the analysis of smoking in Kahan, *supra* note 23, at 136-39.

88. *Id.* at 130.

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.* at 137-38 (citing Constance A. Nathanson, *Social Movements as Catalysts for Policy Change: The Case of Smoking and Guns*, 24 J. HEALTH POL. POL'Y & L. 421, 436 (1999)).

95. *Id.* at 137.

96. *Id.* (alteration in original) (quoting CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEPT OF HEALTH & HUMAN SERVS., REDUCING TOBACCO USE: A REPORT OF THE SURGEON GENERAL 40 (2000)) (internal quotation marks omitted).

example illustrates that, while people *are* responsive to scientific information, awareness of cultural perspectives also is necessary to change. Regulators could not make real progress in regulatory reform until they challenged the expressive value of smoking through reframing.

Therefore, while the prevalence of an individualistic worldview presents numerous challenges to supporters of the ordinance, the tobacco example provides an encouraging illustration of how expressive strategies can transform even dominant cultural worldviews.

#### IV. EXPRESS STRATEGIES TO BE EMPLOYED BY SUPPORTERS OF THE ORDINANCE

This Part details two expressive strategies that supporters of the ordinance should adopt. First, Section IV.A suggests that supporters of the ordinance can directly breakdown their opponents' primary expressive claim, namely, that the ordinance harms individual choice, by showing that the ordinance does not in fact harm informed decisionmaking. Second, Section IV.B contends that, while opponents of the ordinance assume that consumer *economic* interests are the most important concern, proponents of the ordinance should argue that consumer *protection* interests are more critical.

##### *A. Challenging the Inherent Assumptions of an Individualistic Worldview*

Critics of the ordinance primarily are concerned with the fact that the regulation encroaches on individual free choice. This argument assumes, however, that prior to the ordinance's enactment, consumers were able to make informed choices that reflected their preferences and desires. However, this assumption was not true, for "[i]ndividuals' desires and preferences are not always reflected in the choices they [sic] make. A lack of information, maturity, or voluntariness can thwart the realization of desires."<sup>97</sup> Specifically, substantial evidence shows that consumers do not make informed decisions about fast food consumption because they are not properly educated about the basic dietary knowledge that is needed to critically assess encountered health and nutritional claims. Further exacerbating this problem is that restaurants and food manufacturers often use marketing strategies that are misleading and deceptive.

##### *1. The General Public Lacks Health Literacy*

Most Americans lack even a very basic understanding of nutritional science. In 2003, the Surgeon General declared that individuals urgently need fundamental education on basic "health literacy," defined as "the ability of an

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97. Thaddeus Mason Pope, *Balancing Public Health Against Individual Liberty: The Ethics of Smoking Regulations*, 61 U. PITT. L. REV. 419, 456 (2000).

individual to understand, access, and use health-related information and services.”<sup>98</sup> For example, a 2011 survey found that only nine percent of Americans could accurately estimate the number of calories they should consume in a day.<sup>99</sup> Likewise, in an all-female study, ninety-one percent of subjects were unaware of the number of calories needed to gain or lose a pound of fat.<sup>100</sup> Even nutrition experts have trouble accurately estimating restaurant food calories. According to a recent study, experienced nutrition professionals underestimate the caloric content of restaurant food by two hundred to nearly seven hundred calories.<sup>101</sup> Outside of estimating the *absolute* number of calories in food, consumers struggle simply to determine the *relative* healthfulness of different food items, as the “[d]ifferences in calories among various options are not always intuitively obvious.”<sup>102</sup> For example, a McDonald’s cheeseburger and a large fries contain fewer calories than a Starbucks blueberry muffin and a twenty-four-ounce mocha Frappuccino.<sup>103</sup> It is important to note that because all of this research studied American adults, young children—the more relevant population group for the San Francisco ordinance debate—are likely to have even less nutritional knowledge.

## 2. Marketers Confuse Decisionmaking and Constrain Parental Authority

In addition to consumers’ own lack of nutritional knowledge, food producers’ advertising tactics create a marketing environment that further constrains individuals’ abilities to make truly independent and informed choices. First, many of the health claims found on food packing are inaccurate, misleading, or even intentionally deceptive. Many food producers add health claims to their products, as these claims increase consumers’ willingness to

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98. Vice Admiral Richard H. Carmona, Acting Assistant Sec’y for the U.S. Surgeon Gen., Remarks at the American Enterprise Institute Obesity Conference (June 10, 2003), *available at* <http://www.surgeongeneral.gov/news/speeches/obesity061003.htm>.

99. INT’L FOOD INFO. COUNCIL FOUND., 2011 FOOD & HEALTH SURVEY: CONSUMER ATTITUDES TOWARD FOOD SAFETY, NUTRITION & HEALTH (2011), *available at* <http://www.foodinsight.org/Content/3840/2011%20IFIC%20FDTN%20Food%20and%20Health%20Survey.pdf>.

100. Press Release: American Women Speak Out About Weight Loss and Their Thoughts on Healthy Eating: Splenda® Sweetener Products and SHAPE Magazine Team Up on Recent Survey That Sheds Light on Weight Loss Perceptions (Jan. 10, 2011), *available at* <http://www.pnnewswire.com/news-releases/american-women-speak-out-about-weight-loss-and-their-thoughts-on-healthy-eating-113202939.html>.

101. DEP’T OF HEALTH & MENTAL HYGIENE BD. OF HEALTH, NOTICE OF ADOPTION OF A RESOLUTION TO REPEAL AND REENACT § 81.50 OF THE NEW YORK CITY HEALTH CODE 6 (2008), *available at* <http://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-50-0108.pdf>.

102. *Id.*

103. Harold Goldstein & Eric Schlosser, Editorial, *Putting Health on the Menu: Requiring Fast-Food and Restaurant Chains To Post Calorie Information Wouldn’t Hurt Them and Could Help Us*, L.A. TIMES, Aug. 5, 2008, <http://articles.latimes.com/2008/aug/05/opinion/oe-schlosser5>.

purchase the food items.<sup>104</sup> However, studies have shown that consumers find these claims misleading and confusing, and consequently they lead consumers to generate inaccurate inferences from these claims.<sup>105</sup>

Furthermore, many researchers have concluded that fast food advertisements and promotions marketed to children are inherently deceptive because (1) young children do not have the full mental development to understand the intent of advertising and (2) many marketing strategies aim to foster emotionally based and *unconscious* reactions. In other words, as stated by the President of the American Pediatric Association, advertising that targets children is inherently deceptive because children neither understand advertising nor have the cognitive abilities to defend against such ads.<sup>106</sup> Moreover, even more directly misleading, “the most common persuasive strategy employed in advertising is to associate the product with fun and happiness, rather than to provide any factual product-related information.”<sup>107</sup> In fact, McDonald’s corporate spokesman Walt Riker has explicitly stated that, “Ronald does not promote food, but fun and activity—the McDonald’s experience.”<sup>108</sup> The use of the toys in marketing children’s meals—the issue in the San Francisco ordinance debate—is a clear example of this type of marketing strategy.

Critics of the ordinance may respond that, even if such marketing tactics effectively influence children, this fact is largely irrelevant to the debate, as it is the parents who should counteract such influence by exercising control and authority over their children. However, food marketers—coining industry terms such as “pester power,” “the nag factor,” and “kidinfluence”—intentionally and openly encourage children to influence their parents’ purchases.<sup>109</sup> Food

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104. Jennifer L. Harris et al., *Nutrition-Related Claims on Children’s Cereals: What Do They Mean to Parents and Do They Influence Willingness To Buy?*, 2 PUB. HEALTH NUTRITION 1 (2011).

105. See, e.g., WHITE HOUSE TASK FORCE ON CHILDHOOD OBESITY REPORT TO THE PRESIDENT. SOLVING THE PROBLEM OF CHILDHOOD OBESITY WITHIN A GENERATION 23, 25 (2010), available at [http://www.letsmove.gov/sites/letsmove.gov/files/TaskForce\\_on\\_Childhood\\_Obesity\\_May2010\\_FullReport.pdf](http://www.letsmove.gov/sites/letsmove.gov/files/TaskForce_on_Childhood_Obesity_May2010_FullReport.pdf); Jennifer Pomeranz, *Front-of-Package Food and Beverage Labeling: New Directions for Research and Regulation*, 40 AM J. PREVENTIVE MED., 382, 385 (2011); see also C. Elliot, *Assessing ‘Fun Foods’: Nutritional Content and Analysis of Supermarket Foods Targeted at Children*, 9 OBESITY REVS. 368, 376 (2008) (discussing how more “policy attention needs to be directed towards the fact that the very existence of a nutrition claim(s) might be misleading”).

106. Michele Simon, *Why the Happy Meal Is a Crime—and Not Just a Culinary One*, GRIST (Jan. 24, 2011), <http://www.grist.org/article/2011-01-24-why-the-happy-meal-is-a-crime-and-not-just-a-culinary-one>.

107. *Clowning with Kids’ Health: The Case for Ronald McDonald’s Retirement*, CORP. ACCOUNTABILITY INT’L 8, <http://www.retireronald.org/files/Retire%20Ronald%20Expose.pdf> (last visited Oct. 27, 2011) (quoting Brian Wilcox et al., AM. PSYCHOLOGICAL ASS’N, REPORT OF THE APA TASK FORCE ON ADVERTISING AND CHILDREN 23 (2004), available at <http://www.apa.org/pi/families/resources/advertising-children.pdf>) (internal quotation marks omitted).

108. *Id.* (quoting Caroline E. Mayer, *McDonald’s Makes Ronald a Health Ambassador*, WASH. POST, Jan. 25, 2005, at E1) (internal quotation marks omitted).

109. Jennifer Pomeranz, *Television Food Marketing to Children Revisited: The Federal Trade*

marketers devote substantial funds to researching how to optimize these strategies. For example, one marketing study was explicitly designed to determine a messaging strategy that most effectively induced children to nag their parents to buy advertised products.<sup>110</sup> Other marketers have created seven categories of nagging tactics and even “categorize[d] parents according to identified stress factors and conditions (such as income, marital status, and guilt) that make a parent more vulnerable to the nagging of their children.”<sup>111</sup> The prevalence of such intentional manipulation strategies is not to be underestimated; one advertising executive essentially admitted that, “we’re *relying* on the kid to pester the mom to buy the product.”<sup>112</sup>

Food marketers’ strategies create strong counter to the San Francisco ordinance critics’ claim that the issue is simply one of exercising parental authority, as the marketing strategies used to sell children’s meals are targeted to directly undermine this parental control. Courts have explicitly recognized that this type of marketing interferes with parents’ independent choices. For example, in a case before the California Supreme Court, plaintiffs charged two advertising agencies, General Foods Corporation and Safeway Stores, “with fraudulent, misleading and deceptive advertising in the marketing of sugared breakfast cereals.”<sup>113</sup> In its decision, the court recognized that even though parents bought the cereals, they “d[id] not exercise a totally independent judgment” in doing as a result of their children’s influence.<sup>114</sup>

### 3. *Quality Versus Quantity of Choice*

Not only are critics of the ordinance overly optimistic about the ability of consumers to make independent, informed choices, they also mistakenly prioritize the quantity of choices available to consumers without considering whether consumers can successfully choose between meaningfully differentiated items. For example, the Yale Rudd Center for Food Policy and Obesity conducted a recent study of children’s menu options from a sample of fast food chains, including those with top sales in 2008 and 2009.<sup>115</sup> The study found that

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*Commission Has the Constitutional and Statutory Authority To Regulate*, 38 J.L. MED. & ETHICS 98, 99 (2010) (footnotes omitted) (internal quotation marks omitted).

110. *Clowning with Kids’ Health: The Case for Ronald McDonald’s Retirement*, *supra* note 107, at 17-18.

111. *Id.* at 17-18 (citing SUSAN LINN, CONSUMING KIDS: PROTECTING OUR CHILDREN FROM THE ONSLAUGHT OF MARKETING & ADVERTISING 34 (2004) and JAMES U. MCNEAL, KIDS AS CONSUMERS: A HANDBOOK OF MARKETING TO CHILDREN (1992)).

112. *Id.* at 17 (emphasis added) (quoting *How Marketers Target Kids*, MEDIA AWARENESS NETWORK, [http://www.mediaawareness.ca/english/parents/marketing/marketers\\_target\\_kids.cfm](http://www.mediaawareness.ca/english/parents/marketing/marketers_target_kids.cfm) (accessed Feb. 19, 2010)) (internal quotation marks omitted).

113. *Comm. on Children’s Television, Inc. v. Gen. Foods Corp.*, 673 P.2d 660, 663 (Cal. 1983) (superseded by statute on other grounds).

114. *Id.* at 674.

115. JENNIFER L. HARRIS ET AL., FAST FOOD F.A.C.T.S.: EVALUATING FAST FOOD NUTRITION

of 3039 possible children's meal combinations, only twelve met nutrition criteria for preschoolers and only fifteen met nutrition criteria for older children.<sup>116</sup> Therefore, almost all of the available choices failed to meet basic nutritional guidelines, and consumers do not have the freedom to make choices among meaningfully different alternatives to the extent that consumers value healthfulness as a key criterion in making consumption choices.

Furthermore, if anything, the enactment of the ordinance is actually expected to increase the number of meaningful choices available to consumers, as fast food restaurants are likely to respond by increasing the number of available healthy meal options. Fast food restaurants indeed have increased their healthy options with the implementation of menu-labeling laws.<sup>117</sup> For example, since introduction of the menu-labeling laws, "Starbucks . . . has changed its 'default' milk from whole milk to reduced-fat milk, . . . Dunkin' Donuts has a new lower-calorie line[,] . . . and McDonald's has reduced the size of a helping of French fries."<sup>118</sup> Therefore, if the effect of the ordinance is to limit countless harmful options while incentivizing an increase in the currently marginal number of healthful options, the ordinance could actually play a positive role in increasing the quality of available choices.

#### *4. Policy Priorities that Justify Limiting Individual Choices*

Even if the ordinance were to constrain individual choice, strong countervailing policy considerations would still justify the law's enactment. First, governmental intervention may be more necessary in cases where it is very difficult for consumers to make personal risk determinations. Making accurate risk assessments about food decisions is difficult, since the present benefit of satisfying hunger and cravings is much more immediate than the future potential harms, which include obesity and diabetes. In other words, the lack of temporal proximity between the consumption of fast food and its ultimate cumulative health effects makes it more difficult for individuals to exercise control and responsibility in making healthy choices and risk assessments.

Second, studies showing that health and nutrition education may be insufficient to motivate people to make healthy eating choices justify the need for more direct government intervention. The intervention of governmental action, in the face of systematic individual failures to act, has occurred frequently in other public health and safety contexts, such as with mandated seatbelt laws.

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AND MARKETING TO YOUTH 17 (2010), available at [http://www.fastfoodmarketing.org/media/FastFoodFACTS\\_Report.pdf](http://www.fastfoodmarketing.org/media/FastFoodFACTS_Report.pdf).

116. *Id.* at 48.

117. Kim Severson, *Calories Do Count*, N.Y. TIMES, Oct. 28, 2008, <http://www.nytimes.com/2008/10/29/dining/29calories.html?pagewanted=all>.

118. *Food Regulation in America: Menu Items*, ECONOMIST, Aug. 28, 2008, <http://www.economist.com/node/12010393>.

Specifically, for the ordinance debate, despite that “Americans are now aware of the importance of good diet or nutrition due to public and private nutrition information programs, it is becoming increasingly clear that nutrition knowledge does not directly predict dietary behavior as those with more knowledge do not necessarily change behavior.”<sup>119</sup> Child-directed obesity regulations that are dependent on personal self-sacrifice are likely to fail.<sup>120</sup>

Third, a growing amount of evidence shows that fast foods actually exhibit addictive properties.<sup>121</sup> There is strong support for the proposition that sugar, in particular, can be addictive.<sup>122</sup> Other studies have not only shown that there are interactions between the neural pathways for appetite and cravings, but also that food deprivation affects reward systems in the same way as drugs and other addictive substances.<sup>123</sup> If these research studies conclusively prove that fast food is indeed addictive, this greatly weakens the argument that personal control and responsibility are the only forces needed to regulate fast food consumption.

### *B. Reshaping Consumer Interests from Economic to Protectionist*

In addition to challenging the belief that the ordinance is harmful to individual free choice, advocates of the ordinance also should reframe the priority they put on consumer *protection* interests, the framework that provides the most compelling support for the ordinance. James Whitman provides a classification of two different types of consumer interests that conceptually align with the two sides of the ordinance debate—consumer *protection* interests and consumer *economic* interests.<sup>124</sup> Consumer *economic* interests are defined as consumers’ interests “in purchasing goods and services at the lowest possible price, in having access to the widest variety of goods and services, in having easy access to credit, in being able to shop at maximally convenient hours and locations, and the like.”<sup>125</sup> Consumer *protection* interests, on the other hand, are

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119. Rodolfo Nayga Jr., *Impact of Sociodemographic Factors on Perceived Importance of Nutrition in Food Shopping*, 31 J. CONSUMER AFF. 1, 1-2 (1997).

120. *Cf.* Peter Barton Hutt, *Regulatory Implementation of Dietary Recommendations*, 36 FOOD DRUG COSM. L.J. 66, 69 (1981) (“If health promotion and disease prevention programs depend solely, or even primarily, on personal self-sacrifice and abjuration, they are doomed to failure.”).

121. Roni Caryn Rabin, *Can You Be Addicted to Foods?*, N.Y. TIMES: WELL BLOG (Jan. 5, 2011, 11:57 AM), <http://well.blogs.nytimes.com/2011/01/05/can-you-be-addicted-to-foods>.

122. See Nicole M. Avena et al., *Evidence for Sugar Addiction: Behavioral and Neurochemical Effects of Intermittent, Excessive Sugar Intake*, 32 NEUROSCIENCE & BIOBEHAVIORAL REVS. 20, 32 (2008); Hollis Templeton, *Food, Fitness, and Addiction*, FITBIE, <http://fitbie.msn.com/lose-weight/food-fitness-and-addiction> (last visited Oct. 29, 2011).

123. Takashi Yamamoto, *Brain Mechanisms of Sweetness and Palatability of Sugars*, NUTRITION REVS. S5, S5 (2003).

124. See James Q. Whitman, *Consumerism Versus Producerism: A Study in Comparative Law*, 117 YALE L.J. 340, 366-67 (2007).

125. *Id.* at 366.



supported by “consumer *protection and safety* legislation, that is, legislation on such matters as products liability, the purity of food and drugs, nondeceptive advertising, and the like.”<sup>126</sup> Opponents of the ordinance frame their claims in favor of supporting the *economic* interests of consumers. In response, supporters of the ordinance should reframe the debate to focus on the *protection* interests of consumers.

Prioritizing consumer protection interests over consumer economic interests allows for a shift from a more solidaristic to a more individualistic conception of the ordinance debate. Consumer economic interests align with an individualistic worldview, as consumption is generally considered an individual’s personal choice.<sup>127</sup> Oppositely, consumer protection interests align with a solidaristic worldview, as health and safety concerns are generally framed as public health issues.<sup>128</sup> Therefore, this reframing would allow supporters of the ordinance to address the public consequences of personal consumption.

Shifting to an emphasis on consumer protection interests also would necessitate a shift in the level of risk born by society. The combination of a regulatory approach and focus on consumer protection interests is termed the “precautionary principle strategy,” which is a means by which food is regulated in the European Union.<sup>129</sup> Under the precautionary principle, “when there is scientific uncertainty as to the nature of [the] damage or the likelihood of the risk” posed by some activity, “then decisions should be made so as to prevent such activit[y] . . . unless and until scientific evidence shows that the damage will not occur.”<sup>130</sup> In other words, in the face of scientific uncertainty, regulators are to err on the side of caution, even when there is no demonstrable risk. By contrast, the dominant American approach is to prioritize consumer economic interests, and consequently, “the American sovereign consumer model asks the individual to accept significantly more risk in life than his European counterpart.”<sup>131</sup> The U.S. model, however, fails to account for the fact that the bearing of more risk may not lead to the socially optimal outcome for consumers. The optimal level of risk ultimately is a cultural, rather than empirical, question.

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126. *Id.* at 367.

127. *Id.* (“The spirit of law protecting the consumer economic interest . . . idealizes the consumer as sovereign.”).

128. See Lawrence, *supra* note 33, at 58.

129. World Health Org. (WHO) Secretariat for the Fourth Ministerial Conference on Env’t & Health, Budapest, June 2004, *Dealing with Uncertainty—How Can the Precautionary Principle Help Protect the Future of Our Children* (WHO, Working Paper No. EUR/04/5046267/11, 2004), in WORLD HEALTH ORG., *THE PRECAUTIONARY PRINCIPLE: PROTECTING PUBLIC HEALTH, THE ENVIRONMENT AND THE FUTURE OF OUR CHILDREN* 15, 15 (Marco Martuzzi & Joel A. Tickner eds., 2004), available at [http://www.euro.who.int/\\_data/assets/pdf\\_file/0003/91173/E83079.pdf](http://www.euro.who.int/_data/assets/pdf_file/0003/91173/E83079.pdf).

130. *Cloning, 2002: Hearings Before the Subcomm. on Labor, Health and Human Servs., and Educ., and Related Agencies of the S. Comm. on Appropriations*, 107th Cong. 19 (2002) (statement of Brent Blackwelder, President, Friends of the Earth).

131. Whitman, *supra* note 124, at 390.

If consumers feel strongly that they do not want to run a given risk, even where the evidence shows otherwise, the government should not impose that risk on the population.<sup>132</sup> A narrow conception of consumer interests that only focuses on consumer economic interests, however, completely prevents a discussion of this critical social issue.

### *1. Potential Challenges to Establishing the Consumer Protection Interest Framework*

In addition to the relative dominance of the individualistic worldview in the United States, there are also other aspects of American culture that may impede deliberate attempts to reposition the meaning of consumer interest. Specifically, it may be difficult for supporters of the ordinance to explicitly discuss the expressive elements of the childhood obesity debate because this dialogue necessarily engages a number of other political and sensitive societal issues.<sup>133</sup> For example, deep examination of the causes of childhood obesity prompts us to awkwardly point the finger at parents, particularly working mothers.<sup>134</sup> For some feminists, it is a particularly uncomfortable notion that all of the gains that women have made in the workforce in terms of gender equality and personal empowerment may also have contributed directly to the rising rates of childhood obesity.<sup>135</sup> Some feminists may perceive of working mothers as “selfishly” pursuing their own careers, leaving their children to eat junk food at McDonald’s instead of being “properly” cared for at home. Although the question of proper parenting is massively important in American society, it also is not often openly discussed, as parenting is viewed as a particularly private sphere that should not be intruded upon by others’ morals and values.

Another uncomfortable aspect of U.S. culture tied to the obesity debate is that the core of American cuisine is often characterized by items such as hamburgers, fries, and other particularly obesogenic foods that are often most blamed for contributing to the obesity crisis.<sup>136</sup> Indeed, some commentators

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132. See Caroline E. Foster, *Public Opinion and the Interpretation of the World Trade Organisation’s Agreement on Sanitary and Phytosanitary Measures*, 11 J. INT’L ECON. L. 427, 427 (2008).

133. This Note simply introduces these issues and a fuller analysis should be conducted elsewhere.

134. John Cawley & Feng Liu, *Maternal Employment and Childhood Obesity: A Search for Mechanisms in Time Use Data*, (Nat’l Bureau of Econ. Research, Working Paper No. 13600, 2007), available at <http://www.nber.org/papers/w13600.pdf>.

135. Bob Cutler, *Keeping Kids Happy at No Cost to Mom: C3’s Position on County of Santa Clara Toy Ban*, JENNINGS SOC. MEDIA 2 (May 7, 2010), [http://jenningsocialmedia.com/downloads/C3.SANTACLARA\\_Final.pdf](http://jenningsocialmedia.com/downloads/C3.SANTACLARA_Final.pdf) (citing “dual-income families resulting in less supervised time” for kids as contributing to the childhood obesity crisis).

136. See SIDNEY MINTZ, *TASTING FOOD, TASTING FREEDOM: EXCURSIONS INTO EATING, POWER, AND THE PAST* 116-18 (1997).

explicitly have demonized anti-obesity efforts as anti-American.<sup>137</sup> Other individuals have sympathized with narratives knowingly glorifying the excessive and unhealthful nature of fast food as symbolic of the rebellious, masculine aspect of American identity.<sup>138</sup> Similarly, some obesogenic foods are associated with specific racial identities, and, once again, political correctness creates great discomfort with the singling out of a particular ethnic group's eating habits.<sup>139</sup> Therefore, the expressive nature of the obesity debate can implicate questions of race, gender, and national identity that make individuals unwilling to engage in these conversations.

## 2. *Factors Indicating Likelihood of Establishing the Consumer Protection Interest*

Though the previous discussion focuses on potential limitations to reframing efforts, there are also other factors indicating that a shift in the United States towards a more consumer protectionist approach is possible. Historical examples show that shifts to different types of consumerism have been achieved through careful and calculated advocacy. For example, the rise of American consumerism in the early twentieth century was an intentional effort to create justice and social peace in response to rising class tensions between labor and capital.<sup>140</sup> This deliberate political program shifted people's conceptualizations of their primary identities away from highly differentiated producer identities to a single consumer identity with a shared common interest in buying "cheap" and "good" products.<sup>141</sup>

Another example contemporaneous with the rise of American consumerism reveals that the United States already has managed to shift from a predominantly individualistic to a solidaristic cultural worldview. This shift has occurred, however, in the context of producer, not consumer, concerns. During the

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137. See, e.g., Craig Lambert, *The Way We Eat Now: Ancient Bodies Collide with Modern Technology To Produce a Flabby, Disease-Ridden Populace*, HARV. MAG., May-June 2004, <http://harvardmagazine.com/2004/05/the-way-we-eat-now.html>.

138. Michael Benjamin, *On Happy Meals and Individual Choices*, EPOCH TIMES (May 5, 2011), <http://www.theepochtimes.com/n2/opinion/on-happy-meals-and-individual-choices-55887.html> (arguing that San Francisco's ban is an example of the diminishing of the "[r]ugged individualism [that] once typified that which was great about the American character. Today, Americans have ceded their individual responsibility to government, politicians, and trial lawyers").

139. See, e.g., SONYA A. GRIER, AFRICAN AMERICAN & HISPANIC YOUTH VULNERABILITY TO TARGET MARKETING: IMPLICATIONS FOR UNDERSTANDING THE EFFECTS OF DIGITAL MARKETING (2009), available at <http://digitalads.org/documents/Grier%20NPLAN%20BMSG%20memo.pdf>; Ross D. Petty et al., *Regulating Target Marketing and Other Race-Based Advertising Practices*, 8 MICH. J. RACE & L. 335, 356-58 (2003) (discussing the fact that certain minorities disproportionately consume certain harmful products and have higher rates of obesity than whites).

140. Whitman, *supra* note 124, at 361.

141. *Id.*

Progressive Era, the rise of industrialism and the inequity between factory owners and workers challenged the concept of “free” labor. Workers were “free” to contract their labor to employers, but how much actual freedom and choice did workers have in this exchange?<sup>142</sup> Specifically, progressives repudiated the “negative” liberties associated with a laissez-faire labor market, arguing that “free choice in employment contracts did not make a worker more free if he could choose only among terrible offers.”<sup>143</sup> Instead, progressives argued for “positive” liberty, in which the government would arrange economic life to spread meaningful opportunities more broadly among its citizens.<sup>144</sup> Therefore, there was a shift away from traditional laissez-faire individualism and the myth of self-reliance to a general acceptance of a solidaristic worldview that embraced expert management.<sup>145</sup> As Woodrow Wilson stated in *The New Freedom*, “[T]o let the individual alone is to leave him helpless as against the obstacles with which he has to contend.”<sup>146</sup> Therefore, at least with respect to producer concerns in the United States, there was a shift in the conceptualization of free choice as more than a negative freedom from interference: free choice also came to be viewed as a positive freedom to choose among attractive alternatives.<sup>147</sup>

However, progressives did not view this shift as rejecting individual choice and democracy, but as simply adapting these values to modern conditions.<sup>148</sup> In many ways, this shift also signaled a return to the core of Adam Smith’s philosophies; even with his great respect for and optimism in free markets, Smith always insisted that the free market be utilized in service of *dignity* and other human values.<sup>149</sup> Progressives did not see any inconsistencies with valuing both free markets and dignity, for in the same speech in which Roosevelt “called for a renewal of individualism and self-reliance, [he] announced that initiative and energy alone could not sustain a complex economy.”<sup>150</sup> In this new complex economy, a more developed bureaucratic state was necessary to create real choice and dignity for laborers: a state that could allow autonomy and vulnerability to mutually coexist. This historical example closely parallels the current debate about consumer protections and shows that heightened state intervention is not mutually exclusive with consumer choice.

Lastly, aside from the desirability of adopting cultural worldviews, there are pragmatic factors that are also already pushing the United States to embrace

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142. JEDIDIAH PURDY, A TOLERABLE ANARCHY 177 (2009).

143. *Id.* at 183.

144. *Id.* at 202.

145. *Id.* at 182.

146. *Id.* at 183 (alteration in original) (quoting WOODROW WILSON, *THE NEW FREEDOM: A CALL FOR THE EMANCIPATION OF THE GENEROUS ENERGIES OF A PEOPLE* 284 (1913)) (internal quotation marks omitted).

147. *Id.* at 202.

148. *Id.* at 183.

149. *Id.* at 189 (discussing values animating Adam Smith’s ideology).

150. *Id.* at 183.

consumer protection interests. Indeed, the EU approach to food safety legislation is not solely driven by predominantly cultural worldviews, but also is in part a purely pragmatic response to some recent food safety scandals. Therefore, as the number of food safety incidences increase in the United States, citizens will demand more food safety protections. Indeed, in the last several years, there have been widespread food safety issues with high public saliency, including salmonella contaminations of both tomatoes<sup>151</sup> and peanuts that have caused multiple deaths.<sup>152</sup> Even with, or perhaps as a result of, great technological advances in farming and other aspects of food production, there were still forty-eight million cases of food-borne illness in the United States in 2010.<sup>153</sup> Therefore, the recent passage of the FDA Food Safety Modernization Act, which is more focused on consumer protection interests than previous legislation, is partially a direct, pragmatic response to these recent food safety scandals and concerns.<sup>154</sup>

#### *a. Addressing the Illiberal Criticism of Reframing the Ordinance Debate*

However, beyond the issue of whether the prominence of the consumer protection interest *may* be expanded, it is critical to address whether it *should* be expanded. In this Subsection, I respond to a potential criticism of my central proposal, which is that calling for supporters to directly address the expressive values of the ordinance is prohibitively illiberal. Using an expressive framework may be an effective strategy, but should it nonetheless not be adopted because is it troublingly undemocratic to so openly value the cultural worldviews of a specific sub-group? Even if the weight of scientific knowledge indicates that the ordinance creates substantial community health and social benefits, does the value of “unbiased” decisionmaking outweigh the potential health outcome

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151. *Tomatoes Pulled Off Shelves, Menus Amid Salmonella Scare*, FOXNEWS.COM (June 19, 2008), <http://www.foxnews.com/story/0,2933,364448,00.html>.

152. Editorial, *Dangerous Food*, N.Y. TIMES, Feb. 17, 2009, <http://www.nytimes.com/2009/02/17/opinion/17tue1.html>.

153. *48 Million U.S. Cases of Food-Borne Illness in 2010 Push Industry Toward RFID-Enabled Food Safety Systems*, SUPPLY & DEMAND CHAIN EXECUTIVE (Apr. 18, 2011), [http://www.sdcexec.com/web/online/FulfillmentLogistics-Trends/48-Million-US-Cases-of-Food-borne-Illness-in-2010-Push-Industry-toward-RFID-enabled-Food-Safety-Systems/15\\$13471](http://www.sdcexec.com/web/online/FulfillmentLogistics-Trends/48-Million-US-Cases-of-Food-borne-Illness-in-2010-Push-Industry-toward-RFID-enabled-Food-Safety-Systems/15$13471).

154. FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified in scattered sections of 21 U.S.C.); see Patrik Jonsson, *Food Safety Bill 101: What Are the Facts and Myths?*, CHRISTIAN SCI. MONITOR, Nov. 23, 2010, <http://www.csmonitor.com/USA/Politics/2010/1123/Food-safety-bill-101-What-are-the-facts-and-myths> (finding that the food safety bill gives “the Food and Drug Administration more power to recall tainted products, strengthen inspections of vegetable and meat processors, and demand that producers follow tougher standards for keeping food safe”); *Obama Signs Food Safety Bill*, CNN (Jan. 4, 2011), [http://articles.cnn.com/2011-01-04/politics/obama.food.safety\\_1\\_food-safety-fda-power-commissioner-margaret-hamburg?\\_s=PM:POLITICS](http://articles.cnn.com/2011-01-04/politics/obama.food.safety_1_food-safety-fda-power-commissioner-margaret-hamburg?_s=PM:POLITICS) (describing the implications of the Act’s passage).

benefits? These questions highlight the tensions that frequently exist between rational risk regulation and democratic decisionmaking.<sup>155</sup> Addressing this issue is critical, as otherwise critics may forcefully argue that cultural cognition theory leaves individuals either trapped between a state of illiberal and biased policymaking or in an equally unfavorable nihilistic state of total inaction that a strict form of cultural relativism can imply.

Democratic decisionmaking is associated with a general norm against couching arguments explicitly in moral terms.<sup>156</sup> “Liberalism is famously opposed to public moralizing, or at least to certain robust forms of it,”<sup>157</sup> for statistical and scientific explanation is perceived as more “rational,” and therefore more “legitimate,” than naked appeals to values.<sup>158</sup> Consequently, groups oftentimes do not resort to explicitly using expressive moral frames except in “extreme” circumstances, such as when a law is passed that directly challenges their beliefs, and they are placed in a defensive mode, as is the case with the opponents of the San Francisco ordinance.<sup>159</sup>

However, Max Weber’s theory of objectivity and subjectivity,<sup>160</sup> which rejects the notion that subjectivity inherently is antagonistic to accessing reality and truth, shows that the role of subjectivity in knowledge creation does not necessarily imply the existence of a problematic bias.<sup>161</sup> Although developed in a different historical and intellectual context, Weber’s 1942 theory of knowledge lends a normative justification for the subjective political decisionmaking that necessarily results under cultural cognition theory. Weber believed that subjectivity is what uniquely enables a meaningful and accurate account of the world.<sup>162</sup>

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155. See Dan M. Kahan et al., *Fear of Democracy: A Cultural Evaluation of Sunstein on Risk*, 119 HARV. L. REV. 1071, 1073 (2006) (reviewing CASS R. SUNSTEIN, *LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE* (2005)) (discussing the relationship between democratic decisionmaking and rational risk regulation).

156. STEPHEN HOLMES, *PASSIONS AND CONSTRAINT: ON THE THEORY OF LIBERAL DEMOCRACY* 203 (1995) (describing the “range and variety of self-censorship common in liberal democratic societies”).

157. Kahan, *supra* note 67, at 478.

158. *Id.* at 446.

159. *Id.* at 493.

160. MAX WEBER, “OBJECTIVITY” IN *SOCIAL SCIENCE AND SOCIAL POLICY* (1904), *reprinted in* THE *METHODOLOGY OF SOCIAL SCIENCES* 49, 49-112 (Edward A. Shils & Henry A. Finch eds. & trans., Transaction Publishers 2011) (1949).

161. See *id.* at 57-58, 81-84.

162. While this Note focuses on the role of subjectivity in Weber’s theory, it is critical to note that Weber *does not* reject the existence of objectivity. Weber recognizes both objectivity and subjectivity and argues that both are necessary for creating scientific study: empirical knowledge is objective and retains its validity across individual variations in values, while value judgments are subjective and are *not* universally consistent. See *id.* at 58, 80. However, Weber does separate the two concepts, “*insist[ing] on the rigorous distinction between empirical knowledge and value-judgments*,” for objectivity and subjectivity each play a vital but distinct role in the process of knowledge formation. See *id.* at 49.

Weber's theory describes reality as an infinite chaos that has no innate significance, and accordingly there is no inherent principle for selecting the subjects that science should pursue.<sup>163</sup> Rather, the determination of what to study is determined by the researcher, and this is an inherently subjective process, as what the researcher believes is important to study is determined by the specific values that the researcher holds.<sup>164</sup> Therefore, subjectivity is necessary to construct order and meaning in the world, and, consequently, *all* sciences are subjective in the sense that they are dependent on values as determinants of their objects of study.<sup>165</sup> Accordingly, subjectivity should not be conflated with bias, which connotes that a perspective is inaccurate and not as "true" as an unbiased view. A subjective perspective means that the perspective is positioned from a specific viewpoint that may not be universal across all individuals, but this does not mean that this perspective is consequently untrue or otherwise deficient.<sup>166</sup> Weber's theory of knowledge implies that all knowledge is necessarily subjective, meaning that there is no single "true" understanding of the world that is most accurate.<sup>167</sup> Subjectivity therefore should be conceptualized more as an enabling, vital step in knowledge production.<sup>168</sup>

This conceptualization of subjectivity as a perspective, rather than a bias, is crucial to the San Francisco ordinance debate, because this approach refutes critics' argument that the ordinance lacks legitimacy because it champions liberal values. Opponents claim that, since the ordinance comes from San Francisco, with its perceived radical liberal identity, it is problematically biased because it is based on a particular *cultural* perspective rather than on *objective* social goals.<sup>169</sup> In other words, the opponents object to the fact that ordinance represents subjective liberal values, rather than objectively sound public health policies. However, Weber's theory shows that subjective liberal values and objective health policies are not necessarily mutually exclusive, as there exists no single, true objective framework through which to understand the debate, only multiple frameworks with differing perspectives. Also, in opposing the "cultural partisanship" evident in San Francisco's policies, critics of the ordinance fail to fully acknowledge how their differing cultural worldviews are driving their own beliefs.<sup>170</sup>

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163. *See id.* at 62-62, 72, 82.

164. *See id.*

165. *See id.*

166. *See id.* at 84.

167. *See id.* at 84, 111.

168. *See id.* at 110-11.

169. *See, e.g.,* Trevor Hunnicutt, *San Francisco Supes vs. Ronald McDonald*, BOS. GLOBE, Oct. 2, 2010, [http://www.boston.com/news/nation/articles/2010/10/02/san\\_francisco\\_supes\\_vs\\_ronald\\_mcdonald](http://www.boston.com/news/nation/articles/2010/10/02/san_francisco_supes_vs_ronald_mcdonald).

170. This phenomenon in which one can identify the subjective cultural basis of others' perceptions without the ability to similarly recognize the cultural influences on one's own beliefs is described by cultural cognition theory as "naïve realism." *See* Kahan, *supra* note 23, at 130-31.

In sum, Weber's theory provides an account of knowledge formation that acknowledges the key role of subjectivity, but frames subjectivity positively as a situated perspective rather than as a bias. This theory allows for both a more nuanced understanding of the objections of the opponents of the ordinance and support for the strategic response that I propose the supporters of the ordinance should adopt.

#### CONCLUSION AND NEXT STEPS—RECRUITING PHYSICIANS AS POLICY ENTREPRENEURS

This Note began as an exploration of why the passage of a relatively narrow city ordinance generated such an intense national debate. Analysis of the arguments on both sides reveals that the key division between supporters and opponents of the ordinance is not about the actual effects of the ordinance, but what the ordinance fundamentally symbolizes about the proper relationship between individual responsibility and governmental intervention. Therefore, for their arguments to gain broad acceptance, supporters of the ordinance must explicitly address the expressive meaning of the ordinance. They must first directly counter the assumption that the ordinance actually interferes with individual choice and informed decisionmaking and then reframe the debate to prioritize consumer protection interests over consumer economic interests.

Though this process is critical, it may be especially challenging, as liberal-leaning groups generally are less likely than their conservative counterparts to use explicit moral arguments.<sup>171</sup> Indeed, as detailed earlier, opponents of the ordinance already are framing their arguments in expressive terms, loading their claims with highly salient expressive and value-based charges, framing the ordinance as suffocating individual choice and discouraging personal responsibility. It is imperative that proponents of the ordinance directly respond to these expressive claims.

However, there remains the question of which stakeholders can best serve as the "policy entrepreneurs," who will take the principal initiative and responsibility for reframing the expressive value of the ordinance debate. "Individuals reflexively reject information inconsistent with their predispositions when they perceive that it is being advocated by experts whose values they reject and opposed by ones whose values they share."<sup>172</sup> As previously discussed, San Francisco's ultra-partisan cultural identity prevents those from opposing cultural

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171. Kahan, *supra* note 67, at 489 ("[D]efections from the norm against public moralizing are not uniform across moral commitments and cultural styles. Citizens who support egalitarianism and civic solidarity are more likely to see appeal in liberal public reason, whether out of principle or pragmatic calculation; citizens who support hierarchy and individualism tend to put little value on liberal public reason and are in fact likely to be horrified by the suggestion that moralizing be banished from political discourse.").

172. Kahan et al., *supra* note 82, at 169.



views from accepting the city as a legitimate source of policy. Rather, people are more receptive to experts whom they perceive to have values that are on both sides of the debate.

While it is beyond the scope of this Note to fully analyze the landscape of possible stakeholders in the ordinance debate, I propose that physicians are uniquely situated to enact change in that they have the professional authority, veracity, and legitimacy to serve as the entrepreneurs of a policy campaign. Physicians have an accepted public role in “‘advocacy for and participation in improving the aspects of communities that affect the health of individuals,’ and they have a ‘primary ethical and professional responsibility for the health of the community members they serve.’”<sup>173</sup> Indeed, this conceptualizes the role of the physician as that of the scientist-citizen, someone who embodies both “the scientific duty to see the factual truth as well as the practical duty to stand up for his or her own ideals.”<sup>174</sup> In other words, the scientific and moral agent are dual roles that are both necessary. Therefore, physicians can play a key role in leading the consumer protection interest reframing.<sup>175</sup>

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173. Roberta R. Friedman & Marlene B. Schwartz, *Public Policy To Prevent Childhood Obesity, and the Role of Pediatric Endocrinologists*, 21 J. PEDIATRIC ENDOCRINOLOGY & METABOLISM, 717, 723 (2008) (quoting Russell L. Gruen et al., *Physician-Citizens—Public Roles and Professional Obligations*, 291 JAMA 94, 94 (2004)).

174. WEBER, *supra* note 160, at 58.

175. However, there is a fine line that should be observed. Though some insist that physicians need to become much more political as a collective group, it is critical to not let their status as partisans go too far, as currently their effectiveness in speaking to diverse cultural groups derives from partially the fact that they are perceived of as politically neutral entities. See Kahan, *supra* note 23, at 145-47 (discussing the importance for “cultural vouchers,” who are “individuals bearing authority and credibility within their cultural groups,” in enacting controversial legislation).

