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Responding to Public Health Emergencies on Tribal Lands: Jurisdictional Challenges and Practical Solutions

Justin B. Barnard*

Abstract:

Response to public health emergencies on tribal lands poses a unique challenge for state and tribal public health officials. The complexity and intensely situation-specific nature of federal Indian jurisprudence leaves considerable question as to which government entity, state or tribal, has jurisdiction on tribal lands to undertake basic emergency measures such as closure of public spaces, quarantine, compulsory medical examination, and investigation. That jurisdictional uncertainty, coupled with cultural differences and an often troubled history of tribal-state relations, threatens to significantly impede response to infectious disease outbreaks or other public health emergencies on tribal lands. Given that tribal communities may be disproportionately impacted by public health emergencies, it is critical that tribal, state, and local governments engage with each other in coordinated planning for public health threats.

This Article is offered as a catalyst for such planning efforts. The Article identifies some of the most pressing jurisdictional issues that may confront governments responding to a public health emergency on tribal lands, with the aim of highlighting the nature of the problem and the need for action. The Article goes on to examine the most promising means of addressing jurisdictional uncertainty: intergovernmental agreements. Already utilized in many areas of

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This Article is the work of the author only, and does not represent the views of the Office of the Maine Attorney General. The legal status of the federally recognized Indian tribes in Maine is largely shaped by the Maine Indian Claims Settlement Act, 25 U.S.C. §§ 1721-35 (2012), and the Maine Implementing Act, ME. REV. STAT. tit. 30, §§ 6201-14 (2014). In light of those enactments, it is the position of the Office of the Maine Attorney General that the legal principles discussed in this Article do not apply to Maine's tribes.

shared interest between tribe and state, intergovernmental agreements offer neighboring state, local, and tribal governments a vehicle for delineating roles and authorities in an emergency, and may lay the groundwork for sharing resources. The Article surveys various representative tribal public health intergovernmental agreements, and concludes with suggestions for tribes and state or local governments looking to craft their own agreements.

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INTRODUCTION

The problem of trans-border coordination poses one of the more vexing and persistent problems in the field of public health. Threats to the public health are rarely confined to one political jurisdiction. Rather, in an extensively interconnected modern world, public health threats tend to follow the rapid flow of people and goods between localities.¹ Proper planning and agreements for reporting information, coordinating investigation and countermeasures, and sharing resources across borders are vital for an effective response to public health emergencies.

Meeting this imperative for trans-border coordination is difficult enough between two sovereigns with clear jurisdictional boundaries and lines of authority. The borders that delineate American Indian lands within the United States, however, present a special and challenging case. A shifting and complex body of law controls jurisdiction on Indian lands. This leaves many open questions regarding the scope of tribal and state authority to regulate and respond to threats to public health. Jurisdictional uncertainty is compounded in some states by a rocky history of state-tribal relations,² as well as by simple geography: tribal lands may be fragmented and “checkerboarded” with non-Indian lands within a state,³ or they may straddle the border between two or more states.⁴

Challenges notwithstanding, observers have identified a strong need for states and tribes to coordinate responses to public health emergencies on Indian lands.⁵ There are 566 federally recognized Indian tribes and Alaska Native

1. See Lawrence O. Gostin, *Global Health Law Governance*, 22 EMORY INT'L L. REV. 35, 35 (2008) (“The determinants of health do not originate solely with the national borders, pathogens, air, food, water, and even lifestyle choices. Health threats, rather, spread inexorably to neighboring countries, regions, and even continents”).

2. See Rick Hogan et al., *Assessing Cross-Sectoral and Cross-Jurisdictional Coordination for Public Health Emergency Legal Preparedness*, 36 J. L. MED. & ETHICS 36, 39 (2008).

3. A marked example of such “checkerboarding” can be found in Oklahoma, where police reportedly have to carry GPS units to track jurisdictional boundaries. See Angela R. Riley, *Indians and Guns*, 100 GEO. L.J. 1675, 1731 (2012).

4. The Navajo Nation, for example, extends across parts of Arizona, New Mexico, and Utah. See Paul Spruhan, *Standard Clauses in State-Tribal Agreements: The Navajo Nation Experience*, 47 TULSA L. REV. 503, 504 (2012).

5. See, e.g., Amy Groom et al., *Pandemic Influenza Preparedness and Vulnerable Populations in Tribal Communities*, 99 AM. J. PUB. HEALTH S271, S271 (2009) (“Tribal and state leadership should . . . cooperate closely to clarify responsibilities that may cross jurisdictional lines, legal authorities should be defined for specific public health activities needed to assist vulnerable populations in tribal communities, and legal tools, such as mutual aid agreements, should be used to help accomplish these tasks”); Cheryl H. Bullard et al., *Improving Cross-Sectoral and Cross-Jurisdictional Coordination for Public Health Emergency Preparedness*, 36 J. L. MED. & ETHICS 57, 59 (2008) (identifying gap and suggesting steps to improve tribal coordination with local, state

villages distributed across a majority (thirty-five) of the fifty states.⁶ These tribes, with populations ranging from hundreds to hundreds of thousands,⁷ live on land bases that may be a few acres or tens of thousands of acres.⁸ The public health infrastructures among tribes vary greatly; some have their own health departments and health codes while others have no public health infrastructure at all.⁹ Public health emergencies may also pose a greater threat to tribes than to the general American population due to a variety of factors, including prevalence of chronic disease, poverty, and difficulties accessing medical care.¹⁰ In both the 1918-1919 influenza pandemic and the 2009 H1N1 influenza event, the mortality rate among Indians in the United States was roughly four times that of other groups.¹¹ Recent amendments to the federal Robert T. Stafford Disaster Relief and Emergency Assistance Act¹² allow tribes to directly petition for a federal emergency declaration and receive federal assistance in the same manner as state governments. These changes have improved tribal emergency response capacity,¹³ as have federal, state, and tribal initiatives to encourage tribal public health emergency planning. However, these enhancements to tribal preparedness do not eliminate the need for coordination with tribal neighbors.

This Article examines the vital issue of response to public health emergencies on tribal lands from the state perspective. It explores both the legal challenges of responding to public health emergencies that cross tribal borders as well as the practical means of addressing those challenges through cooperation with tribes. Part I provides a brief overview of the types of emergency measures that might be used to address public health emergencies on tribal lands. Part II surveys the legal landscape for state public health officials contemplating a response to a public health emergency on tribal lands, cataloging some of the jurisdictional issues that might arise in the course of an emergency. Part III

and federal governments on public health emergency preparedness).

6. See Indian Entities Recognized and Eligible To Receive Services From the Bureau of Indian Affairs, 77 Fed. Reg. 47868 (Aug. 10, 2012).

7. See Groom et al., *supra* note 5, at S271.

8. See Ralph T. Bryan et al., *Public Health Legal Preparedness in Indian Country*, 99 AM. J. PUB. HEALTH 607, 608 (2009).

9. *Id.* at 609.

10. See Ctrs. for Disease Control & Prevention, *Deaths Related to 2009 Pandemic Influenza A (H1N1) Among American Indian/Alaska Natives—12 States, 2009*, 58 MORTALITY & MORBIDITY WKLY. REP. 1341, 1341 (Dec. 11, 2009).

11. *Id.*; Groom et al., *supra* note 5, at S271.

12. Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1974, Pub. L. No. 93-288, 88 Stat. 143 (codified as amended at 42 U.S.C. §§ 5121-5206 and various sections of titles 12, 16, 20, 26, and 38 of the United States Code).

13. Disaster Relief Appropriations Act of Jan. 29, 2013, Pub. L. No. 113-2, § 1110, 127 Stat. 4, 47-49 (codified at 42 U.S.C. §§ 5122, 5123, 5170, 5191 (2012)).

discusses the negotiation of intergovernmental agreements, one practical avenue for resolving legal impediments to emergency response. Part IV describes current intergovernmental agreements in the arena of tribal public health emergency response and planning. The conclusion suggests specific issues that should be addressed in an agreement between tribe and state to clarify roles, responsibilities, and authorities in a public health emergency.

I. LEGAL MEASURES AVAILABLE FOR RESPONSE TO A PUBLIC HEALTH EMERGENCY ON TRIBAL LANDS

To appreciate the challenges of responding to a public health emergency across tribal borders, one must be familiar with the legal tools at a state's disposal for addressing public health threats. The full measure of legal mechanisms and authorities that can be used in response to a public health emergency arises from a "tangled architecture" of federal, state, and local laws.¹⁴ The brief discussion below introduces some of the more commonly invoked authorities under state law to respond to a public health emergency.

The exercise of public health authority has historically been the province of the states, as it is one of the police powers explicitly reserved to them by the Tenth Amendment.¹⁵ Pursuant to that reserved authority, each state in the Union has enacted laws to control infectious disease and respond to public health emergencies. These laws created a diverse array of state-specific authorities and procedures.¹⁶ In many cases, states also delegated response authorities to local units of government.¹⁷ The scope of this state and local authority to respond to

14. Lance Gable, *Evading Emergency: Strengthening Emergency Responses Through Integrated Pluralistic Governance*, 91 OR. L. REV. 375, 396 (2012).

15. See U.S. CONST. amend. X ("The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."); *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824) (listing among the police powers reserved to the States "[i]nspection laws, quarantine laws, [and] health laws of every description").

16. Lawrence O. Gostin et al., *The Law and the Public's Health: A Study of Infectious Disease Law in the United States*, 99 COLUM. L. REV. 59, 63 (1999). In the last decade or so, there has been a significant effort to modernize state public health laws to address current challenges. Following the September 11, 2001 terrorist attacks and the anthrax attacks later that year, the Centers for Disease Control asked Lawrence Gostin, professor and attorney with the Center for Law and the Public's Health, to draft model legislation to strengthen state public health emergency response capacity. See Daniel S. Reich, *Modernizing Local Responses to Public Health Emergencies: Bioterrorism, Epidemics, and the Model State Emergency Health Powers Act*, 19 J. CONTEMP. HEALTH L. & POL'Y 379, 383 (2003). That undertaking eventually produced the Model State Emergency Health Powers Act (MSEHPA). *Id.* Legislation based on the MSEHPA has been introduced in a majority of states, and a good number of those measures have been passed into law. *Id.* at 384-85.

17. The Supreme Court has expressly upheld the delegation of state police powers to local government entities. See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) ("[T]he state may

public health threats has been held to be quite broad and, where necessary, to justify significant restrictions on individual liberties.¹⁸ Depending on the state, the availability of specific public health authorities may depend upon a state or local declaration of emergency.¹⁹

Social distancing measures, even if rarely implemented, are among the most familiar and foundational tools at a state's disposal for responding to a public health threat.²⁰ Quarantine laws typically allow a state to separate from the general population and confine people who have been (or may have been) exposed to a contagious disease. Isolation laws, similar in effect, allow the separation and confinement of individuals who have been (or are reasonably believed to have been) actually infected.²¹ State laws generally provide for enforcement of quarantine and isolation by means of a civil fine, criminal penalty, or both.²² Many states explicitly authorize or call for police assistance in enforcement.²³ Some states may require a court order to initiate quarantine or isolation, absent exigent circumstances,²⁴ while others may require recourse to the courts for enforcement of a quarantine or isolation order.²⁵

Social distancing may also include measures with broader, less targeted effect. Quarantine orders may, for example, be issued for entire towns, cities, or counties.²⁶ State or local health officials may also have authority to issue orders

invest local bodies called into existence for purposes of local administration with authority in some appropriate way to safeguard the public health and the public safety. The mode or manner in which those results are to be accomplished is within the discretion of the state”).

18. *See, e.g., id.* at 26 (upholding compulsory vaccination law and noting that “the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint”).

19. *See, e.g.,* N.M. STAT. ANN. §§ 12-10A-1 (2014) (setting forth authorities and procedures for declared public health emergency).

20. Edward P. Richards, *Dangerous People, Unsafe Conditions*, 30 J. LEGAL MED. 27, 34 (2009) (noting that isolation and quarantine are “relatively rare in modern public health practice”).

21. *See, e.g.,* MONT. CODE ANN. § 50-1-204 (2014); N.M. STAT. ANN. § 12-10A-8 (2014); R.I. GEN. LAWS §§ 23-8-4 (2014); *see also* Reich, *supra* note 16, at 406-09 (explaining distinction between quarantine and isolation).

22. *See, e.g.,* MO. REV. STAT. § 192.320 (2015) (violation of quarantine or isolation a misdemeanor); MONT. CODE ANN. § 50-1-204 (2015) (violation of quarantine punishable by fine of between \$10 and \$100); N.H. REV. STAT. § 141-C:21 (2015) (same); S.C. CODE ANN. § 44-4-530(C) (2015) (violation of quarantine a felony).

23. *See, e.g.,* KAN. STAT. ANN. § 65-129b(a)(2) (2014); MISS. CODE ANN. § 41-23-5 (2015); S.C. CODE ANN. § 44-1-100 (2015).

24. *See, e.g.,* ARIZ. REV. STAT. ANN. § 36-789(B) (2015); HAW. REV. STAT. § 325-8(e), (f) (2015).

25. *See, e.g.,* N.H. REV. STAT. § 141-C:13 (2015).

26. KAN. STAT. ANN. § 65-126 (2014); LA. REV. STAT. ANN. § 40:7 (2014).

prohibiting public gatherings,²⁷ closing schools,²⁸ or closing and prohibiting entrance to other buildings accessible to the public.²⁹

Other emergency powers focus more directly on identifying and treating infected individuals. Most jurisdictions have laws that permit public health officials to conduct and compel individuals to submit to medical examinations,³⁰ treatment for contagious disease,³¹ and vaccinations.³² While such provisions are often subject to exemptions for religious and other reasons, they typically require quarantine or isolation of those who refuse to comply.³³ Other treatment-related emergency authorities may include the power to secure healthcare facilities for public use,³⁴ ration medical supplies,³⁵ and access medical records.³⁶

A public health emergency may also justify action to secure personal or real property. Livestock and domestic animals are of particular concern, and many jurisdictions explicitly authorize the inspection, quarantine, seizure, or destruction of animals that may transmit diseases to humans.³⁷ Other provisions more generally authorize the seizure and destruction of property that poses a risk to public health.³⁸

State and local public health officials also have broad investigative powers with respect to public health threats. Mississippi grants sweeping authority to its health department “to investigate and control the causes of epidemic, infectious and other disease affecting the public health, . . . and in pursuance thereof, to exercise such physical control over property and individuals as the department

27. *See, e.g.*, KAN. STAT. ANN. § 65-119 (2014); MICH. COMP. LAWS § 333.2453(1) (2015); N.H. REV. STAT. § 141-C:16-b (2015); OHIO REV. CODE ANN. § 3707.26 (2015).

28. *See, e.g.*, N.J. STAT. ANN. § 26:4-5 (2015); OHIO REV. CODE ANN. § 3707.26 (2015).

29. *See, e.g.*, HAW. REV. STAT. § 128-8(2) (2015); ILL. REV. STAT. ch. 20, § 2305/2(b) (2015); N.H. REV. STAT. § 141-C:16-a (2015).

30. *See, e.g.*, ARIZ. REV. STAT. ANN. § 36-787(B)(1) (2015); ILL. REV. STAT. ch. 20, § 2305/2(d) (2015); KAN. STAT. ANN. § 65-129b(a)(1)(A) (2014); NEV. REV. STAT. § 441A.160(2)(b) (2014).

31. *See, e.g.*, ARIZ. REV. STAT. ANN. § 36-787(C)(1) (2015); ILL. REV. STAT. ch. 20, § 2305/2(e) (2015); KAN. STAT. ANN. § 65-129b(a)(1)(A) (2014); N.H. REV. STAT. §§ 141-C:11(III), 141-C:15(I) (2015).

32. *See, e.g.*, HAW. REV. STAT. § 325-32 (2015); MISS. CODE ANN. § 41-23-37 (2015).

33. *See, e.g.*, KAN. STAT. ANN. § 65-129b(a)(1)(C) (2014); N.M. STAT. ANN. §§ 12-10A-12(B), 12-10A-13(B) (2014).

34. *See, e.g.*, N.M. STAT. ANN. § 12-10A-6(A)(1) (2014); S.C. CODE ANN. § 44-4-310 (2015).

35. *See, e.g.*, N.M. STAT. ANN. § 12-10A-6(A)(2), (B) (2014); S.C. CODE ANN. § 44-4-330(B) (2015).

36. *See, e.g.*, ILL. REV. STAT. ch. 20, § 2305/2(h) (2015); S.C. CODE ANN. § 44-1-80(B)(3) (2015).

37. *See, e.g.*, ILL. REV. STAT. ch. 20, § 2305/2(g) (2015); N.C. GEN. STAT. § 130A-145 (2015).

38. *See, e.g.*, HAW. REV. STAT. § 128-8(2) (2015); OHIO REV. CODE ANN. § 3707.12 (2015).

may find necessary for the protection of the public health.”³⁹ Investigative authorities often expressly include the power to enter and inspect private property,⁴⁰ and may include other administrative investigation powers such as the ability to subpoena individuals and documents.⁴¹

What can be gleaned from the discussion above is that public health emergency authorities typically permit significant governmental intrusion into and curtailment of personal and community rights to property, bodily integrity, association with others, and freedom of movement.⁴² The coercive nature of these measures, coupled with the jurisdictional uncertainty discussed in Part III, underscores the need for tribal and state governments to work together. It is important to ensure that the government entity implementing a particular response to a public health threat does so with a mantle of legitimacy and the support of its neighboring sovereign.

II. THE LEGAL LANDSCAPE FOR RESPONSE TO PUBLIC HEALTH EMERGENCIES IN INDIAN COUNTRY

Federal Indian law has a well-deserved reputation for its complexity. As one leading scholar has characterized it, the body of Indian law “is rooted in conflicting principles that leave the field in a morass of doctrinal and normative incoherence.”⁴³ This doctrinal incoherence is not the only element that makes Indian law challenging; its pattern of development also plays a fundamental role. Decisions in individual federal court cases involving tribes often rest on a variegated foundation of federal law, treaties, historical circumstance, and consideration of the conflicting federal, state, and tribal interests in the case at hand. As a consequence, few broad principles can reliably be applied from one

39. MISS. CODE ANN. § 41-23-5 (2015); *see also* N.H. REV. STAT. § 141-C:9 (2015) (authorizing investigation of communicable diseases, including “interviews with reporting officials, their patients, and other persons affected by or having information pertaining to the communicable disease, surveys of such individuals, inspections of buildings and conveyances and their contents, and laboratory analysis of samples collected during the course of such inspections”); S.C. CODE ANN. § 44-1-80(A) (2015) (requiring state health board to “investigate the reported causes of communicable or epidemic disease and must enforce or prescribe these preventive measures as may be needed to suppress or prevent the spread of these diseases by proper quarantine or other measures of prevention”).

40. *See, e.g.*, MINN. STAT. § 144.0535 (2015); N.D. CENT. CODE § 23-35-12(2) (2013); NEV. REV. STAT. § 441A.160(2)(a) (2014).

41. *See, e.g.*, MINN. STAT. § 144.054 (2015).

42. The foregoing is neither a comprehensive list of authorities nor representative of every jurisdiction.

43. Philip P. Frickey, *Adjudication and Its Discontents: Coherence and Conciliation in Federal Indian Law*, 110 HARV. L. REV. 1754, 1754 (1997).

decided case to the next.⁴⁴

State governments planning for a response to a public health emergency that crosses tribal borders thus confront an uncertain legal landscape. They do so with precious little guidance: no published federal court decisions address state and tribal authorities responding to a natural disaster or public health emergency. Rather, state public health officials must take what cues they can from existing precedents that address the division of state and tribal authority generally.⁴⁵

This Part attempts to identify some of the legal complications that might arise from a public health emergency response that crosses tribal borders and describes the relevant principles of Indian law. The variability of Indian law between different tribes and circumstances permits few firm predictions as to how the law might be applied in a specific situation.⁴⁶ This discussion is intended as a starting point for the consideration of the types of legal barriers a state might encounter—absent a formal cooperative agreement—in trying to coordinate an emergency response involving tribal populations and land.

A. Threshold Issues: Sources of Law and Geographic Area of Application

Before turning to particular legal issues that may arise during a public health emergency response involving a tribe, it is worth briefly canvassing two

44. As David Getches described it, not only are the few clearly announced “rules” in Indian law periodically replaced with new rules or exceptions, “[e]ven the ‘rules’ tend to require case-by-case analysis of each situation, and this requires a look at highly variable demographic facts produced by a mix of past policies and historical accidents.” David H. Getches, *Negotiated Sovereignty: Intergovernmental Agreements with American Indian Tribes as Models for Expanding First Nations’ Self-Government*, 1 REV. CONST. STUD. 120, 143 (1993).

45. While this discussion is largely framed from the state perspective, many states have delegated public health emergency response authorities to local units of government. Courts tend to apply the same analysis and standards to local governments in their dealings with tribes as they do to the states; the most that can be said as a general matter is that the authority of a local government to take action on tribal land will be no greater than that of a state, and may in some circumstances be more circumscribed. *See, e.g., California v. Cabazon Band of Mission Indians*, 480 U.S. 202, 212 n.11 (1987) (noting doubt as to whether Congress, in measure transferring jurisdiction over tribal land to state, had authorized the application of local laws to reservations); *Segundo v. City of Rancho Mirage*, 813 F.2d 1387, 1390 (9th Cir. 1987) (tribal lands subject only to state laws, not local regulation).

46. Taking this caution a step further, some commentators have suggested that the variability in tribal history and circumstance defeats—or at least should defeat—any effort to develop a coherent, uniformly applicable body of “Indian law.” *See* Saikrishna Prakash, *Against Tribal Fungibility*, 89 CORNELL L. REV. 1069 (2004); *see also* Ezra Rosser, *Ambiguity and the Academic: The Dangerous Attraction of Pan-Indian Legal Analysis*, 119 HARV. L. REV. F. 141 (2005) (critiquing the “one-size-fits-all” approach to Indian law and arguing for analysis of legal issues on a tribe-by-tribe basis).

threshold matters: the basic sources of “Indian law”⁴⁷ and the geographic area to which it pertains.

Federal Indian law derives from the Indian Commerce Clause of the Constitution, which grants Congress the authority to “regulate Commerce with foreign Nations and among the several states and with the Indian tribes.”⁴⁸ This grant of authority to Congress to regulate Indian relations, coupled with the Supremacy Clause,⁴⁹ means that federal law controls issues of sovereignty and jurisdiction.⁵⁰ Federal control, however, does not necessarily mean uniformity. In some areas, Congress has enacted broad laws that affect the status of all Indian tribes within the United States; however, it has also exercised Indian Commerce Clause authority to enact laws that affect only tribes in particular states⁵¹ or that authorize states and tribes to redefine their legal relationship.⁵² This uneven body of statutory law stands alongside other types of federal law that may supply the controlling authority for a given tribe or issue of Indian law. This includes treaties (ratified by Congress under its Indian Commerce Clause authority),⁵³ regulations promulgated by a number of executive branch agencies,⁵⁴ and executive orders.⁵⁵

Often, there is no specific federal law or treaty provision controlling the issues that arise from state-tribal relations, and federal courts have been left to fill the gaps. The United States Supreme Court in particular has played a central role

47. “Indian law” here refers to the law governing the relation of tribes to other governments, not the laws enacted by tribes to govern their own lands and peoples.

48. U.S. CONST. art. I, § 8, cl. 3.

49. U.S. CONST. art. VI, cl. 2.

50. See *Winton v. Amos*, 255 U.S. 373, 391 (1921) (“It is thoroughly established that Congress has plenary authority over the Indians and all their tribal relations, and full power to legislate concerning their tribal property.”); see also *Morton v. Mancari*, 417 U.S. 535, 551-52 (1974) (“The plenary power of Congress to deal with the special problems of Indians is drawn both explicitly and implicitly from the Constitution itself.”).

51. For example, in 1953, Congress enacted a measure transferring civil and criminal adjudicatory jurisdiction over tribal lands to five states (California, Minnesota, Nebraska, Oregon, and Wisconsin). See Pub. L. No. 83-280, 67 Stat. 588 (1953) (codified at 18 U.S.C. § 1162 (2012), 28 U.S.C. § 1360 (2012)).

52. See, e.g., Indian Civil Rights Act, Pub. L. No. 90-284, §401, 82 Stat. 73, 78 (1968) (codified at 25 U.S.C. § 1321 (2012)) (authorizing states to assume criminal jurisdiction over Indian country with the consent of the tribe).

53. See, e.g., *Cree v. Flores*, 157 F.3d 762 (9th Cir. 1998) (holding that terms of 1855 Treaty with the Yakamas exempted tribal members from various state fees related to licensing and operating trucks on state highways).

54. See 25 C.F.R. § 1.1 (1960).

55. Executive orders played a particularly pivotal role in the establishment of reservations in the latter half of the nineteenth century and continuing until 1919, when Congress discontinued the practice. See COHEN’S HANDBOOK OF FEDERAL INDIAN LAW § 1.03(9) (Nell Jessup Newton ed., 2012).

in defining the nature and extent of tribal sovereignty. One of the seminal early cases in this area involved Georgia's conviction of a minister who took up residence in the Cherokee nation without first procuring state license or taking an oath to defend the state's laws and constitution. In this case, Chief Justice Marshall described the Indian nations "as distinct, independent political communities, retaining their original natural rights, as the undisputed possessors of the soil, from time immemorial."⁵⁶ In light of this independence and the federal government's exclusive right to regulate relations with the tribes, Marshall held the Cherokee Nation to be "a distinct community occupying its own territory . . . in which the laws of Georgia can have no force, and which the citizens of Georgia have no right to enter, but with the assent of the Cherokees themselves, or in conformity with treaties, and with the acts of congress."⁵⁷ The Court's current view on tribal sovereignty and its relationship to state jurisdiction is starkly different from the vision articulated by Justice Marshall.⁵⁸ Though the federal courts are the major engines driving the development of Indian law, the courts' resolution any particular issue of law is provisional; Congress has plenary authority over tribal relations and may at any time override the courts.⁵⁹

The second threshold issue is how Congress and federal courts define the geographic area where tribes may exercise their sovereignty. The importance of this determination to the state public health official is plain: it identifies areas where a state may have limited authority to unilaterally carry out emergency response measures. Though the extent and exclusivity of tribal jurisdiction over a particular piece of land may depend on who it is owned by (in the case of fee land) or how it is used, at the most basic level it is the concept of "Indian country" that demarcates the geographic boundary at which state jurisdiction ceases to be absolute. Congress has statutorily defined Indian country to mean any one of three things: (1) any land within the limit of an Indian reservation; (2) "dependent Indian communities within the borders of the United States whether

56. *Worcester v. Georgia*, 31 U.S. (6 Pet.) 515, 559 (1832).

57. *Id.* at 561.

58. Justice Scalia's dismissive take on tribal sovereignty in a 2001 opinion, though perhaps not shared by all of his colleagues, captures the extent of the shift: "Though tribes are often referred to as 'sovereign' entities, it was long ago that the Court departed from Chief Justice Marshall's view that the laws of a State can have no force within reservation boundaries. Ordinarily, it is now clear, an Indian reservation is considered part of the territory of the State." *Nevada v. Hicks*, 533 U.S. 353, 361-62 (2001).

59. For example, in *Duro v. Reina*, 495 U.S. 676 (1990), the Court held that a tribe's criminal jurisdiction did not extend to members of other Indian tribes who committed crimes on the tribe's land—i.e., that a tribe only had criminal jurisdiction over its own members. Congress promptly responded with an enactment providing that tribal criminal jurisdiction extended to both member and nonmember Indians. See Pub. L. 101-511, § 8077(b)-(c), 104 Stat. 1856, 1892 (1990) (codified at 25 U.S.C. § 1301(2) (2012)).

within the original or subsequently acquired territory thereof”; or (3) “all Indian allotments, the Indian titles to which have not been extinguished.”⁶⁰

These three categories require further explanation. The first category, Indian reservations, applies to land that has been explicitly reserved by statute or treaty for tribal use. The second category is the most nebulous and potentially broad of the three, but it has been significantly cabined by the Supreme Court. In *Alaska v. Native Village of Venetie Tribal Government*,⁶¹ the Court held that “dependent Indian communities” “refers to a limited category of Indian lands that are neither reservations nor allotments, and that satisfy two requirements—first, they must have been set aside by the Federal Government for the use of the Indians as Indian land; second, they must be under federal superintendence.”⁶² Thus, the second category refers to lands that are similar to reservations because they were set aside for tribal use and are subject to federal oversight. The third describes a category of land created under a federal policy in the late nineteenth and early twentieth centuries that divided tribal land and allotted it to individual tribal members.⁶³ Though a significant portion of this allotted land was ultimately sold to non-Indians, federal courts consider that which remains in Indian control to be Indian country.

B. Civil Regulatory Authority in Indian Country

The legal question of broadest significance for the state public health official is which entity, state or tribal government, has civil regulatory jurisdiction in Indian country.⁶⁴ Who has authority to institute social distancing measures, such as quarantine or closure of public spaces? Who may require the seizure or destruction of private property where necessary to abate a hazard? Who may institute mandatory medical screenings and treatment? Civil regulatory jurisdiction, one of the thorniest issues in an already complex body of law, lies at

60. 18 U.S.C. § 1151 (2012). Although this statute formally defines the Indian country for purposes of criminal jurisdiction, it has been utilized as well for questions of civil jurisdiction. See *Alaska v. Native Vill. of Venetie Tribal Gov’t*, 522 U.S. 520, 527 (1998).

61. *Native Vill. of Venetie Tribal Gov’t*, 522 U.S. at 520.

62. *Id.* at 527.

63. See Indian General Allotment Act of 1887, ch. 119, 24 Stat. 388 (codified at 25 U.S.C. § 331 (2012)); see also *Cnty. of Yakima v. Confederated Tribes & Bands of Yakima Indian Nation*, 502 U.S. 251, 254-56 (1992) (discussing history of allotment policy). Congress eventually ceased the practice of allotting tribal lands in 1934. See Indian Reorganization (Wheeler-Howard) Act, Pub. L. No. 73-383, 48 Stat. 984 (1934).

64. Outside of Indian country, it is settled that, absent an express statement of federal law to the contrary, tribal members are subject to state law, provided that such law is nondiscriminatory. See *White Mountain Apache Tribe v. Bracker*, 448 U.S. 136, 144 n.11 (1980) (citing *Mescalero Apache Tribe v. Jones*, 411 U.S. 145, 148-49 (1978)).

the heart of these and many other questions.⁶⁵ Two distinct and not entirely complementary legal frameworks govern the scope of tribal and state regulatory jurisdiction in Indian country. While there are a few relatively firm precepts in this area—one may, for example, generally presume a tribe’s authority to regulate its own membership within Indian country—many questions are not susceptible to a uniform answer and must be assessed individually.

The leading modern authority on the extent of tribal civil regulatory jurisdiction is the Supreme Court’s 1981 decision in *Montana v. United States*.⁶⁶ There, the Court held that Montana’s Crow Tribe lacked the power to regulate hunting and fishing by non-Indians on lands within its reservation that were owned in fee simple by non-Indians. The Court set forth a number of principles that have endured to the present day, affirming that the “attributes of sovereignty” possessed by tribes necessarily include the powers of self-government over their own members. Among these powers was the authority “to prescribe and enforce criminal laws,” . . . “to determine tribal membership, to regulate domestic relations among members, and to prescribe rules of inheritance for members.”⁶⁷ Those powers came close, however, to marking the furthest reach of tribal sovereignty. The Court went on to hold that, without express Congressional delegation, tribes ordinarily may not exercise any authority “beyond what is necessary to protect tribal self-government or to control internal relations.”⁶⁸ Thus, the Court established what amounts to a default rule dictating that tribes lack jurisdiction to regulate the activities of nonmembers.

The Court added an important caveat to this default rule, suggesting in dicta that there are two situations in which tribes “retain inherent sovereign power to exercise some forms of civil jurisdiction over non-Indians on their reservations, even on non-Indian fee lands.”⁶⁹ The first permits a certain degree of tribal regulation of nonmembers who “enter consensual relationships with the tribe or its members.”⁷⁰ The second reserves a tribe’s “inherent power to exercise civil authority over the conduct of non-Indians on fee lands within its reservation when that conduct threatens or has some direct effect on the political integrity,

65. See CONFERENCE OF W. ATTORNEYS GEN., AMERICAN INDIAN LAW DESKBOOK 106 (Joseph P. Mazurek ed., 2d ed. 1998) (“Among the most difficult and recurring issues in Indian law is the scope of tribal and state civil-regulatory authority in Indian country”).

66. 450 U.S. 544 (1981).

67. *Id.* at 564 (quoting *United States v. Wheeler*, 435 U.S. 313, 326 (1978)).

68. *Montana v. United States*, 450 U.S. 544, 569 (1981).

69. *Id.* at 565.

70. *Id.* (“A tribe may regulate, through taxation, licensing, or other means, the activities of nonmembers who enter consensual relationships with the tribe or its members, through commercial dealing, contracts, leases, or other arrangements.”).

the economic security, or the health or welfare of the tribe.”⁷¹ Notwithstanding the potential breadth of these two *Montana* exceptions, the Court has given them a decidedly cramped reading to date.⁷² They have enjoyed greater currency in the lower courts; for example, in a case decided shortly after *Montana*, the Ninth Circuit applied both exceptions to uphold application of tribal building, health, and safety regulations to a business owned and operated by a non-Indian on fee land within a reservation.⁷³

The question of the reach of *state* authority in Indian country is more complicated. As the Supreme Court candidly acknowledged, “there is no rigid rule by which to resolve the question whether a particular state law may be applied to an Indian reservation or to tribal members.”⁷⁴ Rather, the Court has adopted a case-by-case approach that weighs the state’s interest in application of its law within tribal borders against federal and tribal interests.⁷⁵ According to the Court, a state law that conflicts or interferes with federal and tribal interests is preempted in Indian country unless the gravity of the state’s regulatory interest justifies the intrusion.⁷⁶ Application in the individual case is less simple.

Where the conduct of tribal members in Indian country is concerned, the analysis will typically (though not always) result in the preemption of state law, for, as the Court has suggested, “the State’s regulatory interest is likely to be minimal and the federal interest in encouraging tribal self-government is at its strongest.”⁷⁷ Far less predictable are those cases involving the conduct of non-Indians within Indian country. Such cases, per the Supreme Court, require a “particularized inquiry into the nature of the state, federal, and tribal interests at stake,” with close attention to the language of and policies underlying the federal statutes and treaties relevant to the specific case.⁷⁸ The Court has offered little guidance on how to balance these competing interests, aside from a suggestion that federal authorities should be read against the background “notions of sovereignty that have developed from historical traditions of tribal

71. *Id.* at 566.

72. *See, e.g.,* *Plains Commerce Bank v. Long Family Land & Cattle Co.*, 554 U.S. 316, 329-41 (2008) (rejecting application of both *Montana* exceptions, and emphasizing their limited nature).

73. *Cardin v. De La Cruz*, 671 F.2d 363, 365-67 (9th Cir. 1982).

74. *White Mountain Apache Tribe v. Bracker*, 448 U.S. 136, 142 (1980).

75. As a matter of formal doctrine, the Court has suggested that there are “two independent but related barriers to the assertion of state regulatory authority over tribal reservations and members”: the preemptive force of federal law and the tribe’s right to make its own laws and be ruled by them. *Id.* at 142-43. The Court largely condensed these two concerns into a single analytical framework to be applied in cases involving the application of state civil regulatory laws to Indian country.

76. *See California v. Cabazon Band of Mission Indians*, 480 U.S. 202, 216 (1987).

77. *White Mountain Apache Tribe*, 448 U.S. at 144.

78. *Id.* at 144-45.

independence.”⁷⁹ The Court’s analysis in individual cases has, consistent with its articulated framework, been heavily rooted in the particular federal, tribal, and state policies and interests at stake, and thus has generated little in the way of generalizable principles.⁸⁰ The Court has shown a willingness to hold state law preempted even where it may apply to conduct by non-members, such as a motor-carrier and fuel use tax that Arizona sought to levy on two non-Indian corporations contracting with a tribe for on-reservation work.⁸¹ However, the Court has also permitted narrow applications of state law to tribally operated businesses that serve non-members, as in the case of tobacco taxes⁸² and liquor licensure.⁸³

This contrast in precedent illustrates the legal uncertainty facing the state public health official: in a typical case, neither state nor tribal government would have plenary authority to carry out public health emergency response measures in Indian country. Pursuant to its retained right of self-government,⁸⁴ a tribal government would likely have authority to pursue emergency measures affecting its own members—e.g., requiring mandatory medical screenings for tribal members, or ordering the closure of tribal schools and daycares—provided that its laws explicitly authorize such measures.⁸⁵ By the same token, it is unlikely that state emergency laws would reach tribal members living in Indian country absent specific provisions in a treaty or federal law.⁸⁶ Beyond this, however, little can be predicted with certitude. In light of *Montana*, a federal court would likely not countenance a tribe’s application of coercive or rights-limiting emergency measures to non-members and their property.⁸⁷ But state law may not apply in

79. *Id.* at 145; see also *Rice v. Rehner*, 463 U.S. 713, 719-20 (1983) (describing the role of historical notions of tribal sovereignty as the backdrop for the preemption balancing analysis).

80. See, e.g., *White Mountain Apache Tribe*, 448 U.S. at 145-53; *Cabazon Band of Mission Indians*, 480 U.S. at 214-22.

81. *White Mountain Apache Tribe*, 448 U.S. 136.

82. *Moe v. Confederated Salish & Kootenai Tribes of Flathead Reservation*, 425 U.S. 463, 481-83 (1976) (holding that tribal smokeshop could be required to collect and remit state tobacco taxes for sales to non-Indians).

83. See *Rice*, 463 U.S. 713 (upholding application of state licensure requirements for sale of liquor by federally licensed Indian trader).

84. See, e.g., *Montana v. United States*, 450 U.S. 544, 564 (1981).

85. For examples of tribal code provisions outlining quarantine procedures and other emergency public health authorities, see E. BAND CHEROKEE CODE §§ 130-5 (2011); NAVAJO NATION CODE § 2101 (2002).

86. See *White Mountain Apache Tribe*, 448 U.S. at 144.

87. A court could, of course, find that the need for an effective response to public health threats brings tribal emergency provisions with the second *Montana* exception, implicating a tribe’s “inherent power to exercise civil authority over the conduct of non-Indians . . . when that conduct threatens or has some direct effect on the . . . the health or welfare of the tribe.” *Montana*, 450 U.S. at 566.

these situations either, leaving such individuals in a jurisdictional limbo: the mere fact that tribes may not have jurisdiction over non-members living in Indian country does not automatically establish the application of state law.⁸⁸

Jurisdiction over businesses that serve both tribal members and non-members—such as hotels, restaurants, private schools, and daycares—present particularly difficult questions. Consider the situation of an on-reservation, tribally operated casino that serves predominantly non-tribal visitors. In the early stages of a public health emergency, it is possible that state and tribal governments might disagree as to the necessity of closure given the conflicting interests at stake. Casinos represent a vital source of income for some tribes, but they are also a congregating place for travelers that could facilitate the rapid spread of a contagious disease. However great a risk a casino might pose, a state may lack the authority to order its closure over tribal objection given the particular legal framework for regulation of casinos in Indian country.

Conflict over regulation of Indian casinos first came to a head in the late 1980s when the Supreme Court reviewed a case involving the application of state gaming laws to bingo operations by several tribes in California. The Court held that, in light of the important federal and tribal interests in the revenue and employment opportunities created by on-reservation gaming, state laws regulating bingo could not reach the tribe's operations.⁸⁹ Congress responded by enacting the Indian Gaming Regulatory Act (IGRA).⁹⁰ The IGRA created a regulatory regime that offered states some measure of control by largely limiting tribal gaming to those types already permitted in a state and by requiring tribes to negotiate a State-Tribal gaming compact prior to operating most casino-type gaming.⁹¹ The IGRA suggests, but does not require, that a State-Tribal compact include provisions clarifying the allocation of civil and criminal jurisdiction over gaming activities.⁹² Absent such agreement, the IGRA makes clear that tribal law, not state law, governs on-reservation gaming.⁹³

88. One can imagine that particular exercises of state authority, even when applied to non-members, might make for close cases under the Supreme Court's interest-balancing framework—for example, measures involving the seizure, closure, or condemnation of real property within Indian country.

89. *California v. Cabazon Band of Mission Indians*, 480 U.S. 202 (1987).

90. 25 U.S.C. §§ 2701-5 (2012).

91. *Id.* §§ 2703(7)-(8), 2710(b)(1), (d)(1) (2012).

92. *Id.* § 2710(d)(3)(C) (2012).

93. *See id.* § 2071(5) (2012) (finding that “Indian tribes have the exclusive right to regulate gaming activity on Indian lands if the gaming activity is not specifically prohibited by Federal law and is conducted within a State which does not, as a matter of criminal law and public policy, prohibit such gaming activity”); §§ 2710(a), (d)(4)-(5), 2713(d) (2012); *see also* S. REP. NO. 100-446, at 5-6 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3071, 3075 (describing the IGRA as a “a framework for the regulation of gaming activities on Indian lands which provides that in the

In a given situation, a state and tribe might address public health regulatory authority for tribal casino operations in a State-Tribal compact. Such agreements, however, might also be limited to the narrow regulation of the actual gambling operations and not the associated accommodations. Absent any clear agreement, jurisdiction would depend on a balancing of the interests at stake, which the Senate's Indian Affairs Committee concisely outlined in its report recommending passage of the IGRA:

A tribe's governmental interests include raising revenues to provide governmental services for the benefit of the tribal community and reservation residents, promoting public safety as well as law and order on tribal lands, realizing the objectives of economic self-sufficiency and Indian self-determination, and regulating activities of persons within its jurisdictional borders. A State's governmental interests with respect to . . . gaming on Indian lands include the interplay of such gaming with the State's public policy, safety, law and other interests, as well as impacts on the State's regulatory system, including its economic interest in raising revenue for its citizens.⁹⁴

At least one court has weighed these interests and determined that a county government's public health and safety concerns cannot justify enforcement of the county's health and safety regulations in an on-reservation casino.⁹⁵ Others have addressed the somewhat distinct question of jurisdiction over tort claims arising from casino incidents; in doing so, these courts reached conflicting conclusions on the extent of state jurisdiction.⁹⁶ These few decided cases fail to shed light on how courts may determine jurisdiction in the context of a public health emergency, where the state's governmental interests in public safety would be significantly sharpened.⁹⁷

Any discussion of civil regulatory jurisdiction in Indian country must

exercise of its sovereign rights, unless a tribe affirmatively elects to have State laws and State jurisdiction extend to tribal lands, the Congress will not unilaterally impose or allow State jurisdiction on Indian lands for the regulation of Indian gaming activities").

94. S. REP. NO. 100-446, at 13 (1988), *reprinted in* 1988 U.S.C.C.A.N. 3071, 3083.

95. *See In re Sonoma Cnty. Fire Chief's Application*, No. C 02-04873 JSW, 2005 WL 1005079 (N.D. Cal. Apr. 29, 2005).

96. *Compare Muhammad v. Comanche Nation Casino*, No. CIV-09-968-D, 2010 WL 4365568 (W.D. Okla. Oct. 27, 2010) (holding that tribal courts have exclusive jurisdiction over casino tort claims), *with Cossey v. Cherokee Nation Enters.*, 212 P.3d 447 (Okla. 2009) (holding that tort claims arising from accidents in on-reservation casino may be brought in state courts).

97. Additionally, it is worth noting that federal law grants the Chairman of the National Indian Gaming Commission certain authority to order temporary closure of gaming facilities. *See* 25 U.S.C. § 2705(a)(1) (2012). While the grounds for that authority are limited, they include violations of tribal ordinances, *id.* § 2713(b) (2012), which could provide a basis for federal closure of a casino to the extent that tribal public health provisions were implicated.

acknowledge the existence of 25 U.S.C. § 231, a long dormant federal statute. Enacted in 1929, the statute authorizes the Secretary of the Interior⁹⁸ to prescribe regulations permitting the agents or employees of a state to enter Indian country for the purpose of, among other things, “making inspection of health . . . conditions and enforcing sanitation and quarantine regulations.”⁹⁹ No regulation has ever been promulgated under 25 U.S.C. § 231.¹⁰⁰ However, even absent implementing regulations, at least one court interpreted § 231 to be an expression of Congressional intent to transfer plenary public health regulatory jurisdiction over Indian country to the states.¹⁰¹ The impact of the statute on the balance of Indian and state public health regulatory jurisdiction has never been directly presented in a court case. A broad view of § 231 seems unlikely to prevail today, given that state authority under § 231 is contingent on an act of federal delegation that has not occurred in over eighty years.

C. Authority of State Officials to Enter Indian Country

Closely related to civil regulatory jurisdiction is the question of the authority of state officials to enter Indian country, whether to investigate public health threats, enforce state emergency measures, or deliver aid (such as antivirals or food). Federal courts have long recognized that tribes possess a landowner’s “traditional and undisputed power to exclude persons whom they deem to be

98. The responsibilities of the Secretary with respect to Indian public health have since been transferred to the Department of Health and Human Services. *See* 42 U.S.C. § 2001 (2012).

99. 25 U.S.C. § 231 (2012).

100. *See* *Confederated Bands & Tribes of Yakima Indian Nation v. Washington*, 550 F.2d 443, 446 n.8 (9th Cir. 1977) (en banc). The Centers for Disease Control and Prevention (CDC) has proposed regulations under § 231 that would allow the Director of the CDC, with the concurrence of the Indian Health Service Director and after consulting with the affected tribes, to authorize state officials to enter Indian country, but only for the sole purpose of enforcing *federal* quarantine regulations. *See* *Control of Communicable Diseases*, 70 Fed. Reg. 71892 (proposed No. 30, 2005) (to be codified at 42 C.F.R. pts. 70 & 71). The regulations have not been adopted.

101. *See* *Anderson v. Gladden*, 188 F. Supp. 666, 677 (D. Or. 1960) (suggesting in dicta that § 261 “surrendered to the states all jurisdiction over Indians and Indian Reservations in the field of health and education and gave the states, through the Secretary of the Interior, complete jurisdiction in connection with enforcing sanitation and quarantine regulations and compulsory school attendance in such field”). While this may be the broadest extant reading of § 261, it is not alone in overlooking the federal authorization necessary for states to exercise public health authority in Indian country. *See, e.g.,* *Snohomish Cnty. v. Seattle Disposal Co.*, 425 P.2d 22 (Wash. 1967) (suggesting in dicta that § 231 granted the states “jurisdiction to inspect and regulate health, sanitation, and related matters on Indian tribal lands”); *Acosta v. San Diego Cnty.*, 272 P.2d 92, 97 (Cal. Ct. App. 1954) (suggesting in dicta that § 231 authorizes the states “to enter upon Indian lands for the purpose of making inspection of health and educational conditions and enforcing sanitation and quarantine regulations”).

undesirable from tribal lands.”¹⁰² This right of exclusion was generally understood to extend to state officials¹⁰³ until the Supreme Court’s 2001 decision in *Hicks v. Nevada*.¹⁰⁴ In *Hicks*, the Court introduced considerable uncertainty into the question of whether state officials have authority to enter and carry out their responsibilities in Indian country.

Hicks came before the Court on a question of tribal court jurisdiction; the operative issue was whether a tribal court could exercise jurisdiction over claims by a member of the Fallon Paiute-Shoshone Tribes, Floyd Hicks, against various Nevada state game wardens.¹⁰⁵ Acting on information suggesting that Hicks illegally killed a California bighorn sheep off-reservation, the game wardens executed search warrants on Hicks’ property on two separate occasions.¹⁰⁶ Because Hicks resided on the Tribes’ reservation, the wardens took the precaution in both instances of procuring a tribal-court warrant in addition to a state-issued warrant.¹⁰⁷ They did not find incriminating evidence on either occasion. The searches resulted in damage to Hicks’s property, leading Hicks to bring suit in tribal court against the tribal court judge, various tribal officers, and Nevada’s game wardens, alleging various violations of his rights.¹⁰⁸ The wardens and the State of Nevada filed a declaratory judgment action in the Federal District Court seeking a declaration that the tribal courts lacked jurisdiction.¹⁰⁹ Both the District Court and the Ninth Circuit ruled against the state, finding the tribal court’s exercise of jurisdiction proper.¹¹⁰ The Supreme Court disagreed.

The determinative issue for the Court was whether the Tribes’ regulatory

102. *Reina*, 495 U.S. at 698; see also *New Mexico v. Mescalero Apache Tribe*, 462 U.S. 324, 333 (1983) (“A tribe’s authority to exclude nonmembers entirely or to condition their presence on the reservation is . . . well established.”).

103. See, e.g., *State v. Hicks*, 196 F.3d 1020, 1028 (9th Cir. 1999) (“The tribal court was free to exclude state officials engaged in law enforcement activities on the reservation.”), *rev’d*, 533 U.S. 353 (2001); *Cnty. of Lewis v. Allen*, 163 F.3d 509, 514 (9th Cir. 1998) (noting that, in entering into law enforcement agreement with State, tribe “gave up its landowner’s right to exclude state officials engaged in law enforcement activities on the reservation.”); *Miccosukee Tribe of Indians of Fla. v. United States*, No. 00–3453CIV, 2000 WL 35623105 (S.D. Fla. Dec. 15, 2000) (holding that State Attorney could not effectuate service of process on tribal land); see also *Worcester v. Georgia*, 31 U.S. 515, 561 (1832) (holding that “the citizens of Georgia have no right to enter” the territory of the Cherokee nation “but with the assent of the Cherokees themselves, or in conformity with treaties, and with the acts of [C]ongress”).

104. *Hicks*, 533 U.S. at 353.

105. *Id.* at 355.

106. *Id.* at 356.

107. *Id.*

108. *Id.*

109. *Id.* at 357. This followed rulings by the tribal court and a tribal appeals court that the courts could properly exercise jurisdiction over claims against state officials. *Id.*

110. *Id.*

jurisdiction extended to the on-reservation conduct of the state game wardens.¹¹¹ Applying *Montana*,¹¹² the Court asked whether regulation of state officials executing search warrants for off-reservation crimes was essential to tribal self-government or internal relations.¹¹³ The Court held that it was not.¹¹⁴ In the course of reaching that conclusion, the Court offered some strong indications (arguably dicta¹¹⁵) of how it would resolve the converse question¹¹⁶: the scope of a state official's authority to enter tribal land in execution of his duties. While acknowledging that state regulatory authority will not generally reach the activities of tribal members on tribal land, the Court noted that it had, upon occasion, found state regulation appropriate where the state's off-reservation interests are implicated—as, for example, in permitting states to require tribal businesses to collect state cigarette taxes from nonmembers, or allowing state jurisdiction over crimes committed by members off-reservation.¹¹⁷ Past cases had left unanswered the question of whether the State's regulatory authority in such circumstances “entails the corollary right to enter a reservation (including Indian fee lands) for enforcement purposes.”¹¹⁸ At least in the case at bar—execution of a search warrant for an alleged off-reservation crime—the Court suggested that it did. Relying on a pair of cases from the nineteenth century, the *Hicks* Court found indications that the “process” of state courts had historically been understood to extend to Indian country, and reasoned that such “process” likely included the authority to issue search warrants for off-reservation conduct.¹¹⁹

111. *Id.* at 358. The Court had previously held that a tribe's adjudicative jurisdiction cannot extend beyond its legislative jurisdiction, and thus, the Court reasoned, the absence of the latter would necessarily mean the absence of the former. *Id.* at 357-58 (citing *Strate v. A-1 Contractors*, 520 U.S. 438, 453 (1997)).

112. See *supra* Part II.B.

113. The Court categorically rejected the application of the other *Montana* exception (relating to regulation of nonmembers who enter consensual relationships with the tribe), *Hicks*, 533 U.S. at 359 n.3, noting that the exception “obviously” was not intended to apply to “[s]tates or state officers acting in their governmental capacity,” *id.* at 371-72.

114. It would risk understatement to note that the *Hicks* decision was, and continues to be, controversial. In a reaction that typifies the decision's scholarly reception, one academic characterized *Hicks* as “a stunning example of how [the Court] pursues the Justices' larger agendas in Indian cases while ignoring and misapplying Indian law principles.” David H. Getches, *Beyond Indian Law: The Rehnquist Court's Pursuit of States' Rights, Color-Blind Justice and Mainstream Values*, 86 MINN. L. REV. 267, 329-30 (2001).

115. See, e.g., *State v. Cummings*, 679 N.W.2d 484, 488-89 (S.D. 2004) (characterizing as dicta the Court's discussion in *Hicks* of state authority to enter Indian country).

116. See *Jones ex rel. Murray v. Norton*, No. 2:09-cv-00730-TC-SA, 2010 WL 2990829, at *3 (D. Utah July 26, 2010) (observing that “*Hicks* concerned tribal authority rather than the authority of the state”).

117. *Hicks*, 533 U.S. at 362.

118. *Id.* at 363.

119. *Id.* at 363-64.

For the state official whose duties may take him into Indian country, *Hicks* leaves many open questions.¹²⁰ There is considerable uncertainty even when, as in *Hicks*, investigation of off-reservation crimes is at issue. In a 2004 case, for example, the South Dakota Supreme Court affirmed the suppression of evidence obtained from a tribal member during a traffic stop after a state officer pursued him onto a reservation for an off-reservation traffic offense.¹²¹ In so doing, the court distinguished *Hicks* on the grounds that “in *Hicks*, tribal sovereignty was being used as a sword against state officers” whereas here “tribal sovereignty [was] being used as a shield to protect the Tribe’s sovereignty from incursions by the State.”¹²²

Beyond the narrow criminal investigation context of *Hicks*, it is difficult to say what authority, if any, state officials may exercise in Indian country.¹²³ The Court in *Hicks* acknowledged this open question and suggested that any action by state officials unrelated to law enforcement “is potentially subject to tribal control depending on the outcome of [the] *Montana* analysis.”¹²⁴ Nonetheless, one may extrapolate at least two general principles from *Hicks*. First, a tribe’s authority to regulate or exclude state officers from Indian country will be related to the scope of the state’s regulatory jurisdiction over the matter at issue.¹²⁵ Thus, where the state’s claim of regulatory authority is strongest—e.g., over nonmembers on fee land—state officials are most likely to have authority to enter Indian country to carry out their duties. Where it is weakest—over tribal members on reserved or tribally owned land—a state official’s authority is most in question.

Second, the mere fact of state regulatory jurisdiction does not necessarily grant authority for state officials to enter Indian country. In *Hicks*, the Supreme Court did not locate the state wardens’ authority to execute warrants in Indian country in the states’ general criminal jurisdiction over off-reservation crimes.

120. Indeed, the Court took pains to confine its decision in *Hicks* to the precise circumstances before it. *See id.* at 358 n.2 (“Our holding in this case is limited to the question of tribal-court jurisdiction over state officers enforcing state law.”).

121. *State v. Cummings*, 679 N.W.2d 484, 484 (S.D. 2004).

122. *Id.* at 487. *But see State v. Harrison*, 238 P.3d 869 (N.M. 2010) (holding on similar facts that state officer had authority to pursue tribal member onto reservation and obtain evidence of DWI violation).

123. The Ninth Circuit, for example, has taken a very narrow view of *Hicks*, characterizing it as a single, limited exception to a tribe’s general power to exclude nonmembers from tribal land. *See Water Wheel Camp Recreational Area v. Larance*, 642 F.3d 802, 813 (9th Cir. 2011).

124. *Nevada v. Hicks*, 533 U.S. 353, 373 (2001).

125. The questions of state and tribal regulatory jurisdiction are, to be sure, distinct and not entirely complementary. However, *Hicks* suggests that a determination of the importance to tribal self-government of regulating state officials will depend on the extent of the state’s authority in the substantive area at issue. *See id.* at 360-65.

Rather, the Court relied on case precedent regarding the extension of state court “process” to tribal lands.¹²⁶ Consider state taxation of on-reservation cigarette sales to nonmembers, an area in which states have unambiguous authority to regulate Indian country conduct. Rather than acting within Indian country, state officials typically seize cigarettes outside of tribal borders.¹²⁷ To the extent that this evinces a possible gap between regulatory authority and enforcement authority in Indian country, a distinction between the two would not be surprising. Ratifying the extension of state laws to Indian country is a lesser offense to Indian sovereignty, at least symbolically, than is authorizing state officials to actually enter and enforce those laws over tribal objection.

The uncertainties here can be addressed through express agreements with the tribes as to the authority of state officials in Indian country.¹²⁸ Absent such an agreement, however, significant questions concerning the ability of state officials to enter Indian country will persist. This lack of clarity may impede coordination of an effective response to a public health emergency.

D. Adjudicatory Authority in Indian Country

Issues of adjudicatory authority may arise from public health emergencies in Indian country in two situations: (1) where judicial orders (such as temporary restraining orders) are needed to implement emergency authorities; and (2) in subsequent litigation related to an emergency response (e.g., tort claims for injuries suffered by responders or property damaged in a response). At the broadest level, the scope of adjudicatory authority should mirror the scope of civil regulatory authority, but this becomes considerably less clear when considered in light of the details of litigating a case. The following is a brief overview of the law on adjudicatory jurisdiction.

The leading Supreme Court case on the adjudicatory jurisdiction of tribal

126. *Id.* at 363-64.

127. *See, e.g.,* Muscogee (Creek) Nation v. Pruitt, 669 F.3d 1159, 1180-83 (10th Cir. 2012) (affirming legality of state’s practice of seizing cigarettes lacking state tax stamp en route to a reservation); *see also* Okla. Tax Comm’n v. Citizen Band Potawatomi Indian Tribe of Okla., 498 U.S. 505, 514 (1991) (noting that “States may . . . collect the sales tax from cigarette wholesalers, either by seizing unstamped cigarettes off the reservation or by assessing wholesalers who supplied unstamped cigarettes to the tribal stores.” (internal citation omitted)). Indeed, in *Washington v. Confederated Tribes of Colville Indian Reservation*, 447 U.S. 134, 162 (1980), the Supreme Court expressly reserved (and has not subsequently answered) the question of whether state officials could enter a reservation to seize cigarettes.

128. *See, e.g.,* Cnty. of Lewis v. Allen, 163 F.3d 509, 514 (9th Cir. 1998) (describing an Agreement under which “county law enforcement officers (as agents of the state) have an express right to come onto the reservation and exercise jurisdiction over Indians. They have authority to patrol the reservation, investigate minor crimes and make arrests.”).

courts, *Strate v. A-1 Contractors*,¹²⁹ arose from an accident between two non-Indians on a state highway running through the Fort Berthold Reservation in North Dakota. The accident produced a tort suit in tribal court, a declaratory judgment action in federal court, and, ultimately, an opportunity for the Supreme Court to assess the scope of the tribal adjudicatory jurisdiction. The Court rejected a reading of its precedents that would grant a tribe adjudicatory authority over nonmembers in situations where it lacked regulatory authority. Rather, the Court held that a tribe's adjudicatory jurisdiction over nonmembers does not exceed its regulatory jurisdiction.¹³⁰ The Court thus applied its *Montana* analysis (governing the scope of tribal regulatory jurisdiction) to determine whether adjudicatory jurisdiction over the subject tort suit was proper.¹³¹ The *Strate* Court held that the minimal tribal interests at stake could not justify jurisdiction over a suit between nonmembers.¹³²

While establishing that a tribe may not adjudicate where it lacks the power to regulate, *Strate* leaves unresolved the question of whether a tribe's adjudicatory authority may in fact be narrower than its regulatory authority.¹³³ Following *Strate*, courts have generally treated the two as coextensive, applying *Montana* to determine whether adjudicatory jurisdiction properly lies with a tribal court. This approach is particularly likely to prevail where adjudication is directly incident to a proper exercise of tribal regulatory authority—as would be the case, for instance, if a temporary restraining order were sought to enforce an emergency order issued by tribal authorities and directed at tribal members. There is greater room for question when the object of the tribe's regulatory authority diverges from the subject matter of the adjudication. For example, a court could find that a tribe has the regulatory authority to exclude state public health officials from tribal land, but lacks adjudicatory jurisdiction over tort suits arising from acts by such officials on tribal land.¹³⁴

129. 520 U.S. 438 (1997).

130. *Id.* at 453.

131. *Id.* at 456-59.

132. *Id.*

133. *See Nevada v. Hicks*, 533 U.S. 353, 358 n.2 (2001).

134. The question of adjudicatory jurisdiction over state officials is, to be clear, an open question; it is certainly possible that state officials who caused injury to individuals or property in carrying out emergency response measures in Indian country would be subject to suit in tribal court. In *Hicks*, the Supreme Court barred jurisdiction over suits against state officials in one narrow area—execution of search warrants for off-reservation crimes—but preserved the possibility that suit against state officials in tribal court might be proper in other circumstances. *Id.* at 373. Tribal court jurisdiction over such a suit would perhaps more likely be found proper where a state official acted beyond the scope of his or her proper jurisdiction. *Cf. id.* at 386 (Ginsburg, J. concurring) (noting possibility of tribal court jurisdiction over “state officials engaged on tribal land in a venture or frolic of their own”).

Similarly, state court jurisdiction over matters pertaining to Indian country, such as torts occurring in the conduct of public health emergency operations, mirrors state regulatory authority. Thus, absent a specific enactment by Congress, determination of state adjudicatory jurisdiction rests on the same nebulous interest-balancing test¹³⁵ used to assess the reach of state regulatory jurisdiction.¹³⁶

A significant complicating factor with respect to state court jurisdiction is a 1953 Congressional enactment commonly referred to as P.L. 280, which transferred civil and criminal jurisdiction over Indian country to five states, and also permitted other states to electively assume jurisdiction.¹³⁷ While the basic jurisdictional transfer effected by Public Law 280 is relatively clear,¹³⁸ giving state courts jurisdiction over “civil causes of action between Indians or to which Indians are parties which arise in . . . Indian country,”¹³⁹ the enactment left in its wake some difficult questions regarding the law to be applied in such cases.¹⁴⁰ Moreover, Public Law 280 allowed states that voluntarily assumed jurisdiction over Indian country to exercise partial rather than full jurisdiction.¹⁴¹ This means that, in some states, determining which sovereign has adjudicatory jurisdiction in Indian country may depend not only on the identity of the parties, but also on the

135. *See supra* Part II.B.

136. *See* *Three Affiliated Tribes of Fort Berthold Reservation v. Wold Eng’g, P.C.*, 467 U.S. 138, 147-50 (1984) (applying balancing analysis articulated in *White Mountain Apache Tribe v. Bracker*, 448 U.S. 136, 136 (1980) to question of state court jurisdiction); *AMERICAN INDIAN LAW DESKBOOK*, *supra* note 65, at 154-58 (concluding that same substantive analysis is used for questions of state adjudicatory and regulatory jurisdiction).

137. *See* Pub. L. No. 83-280, 67 Stat. 588 (1953) (codified at 18 U.S.C. § 1162 (2012), 28 U.S.C. § 1360 (2012)). The five states to which P.L. 280 transferred jurisdiction are California, Minnesota, Nebraska, Oregon, and Wisconsin; subsequent legislation added Alaska to the list.

138. It must be noted that individual questions of jurisdiction under P.L. 280 can be quite involved, as there are specific exceptions in law even for the so-called “mandatory” states named in the statute. *See, e.g.*, 18 U.S.C. § 1162(a) (2012) (carving out specific communities, such as the Warm Springs Reservation in Oregon, from the general transfer of jurisdiction).

139. 28 U.S.C. § 1360(a) (2012).

140. Two basic choice-of-law issues may be encountered in civil cases arising from Indian country in P.L. 280 jurisdictions. First, P.L. 280 specifically provided for the continued application of tribal law “if not inconsistent with any applicable civil law of the State,” necessitating close analysis of whether tribal law is, in fact, consistent with state law. 28 U.S.C. § 1360(c) (2012). Second, the Supreme Court has held that P.L. 280 did not “confer general state civil regulatory control over Indian reservations,” and thus certain regulatory measures (such as taxes) cannot be imposed on Indians solely on P.L. 280’s authority. *See Bryan v. Itasca Cnty.*, 426 U.S. 373, 384 (1976). The line between regulatory laws and laws that may be properly applied in Indian country cases is, unsurprisingly, not always clear. *See AMERICAN INDIAN LAW DESKBOOK*, *supra* note 65, at 160.

141. *See Washington v. Confederated Bands & Tribes of Yakima Indian Nation*, 439 U.S. 463 (1979) (rejecting challenge to Washington’s partial assumption of jurisdiction over Indian country pursuant to P.L. 280).

type of action or claim being filed.

E. Criminal Jurisdiction in Indian Country

State public health officials will be less concerned with the boundaries of federal, tribal, and state criminal jurisdiction in Indian country than with matters of civil jurisdiction. Nonetheless, issues of criminal jurisdiction may arise where state or tribal codes prescribe criminal penalties for violation of emergency response measures, such as quarantine.

As a general matter, criminal jurisdiction in Indian country “is governed by a complex patchwork of federal, state, and tribal law,”¹⁴² application of which depends upon, among other things, the identities of perpetrators and (if any) victims. The starting place for most jurisdictional analyses is 18 U.S.C. § 1152. That statute extends to Indian country the “general laws of the United States” that apply to crimes committed in federal enclaves, giving the federal government general jurisdiction, with some significant exceptions. The statute does not apply to “offenses committed by one Indian against the person or property of another Indian,” over which the tribes have exclusive jurisdiction (as to minor crimes),¹⁴³ “nor to any Indian committing any offense in the Indian country who has been punished by the local law of the tribe, or to any case where, by treaty stipulations, the exclusive jurisdiction over such offenses is or may be secured to the Indian tribes respectively.”¹⁴⁴ While this federal statute might be read to leave no place for state criminal jurisdiction, a long line of Supreme Court precedent assigns states exclusive jurisdiction over crimes involving only non-Indians but committed in Indian country.¹⁴⁵ Moreover, with respect to civil adjudicatory jurisdiction, Public Law 280 transferred criminal jurisdiction over Indian country crimes to five states, and permitted other states to assume jurisdiction in whole or part.¹⁴⁶

This Article does not purport to fully map the overlapping lines of criminal jurisdiction, as the type of criminal offense that may arise from a public health emergency presents a special and narrow case—albeit one with some complications of its own. Public health offenses of this ilk (e.g., violation of quarantine) are victimless crimes. Although a violation of a public health

142. *Duro v. Reina*, 495 U.S. 676, 680 n.1 (1990), *superseded by statute*, Pub. L. 101-511, 104 Stat. 1892 (codified as amended at 25 U.S.C. § 1301(2) (2012)).

143. 18 U.S.C. § 1152 (2012). A separate statute gives the federal government exclusive jurisdiction over major crimes such as murder and kidnapping between Indians. *See* 18 U.S.C. § 1153 (2012).

144. 18 U.S.C. § 1152 (2012).

145. *See Reina*, 495 U.S. at 680 n.1.

146. *See* 18 U.S.C. § 1162 (2012); *see also supra* note 137.

emergency measure might pose a threat of serious societal harm, a distinctive characteristic of such an offense is that the violation itself has no immediate victim. For violations committed by non-Indians, it is relatively clear as a matter of law that victimless crimes come within state jurisdiction.¹⁴⁷ When the offender is a tribal member, the matter is not so clear. Whereas section 1152 leaves jurisdiction over lower-level crimes *between* Indians to tribes, the statute is silent as to victimless crimes by Indians. Case law is split as to whether or not such crimes fall exclusively within tribal jurisdiction.¹⁴⁸ Even assuming section 1152 applies to at least some victimless crimes by Indians, tribes would still retain concurrent jurisdiction under their own laws to punish violations of public health emergency measures by Indians¹⁴⁹—and, pursuant to section 1152, punishment under tribal law would deprive the federal government of jurisdiction. However, this does not foreclose the possibility of the federal government prosecuting an Indian offender under the “general laws of the United States.” This phrase refers not to the generally applicable laws that apply anywhere in the United States, but rather the laws applied in federal enclaves. The applicable law is primarily state law, as the federal Assimilative Crimes Act¹⁵⁰ largely incorporates the substantive criminal law of the state or territory in which a federal enclave is located. So, at least in theory, under section 1152, the federal government could prosecute an Indian for violation of a state quarantine law.¹⁵¹

147. *See, e.g.*, *United States v. Langford*, 641 F.3d 1195, 1197-99 (10th Cir. 2011) (holding that state had exclusive jurisdiction over prosecution of non-Indian for being spectator at a cockfight in Indian country); *People v. Collins*, 826 N.W.2d 175, (Mich. Ct. App. 2012) (holding that state had jurisdiction over prosecution of non-Indians for possession of controlled substance in Indian country).

148. *Compare* *United States v. Quiver*, 241 U.S. 602 (1916) (Indian-against-Indian exception includes the arguably victimless offense of adultery committed between Indians), *and* *United States v. Blue*, 722 F.2d 383, 386 n.4 (8th Cir. 1983) (citing *Quiver* and noting that § 1152’s “Indian against Indian exception has been read very broadly to include ‘victimless crimes’ affecting only Indians”), *with* *United States v. Thunder Hawk*, 127 F.3d 705, 708-09 (8th Cir. 1997) (holding that offense of driving under the influence fell outside of the Indian-against-Indian exception and distinguishing *Quiver* on the grounds that it involved “domestic relations, an area traditionally left to tribal self-government”), *and* *United States v. Sosseur*, 181 F.2d 873, 876 (7th Cir. 1950) (United States had jurisdiction to prosecute Indian defendant for illegally operating slot machines). *See also* AMERICAN INDIAN LAW DESKBOOK, *supra* note 65, at 91 (noting that it “appears doubtful” that the Indian-against-Indian exception applies to all victimless crimes by Indians).

149. *See, e.g.*, CHEROKEE CODE § 130-6(f) (2011) (prescribing criminal penalties for violation of quarantine or isolation orders), *id.* at § 130-13 (2011) (authorizing arrest to enforce quarantine ordinance).

150. Codified as amended at 18 U.S.C. § 13 (2012).

151. This is exceedingly unlikely for any number of reasons, not least among them that the federal government has its own quarantine authority in Indian country and is thus unlikely to rely upon state enactments. *See* 25 U.S.C. § 198 (2012) (granting broad authority to isolate or quarantine “any Indian afflicted with tuberculosis, trachoma, or other contagious or infectious

This example raises a second distinguishing characteristic of this type of public health offense: it is merely an enforcement mechanism for a set of civil regulatory authorities. Given the low likelihood that a court would find state public health emergency laws applicable to tribal members in Indian country at all, it seems perverse to suggest that the federal government could use section 1152 to bootstrap those laws into Indian country. Indeed, case law interpreting the Assimilative Crimes Act has found that the statute only imports a state's *prohibitory* laws, not its *regulatory* laws.¹⁵² Courts have made the same distinction in interpreting the reach of Public Law 280's transfer of criminal jurisdiction to the states.¹⁵³ According to the Ninth Circuit Court of Appeals, the essence of this distinction is whether the state statute at issue is "intended to prohibit particular conduct in order to promote the general welfare," or rather is "primarily a licensing law aimed at regulating particular conduct."¹⁵⁴ A state law penalizing noncompliance with a public health emergency measure does not fit easily into one category or the other. However, it is very likely that, where the penal provision is merely an aid to a civil regulatory system—and where a violation cannot exist without the state first exercising its regulatory authority by issuing a quarantine order or other emergency measure—a court would find the law itself regulatory and thus not applicable to tribal members in Indian country.¹⁵⁵

Though no formal regulatory/prohibitory distinction controls the reach of state criminal jurisdiction over non-Indians in Indian country, enforcement of a state law penalizing a violation of an emergency measure such as a quarantine order presupposes state authority to apply the measure in the first place. Thus, whether a state has the criminal enforcement authority as against a non-Indian necessarily depends upon whether the state's civil regulatory jurisdiction extends to Indian country in the individual circumstances at hand. This determination

diseases").

152. *See* *United States v. Dotson*, 615 F.3d 1162, 1165-66 (9th Cir. 2010).

153. *See* *California v. Cabazon Band of Mission Indians*, 480 U.S. 202, 207-14 (1987). Accordingly, the ability of a state that has assumed jurisdiction under P.L. 280 to criminally enforce its public health emergency laws in Indian country will turn on whether such laws are deemed prohibitory or regulatory.

154. *Dotson*, 615 F.3d at 1168 (quoting *United States v. Clark*, 195 F.3d 446, 450 (9th Cir. 1999)).

155. As the Ninth Circuit has noted, the rationale for the argument that regulatory offenses should be carved out from the Assimilative Crimes Act is that Congress did not intend to allow "a state [to] enforce its regulatory system on the federal jurisdiction by making criminal any failure to comply with those regulations (i.e., licenses, permits, etc.)." *Clark*, 195 F.3d at 450 (quoting *United States v. Marcyes*, 557 F.2d 1361, 1364 (9th Cir. 1977)). That said, in *Clark*, the court found a state law criminalizing the unlicensed practice of law prohibitory in nature, even though the law was, arguably, closely tied to the state's professional licensing regulation. *Id.* at 449-50.

would rely on the interest-balancing analysis described in Part II.B above.

Generally, tribes have criminal jurisdiction over violations by Indians of their own public health laws (possibly concurrent with the federal government).¹⁵⁶ A state's plenary jurisdiction over crimes involving only non-Indians may furnish the state with some authority to enforce criminal violations of state public health laws in Indian country. However, as with most other questions of federal Indian law, those general principles may give way in the specific circumstances of an individual case.

III. NAVIGATING JURISDICTIONAL UNCERTAINTY IN PRACTICE: THE INTERGOVERNMENTAL AGREEMENT

Most state or tribal officials who have occasion to interact with their governmental counterparts should be familiar with the challenges thus far discussed, as well as with the negotiation of intergovernmental agreements (IGAs). This Part briefly introduces the concept of the intergovernmental agreement and makes the case for its application to the context of public health emergency authorities.

The Indian law scholar David Getches has referred to intergovernmental agreements as a "device of necessity" for tribes and neighboring governments.¹⁵⁷ An IGA is an agreement or memorandum of understanding (MOU) negotiated between a tribe and a neighboring government to clarify some aspect of their legal relationship. In some cases, these agreements permit cooperation and sharing of resources. The use of IGAs with tribes in the United States is widespread. They address such diverse subjects as law enforcement authorities, water rights, regulation of hunting and fishing, taxation, waste disposal, economic development, and social service delivery.¹⁵⁸ IGAs help "close the gap between concepts of sovereignty and the necessities of governance," and, at their best, function to "give practical meaning to broad legal principles, to effectuate court decisions and legislative delegations of authority, and to clarify ambiguous laws."¹⁵⁹

The exigencies of a public health emergency make IGAs, and the clarity

156. Note that, even where jurisdiction over an offender lies with the state, tribal officers "may exercise their power to detain the offender and transport him to the proper authorities." *Duro v. Reina*, 495 U.S. 676, 697 (1990). Thus, tribal officers could likely assist in enforcement of a state public health order against non-Indians.

157. Getches, *supra* note 44, at 121.

158. See *id.* at 122; AMERICAN INDIAN LAW DESKBOOK, *supra* note 65, at 404-30; Frank R. Pommersheim, *Tribal-State Relations: Hope for the Future?*, 36 S.D. L. REV. 239, 258-67 (1991).

159. Getches, *supra* note 44, at 121.

they can provide, particularly attractive.¹⁶⁰ However, there may be limitations to what can be accomplished through direct negotiation between a tribe and a neighboring state or local government. Jurisdictional uncertainty is perhaps the most obvious, though not the only,¹⁶¹ impetus for a state to negotiate an IGA with a tribe addressing responses to public health emergencies in Indian country. Federal and state laws generate, rather than answer, questions as to who has jurisdiction to pursue emergency response measures in areas that are likely to be of concern to state public health officials. This “uncertainty leaves tribes, state governments, and local governments to act at their peril, not knowing whether assertions of jurisdiction will be upheld or not.”¹⁶²

Even in instances where the law is more settled, differences in the *perception* of the extent of tribal sovereignty may necessitate a cooperative agreement between tribe and state to clarify responsibilities and authorities. It has been said that “[t]he success of any legal system depends upon its acceptance by the people to whom it applies.”¹⁶³ Given the coercive nature of many public health emergency measures—which may require holding individuals against their will, entering or destroying property, or closing down public spaces and businesses—the perceived legitimacy and acceptance of the implementing government’s authority seems especially critical to the success of the response. Indeed, disputes over tribal sovereignty have ended in armed stand-offs between tribal members and the local, state, and federal government officials.¹⁶⁴

Public health emergencies afford little opportunity to resolve legal uncertainty or to reconcile conflicting understandings of the scope of tribal

160. Even outside of the tribal context, the importance of intergovernmental agreements to public health emergency response has widely been noted. *See, e.g.*, Daniel D. Stier & Richard A. Goodman, *Mutual Aid Agreements: Essential Legal Tools for Public Health Preparedness and Response*, 97 AM. J. PUB. HEALTH S62 (2007); Hogan et al., *supra* note 2, at 39.

161. In states where transfer of allotments has created extensive “checkerboarding” of Indian and non-Indian lands, the practical challenges of regulating and policing these fragmented jurisdictions may also serve as a strong motivation to form intergovernmental agreements. *See* Riley, *supra* note 3, at 1731.

162. Getches, *supra* note 44, at 143.

163. KARL LLEWELLYN & EDWARD ADAMSON HOEBEL, *THE CHEYENNE WAY: CONFLICT AND CASE LAW IN PRIMITIVE JURISPRUDENCE* 239 (1941).

164. For example, in 1976, amidst a jurisdictional dispute, members of the Oneida Nation in New York barricaded the road leading onto the Oneida’s land and refused to let local police officers pass. Ray Halbritter & Steven Paul McSloy, *Empowerment or Dependence? The Practical Value and Meaning of Native American Sovereignty*, 26 N.Y.U. J. INT’L L. & POL. 531, 559-60 (1994). Another high-profile incident took place in 1973, when there was a seventy-one-day stand-off between members of the American Indian Movement and local, state, and federal authorities over issues relating to the federal government’s treaty obligations with the Sioux Nation. *See* Scott R. Tkacz, Note, *In Katrina’s Wake: Rethinking the Military’s Role in Domestic Emergencies*, 15 WM. & MARY BILL RTS. J. 301, 310 (2006).

sovereignty. While a state or tribal government might petition a court for emergency authority, that court may be unable or unwilling to expeditiously clarify complicated and politically sensitive jurisdictional issues. Moreover, state and tribal officials may lack the time and resources to brief complex questions of law amidst a crisis. Even if a court were to quickly resolve a jurisdictional dispute, the prevailing government would likely find implementation of its emergency authority difficult or impossible without the cooperation of the other sovereign.

The potential challenges of working through jurisdictional issues during an active emergency only serve to highlight the value of an IGA. Such an agreement, instituted *before* an active emergency, would establish and specify roles, responsibilities, and authorities to which the involved governments could agree. Negotiating an agreement in advance allows a tribe and state or local government to clarify the application of broad and uncertain jurisdictional principles in very specific contexts likely to arise in a public health emergency. Additionally, the process of negotiation may foster a cooperative relationship between tribal and state or local governments that the involved governments can codify in an IGA or pledge of mutual assistance.¹⁶⁵

While the practical dividends of negotiating such an agreement are plain, there is some question as to the legal status and enforceability of an intergovernmental agreement between tribal and state or local governments. In certain areas—such as the disposition of tribal lands or trust property¹⁶⁶—federal law explicitly prohibits the formation of agreements with tribes absent federal approval. Federal law also expressly authorizes states and tribal governments to negotiate compacts on certain subjects, such as tribal gaming¹⁶⁷ and child custody proceedings.¹⁶⁸ In areas not reached by federal statute, it is not clear whether an agreement directly negotiated between a tribe and a state or local government (without federal involvement) has any legal force.¹⁶⁹ For the most part,

165. See Pommersheim, *supra* note 158, at 268 (noting that the goal of negotiating intergovernmental agreements is not just “to narrow the band of likely areas of litigation,” but also, “as part of that process, to increase mutual respect and the ability to solve common problems”).

166. See 25 U.S.C. § 177 (2012).

167. See *id.* § 2710(d)(3) (2012).

168. See *id.* § 1919 (2012).

169. Compare AMERICAN INDIAN LAW DESKBOOK, *supra* note 65, at 406 (“Generally, cooperative agreements that do not involve tribal lands or trust property do not require federal approval . . .”), and Getches, *supra* note 44, at 145 (“Neither federal permission or federal approval is generally required for interjurisdictional agreements”), with Joel H. Mack & Gwyn Goodson Timms, *Cooperative Agreements: Government-to-Government Relations to Foster Reservation Business Development*, 20 PEPP. L. REV. 1295, 1305, 1313 (1993) (noting that it is unclear both whether federal approval is required for state-tribal cooperative agreements and whether such agreements are enforceable), and Note, *Intergovernmental Compacts in Native American Law:*

enforceability is beside the point; the primary value of an agreement is its clarification of expectations, procedures, and roles. Whether or not such agreements have the force of law on their own, it is often impracticable to obtain judicial enforcement of agreement obligations during an emergency. However, where a provision lasts longer than the emergency itself—disclaimers of liability for actions taken during a response, or provisions for reimbursement—the question of enforceability is more likely to come before a court.

Finally, there is the question of an agreement's validity under the laws of the governmental parties entering into it. Many states have statutes that specifically authorize their administrative agencies and/or local governments to form agreements with tribes.¹⁷⁰ Tribal constitutions may also contain provisions specifying the authority, procedures, or circumstances for entering into agreements with other governmental entities.¹⁷¹ While compliance with state and tribal procedures will not resolve the question of an agreement's validity under federal law, it will at the very least increase the likelihood that the agreement would survive judicial scrutiny.

IV. INCIDENCE OF PUBLIC HEALTH EMERGENCY PREPAREDNESS AGREEMENTS BETWEEN TRIBES AND STATE OR LOCAL GOVERNMENTS

In recent years, many states have increased their focus on trans-border coordination with tribes on public health and other issues. This is manifest in strengthened tribal consultation policies, funding agreements, and engagement with tribes on regional and state emergency planning. Though these efforts have no doubt improved cooperation between the tribes and their neighboring governments, they have not necessarily generated comprehensive agreement on the difficult jurisdictional issues addressed in the preceding sections.

The following are the results of a preliminary investigation of the incidence of IGAs on public health emergency measures between tribes and states or local governments. Part V draws on publicly available agreements and the author's

Models for Expanded Usage, 112 HARV. L. REV. 922, 924 (1999) ("Federal statutes and caselaw restrict the lawful authority of tribes and states to make binding agreements between themselves, and prohibit almost all tribal-state compacts absent approval by the Secretary of Interior"). Even if an intergovernmental agreement were not directly enforceable, it might have some weight in the balancing of state, federal, and tribal interests utilized to determine the scope of state civil authority in Indian country. *See supra* Part II.B.

170. *See, e.g.*, MONT. CODE ANN. § 18-11-103 (2014); WASH. REV. CODE ANN. §§ 39.34.020(1), 39.34.030 (2015). At least one state has a provision specifically authorizing state agencies to form agreements with tribes to implement public health emergency response measures. *See* N.M. STAT. ANN. § 12-10A-18 (2014).

171. *See, e.g.*, CONST. OF THE COLO. RIVER INDIAN TRIBES art. VI, § 1; CONST. OF THE TOHONO O'ODHAM NATION art. VI, § 1(f).

own discussions with public health officials and nonprofit public health organizations in Arizona, Maine, New Mexico, Oklahoma, and Washington regarding planning efforts with tribes in those states.¹⁷² The investigation uncovered a number of IGAs, which can be coarsely assigned into two categories: those that comprehensively address aid to be given or roles and responsibilities during a public health emergency, and those that address more discrete matters or facilitate preparedness activities more generally.

Given the relatively small sample of officials contacted and states surveyed, this Article cannot—and does not purport to—offer a comprehensive picture of planning efforts nationwide. There may be many more jurisdictions that have addressed, or are in the process of addressing, emergency response authorities and responsibilities. Insofar as the states included have within their borders some of the largest tribes in the country, the paucity of agreements between these states and neighboring tribes addressing substantive jurisdictional issues suggests that there is more work to be done in this arena.

A. Comprehensive Mutual Aid Agreements

Of the IGAs analyzed for this Article, only those from the State of Washington comprehensively address the exchange of aid and/or delineation of responsibilities and authorities between tribal and neighboring governments during a public health emergency. In the interest of coherence, the agreements are ordered according to degree of devolution of public health response authority by the tribal party: substantial devolution, contingent devolution, and no devolution.

At one end of the continuum is an MOU between the Snoqualmie Indian Tribe and the Public Health Department for Seattle and King County.¹⁷³ The agreement states upfront that “*this MOU is not a legally binding document*, but rather signifies the belief and commitment of the signator[ies] . . . that in the event of a region-wide disaster, the needs of the community may be best met if they cooperate and coordinate their response efforts.”¹⁷⁴ The agreement contemplates three areas of cooperation: (i) communication and coordination of response efforts during an emergency between the parties’ respective health officers; (ii) an annual meeting and ongoing communication to address emergency response issues outside the context of an actual emergency; and (iii)

172. Most of these states were chosen for their significant tribal populations.

173. Intergovernmental Memorandum of Understanding, Pub. Health-Seattle & King Cnty., Snoqualmie Indian Tribe, Oct. 12, 2007, *available at* <http://nwtemc.org/Documents/IMOU-PHSCC-Tribe.pdf> (last visited Apr. 29, 2015).

174. *Id.* at 1 (emphasis in original).

sharing of surplus staff, pharmaceuticals, and supplies during an emergency to the extent available.¹⁷⁵ Consistent with the nonbinding nature of the agreement, cooperative efforts are framed not as obligatory, but as endeavors that the parties “may” undertake at their discretion.¹⁷⁶

At the other end of the spectrum is an agreement between the Puyallup Tribe of Indians and the Tacoma-Pierce County Health Department.¹⁷⁷ The agreement grants the Department broad jurisdiction over “Tribal Lands, People on Tribal Lands and Tribe members off Tribal Lands . . . for purposes of epidemiological research, investigation, prevention, containment and treatment related to a Disease or Contamination Event affecting human health.”¹⁷⁸ Crucially, the agreement also spells out many of the corollary details necessary to give effect to its jurisdictional grant. These include (i) access to tribal lands for county officials to carry out their investigative and response duties; (ii) a guarantee that the tribe will give full faith and credit to detention, isolation, and quarantine orders issued by state courts; (iii) a guarantee of assistance from tribal police in enforcing such orders; and (iv) use of tribal personnel, facilities, and materials where necessary to support isolation or quarantine.¹⁷⁹ Other provisions safeguard the rights of tribal members, calling for the county to adhere to state law safeguards in employing social distancing measures and providing for challenges to those measures in either tribal or county courts.¹⁸⁰

175. *Id.* at 1-2.

176. The only item slightly at odds with the otherwise carefully noncommittal nature of the agreement is a provision requiring that the costs associated with the sharing of staff or materials be carefully tracked “for reimbursement after the event is over.” *Id.* at 2. Given the disclaimer at the front of the agreement, it is unlikely that this would be construed to create a binding obligation of reimbursement.

177. Mutual Aid Agreement, Puyallup Tribe of Indians, Tacoma-Pierce Cnty. Health Dept., (Sept. 7, 2005), http://www.michigan.gov/documents/mdch/ISOLATION__QUARANTINE_-_Puyallup_-_TPCHD_Public_Health_Mutual_Aid_201022_7.pdf [hereinafter Puyallup Mutual Aid Agreement]. A substantially identical agreement appears to have been proposed between the Lummi Nation and Whatcom County in Washington, but, according to officials from the Whatcom County Health Department, was never put in place. See Memorandum of Understanding, Lummi Nation, Whatcom Cnty. Health Dept., 2006, available at <http://nwtemc.org/Documents/Lummi%20Nation%20revised.doc> (last visited Apr. 29, 2015); Email from Marcus Deyerin, Emergency Response Program Specialist, Whatcom County Health Department to Author (May 14, 2013) (on file with author).

178. Puyallup Mutual Aid Agreement, *supra* note 177, at 2.

179. *Id.* at 2-3.

180. *Id.* at 3. The agreements also contain provisions that, among other things, state that the aid provided for therein is gratuitous; clarify that the parties are legally responsible for their own actions and omissions; require the maintenance of certain types of insurance policies; require that medical records be maintained in compliance with state and federal confidentiality laws; and call for the sharing of disease or contaminant information where necessary to avert harm to personnel performing services under the agreements. *Id.* at 3-4.

The most interesting of the Washington agreements is the one that stakes out the middle ground, arising from collaborations among a number of tribes and counties in Washington's Olympic Peninsula. The agreement addresses issues of public health emergency coordination in the absence of consistent public health infrastructure among the various governments with jurisdiction in the Peninsula.¹⁸¹ With the help of a facilitator from the Washington Department of Health, three county health departments¹⁸² and seven tribes¹⁸³ came together to draft an agreement that would not only improve public health emergency preparedness within the region, but also honor the sovereignty of the parties by providing enough flexibility to fit their varying circumstances. The resulting agreement, eventually signed by all participating governments, reflects a balance of those priorities and objectives.

Like the Snoqualmie agreement, the Olympic Regional Mutual Aid Agreement is premised explicitly on the fact that, while the parties acknowledge the necessity for collaboration, the agreement does not create a binding legal duty to provide mutual aid.¹⁸⁴ However, the Olympic Agreement offers a much more comprehensive set of expectations and procedures for coordination and for invoking assistance during an emergency. At bottom, the Agreement is a mechanism through which tribes can temporarily fill gaps in their public health infrastructure and expertise in order to respond to a public health emergency. Noting that some of the tribal signatories represent tribes without health officers or complete health codes, the Agreement lays out two options for tribes to exercise their public health authority in an emergency.¹⁸⁵ First, the tribe may choose to grant the closest county health department permission to exercise public health response authority over tribal lands and all inhabitants therein under the procedures and authority of local, state, federal, and—if there is a tribal

181. See Susan Ferguston et al., *The Olympic Regional Tribal-Public Health Collaboration and Mutual Aid Agreement and Operation Plan: Challenges and Solutions*, available at http://www.npaihb.org/epicenter/emergency_preparedness_conference_2010_presentations (last visited Apr. 29, 2015) (follow third link from the bottom to Dr. Ferguston's presentation); Telephone Interview with John Erikson, Special Assistant, Pub. Health Emergency Preparedness & Response, Wash. Dep't of Health (Apr. 4, 2013).

182. These are the Kitsap County Health District, the Clallam County Health Department, and the Jefferson County Health Department. See Ferguston et al., *supra* note 181.

183. These include the Hoh Tribe, Jamestown S'Klallam Tribe, Lower Elwha Klallam Tribe, Makah Tribe, Port Gamble S'Klallam Tribe, Quileute Tribe, and Suquamish Tribe. *Id.*

184. See Olympic Regional Tribal-Pub. Health Collaboration & Mutual Aid Agreement 1, 4 (2009), <http://www.doh.wa.gov/Portals/1/Documents/5100/Olympic-Regional-Tribal-Public-Health-Mutual-Aid-Agreement.pdf> (last visited April 21, 2015) [hereinafter Olympic Regional Mutual Aid Agreement].

185. *Id.* at 5-7.

health code provision on point—tribal law.¹⁸⁶ Second, the tribe may elect to retain its public health response authority but rely on the county health departments for technical assistance.¹⁸⁷ In either case, the tribe and county governments have the right to decline or rescind a request or offer of assistance at any time.¹⁸⁸

The Olympic Regional Mutual Aid Agreement thus lays the foundation for the sort of devolution of public health authority the Puyallup agreement contemplates. At the same time, the Olympic Regional Mutual Aid Agreement allows tribes to choose whether to actually transfer authority to the county health department—and allows the county to choose whether to accept that authority—on a case-by-case basis. The Agreement goes on to cover various matters ancillary to the provision of assistance: (i) specifying the chain of command for staff and resources shared under the agreement;¹⁸⁹ (ii) providing for reimbursement for the costs of personnel and resources utilized during an emergency;¹⁹⁰ (iii) requiring proper registration of personnel under the State's emergency laws (entitling them to certain benefits and protections);¹⁹¹ and (iv) disclaiming liability for the acts and omissions of the other party's personnel.¹⁹² To aid coordination and implementation, the Agreement also calls for the parties to participate in an initial regional exercise and exchange their individual emergency preparedness plans.¹⁹³ Lastly, the Agreement sets forth a detailed dispute resolution process that ranges from informal discussions to mediation and, if necessary, binding arbitration. Moreover, the dispute resolution process includes a provision for enforcement of arbitration awards in tribal or federal court, depending on the party seeking equitable relief.¹⁹⁴

The multiplicity of approaches within the State of Washington alone speaks to the variety of ways in which tribes and state or local public health officials can address questions surrounding public health emergency response authorities. Some tribes may be willing to turn over responsibility for public health emergencies to another governmental entity. Others may prefer an approach that

186. *Id.* at 6.

187. *Id.*

188. *Id.*

189. *Id.* at 7. The agreement provides that non-medical personnel and resources are placed under the command of the requesting party's leadership, while medical personnel remain under the supervision of the responding party's health officer.

190. *Id.* at 8.

191. *Id.*; see also, WASH. ADMIN. CODE § 118-04-080 (2015).

192. Olympic Regional Mutual Aid Agreement, *supra* note 184, at 9.

193. *Id.* at 5.

194. *Id.* at 10-12. The agreement calls for awards to be enforced against tribes in tribal court, and against county health departments in federal court (or, if federal jurisdiction is lacking, in county court). *Id.* at 11.

maintains tribal control over emergency response. To be sure, there is no single model appropriate to every situation.

B. Funding and Single Subject Agreements

Although few of the states researched for this Article had direct public health emergency IGAs like Washington's, the other four states each had some form of relevant or analogous agreement in place. Most prevalent among such agreements were provisions related to funding for tribal public health preparedness activities. The majority of the states had entered into such IGAs with at least some of the tribes within state lines. These agreements typically passed through to the tribes a portion of the state's Centers for Disease Control (CDC) grant funding in exchange for a specific set of public health preparedness deliverables. Some of the more common IGA provisions focused narrowly on tribal readiness deliverables, such as the completion of a public health preparedness self-assessment tool.¹⁹⁵ Other IGAs encouraged intergovernmental coordination by requiring tribal participation in regional or state-wide planning discussions, preparedness exercises, and trainings.¹⁹⁶

Arizona's funding agreements warrant special mention. Arizona forged agreements with twelve of the twenty-one tribes having a presence in the state, whereby the state would provide funding (through the CDC Public Health Emergency Preparedness Cooperative grants) for public health preparedness work.¹⁹⁷ Unique to Arizona's agreements are their comprehensive scope. The agreements, which cover a five-year term, require the tribes to hire or appoint a public health preparedness coordinator who becomes responsible for a substantial roster of deliverables and activities.¹⁹⁸ Each contracting tribe must: (i) develop its

195. See, e.g., Intergovernmental Grant Agreement, N.M. Dept. of Health-Pueblo of Zia, 2013 (deliverables include "[c]onduct a tribal self assessment of Public Health Emergency Preparedness using the Public Health and Healthcare Capabilities Planning Guide (CPG) prepared by the CDC").

196. See, e.g., *id.* (requiring tribal emergency coordinator or representative to attend state emergency preparedness stakeholder meetings); Intergovernmental Grant Agreement, N.M. Dep't of Health-Pueblo, 2013 (requiring "essential tribal personnel" to participate in Cities Readiness Initiative trainings and drills); Intergovernmental Agreement, Ariz. Dep't of Health Servs.—Hopi Tribe, 2010 (requiring tribal participation in quarterly meetings of regional public health preparedness committee); Sample Statement of Work for Healthcare Coalition Agreements between the Wash. Dep't of Health and tribes (provided by the Washington Dept. of Health by email to the author on Apr. 19, 2013) (requiring tribal participation in regional coalition meetings and public health emergency preparedness training and exercises).

197. Telephone Interview with Teresa Ehnert, Bureau Chief, Pub. Health Emergency Preparedness, Ariz. Dep't of Health Servs. (Apr. 22, 2013); Telephone Interview with Michael Allison, Native American Liaison, Ariz. Dep't of Health Servs. (Apr. 12, 2013).

198. See, e.g., Intergovernmental Agreement, Ariz. Dept. of Health Servs.—Navajo Nation, 2010, at 12 (on file with author).

own public health emergency preparedness and response plan and update it on an annual basis; and (ii) participate in the development of regional preparedness plans maintained by the county, state, and/or Indian Health Services.¹⁹⁹ The agreements direct tribes to draft plans for dispensing mass prophylaxis and medical countermeasures to tribal members, develop a tribal volunteer coordination plan for emergencies, and—to the extent consistent with its emergency preparedness plan—enter into mutual aid agreements with local jurisdictions.²⁰⁰ Other deliverables include, but are not limited to: attendance at regional preparedness meetings; participation in public health emergency and Strategic National Stockpile (SNS) exercises; and participation in various activities related to disease surveillance and outbreak investigation.²⁰¹ The Arizona Department of Health Services has contracted with an elder in the Fort Mojave Tribe to act as liaison on public health emergency preparedness with other tribal governments. The elder facilitates coordination with the tribes on these grant activities and related work.²⁰²

Several state and local governments have also formed agreements with tribes to facilitate transfer of SNS²⁰³ medical assets to the tribe for distribution to tribal members.²⁰⁴ The agreements generally provide for SNS assets to be delivered in an emergency to a location specified in the agreement²⁰⁵ or chosen by tribal leaders at the time of delivery,²⁰⁶ for dispensation (at no charge)²⁰⁷ solely to tribal members and employees.²⁰⁸ The tribe provides the location, personnel, and

199. *Id.* at 12-13.

200. *Id.*

201. *Id.* at 13.

202. Telephone Interview with Teresa Ehnert, *supra* note 197; Telephone Interview with Michael Allison, *supra* note 197.

203. The Strategic National Stockpile is a federally administered and maintained stockpile of pharmaceuticals and medical supplies available for distribution in the event of a public health emergency. See Office of Pub. Health Preparedness & Response, *Strategic National Stockpile (SNS)*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/phpr/stockpile/stockpile.htm> (last visited Apr. 29, 2015). The federal government will deliver SNS assets to the states in the event of an emergency, and states are responsible for planning for distribution to local communities. *Id.*

204. See, e.g., Memorandum of Understanding, Me. Dep't of Health & Hum. Servs., Ctr. for Disease Control & Prevention-Passamaquoddy Tribe at Indian Township, 2012 (on file with author) [hereinafter Passamaquoddy SNS Agreement]; Agreement to Provide Strategic National Stockpile Assets, Maricopa Cnty. Dep't of Health, Office of Preparedness & Response-Gila River Indian Cmty., 2012 (on file with author) [hereinafter Maricopa Cnty. SNS Agreement].

205. See Maricopa Cnty. SNS Agreement, *supra* note 204, at 1.

206. See Passamaquoddy SNS Agreement, *supra* note 204, at 1-2.

207. See Maricopa Cnty. SNS Agreement, *supra* note 204, at 2; Passamaquoddy SNS Agreement, *supra* note 204, at 2.

208. See Maricopa Cnty. SNS Agreement, *supra* note 204, at 1-2; Passamaquoddy SNS Agreement, *supra* note 204, at 2-3.

equipment (e.g., tables, chairs, computers, and copiers) for the distribution. The tribe also assumes responsibility for distributing product information to recipients and keeping records of the dispensation.²⁰⁹ The delivering state or county government must ensure that the tribe can access medical protocols associated with the pharmaceuticals to be dispensed. The delivering government may also provide training or technical assistance on dispensation.²¹⁰ An agreement from Maricopa County, Arizona addressed security for SNS assets. It specified that armed personnel may accompany assets to the delivery point, but only if the weapons are carried by “certified [state] peace officers” under the direction of the county’s Department of Health.²¹¹

Finally, some agreements address the sharing of public health data, which can be crucial both during a public health emergency and for normal disease surveillance purposes. In its simplest form, such an agreement between a local health department and a tribe requires each party to provide notice to the other of any disease outbreak that may lead to widespread illness.²¹² However, the data-sharing obligations need not be perfectly symmetrical. For instance, an agreement between the Gila River Indian Community and the Arizona Department of Health Services requires the tribe to provide ongoing communicable disease reports for individuals within the community. In return, the agreement obligates the Department to disclose on an annual basis a much broader set of data relating to individuals residing in the Gila River Indian Community, including birth and death records, hospital discharge database files, communicable disease surveillance and tracking data, and birth defect and cancer registry information.²¹³

CONCLUSION: KEY ELEMENTS OF A STATE-TRIBAL AGREEMENT ON PUBLIC HEALTH EMERGENCY RESPONSE

It would behoove policymakers and practitioners to understand the basic

209. See Maricopa Cnty. SNS Agreement, *supra* note 204, at 2; Passamaquoddy SNS Agreement, *supra* note 204, at 2, 4.

210. See Maricopa Cnty. SNS Agreement, *supra* note 204, at 1-2; Passamaquoddy SNS Agreement, *supra* note 204, at 3.

211. See Maricopa Cnty. S.N.S. Agreement, *supra* note 204, at 2.

212. See, e.g., Mutual Assistance Agreement, Chippewa Cnty. Health Dep’t-Sault Tribe Health Ctr. (date unknown) (on file with author) (providing that “[i]n the event there is an occurrence of disease that may cause widespread illness . . . , the part that first is made aware of the case will report the case to the other entity within 24 hours of becoming aware of the potential illness and keep the other entity apprised of the ensuing investigation to ensure coordination of investigation if necessary”).

213. Agreement, Gila River Indian Cmty.-Ariz. Dept. Health Servs., Jun. 1, 2000, at 1 (on file with author).

provisions that make for an effective, comprehensive public health mutual aid agreement.²¹⁴ However, certain issues are of particular concern in the context of tribal public health. Perhaps most important to any agreement between a tribe and a neighboring government on issues of public health emergency response is clarity of scope. That is, an IGA should resolve, not exacerbate, the jurisdictional uncertainty created by federal Indian law precedents. Achieving clarity can be a simple matter where the scope of the agreement is broad. For example, one such agreement provides for the transfer of jurisdiction over “Tribal Lands, People on Tribal Lands and Tribe members off Tribal Lands.”²¹⁵ Where an agreement is more targeted in effect, however, drafters should take care to consider the factors that create jurisdictional uncertainty and to address them precisely as possible.

Questions of scope do not have clear-cut answers. First, scope raises the issue of geography: which lands are covered? The boundaries of a reservation provide an easy reference point. Nevertheless, tribal lands come in many different forms and configurations and are often mixed in with non-Indian lands. When defining the geographic scope of a particular provision, it is imperative that drafters be as specific as possible in addressing issues such as whether non-Indian fee land will be covered by the document.²¹⁶ A related question pertains to applicability: to whom does a particular provision of an agreement apply? Tribal members only? Non-member Indians on tribal lands? Non-Indians on tribal lands? Clarity is particularly important with respect to applicability given the uncertain status of both state and tribal jurisdiction over non-Indians residing within tribal boundaries.²¹⁷

Drafters should also plainly define the authorities of each involved party, regardless of whether the agreement contemplates complete transfer of such authorities, sharing of authorities, or, as in the Olympic Regional Mutual Aid Agreement discussed above, merely an option to grant the subject authorities at the party’s discretion.²¹⁸ Even in an agreement providing for a plenary grant of

214. For a good overview of standard mutual aid agreement provisions, see Daniel D. Stier & Melisa L. Thombley, *Public Health Mutual Aid Agreements—A Menu of Suggested Provisions*, CTRS. FOR DISEASE CONTROL & PREVENTION (2007), http://www.cdc.gov/phlp/docs/Mutual_Aid_Provisions.pdf.

215. Puyallup Mutual Aid Agreement, *supra* note 177, at 2.

216. For example, the Puyallup Mutual Aid Agreement defines the geographic scope to include “land within the Puyallup Reservation boundary, Puyallup Tribal Trust Lands, Puyallup Tribal Member Trust Lands, and lands governed by the Puyallup Tribe of Indians Settlement Agreement of 1989, 25 U.S.C. § 1773 (2012) and, collectively, as those lands may be added to or subtracted from, from time to time.” Puyallup Mutual Aid Agreement, *supra* note 177, at 1.

217. Again, the Puyallup Mutual Aid Agreement provides a good example, defining its scope to include “members of the Tribe and Indian and Non-Indian employees, residents, visitors, guests and other people on Tribal Lands.” *Id.*

218. Olympic Regional Mutual Aid Agreement, *supra* note 184, at 5-7.

public health investigative and response authorities, the parties should consider the specific types of actions a public health emergency might require. To that end, such actions should be individually enumerated to avoid uncertainty or disputes later on. In an agreement that provides for exercise of less than total authority, it is critical that drafters specifically define and limit the powers that each party may exercise. These may include: closure of daycares, schools, and businesses open to the public, both tribally owned and otherwise; prohibition of public gatherings; isolation and quarantine; seizure and destruction of property; medical examination and compulsory vaccination or treatment; and access to private lands for investigative activities.

It is just as important that drafters consider the types of subsidiary measures that may become necessary in the exercise of each party's respective authorities. For example, even if an agreement grants a tribe and state concurrent authority to order quarantine of tribal members on reservation land, a state official may encounter practical barriers to exercising the authority if there is no provision for assistance from tribal police and recourse to tribal courts for enforcement. The parties negotiating the agreement should make explicit decisions regarding access to lands by responding officials, the role of the receiving party's law enforcement officials, and the use of the receiving party's facilities, personnel, and materials to aid in the response (e.g., using governmental facilities for distribution of pharmaceuticals).²¹⁹

Drafting parties should also address the legal mechanisms for exercise of the authority arising from the agreement. Foremost among these is the source of the law that will be applied; if the tribe lacks a comprehensive public health code, this may mean the importation of state law standards to provide authority for a response. Likewise, an agreement should identify the court or courts that will have jurisdiction to enforce and hear appeals from emergency orders. Finally, the drafters should consider how best to ensure that emergency orders are honored and enforced by both governmental parties. One approach to this is through a provision simply stating that the parties will give full faith and credit to orders issued by the other.²²⁰ However, a full faith and credit provision would not necessarily preclude arguments by an individual subject that the issuing government lacks jurisdiction. For example, a non-Indian residing on reservation lands might object to a tribal government's order requiring seizure of his property, even if there is a full-faith-and-credit agreement between tribal and state governments. Concurrent orders by state and tribal authorities may therefore be advised in areas of jurisdictional uncertainty. Such an arrangement should be

219. See, e.g., Puyallup Mutual Aid Agreement, *supra* note 177, at 2-3.

220. See, e.g., *id.* at 2.

memorialized in an advance agreement. Moreover, parties may wish to prepare and exchange form orders ahead of time to ensure smooth coordination during an emergency.²²¹

There are numerous other items that drafters should address that are not specific to the tribal-state context. These include reimbursement for aid, liability (and liability protections) for actions taken by personnel in offering aid or carrying out a response, licensing of emergency responders, maintenance of insurance policies, sharing of information, coordination of public messaging, and dispute resolution.²²²

Forming an agreement between tribal and state governments is not a simple matter of sitting down at a table and picking appropriate provisions from a menu of choices. Internal politics, history, cultural differences, and relational barriers must be taken into account.²²³ However, the need is plain for cross-border cooperation between tribes and neighboring governments to respond to public health threats. The use of table-top exercises and drills may help the parties assess the sufficiency of a proposed agreement—and test assumptions²²⁴—ahead of an emergency.²²⁵ The process of exploring and memorializing tribal and state public health authorities, responsibilities, and roles will offer both sides some amount of clarity and predictability. It may even form the foundation for a cooperative relationship. This type of good working relationship is vital to coordinating an effective and practicable emergency response between tribal and state governments. Given the omnipresent threat of a widespread public health emergency, tribes and states must look past the challenges and work together to form IGAs that will safeguard their mutual interest in the public health during an emergency.

221. Cf. Clifford M. Rees et al., *Assessing Information and Best Practices for Public Health Emergency Legal Preparedness*, 36 J.L. MED. & ETHICS 42, 44 (2008) (discussing importance of ready-to-use legal instruments in an emergency).

222. See generally Stier & Thombley, *supra* note 214, Olympic Regional Mutual Aid Agreement, *supra* note 184; Puyallup Mutual Aid Agreement, *supra* note 177.

223. Several commentators have addressed the factors that may aid—or impede—negotiation of agreements between tribes and neighboring governments. See, e.g., AMERICAN INDIAN LAW DESKBOOK, *supra* note 65, at 414-16; Getches, *supra* note 44, at 163 n.113.

224. The 2009 H1N1 pandemic highlighted some of the ways in which basic assumptions can differ between tribe and state/federal public health officials. The CDC's protocols for distribution of antivirals at the time prioritized dispensation to pregnant women, whereas many tribes insisted that tribal elders take priority, in light of their central and cherished role in tribal communities. Several state officials recounted that the mismatch of priorities did not become clear until arrangements were being made for distribution of SNS materials during the pandemic. Telephone Interview with John Erikson, *supra* note 181; Telephone Interview with Mary Schmuacher, Chief of the Bureau of Health Emergency Mgmt., N.M. Dep't of Health (Mar. 8, 2013).

225. See Stier & Goodman, *supra* note 160, at S63.

Hatch-Waxman Turns 30: Do We Need a Re-Designed Approach for the Modern Era?

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Abstract:

In 1984, Congress passed the Hatch-Waxman Act, which catalyzed the creation of the modern generic drug industry. Generic drugs today account for eighty-four percent of all prescriptions dispensed, but less than twenty percent of drug costs. Despite this success, numerous problems in the generic drug market have emerged. Some involve the deliberate manipulation of the Hatch-Waxman system, while others have arisen more unexpectedly, such as the Supreme Court's 2011 decision in *Pliva v. Mensing* that could undermine consumer confidence in generic drugs. We discuss these emerging challenges and propose updates to the Hatch-Waxman Act to continue support for the timely emergence of safe generic drugs.

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INTRODUCTION

The last major piece of legislation that revolutionized the U.S. prescription drug market was Drug Price Competition and Patent Term Restoration Act of 1984, which is more commonly known as the Hatch-Waxman Act.¹ Observing a pharmaceutical marketplace dominated by expensive brand-name drugs despite their patent protection having lapsed, while also hearing complaints from brand-name manufacturers about the rising costs of innovative drug development, legislators constructed the Hatch-Waxman Act to give brand-name pharmaceutical manufacturers additional incentives to develop new drugs. At the same time, the Hatch-Waxman Act reduced drug prices for unpatented drugs by facilitating regulatory approval of low-cost, high-quality generic prescription drugs.² Generic drugs are therapeutically equivalent to brand-name products made by first-entry or pioneer manufacturers. The factors defining therapeutic equivalence include both pharmaceutical equivalence and bioequivalence.

By nearly every measure, the Hatch-Waxman Act has been remarkably impactful.³ In 2012, generic drugs made up about eighty-four percent of all U.S. prescriptions dispensed.⁴ Generic drugs are available in nearly every therapeutic class, have become the standard of care for many common diseases, and are less expensive in the United States than in most other countries.⁵ The success of generics translates into improved medication adherence⁶ and dramatically reduced healthcare costs—more than a trillion dollars in the past decade, according to the Government Accountability Office.⁷ At the same time, Hatch-

1. Pub. L. No. 98-417, 98 Stat. 1585 (1984).

2. H.R. REP. NO. 98-857(I), at 14–15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2647-48; Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived Their Usefulness?*, 39 IDEA 389, 389 (1999).

3. See, e.g., Mark Metzke, *Increasing Follow-on Biologics Competition with a New Biologics Act*, 39 AIPLA Q.J. 357, 371 (2011) (“From a utilitarian standpoint, the Hatch-Waxman Act worked.”). But see JEREMY A. GREENE, *GENERIC: THE UNBRANDING OF MODERN MEDICINE* 88 (2014) (arguing that “a single piece of legislation signed into law in 1984 did not create the modern generic drug industry . . . By the time the Hatch-Waxman Act was passed in 1984, the existence of such an industry was no longer really in question, as it had been in the beginning of the 1960s”).

4. Katie Thomas, *U.S. Drug Costs Dropped in 2012, but Rises Loom*, N.Y. TIMES, Mar. 19, 2013, at A1.

5. Patricia M. Danzon & Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, HEALTH AFF. W3-521, W3-528 (2003).

6. William H. Shrank et al., *The Implications of Choice: Prescribing Generic or Preferred Pharmaceuticals Improves Medication Adherence for Chronic Conditions*, 166 ARCH. INTERNAL MED. 332, 335 (2006) [hereinafter *The Implications of Choice*] (finding that the proportion of days covered, a measure of adherence was 12.6% greater for patients initiated on generic versus non-preferred medications).

7. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-371R, *DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE* 4 (2012). See generally COUNCIL OF ECON. ADVISERS, EXEC.

Waxman was also a boon to the brand-name drug industry by providing market exclusivity extensions, which translated into billions of dollars in additional revenue. Since Hatch-Waxman, transformative drugs brought to market based in part on investment by brand-name drug companies have offered advances in clinical care for infectious diseases like HIV, cardiovascular disease, and rheumatologic disease, as well as for numerous hereditary genetic disorders.⁸

Thirty years later, however, the Hatch-Waxman Act has in some corners of the prescription drug marketplace become a victim of its own success. Numerous issues now affect patient access to generic drugs and prevent the generic drug industry from having an even more substantial effect on U.S. healthcare spending. Some of these issues, like business deals between brand-name and generic manufacturers that serve to delay the introduction of bioequivalent generic drugs, were spawned by the provisions of the Hatch-Waxman Act itself. Other such issues were barely contemplated in the early 1980s when the statute was designed, such as authorized generics, which emerged as a viable variation on the concept of a generic drug only after traditional generic manufacturers demonstrated the success of their business model under the Hatch-Waxman Act and the resulting generic drug approval system advanced at the Food and Drug Administration (FDA).

In light of the Hatch-Waxman Act's thirtieth anniversary in September 2014, we sought to review the generic drug approval system. While the structure of the legislation may have been appropriate in the context of the pharmaceutical market in the late 1970s and early 1980s, a substantially different drug market in the twenty-first century presents challenges that may not be readily addressed under the current regulatory regime. Part I of this Article reviews the background and origins of the Hatch-Waxman Act and explains the balanced incentive system it created. Part II examines the beneficial legacy of the Hatch-Waxman Act. Part III synthesizes criticisms and potential problems that have been created or become evident over the past thirty years and identifies areas for potential legislative amendment. Part IV concludes by summarizing the key areas that could form the basis for reconsideration of the 1984 legislation: delays to generic drug availability, tactics that reduce access to or raise the costs of generic drugs, and oversight of evolving knowledge about safe and effective prescribing of generic drugs.

OFFICE OF THE PRESIDENT, THE ECONOMIC CASE FOR HEALTH CARE REFORM 9-17 (2009), http://www.whitehouse.gov/assets/documents/CEA_Health_Care_Report.pdf (discussing inefficiencies within the United States healthcare system).

8. Aaron S. Kesselheim & Jerry Avorn, *The Most Transformative Drugs of the Past 25 Years: A Survey of Physicians*, 12 NATURE REVIEWS: DRUG DISCOVERY 425, 425 (2013) (describing the most and second-most transformative drug and drug classes in fourteen fields of medicine).

I. THE HATCH-WAXMAN ACT: BACKGROUND AND REGULATORY FRAMEWORK

A. Background and Origins of the Hatch-Waxman Act

The Hatch-Waxman Act had its origins in policymakers' dissatisfaction with the regulation of prescription drugs that hindered the ability of generic manufacturers to market low-cost copies of brand-name drugs. Prior to 1984, the most significant federal legislation affecting the pharmaceutical market was the 1962 Kefauver-Harris Amendments to the Food, Drug, and Cosmetic Act (FDCA). The Kefauver-Harris Amendments gave the FDA the power to require pharmaceutical manufacturers to prove that their drugs were safe and efficacious before the drugs could be sold.⁹ Premarket clinical (i.e., human) trials of the drugs were needed to provide this proof of safety and efficacy. Following this piece of legislation, in 1963 the FDA issued regulations requiring manufacturers to file investigational new drug (IND) applications before commencing clinical trials.¹⁰ In these rules, the FDA laid out the expected progression of pre-approval clinical trials, starting with Phase 1 trials, usually in a small number of healthy volunteers, to determine a safe dosage range. The next step was Phase 2 dose-determining studies in a limited number of patients with the disease intended to be treated that also could provide some initial efficacy data. The final stage in the pre-approval clinical trial process was larger Phase 3 studies, which were described as adequate and well-controlled investigations providing efficacy and safety data sufficient for approval.

Pursuant to the FDCA, the submission of a New Drug Application (NDA) was the final step following a successful clinical trial process. An NDA demonstrated the clinical circumstances in which a manufacturer's drug appeared to be both useful and sufficiently safe,¹¹ and generally included reports of clinical trials, as well as pharmacologic, preclinical, and other data compiled during a drug's development. The FDA reviews the NDA to determine if there is "a lack of substantial evidence that the drug will have the effect it purports or is represented to have . . . or [the drug's] labeling is false or misleading in any particular."¹² The statute also defines "substantial evidence" as "evidence consisting of adequate and well-controlled investigations, including clinical investigations . . . [showing] the drug will have the effect it . . . is represented to have."¹³ Thus, to have a drug approved by the FDA, a manufacturer needs to

9. S. REP. NO. 87-1744 (1962), *reprinted in* 1962 U.S.C.C.A.N. 2884, 2886.

10. Part 130—New Drugs: Procedural and Interpretive Regulations; Investigational Use, 28 Fed. Reg. 179 (Jan. 8, 1963) (codified at 21 C.F.R. pt. 130.3).

11. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b) (2012).

12. § 355(d).

13. *Id.*

show it is both safe and efficacious in clinical trials. Moreover, because “adequate and well-controlled investigations” was written in the plural form, the FDA interpreted the statute to prefer at least two separate comparative clinical trials, which usually were performed as Phase 3 trials.¹⁴

By requiring the FDA to make an affirmative approval decision on an NDA before a new prescription drug could be marketed, the Kefauver-Harris Amendments thrust the FDA into a gatekeeper role in verifying how a prescription drug worked.¹⁵ After the Amendments, it took substantial resources for a drug company to sell a new prescription drug because developing a new drug and completing the clinical trials necessary for FDA approval were expensive endeavors.¹⁶ Importantly, however, these responsibilities applied equally to brand-name and generic manufacturers that were attempting to market copies of post-1962 brand-name drugs after the expiration of the brand-name manufacturer’s essential patents on the underlying active ingredient.¹⁷ In most other industries, patent expiration means that competitors can join the market and prices can fall, but generic manufacturers seeking to enter the pharmaceutical marketplace with products for which the patent on the underlying active ingredient had expired generally also had to conduct clinical trials to receive approval from the FDA.¹⁸ There were no provisions in the Kefauver-Harris Amendments allowing expedited approval of drugs that were the same as products already approved by the FDA. Instead, new clinical trials had to be conducted even for generic drugs.¹⁹ Prior to 1962, approval costs had not been as substantial of an issue, since no drugs were required to affirmatively prove safety and efficacy prior to FDA approval. While the FDA created an abbreviated new

14. *Warner-Lambert Co. v. Heckler*, 787 F.2d 147, 151 (3d Cir. 1986). The FDA did not view the two-trial requirement rigidly, and subsequent amendments codified FDA practice to require only one trial in certain circumstances.

15. *Significant Dates in U.S. Food and Drug Law History*, FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm128305.htm> (last visited Apr. 12, 2015).

16. DANIEL CARPENTER, *REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA* 316 (2010) (“Yet they had also made drug development more costly, at least in the nominal sense of additional time and money spent in compliance with the regulations.”); Pub. L. No. 87-781, § 102, 76 Stat. 780, 781 (1962).

17. H.R. REP. NO. 98-857(II), at 4 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2688 (noting that the FDA would approve generic copies of pre-1962 drugs without the need for duplicative clinical trials).

18. Richard G. Frank, *The Ongoing Regulation of Generic Drugs*, 357 NEW ENG. J. MED. 1993, 1993 (2007).

19. In 1978, the FDA started a “paper NDA” process to allow approval of generic copies of new drugs introduced post-1962 based on published literature alone, but adequate literature able to support a paper NDA was available for only a fraction of post-1962 drugs, so the impact of the paper NDA process was extremely limited.

drug application (ANDA) process in 1970 to handle “similar and related” products that came on the market between 1938 and 1962, the absence of a legal pathway for generics after 1962 dramatically raised the costs required to bring generic copies of post-1962 drugs to market.²⁰ Since generic drugs were at least the second entrant into the market and would not be able to command the same high prices as original brand-name drugs,²¹ market economics also reduced the incentive for manufacturers to create generic drugs.²²

On the eve of the Hatch-Waxman Act, another substantial barrier to FDA approval of generic drugs emerged and threatened to make entry into the market even more difficult—the application of the experimental use defense to patent liability infringement in the pharmaceutical space. In the 1960s and 1970s, it was common practice for generic companies to experiment with brand-name drugs before patent expiration in anticipation of FDA review.²³ This experimentation process allowed drug companies to prepare a dossier of trials showing that their generic versions of the brand-name product were bioequivalent, or reached similar blood concentration levels and generally worked the same way in the human body. However, this changed in *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, in which the newly created Court of Appeals for the Federal Circuit was asked to decide whether generic companies could conduct testing on patented products solely for the purpose of seeking FDA approval to make a generic copy.²⁴ The controversy arose in the context of a generic version of flurazepam (Dalmene), a widely prescribed anxiolytic and sleeping pill. Before the expiration of the patent on the active ingredient, Bolar, a generic manufacturer, obtained a batch of the drug and began conducting basic pharmacologic tests on it to prepare for its own NDA.²⁵ Roche, the brand-name manufacturer of Dalmane, sued to enjoin Bolar from using its patented product for any purpose whatsoever during the life of the patent. The Federal Circuit agreed with Roche, holding that pre-expiration testing of patent-protected brand-

20. Frank, *supra* note 18, at 1993-94.

21. David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. 37, 37-38 (2005).

22. Richard G. Frank & David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, 6 J. ECON. & MGMT. STRATEGY 75, 83 (1997).

23. See Engelberg, *supra* note 2, at 396 (“[T]he weight of judicial authority and common industry belief and practice supported the view that it was not an act of patent infringement to make or use a patented drug solely for the purpose of seeking approval to market a generic copy of the patented drug.”).

24. 733 F.2d 858 (Fed. Cir. 1984), *superseded by statute*, Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

25. *Id.* at 860; see also *Pfizer, Inc. v. Int’l Rectifier Corp.*, 545 F. Supp. 486 (C.D. Cal. 1980) (rejecting as improper the use within the United States of patented doxycycline tablets without authorization of the patent holder, in order to gain FDA approval).

name drugs was not covered under any experimental use defense to liability for infringement because of the substantial commercial implications of Bolar's actions.²⁶ The court held it to be an act of patent infringement for a generic drug manufacturer to perform tests on a patented product during the patent period where those tests might lead to FDA approval.²⁷ A generic company could not even begin the preclinical and clinical process needed for FDA approval of its own version before all of the relevant patents on the brand-name drug expired. *Roche v. Bolar* served to effectively extend product exclusivity periods and threatened to dampen the market for generic products even further.

Even though the FDA worked to promote availability of generic entry for post-1962 drugs,²⁸ by the late 1970s there were few substitutable generic drugs on the market. About 150 brand-name drugs lacked generic versions despite being off-patent, and generics accounted for only nineteen percent of all prescriptions.²⁹ In one study, only two of the top thirteen drugs between 1976 and 1982 were found to have had generic entry within one year of patent expiration.³⁰ As explained in more detail below, this created problems for patients and public health outcomes. Naturally, patients benefit from the introduction of new brand-name drugs, if those drugs offer substantial advantages in patient care. However, patients also benefit from the low-cost generic drug market that is intended to emerge after the brand-name drug patents expire. The high cost of brand-name drugs can lead to reduced patient adherence to essential drug regimens and to adverse patient outcomes from excessive spending on healthcare products.³¹ The healthcare system also benefits from reasonable drug price competition, which permits payors to cover a greater range of healthcare interventions with the same

26. *Roche v. Bolar*, 733 F.2d at 863.

27. See Kristen E. Behrendt, *The Hatch-Waxman Act: Balancing Competing Interests or Survival of the Fittest*, 57 FOOD & DRUG L.J. 247, 249 (2002) (discussing *Roche v. Bolar*).

28. See *supra* note 19 for discussion of the paper NDA process.

29. See Gerald J. Mossinghoff, *Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process*, 54 FOOD & DRUG L.J. 187, 187 (1999); see also *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, CONG. BUDGET OFF. at ix (July 1998), <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf> (noting generics accounted for 43% percent of prescription drugs sold in the United States in 1996, but only 19% twelve years earlier). In 1970, only 8.9% of prescriptions were for generic drugs, a figure that rose to 12.4% by 1977. Therapeutically Equivalent Drugs, 44 Fed. Reg. 2932 (proposed Jan. 12, 1979); Brian L. Strom et al., *Antisubstitution Law Controversy: A Solution?*, 81 ANNALS INTERNAL MED. 254, 256 (1974) ("Between 1968 and 1970, generic prescriptions increased from 8.1% of all new prescriptions to 8.9%.").

30. Richard E. Caves et al., *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, 1991 BROOKINGS PAPERS ON ECONOMIC ACTIVITY: MICROECONOMICS 1, 19 tbl.2.

31. Joshua J. Gagne et al., *Comparative Effectiveness of Generic and Brand-Name Statins on Patient Outcomes: A Cohort Study*, 161 ANNALS INTERNAL MED. 400, 400 (2014).

investment of resources.

It was in this environment that the Hatch-Waxman Act came into force. The Hatch-Waxman Act was a combination of two separate pieces of legislation that sought to bolster both the brand-name and generic drug industries.³² The Act was intended to make low-cost generics more widely available while simultaneously maintaining adequate incentives for innovation.³³ To do so, it contained provisions in four major subcategories: (1) creation of a separate abbreviated FDA approval pathway for generic drugs proven to be pharmaceutically equivalent and bioequivalent to their brand-name counterparts; (2) a system to adjudicate generic manufacturers' challenges to brand-name drug manufacturers' market exclusivity; (3) assurance of competition-free periods for innovative drug approvals; and (4) extensions of brand-name market exclusivity. Each is discussed in turn.

B. Bioequivalence Pathway for Generic Drugs

Title I of the Act established a formalized and expedited system for approval of generic drug products to ensure a vibrant competitive market and lower prices after the brand-name market exclusivity period ended.³⁴ This system was the ANDA pathway, which allowed a generic manufacturer to seek FDA approval by submitting proof that the generic drug was both pharmaceutically equivalent and bioequivalent to the brand-name version.³⁵ The statute implemented this pathway by permitting applicants to “file with the Secretary an abbreviated application for the approval of a new drug” and specified that such an abbreviated application need only make a few certifications with respect to the drug product. First, the applicant must demonstrate that the conditions of use recommended in the labeling for the new drug are the same as those for a drug already approved by the FDA as safe and effective.³⁶ Second, the applicant must provide “information to show that the other active ingredients of the new drug are the same as the active ingredients of the listed drug,” that the “route of administration, the dosage

32. Mossinghoff, *supra* note 29, at 188.

33. Engelberg, *supra* note 2, at 389 (noting that it was “an unprecedented attempt to achieve two seemingly contradictory objectives, namely, 1) to make lower-costing generic copies of approved drugs more widely available and 2) to assure that there were adequate incentives to invest in the development of new drugs”).

34. Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585-92 (1984) (codified as amended at 21 U.S.C. § 355(j) (2012)).

35. This was in furtherance of the “Price Competition” aspect of the Hatch-Waxman Act. *Abbreviated New Drug Application (ANDA): Generics*, FOOD & DRUG ADMIN. (Sept. 18, 2014), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/>.

36. 21 U.S.C. § 355 (j)(2)(A)(i) (2012).

form, and the strength of the new drug are the same as those of the listed drug,” and that the drug is “bioequivalent to the listed drug.”³⁷ Finally, the applicant must certify that the labeling is the same.³⁸ The government is enjoined from requiring additional scientific information.³⁹ Taken together, the criteria for pharmaceutical equivalence and bioequivalence define therapeutic equivalence.

The FDA promulgated regulations⁴⁰ permitting bioequivalence to be established based on several approaches, the principal one of which became blood level crossover studies typically done in healthy male volunteers. Bioequivalence measures drawn from these studies included time until maximum serum (or plasma) concentration of the drug (C_{\max}) is reached, or the area under a curve (AUC) defined by serum concentration as a function of time. The FDA defined bioequivalence as sufficient demonstration that the ninety percent confidence intervals for the ratio of pioneer-to-generic AUC and C_{\max} fall within an acceptance interval of 0.80-1.25 (known as the “-20%/+25% rule”).⁴¹ A bioequivalent generic drug, therefore, was required to provide an acceptably equivalent amount of the drug into the patient’s blood stream over an equivalent period of time.

The ANDA bioequivalence process permitted approval of generic drugs scientifically proven to work similarly well to their brand-name versions without subjecting those generic drugs to the same clinical trial requirements already completed by the brand-name manufacturer.⁴² If the generic manufacturer could show pharmaceutical equivalence *and* bioequivalence, additional Phase II and Phase III clinical trials would not be necessary.⁴³ Generic manufacturers could thus focus on making their drugs as inexpensively and high-quality as possible. Avoiding the costs of these clinical tests was intended to lead to lower drug prices for consumers and for government payors.⁴⁴

C. Generic Challenges to Brand-Name Market Exclusivity

In addition to the drug product-related certification required of generic drug manufacturers in Title I, the Hatch-Waxman Act required a legal certification

37. § 355 (j)(2)(A)(ii)-(iii).

38. § 355 (j)(2)(A)(v).

39. § 355 (j)(2)(A)(viii).

40. Requirements for Submission of Bioavailability and Bioequivalence Data, 21 C.F.R. § 320.21 (2014).

41. *Guidance for Industry: Bioavailability and Bioequivalence Studies for Orally-Administered Drug Products—General Considerations*, FOOD & DRUG ADMIN. 20 (2003), http://www.fda.gov/ohrms/dockets/ac/03/briefing/3995B1_07_GFI-BioAvail-BioEquiv.pdf.

42. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

43. *See Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2471 (2013).

44. H.R. REP. NO. 98-857(II), at 29-32 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2686, 2713-16.

regarding the status of the patents protecting the brand-name drug. A manufacturer seeking to market a generic drug needed to certify to the FDA one of the following: that no patents existed (Paragraph I); that previous relevant patents were expired (Paragraph II); that they would wait until currently in-force patents expired to market their versions (Paragraph III); or that their versions did not infringe these patents or that the patents were invalid.⁴⁵ The final option, contained in the fourth paragraph of the relevant section of the statute, became known as a “Paragraph IV” certification.

To assist generic drug manufacturers in identifying patents that claimed the brand-name drug, or its uses, the FDA required brand-name manufacturers to list in the book of Approved Drug Products with Therapeutic Equivalence Evaluations—also known as the Orange Book⁴⁶—all relevant patents protecting their products. The Orange Book, first published in 1978, is a compendium of FDA-approved products available for generic substitution.⁴⁷ The two regulatory criteria for listing a patent in the Orange Book are: (1) that the patent claim an approved drug, its formulation, or a method of using the drug; and (2) that the claim can be reasonably asserted in patent infringement litigation.⁴⁸

When a generic manufacturer makes a Paragraph IV certification, it is required to provide notice to the brand-name manufacturer.⁴⁹ An ANDA submission containing such a certification would be deemed an act of patent infringement by the statute, and the brand-name company would be given forty-five days to initiate a lawsuit for alleged infringement.⁵⁰ The brand-name manufacturer’s lawsuit would generate an automatic thirty-month stay during which the FDA could not approve the generic product, in order to allow some time for the legal process to operate.⁵¹ If patent litigation was not yet complete after thirty months, generic companies were eligible to obtain final FDA approval

45. *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, FED. TRADE COMM’N (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf [hereinafter *Generic Drug Entry Prior to Patent Expiration*].

46. *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, FOOD & DRUG ADMIN. (Dec. 21, 2010), <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>.

47. *Id.* The Orange Book was named for its orange cover, which was chosen because the publication date of the first print edition in 1980 was around the time of Halloween. See *Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book): About the Orange Book*, FOOD & DRUG ADMIN. (Feb. 2015), www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm.

48. Submission of Patent Information, 21 C.F.R. § 314.53(b) (2014). One category of patents that are not listable in the Orange Book, for example, is patents covering methods of manufacture.

49. *Id.* at § 314.52.

50. 35 U.S.C. § 271(e)(2) (2012).

51. 21 U.S.C. § 355(j)(5)(B)(iii) (2012).

and launch at risk.⁵² The Act afforded a six-month period of market exclusivity to the first generic manufacturer to certify that the Orange Book-listed brand-name manufacturer's patents were invalid or not infringed.⁵³ Prices during that period would remain higher than they would be in an openly competitive market with multiple generic competitors, incentivizing generic manufacturers to assume the legal fees and risks of challenging brand-name manufacturers' patents.⁵⁴

The goal of creating the Paragraph IV challenge process was to provide a mechanism through which generic manufacturers could challenge weak patents. The pathway was necessary because brand-name drugs were (and are) rarely the subject of a single patent on their underlying active ingredient. Rather, after a successful molecule has been developed, brand-name drug manufacturers often obtain numerous secondary patents on peripheral aspects of the product, such as its coating, salt forms, alternative crystalline structures, and metabolites.⁵⁵ These secondary patents, sometimes issued years after the original molecule's discovery, can extend the effective market exclusivity of the drug beyond the life of the first patent. Yet these secondary patented structures may not add to the efficacy or safety of the original drug. Moreover, the patents themselves are more likely to be invalid as lacking novelty or for being obvious improvements on prior patented structures.⁵⁶ Generic manufacturers seeking to make bioequivalent versions of the underlying active ingredient could also more easily design around secondary patents. Thus, there was a strong public policy rationale for building a system through which generic manufacturers could challenge these patents and obtain permission to market their approved generic versions as soon as possible after expiration of the underlying active ingredient's patent.⁵⁷ Deputizing generic manufacturers to break through the thicket of secondary patents surrounding the original patented molecule would reduce inappropriate or excessive extensions in market exclusivity by the brand-name manufacturer.

52. *Id.*

53. § 355(j)(5)(B)(iv).

54. See generally C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006) (discussing various aspects of the first-filer "bounty").

55. Amy Kapczynski et al., *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE e49470, at *1 (2012).

56. See Allison A. Schmitt, *Competition Ahead? The Legal Landscape for Reverse Payment Settlements After Federal Trade Commission v. Actavis, Inc.*, 29 BERKELEY TECH. L.J. 493, 533 (2014) ("[S]econdary patents are invalidated at a much higher rate than active ingredient patents in Hatch-Waxman litigation.").

57. *Caraco Pharm. Labs. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1678 (2012).

D. Competition-Free Periods for Innovative Drug Approvals

As it created a process for abbreviated approval of generic drugs, the Hatch-Waxman Act provided assurance that brand-name manufacturers of innovative products or uses of drugs would enjoy guaranteed minimum periods of exclusivity. The legislation mandated that the ANDA process for new molecular entities (NMEs) would not be allowed to start until five years after FDA approval of the NME.⁵⁸ This guaranteed any manufacturer, even without a patent, at least five years to earn revenues to recoup research and development (R&D) costs and obtain monopoly profits.⁵⁹ A successful application for a new use or a new formulation (e.g., immediate to modified delayed or extended release) of a previously approved drug based on original clinical investigations would receive three years of market exclusivity.⁶⁰

Because of the thirty-month stay on Paragraph IV certifications, most NMEs—unless they were not covered by a patent—would be expected to receive a minimum of seven-and-a-half years of market exclusivity.⁶¹ However, the Act also superseded *Roche v. Bolar*, allowing generic manufacturers to experiment with brand-name manufacturers' drugs to test their bioequivalent versions before expiration of the patent so that ANDAs could be prepared and submitted to the FDA without additional delay.⁶²

E. Extensions of Brand-Name Market Exclusivity

Title II of the Hatch-Waxman Act provided additional incentives for brand-name drug manufacturers, who had argued that the 1962 Kefauver-Harris

58. 21 U.S.C. § 355(j)(5)(F)(ii) (2012). If the ANDA application contains a Paragraph IV certification, this period is shortened to four years, but the thirty-month stay is extended so as to ensure that 7.5 years elapses from the date of approval. *Id.*

59. § 355(c)(3)(E)(ii); see also Marc Kaufman, *Generic Drugs Hit Backlog at FDA*, WASH. POST, Feb. 4, 2006,

<http://www.washingtonpost.com/wp-dyn/content/article/2006/02/03/AR2006020302598.html> (“The [Office of Generic Drugs] took [in 2005] an average of 20.5 months to review each application . . .”).

60. § 355 (j)(5)(F)(iii).

61. § 355 (j)(5)(F)(ii) (extending the 30-month period “by such amount of time (if any) which is required for seven and one-half years to have elapsed from the date of approval of the subsection (b) application”). Exclusivity could terminate prior to the conclusion of the 30-month period “if before the expiration of such period the district court decides that the patent is invalid or not infringed,” or, if the district court finds infringement, “the date on which the court of appeals decides that the patent is invalid or not infringed.” § 355(j)(5)(B)(iii).

62. 35 U.S.C. § 271(e)(1) (2012); Pradip K. Sahu & K. Shannon Mrksich, *The Hatch-Waxman Act: When Is Research Exempt from Patent Infringement?*, 22 ABA-IPL NEWSL. 23 (2004), http://www.brinkshofer.com/resource_center/85-the-hatch-waxman-act-research-exempt-from-patent-infringement.

Amendments unfairly shortened their effective exclusivity periods by requiring a lengthy process of clinical testing and FDA review.⁶³ The seventeen-year patent term in effect in 1984 began at the time the patent was granted,⁶⁴ which could occur years prior to FDA approval. In cases in which development and approval took especially long, brand-name manufacturers might find that little or no patent term remained by the time the FDA approved the drug for marketing.

The Hatch-Waxman Act addressed this issue by granting brand-name companies “patent term restoration,” or additional time that would be added to the seventeen-year patent term to compensate the patent holder for a portion of the patent term that was lost during the clinical testing phases and FDA review period.⁶⁵ For any first approval of a product subject to a regulatory review period, the extension applied to any patents that claimed products, methods of using the products, or methods of manufacturing the products as long as the patents were still in force at the time of the extension application and had not been extended before.⁶⁶ If more than one patent were asserted as applying to a given drug product, only one patent’s term could be extended.⁶⁷ The period of patent term extension was calculated by adding one half of the time from the filing of the IND to the filing of the NDA to the full time during which the FDA had reviewed the NDA.⁶⁸ Since some of the lost marketing time results from necessary development effort rather than government delay, the extension was capped at five years, and overall could not extend patent expiration past fourteen years from the date of the drug’s FDA approval.⁶⁹ The time extensions did not include time before the issuance of the patent or periods in which the patent holder did not act with “due diligence . . . in seeking FDA approval.”⁷⁰

63. B.P. Nagori et al., *Generic Drug Approval: A U.S. Perspective*, 27 CURRENT MED. RES. & OPINION 541, 543 (2011).

64. The patent term now ends twenty years from the date of filing, 35 U.S.C. § 154(a) (2012), creating an even greater lag between when the patent “clock” begins to run and FDA approval.

65. The issue was also addressed by the enactment of the Prescription Drug User Fee Act of 1992 (PDUFA), Pub. L. No. 102-571, 106 Stat. 4491, which authorized the FDA to collect “user fees” from pharmaceutical manufacturers. These fees allowed the FDA to hire more employees, which reduced the time needed for the FDA to review new drug applications. See Jonathan J. Darrow et al., *New FDA Breakthrough Drug Category: Implications for Patients*, 370 NEW ENG. J. MED. 1252, 1253 (2014).

66. 35 U.S.C. § 156(a)(1)-(2) (2012).

67. § 156(c)(4).

68. § 156(c)(2).

69. § 156(c)(3) & (g)(6).

70. A due diligence limitation could only be invoked by special petition from another party filed within 180 days of the publication of the patent term extension determination. The FDA has never received a petition charging lack of due diligence. *Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program*, FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/smallbusinessassistance/ucm069959.htm>

F. Summary

Title II of the Hatch-Waxman Act provided additional incentives for brand-name drug manufacturers, who had argued that the 1962 Kefauver-Harris Amendments unfairly shortened their effective exclusivity periods by requiring a lengthy process of clinical testing and FDA review.⁷¹ The seventeen-year patent term in effect in 1984 began at the time the patent was granted,⁷² which could occur years prior to FDA approval. In cases in which development and approval took especially long, brand-name manufacturers might find that little or no patent term remained by the time the FDA approved the drug for marketing.

II. THE HATCH-WAXMAN LEGACY

In the years after the Hatch-Waxman Act, hundreds of new generic drugs were approved via the bioequivalence ANDA pathway. For seventeen major drugs with patents expiring between 1990 and 1993, fourteen had generic entry in just over one month following patent expiration.⁷³ State-level “Drug Product Selection” (DPS) laws aided in the widespread use of these generics. In this section, we discuss the various contributors to the legacy of the Hatch-Waxman Act.

A. Innovation by Brand-Name Drug Manufacturers

There have been no direct studies of the success of the Hatch-Waxman Act with respect to brand-name drug innovation, which was one of the two primary goals of the legislation.⁷⁴ Studies investigating the patent terms of new prescription drugs before and after the legislation show an effect on lengthening market exclusivity, as intended. One study found that after passage of the Hatch-

(last updated Mar. 31, 2009) (“At the present time no due diligence petition has been submitted to FDA.”). In addition, according to one report, no patent term extension has ever been limited by lack of due diligence. Jeffrey S. Boone, *Patent Term Extensions for Human Drugs Under the U.S. Hatch-Waxman Act*, 4 J. INTELL. PROP. L. & PRAC. 658, 659-60 (2009).

71. Nagori et al., *supra* note 63, at 543.

72. The patent term now ends twenty years from the date of filing, 35 U.S.C. § 154(a) (2012), creating an even greater lag between when the patent “clock” begins to run and FDA approval.

73. CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 67 app. (1998), <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf>.

74. Examining a broader context, one author uncovered evidence suggesting that overaggressive intellectual property law and enforcement may stifle innovation. See Michael A. Carrier, *Copyright and Innovation: The Untold Story*, 2012 WIS. L. REV. 891 (using survey data from thirty-one CEOs, company founders, and vice-presidents from technology companies, the recording industry, and venture capital firms).

Waxman Act, the market exclusivity period for brand-name drugs introduced between 1990 and 1995 was 11.7 years as a result of the patent term restoration process, compared to 8.1 years for drugs approved between 1980 and 1984.⁷⁵ More recent studies have generally been consistent with the earlier studies, finding that actual average pharmaceutical market exclusivity periods (i.e., the time between approval and first generic entry) are approximately twelve years.⁷⁶

Other studies have looked at the number of new drug introductions. Since the Hatch-Waxman Act was enacted, the number of new drugs approved each year has generally reflected the continued upward trend that has characterized the market since the 1950s.⁷⁷ Studies have also shown an increase in the average R&D expenditures per drug approval.⁷⁸ According to one report, pharmaceutical R&D spending has increased by nine percent annually in real terms.⁷⁹ There does not appear to be a relationship between the cost of innovative drug R&D and the Hatch-Waxman Act.

By contrast, there may be a relationship between the existence of vigorous and timely generic competition and brand-name manufacturers' willingness to invest in innovative drug development. Low-cost generic drugs advance innovation in the pharmaceutical marketplace by forcing innovator

75. Henry G. Grabowski & John M. Vernon, *Effective Patent Life in Pharmaceuticals*, 19 INT'L J. TECH. MGMT. 98, 103, 109 (2000) (finding a mean 11.7 years); Henry G. Grabowski & John Vernon, *Longer Patents for Increased Generic Competition in the U.S.*, 10 PHARMACOECONOMICS 110, 118 (1996) (finding a mean of 8.1 years); Henry G. Grabowski & John M. Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. HEALTH ECON. 383, 389 (1994) (finding a mean of 9-13 years).

76. Henry G. Grabowski & Margaret Kyle, *Generic Competition and Market Exclusivity Periods in Pharmaceuticals*, 28 MANAGERIAL & DECISION ECON. 491, 493 (2007) (reporting 10.5 to 12.5 years for market size categories above \$100 million); C. Scott Hemphill & Bhaven N. Sampat, *Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals*, 31 J. HEALTH ECON. 327, 330 tbl.1 (2012) (finding a mean of 12.15 years).

77. See Bernard Munos, *Lessons from 60 Years of Pharmaceutical Innovation*, 8 NATURE REVIEWS: DRUG DISCOVERY 959, 959 (2009); see also Jonathan J. Darrow & Aaron S. Kesselheim, *Trends in Drug Development and Approval, 1987-2013*, 370 NEW ENG. J. MED. e39 (2014). The number of new molecular entities (NMEs) approved during the twenty years following Hatch-Waxman (1985-2004; 602 NMEs) was 79% greater than during the twenty years prior to Hatch Waxman (1965-1984; 336 NMEs). *Id.*

78. See, e.g., Fabio Pammolli et al., *The Productivity Crisis in Pharmaceutical R&D*, 10 NATURE REVIEWS: DRUG DISCOVERY 428, 428 (2011) (noting that "although investment in pharmaceutical research and development (R&D) has increased substantially in this time, the lack of a corresponding increase in the output in terms of new drugs being approved indicates that therapeutic innovation has become more challenging"); Jack W. Scannell et al., *Diagnosing the Decline in Pharmaceutical R&D Efficiency*, 11 NATURE REVIEWS: DRUG DISCOVERY 191, 191 (2012).

79. WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RESEARCH SERV., CRS-7-5700, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER 16 (2012).

pharmaceutical companies to develop new products that will contribute to the next generation of therapies and medical progress, rather than simply re-investing in their current drug product lines.⁸⁰ Graham and Higgins studied 308 pharmaceutical companies with one FDA-approved product between 1985 and 2001 and found that loss of market exclusivity protection was the “most important predictor” of the arrival of a new product and the number of new product introductions. They concluded that pharmaceutical companies act strategically with respect to new product introductions, timing the introduction according to when exclusivity is expiring on their other products and in particular “targeting the three-year window around the loss of exclusivity to introduce new products.”⁸¹

Thus, data show that the Hatch-Waxman Act increased market exclusivity periods for brand-name drugs, but there is no clear evidence that these longer periods had any impact on rates of brand-name drug innovation. Circumstantial evidence suggests that the vigorous generic substitution market organized by the legislation may help provide a stimulus for brand-name drug innovation. Further, many new products are not genuinely innovative and there has been much consolidation in the pioneer industry with consequent reduction in pipelines for new drug development.

B. Use of Generic Drugs

While the relationship between the passage of the Hatch-Waxman Act and brand-name drug innovation has not been firmly established, the legislation indisputably helped galvanize increases in the overall dispensing of generic drugs in the United States. The less expensive Hatch-Waxman ANDA regulatory approval process was a major factor in allowing generic drugs to reach the market expeditiously and with less up-front investment. As a consequence, generic drugs could be offered at substantially lower prices than their

80. See *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 427 (2d Cir. 1945) (“Many people believe that possession of unchallenged economic power deadens initiative, discourages thrift and depresses energy; that immunity from competition is a narcotic, and rivalry is a stimulant, to industrial progress; that the spur of constant stress is necessary to counteract an inevitable disposition to let well enough alone.”). See generally Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *ESSAYS IN THE THEORY OF RISK-BEARING* 144, 157 (3d ed. 1976) (declaring “the incentive to invent is less under monopolistic than under competitive conditions”); Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 *DUKE L.J.* 1693, 1696 (2008) (arguing that that an excessively strong intellectual property regime can impede innovation).

81. Stuart J. Graham & Matthew J. Higgins, *The Impact of Patenting on New Product Introductions in the Pharmaceutical Industry*, *MUNICH PERS. REPEC ARCH.* 2 (2007), http://mpira.ub.uni-muenchen.de/4574/1/MPRA_paper_4574.pdf.

corresponding brand-name products, which quickly reduced drug costs for patients and payors.⁸² One study showed a more than five-fold increase in the percentage of brand-name prescriptions being filled with generics from 1980 to 1989.⁸³ By 2002, the Federal Trade Commission (FTC) could confidently state that “[b]eyond any doubt, Hatch-Waxman has increased generic drug entry,” noting that the generic drug prescription fill rate had increased to forty-seven percent.⁸⁴ Based on market and other incentives, generic usage continued to increase dramatically to sixty percent in 2005, seventy-four percent in 2009⁸⁵ and eighty-four percent in 2012.⁸⁶

In addition to spurring the creation of a competitive market with numerous generic drug entrants after patent expiration, the Hatch-Waxman Act successfully created a pathway that stimulated generic drug manufacturers to initiate lawsuits challenging existing brand-name drug patents. Generic manufacturer-led Paragraph IV challenges as a fraction of contributions to all new generic drug approvals increased from two percent in the 1980s to approximately twenty percent by 2000.⁸⁷ As the statute intended, studies have shown that Paragraph IV challenges commonly addressed secondary patents covering peripheral components of the drug, rather than the patent on the underlying active ingredient.⁸⁸ Indeed, these same studies show that the patents subject to Paragraph IV challenges also tended to be lower “quality,” defined as being in retrospect much more likely to have been improperly granted by the United

82. See generally *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, CONG. BUDGET OFF. (1998), <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/6xx/doc655/pharm.pdf> (explaining the impact of generic drugs on brand-name drug revenues).

83. Caves et al., *supra* note 30, at 7 (“[G]eneric substitution for brand-written multisource prescriptions is relatively infrequent, confined to 29 percent of these prescriptions in 1989 . . . [as compared to] 5 percent of brand-written multisource prescriptions in 1980.”).

84. *Generic Drug Entry Prior to Patent Expiration*, *supra* note 45, at i.

85. Ernst R. Berndt & Murray Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century After the Waxman-Hatch Legislation*, 18 INT’L J. ECON. BUS. 177, 181 fig.2, 183 tbl.1, 186 (2011).

86. Thomas, *supra* note 4, at A1. IMS is a leading provider of data regarding drug prices and sales. See also *All Together Now: Liberalisation and the Quest for Scale are Pushing Generic-Drug Firms to Merge*, ECONOMIST, July 24, 2008 (“Generics make up nearly two-thirds of the American drugs market by volume, but only thirteen percent by value.”).

87. *Generic Drug Entry Prior to Patent Expiration*, *supra* note 45, at 10 (“According to the data provided by the FDA, during the 1980s (1984-89), only 2 percent of ANDAs contained paragraph IV certifications. This share increased to approximately 12 percent for the 1990s, and it has increased substantially in the last few years: from 1998-2000, approximately 20 percent of ANDAs contained paragraph IV certifications.”).

88. C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 J. EMPIRICAL LEGAL STUD. 613 (2011).

States Patent and Trademark Office (USPTO).⁸⁹

In the late 1970s and early 1980s, the growth of DPS laws in each of the fifty states bolstered the impact of the Hatch-Waxman Act's generic approval and challenge pathways in helping set an environment in which generic competition for brand-name drugs could flourish after their market exclusivity terms expired.⁹⁰ For much of the early twentieth century, generic drug manufacturers were less reputable⁹¹ and many physicians and pharmacists worried about the safety of drugs made by these companies.⁹² By the 1960s, nearly every state had "anti-substitution laws" that required pharmacists to fill physicians' prescriptions exactly as written and not to substitute a similarly named product made by a different manufacturer.⁹³ Generic drugs, because of these barriers, did not present an effective competitive alternative to brand-name drugs, even when they were therapeutically equivalent.⁹⁴

However, after the Kefauver-Harris Amendments introduced assurance of safety and efficacy for new products,⁹⁵ many states started repealing their anti-substitution statutes, replacing them with laws that allowed prescriptions to be filled with FDA-approved generic drugs.⁹⁶ If the FDA certified a generic drug as safe and efficacious for its intended use, there was no clinical or public health reason to prevent it from being substituted at the pharmacy for a prescription written for a bioequivalent brand-name drug. The publication of the Orange Book contributed to the increase in demand for generic drugs occasioned by the repeal

89. *Id.*

90. Allan I. Wertheimer, *The Irony of Drug Product Selection*, 70 AM. J. PUB. HEALTH 473 (1980).

91. DOMINIQUE A. TOBBELL, PILLS, POWER, AND POLICY: THE STRUGGLE FOR DRUG REFORM IN COLD WAR AMERICA AND ITS CONSEQUENCES 165 (2012).

92. *Joint Statement on Antisubstitution Laws and Regulations*, 225 JAMA 142 (1973).

93. Tony Burton et al., *A History of Antisubstitution Laws and Their Replacement by Drug Product Substitution Laws*, in *GENERIC DRUG LAWS: A DECADE OF TRIAL—A PRESCRIPTION FOR PROGRESS* (Theodore Goldberg et al. eds., 1986); Peter Allen Younkin, *A Healthy Business: The Evolution of the U.S. Market for Prescription Drugs 45-72* (2010) (unpublished Ph.D. dissertation, Univ. of Calif., Berkeley), <http://escholarship.org/uc/item/7zx4c61f.pdf>.

94. Henry G. Grabowski & John M. Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, 35 J.L. & ECON. 331 (1992).

95. Daniel P. Carpenter & Dominique A. Tobbell, *Bioequivalence: The Regulatory History of a Scientific Concept*, 85 BULL. HIST. MED. 93 (2011).

96. William H. Shrank et al., *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFF. 1383 (2010) [hereinafter *Substitution Laws*]. Model state Drug Product Selection legislation was developed by the Department of Health and Human Services (HHS) and the Federal Trade Commission (FTC), which set up a structure for state-based drug formularies that would list equivalent drug products, potentially including all drug products determined by the FDA to be therapeutically equivalent. *Therapeutically Equivalent Drugs; Availability of List*, 45 Fed. Reg. 72,582, 72,583 (Oct. 31, 1980) (codified at 21 C.F.R. pt. 20).

of anti-substitution laws and the enactment of DPS laws.⁹⁷ With its central listing of all FDA-approved generic products,⁹⁸ the Orange Book allowed healthcare decision makers to easily determine which generic products were both bioequivalent and pharmaceutically equivalent (meaning they had the same dosage strength and form, e.g., tablet to tablet, capsule to capsule), to the reference-listed brand-name drug.⁹⁹ A key purpose of developing this list of bioequivalent drugs was to make drugs products “sufficiently interchangeable so that price can be a major factor in their selection.”¹⁰⁰

By the mid-1980s, all fifty states had repealed their anti-substitution laws and replaced them with laws encouraging substitution, at the level of the pharmacy, of less-expensive generic drugs approved by the FDA as being pharmaceutically equivalent and bioequivalent to the brand-name version. Some state boards of pharmacy adopted mandatory generic substitution laws.¹⁰¹ These required pharmacists to substitute a less-expensive generic for a brand-name medication unless the prescriber specified that only the brand-name drug should be dispensed. More permissive DPS laws enacted in other states give pharmacists more discretion by allowing, but not requiring, pharmacists to substitute less-expensive generics.¹⁰² In addition, some states require patient consent before substitution of a generic, while other states do not.¹⁰³

The new state DPS laws allowed the Hatch-Waxman Act generic drug approval pathway to flourish¹⁰⁴ because of the unique relationship of the patient,

97. See *Substitution Laws*, *supra* note 96.

98. *Orange Book Preface*, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENTS (34th ed. 2014), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm> (last updated Mar. 14, 2014).

99. *Id.* One of the goals of the Orange Book was to create a list of therapeutically equivalent drugs, and it was believed that “publication of the List will lend to increased consumer awareness of less expensive therapeutically equivalent prescription drug products.” Therapeutically Equivalent Drugs, 45 Fed. Reg. 72,582, 72,583 (Oct. 31, 1980) (codified at 21 C.F.R. pt. 20). This “increased awareness should stimulate greater consumer demand for less expensive therapeutic equivalents, and physicians and pharmacists should be influenced to respond to that demand by prescribing and dispensing such less expensive drug products.” *Id.*

100. OFFICE OF TECH. ASSESSMENT, U.S. CONG., DRUG BIOEQUIVALENCE: A REPORT OF THE OFFICE OF TECHNOLOGY ASSESSMENT DRUG BIOEQUIVALENCY STUDY PANEL 57 (1974).

101. Jesse C. Vivian, *Generic-Substitution Laws*, U.S. PHARMACIST, June 2008, at 30.

102. Shrank et al., *supra* note 96, at 1384.

103. *Id.*

104. Other policies, such as the introduction of tiered formularies by insurance companies, have also incentivized the use of generic medicines. See, e.g., Haiden A. Huskamp et al., *The Effect of Incentive-Based Formularies on Prescription-Drug Utilization and Spending*, 349 NEW ENG. J. MED. 2224, 2231 (2003) (“[A] sizeable minority of patients did change to less expensive tier-1 [i.e. generic] or tier-2 [i.e. preferred non-generic] alternatives [following implementation of a three-tier formulary] . . .”).

prescriber, and payor in the pharmaceutical marketplace: the physician writes the prescription for the medication, the pharmacist dispenses and sells the medication (provided it has the same non-proprietary name), and the patient (or patient's insurer) pays for the medication. The separation of the prescription-writing act from the prescription-paying act caused a disconnect between medication use and payment in ways that hindered or prevented effective price competition. In 1979, an FTC report observed, "the forces of competition do not work well in a market where the consumer who pays does not choose and the physician who chooses does not pay."¹⁰⁵ The FTC report lamented the ability of FDA-approved therapeutically equivalent products to lead to reduced prices because physicians were not involved in paying for drugs and were largely unaware of drug prices. Physicians' lack of awareness of drug prices and spending by patients on drugs persists to the present day.¹⁰⁶ Importantly, as the 1979 FTC report recognized, the price disconnect could be bridged by the pharmacist.¹⁰⁷ The report noted that pharmacists

have both the power and the incentive to respond to lower prices. That is the role envisioned for the drug product selection laws: to transfer some of this power to pharmacists. Consumers are the ones most interested in a lower price, and pharmacists must respond to consumer demand because of direct competition with other pharmacies on prescription prices.¹⁰⁸

With the Hatch-Waxman Act, the number of AB-rated¹⁰⁹ generic versions of

105. Alison Masson & Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of Drug Product Selection Laws*, FED. TRADE COMM'N 2 n.4 (1985), <https://www.ftc.gov/sites/default/files/documents/reports/generic-substitution-prescription-drug-prices-economic-effects-state-drug-product-selection-laws/massonsteiner.pdf>; see also 22 LEGISLATIVE HISTORY OF THE FOOD, DRUG & COSMETIC ACT AND ITS AMENDMENTS 17,368 (1962) (highlighting the absence of prescription drug price competition: "[H]e who orders does not buy and he who buys does not order"); Brief for FTC as Amicus Curiae, *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, Civ. No. 12-3824, 2013 WL 6145117 (E.D. Pa. Nov. 20, 2013), 2012 WL 7649225, at *11 ("The physician, who selects the drug product but does not pay for it—has little incentive to consider price when deciding which drug to prescribe.").

106. See G. Michael Allan et al., *Physician Awareness of Drug Cost: A Systematic Review*, 4 PLOS MED. 1486, 1493 (2007); Fiona M. Scott Morton, *Barriers to Entry, Brand Advertising, and Generic Entry in the U.S. Pharmaceutical Industry*, 18 INT'L J. INDUS. ORG. 1086, 1088 (2000); Ya-Chen Tina Shih & Betsy L. Sleath, *Health Care Provider Knowledge of Drug Formulary Status in Ambulatory Care Settings*, 61 AM. J. HEALTH-SYSTEM PHARMACISTS 2657, 2662 (2004); William H. Shrank et al., *Physicians' Perceived Knowledge of and Responsibility for Managing Patients' Out-of-Pocket Costs for Prescription Drugs*, 40 ANNALS PHARMACOTHERAPY 1534, 1538 (2006).

107. BUREAU OF CONSUMER PROT., FED. TRADE COMM'N, DRUG PRODUCT SELECTION: STAFF REPORT TO THE FEDERAL TRADE COMMISSION 168 (1979).

108. Masson & Steiner, *supra* note 105, at 7.

109. "Multisource drug products listed under the same heading (i.e., identical active

reference brand-name products listed in the Orange Book grew as more generic manufacturers took advantage of the ANDA bioequivalence pathway and, later, Paragraph IV challenges. The state DPS laws helped lead to rapid uptake of bioequivalent generic drugs in practice without the time and expense needed to encourage physicians to change their prescribing practices. After the relevant brand-name manufacturers' exclusivity periods expired, generic manufacturers could compete purely on the basis of price, leading to rapid consumer savings.¹¹⁰ Indeed, early studies showed rapid improvement in consumer access to generic drugs.¹¹¹ Shortly after the Hatch-Waxman Act came into effect, the end of a brand-name drug's market exclusivity period became synonymous with the manufacturer's loss of revenue and the onset of significant generic price competition for that drug. As a result of the Hatch-Waxman Act and pro-substitution DPS laws in each state supporting automatic substitution by the pharmacist,¹¹² generic drugs generally now sell for between twenty and seventy percent of the original price of the drug and take up to ninety percent of the brand's sales within a year after generic entry.¹¹³

C. Impact on Patient Outcomes and Healthcare Spending

Since the Hatch-Waxman Act, studies and substantial clinical experience

ingredient[s], dosage form, and route(s) of administration) and having the same strength . . . generally will be coded AB if a study is submitted demonstrating bioequivalence." FOOD & DRUG ADMIN., APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS xvi (35th ed. 2015).

110. See generally Allen M. Sokal & Bart A. Gerstenblith, *The Hatch-Waxman Act: Encouraging Innovation and Generic Drug Competition*, 10 CURRENT TOPICS MED. CHEM. 1950 (2010) (discussing the intended purposes of the Hatch-Waxman Act).

111. See, e.g., Norman V. Carroll et al., *The Effects of Differences in State Drug Product Selection Laws on Pharmacists' Substitution Behavior*, 25 MED. CARE 1069, 1076 (1987); Theodore Goldberg et al., *Evaluation of Economic Effects of Drug Product Selection Legislation*, 17 MED. CARE 411, 415-17 (1979).

112. Masson & Steiner, *supra* note 105. See generally Shrank et al., *supra* note 96 (discussing the potential cost savings of generic substitution laws).

113. Ann Martin et al., *Recession Contributes to Slowest Annual Rate of Increase in Health Spending in Five Decades*, 30 HEALTH AFF. 11, 18 (2011) (noting that generic drugs cost "30-80 percent less than their brand-name counterparts"); *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, FED. TRADE COMM'N: 8 (2010), <http://www.ftc.gov/os/2010/01/100112payfordelayrpt.pdf>. The variability in the discounts generic drugs can offer over the brand-name version depends on many factors, including the cost of production, but is primarily related to the number of direct generic competitors. See *Generic Competition and Drug Prices*, FOOD & DRUG ADMIN. (Mar. 1, 2010), <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> (revealing that generic drug prices reach about 55% of the brand-name price when two competitors are in the market, 33% when there are five competitors, and 13% when there are fifteen).

have supported the bioequivalence standard as a means of ensuring the efficacy and safety of generic drugs for patients.¹¹⁴ Patients who receive a generic drug have experienced the same beneficial clinical outcomes and risks of side effects as patients taking brand-name drugs. On a pharmacologic level, a review by the FDA of bioequivalence studies conducted between 1996 and 2007 found that the average difference in bioequivalence measures between generic and innovator products was about four percent, and that in nearly ninety-eight percent of the bioequivalence studies, the pharmacodynamics (i.e., the effect of the drug in the human body) of the generic product differed from that of the innovator product by less than ten percent.¹¹⁵ The FDA standard for bioequivalence requires that the bioequivalence measures be within 80-125%, a standard that also applies to the variability between lots of branded drugs.¹¹⁶ This review therefore demonstrated that generics were produced at a level of pharmaceutical quality consistently well within FDA standards.

Thus, as approved, generic drugs have produced the same clinical effects for patients as their brand-name counterparts.¹¹⁷ No prospective randomized controlled trials comparing brand-name and AB-rated generic drugs have shown any clinically significant variations in outcomes between brand-name and generic drugs. Two systematic reviews of studies comparing clinical outcomes from the use of brand-name and generic drugs in all types of cardiovascular disease¹¹⁸ and for epilepsy¹¹⁹ found no evidence of worse clinical outcomes from the use of generic drugs for these conditions. Other well-controlled studies of individual

114. *Therapeutic Equivalence of Generic Drugs: Letter to Health Practitioners*, FOOD & DRUG ADMIN. (Jan. 28, 1998), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm073182.htm>.

115. Barbara M. Davit et al., *Comparing Generic and Innovator Drugs: A Review of 12 Years of Bioequivalence Data from the United States Food and Drug Administration*, 43 ANNALS PHARMACOTHERAPY 1583, 1588 (2009).

116. 21 C.F.R. § 210.3(b)(2) & (10) (2014); *Guidance for Industry: Process Validation*, FOOD & DRUG ADMIN. 6 (Jan. 2011), <http://www.fda.gov/downloads/Drugs/Guidances/UCM070336.pdf> [hereinafter *Process Validation*]; Letter from Roger L. Williams, M.D., U.S. Food & Drug Admin., to Carmen A. Catizone, Nat'l Ass'n of Bds. of Pharmacy 2-4 (Apr. 16, 1997), <http://www.fda.gov/ohrms/dockets/dailys/04/June04/060804/03p-0126-sup0006-Attachment-H-vol3.pdf> [hereinafter Letter from Roger L. Williams to Carmen A. Catizone] (discussing the range of 80-125%).

117. Aaron S. Kesselheim et al., *The Clinical Equivalence of Generic and Brand-Name Drugs Used in Cardiovascular Disease: A Systematic Review and Meta-Analysis*, 300 JAMA 2514, 2524 (2009) (concluding that “generic and brand-name cardiovascular drugs are similar in nearly all clinical outcomes”).

118. *Id.* at 2514.

119. Aaron S. Kesselheim et al., *Seizure Outcomes Following Use of Generic vs. Brand-Name Antiepileptic Drugs: A Systematic Review and Meta-Analysis*, 70 DRUGS 605, 619 (2010).

drugs or drug classes have also concluded that generic substitution does not exacerbate disease¹²⁰ or increase drug-related adverse events.¹²¹

The increased availability of therapeutically equivalent generic drugs approved via the Hatch-Waxman ANDA pathway has had an important and positive effect on patient care. Low-cost generic drugs have been shown to promote adherence to medication regimens,¹²² enhance access to drugs for lower-income patients,¹²³ and reduce financial strain caused by illness.¹²⁴ With these improvements, more patients experience the benefits from essential prescription drug therapies, which translates into better patient health outcomes.¹²⁵ Medication non-adherence, which occurs when patients do not take medications as prescribed by their healthcare providers, is a key public health issue.¹²⁶ A study of patients with hypertension, hyperlipidemia, and diabetes found that one in four patients failed to adhere to their medication regimen.¹²⁷ Non-adherence has been linked to adverse health effects including stroke in hypertensive patients, higher viral load in patients with HIV, and hospitalization and mortality in patients with heart failure.¹²⁸ Overall, approximately 125,000 lives are lost annually from non-adherence.¹²⁹ The cost to the U.S. healthcare system may exceed \$100 billion per year due to complications that could have been prevented

120. Scott T. Devine et al., *Acute Epilepsy Exacerbations in Patients Switched Between A-Rated Anti-Epileptic Drugs*, 26 CURRENT MED. RES. & OPINION 455, 463 (2010).

121. Meytal A. Tsadok et al., *Amiodarone-Induced Thyroid Dysfunction: Brand-Name Versus Generic Formulations*, 183 CANADIAN MED. ASS'N J. E817, E823 (2011).

122. *The Implications of Choice*, *supra* note 6, at 335.

123. See Yuting Zhang et al., *Access to and Use of \$4 Generic Programs in Medicare*, 27 J. GEN. INTERNAL MED. 1251, 1256 (2012) (noting that only 16.3% used a \$4 program in 2007).

124. See Vicki Fung et al., *Responses to Medicare Drug Costs Among Near-Poor Versus Subsidized Beneficiaries*, 48 HEALTH SERVS. RES. 1653, 1661-62 (2013).

125. See Gagne et al., *supra* note 31, at 405.

126. Joyce A. Cramer et al., *Medication Compliance and Persistence: Terminology and Definitions*, 11 VALUE HEALTH 44, 46 (2008); Lars Osterberg & Terrence Blaschke, *Adherence to Medication*, 353 NEW ENG. J. MED. 487, 487 (2005).

127. Michael A. Fischer et al., *Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions*, 25 J. GEN. INTERNAL MED. 284, 288 tbl.4 (2010) (finding that patients over 18 years of age filled 76.5% of their e-prescriptions).

128. Ashley A. Fitzgerald et al., *Impact of Medication Nonadherence on Hospitalizations and Mortality in Heart Failure*, 17 J. CARDIAC FAILURE 664, 668 (2011); Marcia McDonnell Holstad et al., *Adherence, Sexual Risk, and Viral Load in HIV-Infected Women Prescribed Antiretroviral Therapy*, 25 AIDS PATIENT CARE & STDs 431, 437 (2011); Paul Muntner et al., *Low Medication Adherence and the Incidence of Stroke Symptoms Among Individuals with Hypertension: The REGARDS Study*, 13 J. CLINICAL HYPERTENSION 479, 484 (2011) (concluding that "a graded association was present between worse medication adherence and a higher risk for developing new stroke symptoms").

129. Gary E. Applebaum, *Cut Drug Copayments to Bolster "Adherence,"* BALT. SUN, June 16, 2009, http://articles.baltimoresun.com/2009-06-16/news/0906150027_1_non-adherence-health-care-system-improve-patient-adherence.

if patients had taken their medications as prescribed.¹³⁰

One of the key contributors to medication non-adherence is the high cost of prescription drugs.¹³¹ In one survey, one-third of elderly patients reported not filling a prescription or taking a reduced dose as a result of the drug's high out-of-pocket costs.¹³² By contrast, generic drugs' lower prices promote patient adherence to essential medications.¹³³ This can be particularly important for patients with limited income and public insurance programs with constrained budgets. Thus, increasing availability of generic drugs has contributed to substantial improvements in public health outcomes.

The increased availability of generic drugs also has financial benefits for United States taxpayers. As healthcare costs rise, the cost of medications purchased by government programs becomes an important health policy issue.¹³⁴ Within Medicaid—the federal- and state-funded healthcare insurance program for the poor—annual spending on prescription drugs increased from \$22.3 billion in 2007 to \$25.4 billion in 2009. This accounted for 6.6 percent of total Medicaid spending on all services during those years and ten percent of total prescription drug spending in the United States.¹³⁵ High spending on healthcare can be damaging to the economy,¹³⁶ and as a result of high costs, payors have cut benefits or increased co-payments, and public insurers have raised their thresholds for eligibility.¹³⁷ Reducing drug costs thus allows the benefits of all healthcare services to be spread more widely throughout society.¹³⁸ The

130. Osterberg & Blaschke, *supra* note 126, at 488.

131. See Dana P. Goldman et al., *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*, 298 JAMA 61, 65 (2007); Osterberg & Blaschke, *supra* note 126, at 491 tbl.2.

132. Thomas S. Rector & Patricia J. Venus, *Do Drug Benefits Help Medicare Beneficiaries Afford Prescribed Drugs?*, 23 HEALTH AFF. 213, 219 (2004).

133. *The Implications of Choice*, *supra* note 6, at 335.

134. Kelly Kennedy, *States Scramble to Drive Down Medicaid Drug Costs*, USA TODAY, Aug. 12, 2013, <http://www.usatoday.com/story/news/politics/2013/08/11/medicaid-drug-benefit/2636891/> (“The increase in spending for Medicaid, the federal-state health care program for low-income Americans, has bedeviled states for decades.”).

135. *Medicaid Payment for Outpatient Prescription Drugs*, KAISER FAM. FOUND. 1 fig.1 (2011), <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/1609-04.pdf>.

136. Council of Econ. Advisers, *The Economic Case for Health Care Reform*, EXEC. OFF. OF THE PRESIDENT 23, 29 (2009), http://www.whitehouse.gov/assets/documents/CEA_Health_Care_Report.pdf.

137. Kevin Sack & Robert Pear, *States Consider Medicaid Cuts as Use Grows*, N.Y. TIMES, Feb. 18, 2010, at A1.

138. Andrew Pollack, *Cutting Dosage of a Costly Drug Spurs Debate*, N.Y. TIMES, Mar. 16, 2008, <http://www.nytimes.com/2008/03/16/business/16gaucher.html>. See generally Aaron S. Kesselheim et al., *Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending*, 25 HEALTH AFF. 1637 (2006) (discussing the burden placed on Medicaid by rising prescription drug costs).

availability of bioequivalent generic drugs and state DPS laws have reduced pharmaceutical spending and helped rein in healthcare costs.¹³⁹ Indeed, in 2012, pharmaceutical spending fell one percent, the first decrease in nearly two decades, a trend attributed to more widespread generic drug availability.¹⁴⁰

C. Impact on Patient Outcomes and Healthcare Spending

Since the Hatch-Waxman Act, studies and substantial clinical experience have supported the bioequivalence standard as a means of ensuring the efficacy and safety of generic drugs for patients.¹⁴¹ Patients who receive a generic drug have experienced the same beneficial clinical outcomes and risks of side effects as patients taking brand-name drugs. On a pharmacologic level, a review by the FDA of bioequivalence studies conducted between 1996 and 2007 found that the average difference in bioequivalence measures between generic and innovator products was about four percent, and that in nearly ninety-eight percent of the bioequivalence studies, the pharmacodynamics (i.e., the effect of the drug in the human body) of the generic product differed from that of the innovator product by less than ten percent.¹⁴² The FDA standard for bioequivalence requires that the bioequivalence measures be within 80-125%, a standard that also applies to the variability between lots of branded drugs.¹⁴³ This review therefore demonstrated that generics were produced at a level of pharmaceutical quality consistently well within FDA standards.

139. See generally U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE (2012) (discussing cost savings from the use of generic drugs).

140. Thomas, *supra* note 4. It is notable that generic drug usage has increased from nineteen percent to eighty-four percent in the thirty years since the Hatch-Waxman Act, yet overall drug spending largely increased steadily over the same period. Explanations for this trend include an aging of the population, greater use of pharmaceuticals in medical care, and higher prices over time for brand-name prescription drugs. See Panos Kanavos et al., *Higher U.S. Branded Drug Prices and Spending Compared to Other Countries May Stem Partly from Quick Uptake of New Drugs*, 32 HEALTH AFF. 753, 756-57 (2013); Glen T. Schumock et al., *National Trends in Prescription Drug Expenditures and Projections for 2014*, 71 AM. J. HEALTH SYS. PHARMACY 482, 483 (2014).

141. *Therapeutic Equivalence of Generic Drugs: Letter to Health Practitioners*, FOOD & DRUG ADMIN. (Jan. 28, 1998), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm073182.htm>.

142. Barbara M. Davit et al., *Comparing Generic and Innovator Drugs: A Review of 12 Years of Bioequivalence Data from the United States Food and Drug Administration*, 43 ANNALS PHARMACOTHERAPY 1583, 1588 (2009).

143. 21 C.F.R. § 210.3(b)(2) & (10) (2014); *Process Validation*, *supra* note 116, at 6; Letter from Roger L. Williams to Carmen A. Catizone, *supra* note 116, at 2-4.

D. Summary

In the past thirty years, the Hatch-Waxman Act has directly contributed to a revolution in the United States therapeutic marketplace from an environment in the early 1980s in which most prescriptions were filled by brand-name drugs to the present day when most prescriptions are filled by generic drugs. Pro-substitution DPS laws have led to numerous health, social, and economic benefits to U.S. patients and the healthcare system. The impact of this major shift in the generic marketplace on brand-name drug innovation is less clear. While the Hatch-Waxman Act led to longer market exclusivity periods for brand-name drugs, the rate of increase in the number of NMEs approved per year has not measurably changed since the legislation, while the cost of drug development has increased.

III. THIRTY YEARS AFTER HATCH-WAXMAN: CURRENT AND EMERGING CHALLENGES

Despite revolutionary changes in the generic drug market since the Hatch-Waxman Act, the past decade has seen a number of challenges arise that threaten the continued success of the generic drug market. First, despite the systems set up by the Hatch-Waxman Act, market entry of generic drugs has been delayed beyond the point at which they should have been available. This has reduced drug availability and increased unnecessary spending by patients and payors.¹⁴⁴ Delay strategies have been growing in type and scope and can generally be traced to unintended consequences of the legislation or features of the Hatch-Waxman Act that were sensible thirty years ago but have no place in the modern prescription drug market. A second major challenge involves the Supreme Court's recent interpretation of the Hatch-Waxman Act in a way that limits the liability of generic drug companies when patients are harmed by their drugs, which may disincentivize future generic drug use. We review these challenges to the Hatch-Waxman regime in turn and assess whether changes to the legislation are necessary to address these shortcomings.

A. Limits or Delays to Generic Drug Availability Under Hatch-Waxman

In this section, we detail how Hatch-Waxman generic drug approval pathway has evolved in certain ways to support inappropriate extensions in market exclusivity of brand-name drugs.

144. Shirley S. Wang, *TriCor Case May Illuminate Patent Limits*, WALL ST. J., June 2, 2008, <http://www.wsj.com/articles/SB121236509655436509>.

1. Patent Accumulation

The patent-related provisions of the Hatch-Waxman Act provide one mechanism for delaying the availability of generic drugs. Pharmaceutical manufacturers had long relied on patents to protect the intellectual property in their products, given the relative ease with which small-molecule pharmaceutical products can be reverse-engineered. The Hatch-Waxman Act set a floor of five years of guaranteed market exclusivity for all new molecules. Following this five-year period, any additional brand-name drug exclusivity was to be determined by reference to relevant patents that covered the pharmaceutical product, which under the terms of the Hatch-Waxman Act had to be listed in the Orange Book.¹⁴⁵ Expiration of these Orange Book-listed patents marks the initiation of the competitive generic drug market, and it is these patents that are the primary subjects of the Paragraph IV challenge process.

Patents listed in the Orange Book by the brand-name manufacturer provide automatic thirty-month extensions of the guaranteed market exclusivity period if they are challenged through the Paragraph IV litigation process. This thirty-month stay effectively increases the guaranteed minimum market exclusivity period for every new drug that lists patents in the Orange Book from five years to seven years and six months.¹⁴⁶ Importantly, this thirty-month stay is available no matter how weak the patent is or how peripheral the protected feature is to the underlying active ingredient, product, or use.¹⁴⁷ For example, in the case of the proton-pump inhibitor omeprazole (Prilosec), used to treat gastroesophageal reflux disease, the Orange Book-listed patents covering the coating of the pill served as the basis for litigation between the brand-name manufacturer and generic competitors seeking to enter the market.¹⁴⁸ Generic competition emerged only after litigation revealed that the coating by one of the potential generic entrants did not infringe the brand-name product's coating patent. By enabling companies to obtain an automatic thirty-month stay even for secondary patents associated with pharmaceutical products, Hatch-Waxman rewarded brand-name pharmaceutical manufacturers for seeking such patents.

The centrality of patents to the Hatch-Waxman Act's balancing of brand-name and generic drug availability has had numerous consequences for the pharmaceutical market. Chief among these is that the Act reinforced the pursuit

145. Pub. L. No. 98-417, § 102(a)(1), 98 Stat. 1585, 1592 (1984) (codified as amended at 21 U.S.C. § 355(b)(1) (2012)).

146. § 103, 98 Stat. at 1596 (codified as amended at 21 U.S.C. § 355(j)(5)(F)(ii) (2012)).

147. As explained below, it is possible this thirty-month stay could terminate early if patent litigation is resolved prior to the end of the thirty-month period. *See supra* note 61.

148. *See, e.g., In re Omeprazole Patent Litig.*, 536 F.3d 1361 (Fed. Cir. 2008).

of multiple secondary patents, on features such as small changes to formulation, variation in the inactive salt component, or other crystalline structures. Since the early 1980s, there has been substantial growth in the overall number of patents covering pharmaceutical products. Experts have noted that, for example, “the number of patents per new drug has increased dramatically” since the early 1980s.¹⁴⁹ From 1992 to 2012, the combined number of patents granted in classes 424 and 514 (both listed as “Drug, Bio-Affecting and Body Treating Composition”) increased 256 percent—from 3,596 to 9,210.¹⁵⁰ It is not uncommon for marketed drugs to be covered by dozens of unique patents,¹⁵¹ although only a small fraction of these are listed in the Orange Book.¹⁵² For example, a patent map of the HIV protease inhibitors ritonavir and lopinavir—which are marketed together in the United States as a fixed-dose combination product called Kaletra for treatment of HIV infection—found 108 patents and patent applications, all but two of which covered secondary chemical structures or processes for manufacturing the pill.¹⁵³

As the overall number of patents relating to pharmaceutical products has increased, so has the number of Orange Book-listed patents. The total number of Orange Book-listed patents increased by approximately 300 percent from 1992 to 2012.¹⁵⁴ One review found that the number of patents per drug listed in the Orange Book increased over time from around 1.9 in a cohort of drugs approved between 1985-87 to nearly 3.9 in a comparable 2000-02 cohort.¹⁵⁵ Blockbuster drugs tended to have the highest numbers of patents listed in the Orange Book, with an average of over five per drug. Another group of authors examined the 1,261 Orange Book-listed patents related to 528 NMEs approved by the FDA from 1988 to 2005.¹⁵⁶ Of the 432 drugs that were protected by at least one patent, about two-thirds were protected by claims for the chemical compound, meaning that over a third of patented drugs had no chemical compound claims at all.

149. Kapczynski et al., *supra* note 55, at *1.

150. See *Patent Counts by Class by Year: January 1977-December 2014*, U.S. PATENT & TRADEMARK OFF. (Mar. 18, 2015), <http://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcby.htm>.

151. Ron A. Bouchard et al., *Empirical Analysis of Drug Approval-Drug Patenting Linkage for High Value Pharmaceuticals*, 8 NW. J. TECH. & INTELL. PROP. 174, 202 & fig.6d, 203 (2010).

152. Ruben Jacobo-Rubio et al., *Pharmaceutical Patent Litigation: Measuring the Value of Generic Entry Rights and Brand Deterrence* (June 2013) (unpublished manuscript) (on file with authors) (noting that the average branded drug product has five listed patents).

153. Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting Could Extend U.S. Market Exclusivity of HIV Drugs Norvir and Kaletra Through 2028*, 31 HEALTH AFF. 2286, 2288 (2012).

154. Jacobo-Rubio et al., *supra* note 152, at 13 fig.1.

155. Hemphill & Sampat, *supra* note 88, at 619 (“Drugs in the first cohort, approved between 1985 and 1987, have an average of 1.9 patents per drug. In the final (2000 to 2002) cohort, the mean slightly more than doubles to 3.9 patents per drug.”).

156. Kapczynski et al., *supra* note 55, at *2-3.

Eighty-one percent were protected by formulation claims, eighty-three percent by method-of-use claims, and fifty-one percent by claims relating to alternative structures of the product including polymorphs, isomers, prodrugs, esters, and salts. On average these secondary patents were more likely to be found listed in high-sales drugs, and had expiration dates that were six to seven years after the expiration date of the last expiring chemical compound patent.

The growth of secondary pharmaceutical patents, as well as Orange Book patent listings, slows approval of generic drugs and raises the cost of market entry. Prospective generic entrants must expend effort evaluating the thicket of patents surrounding a particular drug product to determine which of them may serve as potential barriers to entry. Some patents can delay competitors and force generic manufacturers to design around certain features of the drug product. In addition, the brand-name manufacturer may make slight changes to the marketed molecule and obtain one or more secondary patents on the slightly altered molecule or its formulation, which has implications for the bioequivalence testing process that the generic manufacturer needs to pursue. Since these patents are generally all issued in the years following the patent on the underlying active ingredient, they can help to extend the market dominance of the brand manufacturer, which can introduce slightly modified products that delay or reduce competition without contributing substantial new therapeutic benefit.¹⁵⁷ For example, the anti-cancer drug imatinib (Gleevec) has been protected by two key patents: the initial patent dating back to 1993, which covers the basic active ingredient (imatinib); and a subsequent patent (dating back to 1998) that covers the product as formulated and marketed for use by patients (the beta crystalline form of imatinib mesylate). The 1993 patent is for the active ingredient, while the 1998 patent is for the end-formulated version as sold.¹⁵⁸ There is no evidence that the beta crystalline form provides relevant clinical improvement over the original version, but it does offer the possibility of extended market exclusivity. In the case of Kaletra, Abbott's secondary patents nominally extend its exclusivity from 2016 to 2028 and beyond in the United States,¹⁵⁹ although some empirical work suggests that weak, late-expiring patents are the most likely to be challenged and subsequently overturned.¹⁶⁰ Though it may be possible to market the older

157. See Jonathan J. Darrow, *Debunking the "Evergreening" Patents Myth*, HARV. L. REC., Dec. 8, 2010, at 6.

158. See Rajshree Chandra, *The Role of National Laws in Reconciling Constitutional Right to Health with TRIPS Obligations: An Examination of the Glivec Patent Case in India*, in GLOBAL PUBLIC HEALTH 381, 391 (Thomas Pogge et al. eds., 2010) (describing Novartis's filing of patents on two formulations of imatinib mesylate in 1993 and 1998).

159. Amin & Kesselheim, *supra* note 153, at 2290.

160. Hemphill & Sampat, *supra* note 88, at 644.

version of Kaletra once its patent and regulatory exclusivities expire in 2020,¹⁶¹ it is likely that these older versions would not be considered interchangeable with the current formulation of the drug. A generic manufacturer would therefore need to separately market their drug product, cutting into prospective cost-savings. Instead of serving as a means to prevent generic substitution, an improved formulation of the listed drug should ideally lead to the removal of the predicate version and should occur in a timely way based on public health considerations.

Of course, it is difficult to parse the impact of Hatch-Waxman from general patenting trends over the past three decades, including the overall rise in the annual number of patents issued in the United States. Other laws such as the 1980 Bayh-Dole Act,¹⁶² which encouraged university patenting, may also have played a role in the proliferation of drug patents. The total number of United States patents issued (excluding design patents and plant patents) increased dramatically from 1981 to 2014—from 65,771 to 300,678—an increase of 357 percent.¹⁶³ While the number of pharmaceutical patents has certainly increased, it is difficult to say whether pharmaceutical innovation has increased equally (or at all) in magnitude. It is even more difficult to determine whether this innovation, however significant from a technical perspective, has been translated into the types of therapeutic advances that matter to patients. What can be said with greater certainty is that many of the patents protecting pharmaceuticals are “weak” (i.e., likely to be found invalid if challenged in court), that the cost of proving patent invalidity is high, and that these weak patents delay generic entry. One study found that generic firms prevailed in seventy-eight (forty-nine percent) of 159 Paragraph IV cases that were litigated to decision,¹⁶⁴ a figure that climbs to seventy-six percent if settlements (which conclude about half of all Paragraph IV challenges) are included.¹⁶⁵ A 2012 study found that more than fifty percent of Paragraph IV lawsuits involved disputes over secondary patents, rather than

161. See *Approved Drug Products with Therapeutic Equivalence Evaluations Patent and Exclusivity Search Results*, Appl. No. 021226, FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021226&Product_No=001&table1=OB_Rx (last visited Mar. 29, 2015) (listing Nov. 22, 2020 as the expiration date of the latest expiring patent on Kaletra, including a six-month pediatric extension).

162. Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended at 35 U.S.C. §§ 200-12 (2012)).

163. See *U.S. Patent Activity Calendar Years 1790 to the Present*, U.S. PATENT & TRADEMARK OFF., http://www.uspto.gov/web/offices/ac/ido/oeip/taf/h_counts.htm (last visited Apr. 18, 2015).

164. Jacobo-Rubio et al., *supra* note 152, at 15 tbl.1; see also *Generic Drug Entry Prior to Patent Expiration*, *supra* note 45, at 16 (finding that generic applicants prevailed in twenty-two (73%) of thirty cases in which a court had resolved the drug patent dispute).

165. Adam Greene & D. Dewey Steadman, *Pharmaceuticals: Analyzing Litigation Success Rates*, RBC CAPITAL MKTS. 4 (2010), <http://amlawdaily.typepad.com/pharmareport.pdf>.

those covering the drug compound.¹⁶⁶ Patent litigation can nevertheless be lengthy and expensive, costing the generic applicant as much as \$10 million.¹⁶⁷ One study found the average time to a district court decision was 2.3 years, with an additional 1.2 years to reach an appellate court decision.¹⁶⁸ The average cost of patent litigation may be \$4.5 million per party or more.¹⁶⁹

Reforms to patent law or alterations to the Hatch-Waxman Act can counteract excessive and wasteful accumulation of low-value pharmaceutical patents. Some have advocated raising the obviousness, novelty, or utility standards, in order to make pharmaceutical patents more difficult to obtain.¹⁷⁰ In 2007, the U.S. Supreme Court revisited the obviousness criterion in its case of *KSR v. Teleflex*,¹⁷¹ setting down a new higher standard for determining obviousness of combinations of two pieces of existing technologies. Societal concern over low-value patents is also reflected in the growing trend among other countries to statutorily raise the bar for obtaining pharmaceutical patents. While current U.S. practice evaluates the appropriateness of pharmaceutical patent applications by focusing primarily on molecular form—asking whether the particular crystalline structure sought to be protected is sufficiently different from a previously described structure—other countries have developed pharmaceutical-specific patent laws that explicitly tie novelty and non-obviousness to the effectiveness of the drug. India, for example, has refined its law to prevent patents on drug products created through minor modifications to previously existing products that do not demonstrate enhanced efficacy.¹⁷²

A second avenue of patent reform that could address the problem of low-value secondary drug patents would be to facilitate patent challenges after they are granted. For example, some have proposed streamlining post-grant opposition

166. Jacobo-Rubio et al., *supra* note 152, at 7.

167. Michael R. Herman, Note, *The Stay Dilemma: Examining Brand and Generic Incentives for Delaying the Resolution of Pharmaceutical Patent Litigation*, 111 COLUM. L. REV. 1788, 1795 n.41 (2011) (citing MARC GOODMAN ET AL., MORGAN STANLEY EQUITY RESEARCH, QUANTIFYING THE IMPACT FROM AUTHORIZED GENERICS 9 (2004)).

168. Jacobo-Rubio et al., *supra* note 152, at 14.

169. Hemphill, *supra* note 54, at 1574 & n.89 (citing AM. INTELLECTUAL PROP. LAW ASS'N, REPORT OF THE ECONOMIC SURVEY 2005, at 22 (2005)) (median expenses on patent litigation with more than \$25 million at risk is \$4.5 million). The outcomes of pharmaceutical patent cases can implicate far more than \$25 million, so even \$4.5 million may be a conservative estimate.

170. FREDERICK M. ABBOTT & GRAHAM DUKES, GLOBAL PHARMACEUTICAL POLICY: ENSURING MEDICINES FOR TOMORROW'S WORLD 34-37 (2009); Jerry Avorn, *Sending Pharma Better Signals*, 309 SCIENCE 669, 669 (2005); John H. Barton, *Reforming the Patent System*, 287 SCIENCE 1933, 1933-34 (2000); Matthew Rimmer, *The Alchemy of Junk: Patent Law and Non-Coding DNA*, 3 OTTAWA L. & TECH. J. 539, 582 (2006).

171. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007).

172. See Rahul Rajkumar & Aaron S. Kesselheim, *Balancing Access and Innovation: India's Supreme Court Rules on Imatinib*, 310 JAMA 263, 263 (2013).

procedures in order to both encourage and reduce the cost of challenges to weak patents.¹⁷³ In general, this approach may be preferable if the percentage of patents that are subject to litigation or licensing is low, because it defers costly examination and limits it to those patents that matter most. Placing yet greater emphasis on post-grant oppositions would continue a trend Congress started in 1980 and significantly expanded in 1999 and 2011.¹⁷⁴ The 2011 Leahy-Smith America Invents Act established new post-grant opposition proceedings through which third parties could challenge the existence of a patent by submitting additional information bearing on patentability of the claimed invention to the USPTO.¹⁷⁵ The presumption of patent validity does not apply in these proceedings.¹⁷⁶ This is in contrast to ordinary judicial proceedings in which a patent is presumed valid and the challenger must prove invalidity by clear and convincing evidence.¹⁷⁷ Post-grant opposition proceedings have the potential for weeding out bad pharmaceutical patents without the protracted time and cost of litigation, though the America Invents Act only permits the broadest type of post-grant opposition proceedings for nine months after issuance of the patent.¹⁷⁸

While patent reform proposals have merit and are consistent with current trends, U.S. lawmakers have been resistant to making market-specific exclusions or changes to patent law. Proposals to change the statutory definition of criteria such as novelty or non-obviousness across the board would be politically challenging. Therefore, a more viable approach could be to revisit the Hatch-Waxman Act and adjust the patent-listing process. For example, the Hatch-Waxman Act could be amended such that the listing of a patent in the Orange Book automatically reopened a post-grant review window of nine months, which would make it symmetric with the America Invents Act.¹⁷⁹ At that point, the patent's invalidity could be administratively reconsidered by the USPTO based on details offered by the generic manufacturers or other interested parties.

173. See, e.g., Michael A. Carrier, *Post-Grant Opposition: A Proposal and a Comparison to the America Invents Act*, 45 U.C. DAVIS. L. REV. 103 (2011); Bronwyn H. Hall & Dietmar Harhoff, *Post-Grant Reviews in the U.S. Patent System: Design Choices and Expected Impact*, 19 BERKELEY TECH. L.J. 989 (2004).

174. See Mark A. Lemley, *Why Do Juries Decide If Patents Are Valid?*, 99 VA. L. REV. 1673, 1722 (2013).

175. Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of 35 U.S.C.).

176. See 35 U.S.C. § 316(e) (2012) ("Evidentiary Standards. In an inter partes review . . . the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.").

177. 35 U.S.C. § 282 (2012).

178. Pub. L. No. 112-29, § 6(d), 125 Stat. 284, 306 (2011) (codified at 35 U.S.C. § 321(c) (2012)).

179. *Id.*

Resolving patent disputes outside of judicial proceedings would increase efficiency. Indeed, the 180-day generic exclusivity period was originally inserted into the Hatch-Waxman Act because of the concern that the patent challenge and litigation process may be too time-consuming and costly for many generic manufacturers without some sort of bonus.¹⁸⁰ Streamlining the patent-challenge process by adopting the USPTO-based pathway for administrative reconsideration of the patent would reduce the need to grant the generic manufacturer 180 days of market exclusivity. The goal of such a pathway would be to reduce the number of weak secondary patents that now populate the Orange Book without the need for a costly—and time-intensive—litigation process that necessarily involves a thirty-month extension of guaranteed exclusivity.¹⁷² If challenging potentially invalid patents could be made less costly, incentivizing the generic manufacturer with a 180-day period of higher prices would become less necessary. Hence, robust generic competition could begin immediately after expiration of any remaining patents. In addition, by minimizing the cost of challenging weak patents, expanded post-grant review could reduce the overall risk of anticompetitive settlements.

More radically, the Hatch-Waxman Act could be altered to permit listing of only original drug compound patents in the Orange Book, as opposed to other drug formulations or methods of use. This avenue would reduce the market impact of all secondary patents, whether strong or weak.¹⁸¹ One positive outcome would be to reduce uncertainty. Brand-name manufacturers would bear less risk of weak patents being invalidated during the regulatory exclusivity period. Generic manufacturers would have a clear date on which they could enter the market at a lower risk.¹⁸² Although secondary patents might still be asserted at

180. See *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1361 (Fed. Cir. 2008) (“The 180-day exclusivity period is important to generic pharmaceutical companies as it promotes patent challenges by enabling a generic company a period to recover its investment in [challenges to Orange Book listed patents].”).

181. This proposed solution draws a bright line, which makes it easier to implement, but also risks reducing the incentives for incremental innovations on drug products that actually do lead to improved clinical benefits. For example, if a different crystalline structure of a drug is discovered after approval that improves its bioavailability or potency in a clinically meaningful way, the patent covering this new formulation would not qualify, reducing the drug company’s motivation to identify such better-acting compounds. But real-life examples of this sequence of events occurring are relatively rare. Most examples of incremental or follow-on innovations in the pharmaceutical market that are clinically meaningful involve major alterations in a drug’s chemical structure that allow it to be taken less often (e.g., once instead of multiple times per day as in the case of metoprolol and extended release metoprolol), or that isolate the more active isomer (e.g., omeprazole and esomeprazole). Changes of this sort are typically filed as under their own NDAs, so our proposal would not affect incentives to innovate these products.

182. See generally James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1 (2005) (expressing concerns

any point prior to expiration, the threat of thirty-month stays would largely be eliminated, in part because, as indicated above, most Paragraph IV challenges are brought against secondary patents. The reduction in the number of Paragraph IV challenges would also reduce the prevalence of 180-day generic exclusivity periods. Transaction costs arising from litigation and patent searching might decline as incentives to file for patent term extensions and obtain thirty-month stays become less important.¹⁸³

Since the combination of five-year data exclusivity and the thirty-month stays arising from Paragraph IV challenges essentially provide pioneer manufacturers with 7.5 years of guaranteed market exclusivity, this proposal threatens to reduce that number to closer to five years.¹⁸⁴ Five years of exclusivity is often sufficient time for most brand-name manufacturers to earn back their investment on a drug and earn a substantial profit. In the case of sofosbuvir (Sovaldi), the transformative oral antiviral agent to treat hepatitis C virus, the brand-name manufacturer paid \$11 billion for the small company making the drug at a late stage, and earned back that investment in the first year the drug was on the market. However, not all drugs have the immediate success of sofosbuvir.¹⁸⁵ Thus, it might be necessary to assure brand-name drug manufacturers that they will benefit from slightly longer market exclusivity periods, since most new drugs will not be brought to market until six to ten years after the original patent on their underlying active ingredient is granted.¹⁸⁶ A two-

about patent quality and the high cost and uncertainty of litigation).

183. In the field of taxation, the use of the standard deduction serves a similar role by encouraging the substitution of numerous small, high-transaction-cost deductions with a single, low-transaction-cost standard deduction. These small, high-transaction-cost deductions are analogous to the numerous secondary patents that could be replaced by a lengthened regulatory exclusivity period.

184. Under Hatch-Waxman, a generic drug manufacturer's application cannot be *filed* until five years have passed. This means that an application to market a generic drug must await review by the FDA's Office of Generic Drugs. Delays at the FDA due to lack of resources have caused a backlog and, as a result, the application review process can take more than three years. The backlog at the Office of Generic Drugs has shortened considerably since 2012, when the FDA Safety and Innovation Act created a generic drug user fee system to enhance FDA resources for generic drug application reviews. So even without the Paragraph IV challenge process, the actual exclusivity period for most products will likely remain between 6 and 8 years.

185. For example, one economist has estimated that the overall break-even point for a "representative portfolio" of approved biologic drugs is approximately 12.9 years, although the estimate includes assumptions highly favorable to originator biotechnology companies, such as \$1.2 billion in capitalized research and development costs. See Henry Grabowski et al., *Data Exclusivity for Biologics*, 10 NATURE REVIEWS: DRUG DISCOVERY 15, 15-16 (2011).

186. See Matthew J. Higgins & Stuart J.H. Graham, *Balancing Innovation and Access: Patent Challenges Tip the Scales*, 326 SCIENCE 370, 370-71 (2009). Europe, Canada, and Japan provide around ten years of drug regulatory exclusivity. In 2009, Congress provided twelve years of exclusivity to new biologics in the United States. Biologics Price Competition and Innovation Act

or three-year longer guaranteed exclusivity period would not necessarily delay generic entry for many drugs already protected by the original patent on the underlying active ingredient, since FDA exclusivity periods (other than six-month pediatric exclusivities) run concurrently with the patent period.

2. Reverse Payment Paragraph IV Challenge Settlements (“Pay for Delay”)

Few aspects of Hatch-Waxman have generated as much controversy or confusion as the settlement of patent litigation between brand-name and generic manufacturers. In general, nearly all civil lawsuits are resolved by settlement—more than ninety-eight percent, according to some estimates¹⁸⁷—although this figure can vary substantially by type of litigation. Settlement is a more amicable means of resolving disputes that not only reduces litigation expenses, but can also resolve issues more quickly and reduce the burden on the judiciary.¹⁸⁸ Naturally, litigation that arises in the Hatch-Waxman context may culminate in settlement when a potential generic competitor challenges a brand-name manufacturer’s Orange Book-listed patent. These settlements may result from reasoned decision-making on behalf of the parties, taking into account the risks of litigation, the strengths of the patents being challenged, and other aspects of the market. However, they have become a source of controversy in recent years in cases with arguably anticompetitive settlement terms. Of particular concern

of 2009, Pub. L. No. 111-148, §§ 7001-03, 124 Stat. 119, 804-21 (2010) (codified at 42 U.S.C. § 262 (2012)). Such a move would be consistent with a recent scholarly proposal to tailor invention protection to the cost and risk of the invention (pharmaceuticals tend to have high cost and risk compared to other inventions). See Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on the Time-to-Market of Inventions*, 61 UCLA L. REV. 672 (2014) (see especially Part VI).

187. E.g., STEVEN SHAVELL, FOUNDATIONS OF ECONOMIC ANALYSIS OF LAW 410 (2004) (noting a state court civil settlement rate of 96% and a federal court civil settlement rate of 98%, and explaining why these figures may be either under- or over-inclusive); Marc Galanter, *The Vanishing Trial: An Examination of Trials and Related Matters in Federal and State Courts*, 1 J. EMPIRICAL LEGAL STUD. 459, 463 tbl.1 (2004) (indicating that 1.8% of civil cases in U.S. District Courts are resolved by trial, and that 2.4% of intellectual property cases are resolved by trial).

188. *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 544 F.3d 1323, 1333 (Fed. Cir. 2008) (“[T]here is a long-standing [judicial] policy in the law in favor of settlements, and this policy extends to patent infringement litigation.”); *Schering Plough Corp. v. FTC*, 402 F.3d 1056, 1073 (11th Cir. 2005) (“The importance of encouraging settlement of patent-infringement litigation . . . cannot be overstated.” (internal quotation marks and citation omitted)); *Doe v. Delie*, 257 F.3d 309, 322 (3d Cir. 2001) (“The law favors settlement, particularly in class actions and other complex cases, to conserve judicial resources and reduce parties’ costs.”); *Stewart v. M.D.F. Inc.*, 83 F.3d 247, 252 (8th Cir. 1996) (“The judicial policy favoring settlement . . . rests on the opportunity to conserve judicial resources”); *In re Androgel Antitrust Litig.*, 687 F. Supp. 2d 1371, 1378 (N.D. Ga. 2010) (quoting *Valley Drug Co. v. Geneva Pharm., Inc.*, 344 F.3d 1294, 1309 (11th Cir. 2003)) (“[L]itigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.”).

are settlements that include substantial payments from a brand-name manufacturer to a potential generic competitor, with the generic manufacturer agreeing to drop its challenge or to introduce its generic only at (or close to) the original patent's expiration date. In such cases, the generic manufacturer appears to be accepting a short-term guaranteed payment instead of pursuing the challenge envisioned under the Hatch-Waxman Act, while the brand-name manufacturer appears to be propping up potentially weak or invalid patents by providing a large enough payment to generic manufacturers to fend off their challenges. Settlements with these terms have been called "reverse payment" (or, more pejoratively, "pay-for-delay" settlements), because unlike most patent settlements in which the alleged infringer agrees to pay a reasonable royalty to end litigation, payments in the Hatch-Waxman context run from brand-name manufacturer to the prospective generic competitor.¹⁸⁹

Commentators have often viewed the delay in generic competition that may accompany such settlements (hence the term "pay-for-delay") as running counter to the intent of Hatch-Waxman, which provides the 180-day exclusivity bounty for the purpose of motivating patent challenges that lead to earlier generic entry.¹⁹⁰ Numerous commentators¹⁹¹ and legislators¹⁹² have expressed concern

189. See *FTC v. Actavis*, 133 S. Ct. 2223, 2235 (2013) ("[W]here only one party owns a patent, it is virtually unheard of outside of pharmaceuticals for that party to pay an accused infringer to settle the lawsuit.").

190. In addition to the use of authorized generics to diminish the value of the 180-day bounty, brand-name companies in the 1990s simply declined to bring suit against the Paragraph IV filer, thus depriving it of the trigger for 180-day exclusivity. This practice ended with *Mova Pharmaceutical Corp. v. Shalala*, 140 F.3d 1060 (D.C. Cir. 1998), which held that the first Paragraph IV ANDA filer was entitled to 180-day exclusivity even if it was not sued.

191. E.g., Roger D. Blair & Thomas F. Cotter, *Are Settlements of Patent Disputes Illegal Per Se?*, 47 ANTITRUST BULL. 491, 534 (2002) (suggesting that reverse-payment settlements should be subject to a rebuttable presumption of illegality); Marcia M. Boumil & Gregory D. Curfman, *On Access and Accountability: Two Supreme Court Rulings on Generic Drugs*, 369 NEW ENG. J. MED. 696, 697 (2013) (noting that "[t]he *Actavis* ruling favors consumers"); Thomas F. Cotter, *Antitrust Implications of Patent Settlements Involving Reverse Payments: Defending a Rebuttable Presumption of Illegality in Light of Some Recent Scholarship*, 71 ANTITRUST L.J. 1069, 1094 (2004) ("[A] rebuttable presumption of illegality still seems to be the most sensible approach"); Joshua P. Davis, *Applying Litigation Economics to Patent Settlements: Why Reverse Payments Should Be Per Se Illegal*, 41 RUTGERS L.J. 255, 260 (2009) (concluding that the use of a rule-of-reason approach would entail substantial transaction costs); Herbert Hovenkamp et al., *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1759 (2003) (suggesting that reverse payment settlements that exceed litigation costs be "presumptively unlawful, shifting the burden of proof to the infringement plaintiff"); Aaron S. Kesselheim et al., *"Pay for Delay" Settlement of Disputes over Pharmaceutical Patents*, 365 NEW ENG. J. MED. 1439, 1443-44 (2011) (generally favoring restrictions on settlements, but suggesting that an enhanced post-grant review process would be even better); Robert Kneuper, *Four Economic Principles Underlying the FTC's Position Against Payments in Patent Settlement Agreements*, 5 ANTITRUST SOURCE 1, 2-4 (Jan. 2006) (explaining that (1) the patent holder has market power; (2) the

with reverse payment settlements, although a number have also defended them as legitimate.¹⁹³ The FTC, an independent, bipartisan agency with a declared

possibility of shared monopoly profits creates an incentive to settle; (3) patents confer are probabilistic rights (i.e., they may be invalid); and (4) consumer welfare losses from delay are large); Erica J. Hemphill Kraus, *A Shift on Pay for Delay: Reopening Doors for Pharmaceutical Competition?*, 367 NEW ENG. J. MED. 1681, 1683 (2012) (“[A]llowing these agreements frustrates the Act’s central precompetitive purpose . . .”); Pier Luigi Parcu & Maria Alessandra Rossi, *Reverse Payment Settlements in the Pharmaceutical Sector: A European Perspective*, 2 EUR. J. RISK REG. 260 (2011) (“[P]otential benefits associated with settlements are of an order of magnitude insufficient to outweigh the certain drawbacks . . .”); Carl Shapiro, *Antitrust Limits to Patent Settlements*, 34 RAND J. ECON. 391, 408 (2003) (arguing that “a naked cash payment flowing from the patentholder to the challenger (in excess of avoided litigation costs) is a clear signal that the settlement is likely to be anticompetitive” but acknowledging that other factors such as risk aversion and asymmetric information can come into play). Many other commentators have discussed reverse payments without taking a strong position in favor or against them. See, e.g., Henry N. Butler & Jeffrey Paul Jarosh, *Policy Reversal on Reverse Payments: Why Courts Should Not Follow the New DOJ Position on Reverse-Payment Settlements of Pharmaceutical Patent Litigation*, 96 IOWA L. REV. 57, 114 (2010) (recommending use of the rule of reason); John E. Lopatka, *A Comment on the Antitrust Analysis of Reverse Payment Settlements: Through the Lens of the Hand Formula*, 79 TUL. L. REV. 235, 264 (2004) (recommending use of the Hand formula); Amanda P. Reeves, *Muddying the Settlement Waters: Open Questions and Unintended Consequences Following FTC v. Actavis*, 28 ANTITRUST 9, 14 (Fall 2013) (explaining how companies and their attorneys should respond to *Actavis*); Miriam Shuchman, *Delaying Generic Competition: Corporate Payoffs and the Future of Plavix*, 355(13) NEW ENG. J. MED. 1297, 1297-1300 (2006) (summarizing several high profile pay-for-delay deals).

192. Preserve Access to Affordable Generics Act, S. 214, 113th Cong. (1st Sess. 2013) (describing reverse payments as “subvert[ing]” the intent of Hatch Waxman); Preserve Access to Affordable Generics Act, S. 3582, 109th Cong. (2d Sess. 2006) (defining reverse payment settlements as an unfair method of competition under § 5 of the Federal Trade Commission Act). Similar bills were proposed in 2007, 2009, and 2011.

193. *Hatch-Waxman Act: Reverse-Payment Settlements*: FTC v. Actavis, 127 HARV. L. REV. 358, 367 (2013) (“[T]he Court should have prioritized judicial administrability by protecting settlement agreements within the scope of the relevant patent.”); Daniel A. Crane, *Per Se Illegality for Reverse Payment Settlements?*, 61 ALA. L. REV. 575, 576 (2010) [hereinafter *Per Se Illegality*] (arguing that a ban on reverse payments would be futile because “creative lawyers are capable of crafting settlement agreements that have the same effects as the most pernicious reverse payment cases but would pass unscathed under a rule focusing on reverse payments”); Ronald W. Davis, *Reverse Payment Settlements: A View into the Abyss, and a Modest Proposal*, 21 ANTITRUST 26, 30 (Fall 2006) (arguing that if the patentee is more likely than not to prevail in litigation “then the patentee and the challenger should enjoy an unqualified right to agree to restrain trade”); Kevin McDonald, *Hatch-Waxman Patent Settlements and Antitrust: On “Probabilistic” Patent Rights and False Positives*, 17 ANTITRUST 68, 75 (Spring 2003) (approving of reverse payments “if the patent is valid and the exclusion of competition no broader than that inherent in the patent”); Stuart N. Senator & Rohit K. Singla, *FTC v. Actavis: Antitrust Litigation over “Reverse-Payment” Pharmaceutical Patent Settlements*, 22 COMPETITION: J. ANTITRUST & UNFAIR COMP. L. SEC. ST. B. CAL. 153, 163 (2013) (noting that under the Supreme Court’s reasoning in *Actavis*, “a reverse payment may be explained—that is, justified—based upon the value of the drug at issue”); Elizabeth Stanley, *An Ounce of Prevention: Analysis of Drug Patent Settlements Under the Hatch-Waxman Act*, 10 GEO. MASON L. REV. 345, 358 (2002) (expressing concern that too harsh a view of

mission to “protect consumers and promote competition,”¹⁹⁴ has condemned reverse payment settlements since 1999.¹⁹⁵ Both Senator Orrin Hatch and Representative Henry Waxman, the co-sponsors of the original 1984 Act, have spoken out against reverse payment settlements.¹⁹⁶ Nonetheless, they have been popular,¹⁹⁷ with a growing number of Paragraph IV cases settling with reverse payments or other terms.¹⁹⁸ These terms invoke the specter of the brand-name manufacturer sharing its monopoly rents in return for a promise to discontinue challenging what may be a weak patent.¹⁹⁹ Reflecting concern about possible consumer harm from anticompetitive settlement agreements, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003

settlements could adversely affect innovation).

194. *What We Do*, FED. TRADE COMM’N, www.ftc.gov/about-ftc/what-we-do (last visited Apr. 9, 2015).

195. *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, FED. TRADE COMM’N 1 (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>; *Generic Drug Entry Prior to Patent Expiration*, *supra* note 45 at 63.

196. 148 CONG. REC. 14,437 (2002) (statement of Sen. Hatch) (“It was and is very clear that the [Hatch–Waxman Act] was not designed to allow deals between brand and generic companies to delay competition.”); 146 CONG. REC. 18,774 (2000) (statement of Rep. Waxman) (introducing bill to deter companies from “strik[ing] collusive agreements to trade multimillion dollar payoffs by the brand company for delays in the introduction of lower cost, generic alternatives”); *see also* Brief for Representative Henry A. Waxman as Amicus Curiae Supporting Petitioner, at 2, *FTC v. Watson Pharm. Inc.*, 113 S. Ct. 2223 (2013) (No. 12-416), 2013 WL 417736, at *2 (calling the shielding of reverse payment settlements from antitrust scrutiny “a significant obstacle to the fulfillment of the important public policies embodied in the Hatch-Waxman [Act]”).

197. *See* Shuchman, *supra* note 191, at 1297-1300 (discussing several such settlements).

198. *See Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2013: A Report by the Bureau of Competition*, FED. TRADE COMM’N 4 (2013), <https://www.ftc.gov/system/files/documents/reports/agreements-filled-federal-trade-commission-under-medicare-prescription-drug-improvement/141222mmafy13rpt-1.pdf> [hereinafter *Overview of Agreements Filed in FY 2013*].

199. *Agreements Filed with the Federal Trade Commission Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012: A Report by the Bureau of Competition*, FED. TRADE COMM’N, 1-2 (2013), <https://www.ftc.gov/sites/default/files/documents/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-and/130117mmareport.pdf> [hereinafter *Overview of Agreements Filed in FY 2012*]. The most recent year for which a report has been issued is 2012. Hatch-Waxman did not restrict the patents listed in the Orange Book to those covering the active ingredient itself. For purposes of Paragraph IV litigation, a patent on the underlying active ingredient is treated the same as a patent on a peripheral feature of the drug, such as its coating or heat stability, or a metabolite or other derivative crystalline structure. In addition, the FDA was not given authority to evaluate the patents listed by the brand-name company to determine their validity or relevance to the potential generic competitors.

requires that settlement agreements between Paragraph IV filers and brand-name companies be reported to the FTC.²⁰⁰

In 2013, the Supreme Court weighed in, holding in *FTC v. Actavis* that reverse payment settlement agreements can sometimes violate antitrust laws.²⁰¹ The Court rejected the view of a growing number of U.S. Courts of Appeals that defendants would be immune from antitrust scrutiny so long as any anticompetitive effects of the settlement fell “within scope of the exclusionary potential of the patent,”¹⁹² noting that the patent at issue “may or may not be valid [and infringed].”²⁰² The Court also disposed of the argument that patentees would find it too expensive to “buy off” other patent challengers by pointing out that if the first-to-file applicant forfeits its 180-day exclusivity right (which could occur following a reverse-payment settlement), no other generic can obtain it, dampening the likelihood of subsequent challenges.²⁰³ In holding that reverse payment settlements are subject to analysis under the rule of reason standard, the Court provided a useful guide to future cases, indicating that the excess of the reverse payment beyond what could be justified by litigation savings or other legitimate explanations could provide a workable surrogate for a patent’s weakness as well as insight into the ultimate question of antitrust violation. The *Actavis* case may slow the number of settlement agreements with reverse payments or other anticompetitive terms, or it may merely influence the content of those agreements; it is too early to tell. While a number of pending cases have been affected by the *Actavis* decision,²⁰⁴ its impact is not yet clear.

If reverse payment settlement agreements continue to prove problematic, a number of reforms could address this unintended consequence of the Hatch-Waxman Act. Currently, the FTC must be notified of reverse payment settlement agreements, but it does not prospectively approve or disapprove them as it does for proposed mergers under the Hart-Scott-Rodino Act.²⁰⁵ The absence of FTC approval means that brand-name and generic manufacturers may proceed

200. Pub. L. No. 108-173, §§ 1111-18, 117 Stat. 2066, 2461-63.

201. 133 S. Ct. 2223 (2013).

202. *Id.* at 2231.

203. *Id.* at 2229.

204. See, e.g., *Merck & Co. v. La. Wholesale Drug Co.*, 133 S. Ct. 2849 (2013) (K-Dur (potassium chloride)); *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523 (D.N.J. 2014) (atorvastatin; dismissing case for failure to meet pleading standards); *In re Nexium (esomeprazole) Antitrust Litig.*, 968 F. Supp. 2d 367 (D. Mass. 2013); *King Drug Co. of Florence, Inc. v. Cephalon, Inc.*, 702 F. Supp. 2d 514 (E.D. Pa. 2013) (Provigil (modafinil)). See generally Brian Sodikoff et al., *Reverse Payments After Actavis: 15 Cases to Follow*, 12 PHARMACEUTICAL L. & INDUS. REP. 999, 1008 (2014) (discussing fifteen cases applying, or soon to apply, the *Actavis* standard and noting that “the contours of post-*Actavis* reverse payment analysis are not definitively established, creating uncertainty”).

205. Pub. L. No. 94-435, 90 Stat. 1383 (1976) (current version at 15 U.S.C. § 18a (2012)).

according to the terms of their agreements without waiting any particular period of time. They also need not negotiate with the FTC prior to entering into the settlement agreement. Legislative amendments to Hatch-Waxman might confer approval power to the FTC and impose a waiting period during which time the FTC could evaluate a proposed settlement. The power to disapprove could help reduce or at least diminish the litigation burden on the FTC, as well as provide an opportunity to negotiate concessions with respect to the terms of any proposed settlement agreement. In addition, under the MMA amendments, failure to file with the FTC can result in civil penalties of up to \$11,000 per day (\$4 million per year).²⁰⁶ However, given that the forty potential reverse payment settlements filed with the FTC in 2012 concerned products that averaged \$268 million in sales per year,²⁰⁷ these penalties may be too small. Finally, the MMA amendments to the Hatch-Waxman Act required filing of only settlement agreements between brand-name and Paragraph IV generic ANDA filers, but not those between brand-name and generic manufacturers that might later have filed a Paragraph IV challenge if not for an earlier agreement. Agreements entered into before the filing of Paragraph IV challenges might not be settlement agreements, but the FTC should be attentive to possible shifts in concerted practices that could result from stricter settlement agreement legislation and decisions.²⁰⁸

3. *Authorized Generics*

In recent years, the rise of a new category of drugs called “authorized generics”²⁰⁹ has threatened the balance between brand-name drug exclusivity periods and generic drug competition established by the Hatch-Waxman Act. Authorized generics are products that are marketed as generics but sold by a brand-name manufacturer or its licensee. Because authorized generics administratively fall under the brand-name company’s original NDA approval, they can be introduced at the brand-name company’s discretion. In most cases, they are sold just prior to the beginning of the 180-day generic exclusivity period

206. Pub. L. No. 108-173, § 1115(a), 117 Stat. 2066, 2463 (2003).

207. *Overview of Agreements Filed in FY 2012*, *supra* note 198, at 1 (noting thirty-one different branded products with combined annual U.S. sales of \$8.3 billion).

208. *See Per Se Illegality*, *supra* note 193, at 576 (“[C]reative lawyers are capable of crafting settlement agreements that have the same effects as the most pernicious reverse payment cases but would pass unscathed under a rule focusing on reverse payments.”).

209. *See Aidan Hollis & Bryan A. Liang, An Assessment of the Effect of Authorized Generics on Consumer Prices* GENERIC PHARM. MFR. ASS’N 2 n.1 (2006), <http://emmanuelcombe.org/hollisliang.pdf> (defining “authorized generic” as “the actual brand-name drug product, manufactured by the brand company, but sold as a generic, competing with independent generics”); *see also* SCHACHT & THOMAS, *supra* note 79, at 11 (“[I]n 2007, 9.3% of prescriptions filled by generic drugs were filled by branded generics.”).

that occurs when the first traditional generic drug enters the market after a successful Paragraph IV challenge. As a result, authorized generics have been criticized as a deliberate attempt to undermine the incentive structure of Hatch-Waxman, as they disincentivize the initiation of Paragraph IV challenges against weak Orange Book-listed patents protecting brand-name products.²¹⁰ The presence of an authorized generic reduces the potential profits available to generic manufacturers by introducing a competitor to the generic during the exclusivity period. A 2009 FTC Report confirmed that authorized generics reduce prices by increasing competition during the 180-day period.²¹¹ Average retail prices were found to be 4.2 percent lower if an authorized generic entered the market than if it did not.²¹² The Report also confirmed the concern that entry by an authorized generic “significantly decreases the revenues”²¹³ of the first-filing generic manufacturer by approximately fifty percent.²¹⁴

Brand-name manufacturers have hinted that consumers benefit from the lower drug prices that authorized generics offer during the 180-day duopoly period.²¹⁵ However, such positive outcomes come at a significant cost if they deter generic manufacturers’ willingness to bring Paragraph IV challenges in the first place. There is not yet conclusive evidence as to whether authorized generics deter the initiation of Paragraph IV challenges.²¹⁶ Some commentators have concluded that authorized generics are unlikely to have a significant deterrent effect. Indeed, Paragraph IV certifications have been frequent despite existing situations in which multiple generic manufacturers might enter the market, such as might result from same-day filings²¹⁷ or filings that pertain to different doses

210. See Beth Understahl, *Authorized Generics: Careful Balance Undone*, 16 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 355, 392-93 (2005).

211. *Authorized Generics: An Interim Report*, FED. TRADE COMM’N 1, 2 (2009), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generics-interim-report-federal-trade-commission/p062105authorizedgenericsreport.pdf> [hereinafter *Authorized Generics*].

212. *Id.* at 6-7; see also Aaron Barkoff, *PhRMA Study Finds Authorized Generics Lead to Lower Drug Prices*, ORANGEBOOKBLOG (June 27, 2006), http://www.orangebookblog.com/2006/06/phrma_study_fin.html (“[W]ith an authorized generic on the market during the exclusivity period, discounts to brand medicines were greater—on average 15.8 percentage points greater—than instances when a generic company did not face competition from an authorized generic.”).

213. *Authorized Generics*, *supra* note 211, at 16.

214. *Id.* at 3.

215. Barkoff, *supra* note 212.

216. Hollis & Liang, *supra* note 209, at 2.

217. *Guidance for Industry: 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day*, FOOD & DRUG ADMIN. 4-5 (2003), www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm072851.pdf.

of the same drug.²¹⁸ Notwithstanding the possibility of entry by authorized generics, the number of Paragraph IV challenges increased dramatically from 35 in 2001 to 242 in 2011,²¹⁹ although it fell to 204 in 2012.²²⁰ That challenges are frequent despite the disincentive created by the introduction of authorized generics can be explained in part by the fact that Paragraph IV challenges can be averted only if *all* generics are deterred from filing under Paragraph IV. Generic manufacturers, however, may each have different business risk tolerance levels, assessments of likely litigation outcome, or thresholds for required return-on-investment. Given this variation, all generic manufacturers are likely to be deterred only when the relevant patents are perceived to be relatively strong or when expected profits are relatively small.²²¹

While the impact of authorized generics on initiation of Paragraph IV challenges by generic manufacturers is not fully known, authorized generics do appear to exert a strong effect on reverse payment settlements. Indeed, in many reverse payment cases, major settlement terms include the brand-name manufacturer's promise either not to market an authorized generic or to allow the generic challenger to market the authorized generic.²²² Thus, the existence of authorized generics as a key negotiating tool in reverse payment settlement cases potentiates the anticompetitive effects and public health complications of those agreements.

Despite their potential to suppress Paragraph IV filings and clear impact in providing a vehicle for settlements in reverse payment cases, authorized generics appear to be a permanent fixture of the pharmaceutical market. Recognizing the potential chilling effect of authorized generics, generic manufacturers have petitioned the FDA to prevent their sale during the 180-day exclusivity period.²²³ These petitions have not been successful, as the FDA does not have authority to

218. Ernst R. Berndt et al., *Authorized Generic Drugs, Price Competition, and Consumers' Welfare*, 26 HEALTH AFF. 790, 793 (2007).

219. Gregory Glass, *The Paragraph Four Report: January 2013* 1 (2013), <http://www.paragraphfour.com/forums/uploads/qn/QN113.pdf>.

220. *Id.*

221. Berndt et al., *supra* note 218, at 794.

222. C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009).

223. See Letter from Mylan Pharm., Inc., to FDA. (Feb. 17, 2004) *Prohibit the Marketing and Distribution of Authorized Generics Until the Expiration of the First Generic Applicant's Exclusivity Period*, Docket No. 2004P-0075, www.fda.gov/ohrms/dockets/dailys/04/feb04/021804/04p-0075-cp00001-vol1.pdf; Letter from Teva Pharm., USA, Inc., to FDA (June 9, 2004) *Prevent Pfizer Inc. from Marketing a Generic Version of Accupril Until After the Expiration of Teva's 180-day Exclusivity Period*, Docket No. 2004P-0261, www.fda.gov/ohrms/dockets/dailys/04/June04/061004/04p-0261-cp00001-01-vol1.pdf.

challenge brand-name manufacturers' actions with respect to drug pricing (as opposed to actions that change the formulation of the drugs being sold). Courts have affirmed the ability for authorized generics to compete with ANDA-approved generic products during the 180-day exclusivity period.²²⁴

Further study on the use and prevalence of authorized generics would help determine whether the public health benefits arising from the decrement in price that they offer during the 180-day exclusivity period is outweighed by the risks that they pose to the efficient functioning of the Hatch-Waxman Paragraph IV challenge process. Even without such evidence, it is clear that their existence undermines the deliberately crafted incentive structure in the Hatch-Waxman Act that intends to reward generic manufacturers for challenging weak or invalid brand-name patents. Since the FDA will not be able to act on authorized generics without additional authority, Congress should consider amending the Act to prohibit the introduction of authorized generics until after the conclusion of the 180-day period.

4. Dose Form or Other Changes in the Listed Drug

One central purpose of the Hatch-Waxman Act was to guarantee a sufficient exclusivity period to the innovator while facilitating generic entry at the end of the exclusivity period. The balance can be tipped in favor of the innovator by the brand-name manufacturer's strategic introduction of a slightly modified form of the product just prior to patent expiration. A common strategy is to introduce the new version while the patent on the old version still prevents competition. Then, before the old patent expires, the brand-name manufacturer engages in intensive marketing to convince physicians to prescribe the new product. The push to switch can be reinforced by discontinuing promotion of the old product, or even taking it off the market altogether, thereby preventing substitution at the pharmacy counter.²²⁵ While such dose formulation or other changes in the listed drug²²⁶ can generally only succeed if the market can be convinced that the new

224. See, e.g., *Teva Pharm. Indus. Ltd. v. FDA*, 355 F. Supp. 2d 111 (D.D.C. 2004), *aff'd sub nom.* *Teva Pharm. Indus. Ltd. v. Crawford*, 410 F.3d 51 (D.C. Cir. 2005) (holding that Pfizer may sell its own authorized generic version of its epilepsy drug gabapentin (Neurontin) during a 180-day exclusivity period granted to Teva Pharmaceuticals).

225. Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLA. L. REV. 1009, 1021-29 (2010); Seth C. Silber & Kara Kuritz, *Product Switching in the Pharmaceutical Industry: Ripe for Antitrust Scrutiny?*, 7 J. GENERIC MEDICINES 119 (2012) ("[T]he market for [the old] product may be greatly depleted.").

226. This process is sometimes referred to by the derogatory term "product hopping" in the literature. See, e.g., Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471 (2008); Mark Metzke, *Targeting Enantiomer Product Hopping with a New "Obviousness" Standard*, 14 UCLA J. L. & TECH. 1 (2010).

version is superior, marketing has long proven successful at making new drugs appear more desirable than justified by their therapeutic value.²²⁷ For example, in the case of the antibiotic doxycycline hyclate extended release (Doryx), which was available in a capsule and nearing the date of expected generic competition, the manufacturer introduced a tablet version at the same dosage strength and withdrew the capsule from the market.²²⁸

To support a change, the original product may also be delisted from pharmaceutical pricing guides, which are used by insurers and hospitals to determine which drugs are available in which forms, and whether they are produced by brand-name or generic manufacturers. For example, in the case of the cholesterol-lowering drug fenofibrate (Tricor), Abbott moved from a 67mg capsule to a 54mg tablet and then to a 48mg tablet. Abbott successfully mitigated competition for more than five years before a coalition of generics manufacturers, retail pharmacies, and class action plaintiffs convinced a court that the manufacturer's behavior had likely violated antitrust laws.²²⁹

Only after consumers become familiar with the new version will the patent expire and competition for the old product begin. By then, however, switching costs have already taken hold in the form of familiarity with the new product. If providers are writing prescriptions for the new drug, the generic version of the old drug cannot be automatically substituted because it will not be AB-rated vis-à-vis the new drug. Substitution of non-AB-rated generics, even if bioequivalent, is generally not permitted under state substitution regimes without express authorization from the prescriber. This means that the physician has to be contacted and the prescription rewritten in order for a generic drug to be dispensed.²³⁰ The strategy is comparable to predatory pricing in that it lures consumers with a price that is initially the lowest available. Soon thereafter, when generic competition emerges for the older product, it becomes more expensive than other options. This is different from predatory pricing insofar as consumers *could* switch a second time to the newly-introduced generic. But generic manufacturers do not engage in sufficient marketing of their products to

227. See generally Jonathan J. Darrow, *Pharmaceutical Gatekeepers*, 47 IND. L. REV. 363 (2014) (explaining why patients, physicians, insurance companies, government regulators, and courts do not effectively screen out drugs with poor therapeutic value).

228. Brief for FTC as Amicus Curiae, *Mylan Pharm. v. Warner Chilcott Pub. Ltd. Co.*, 2:12-cv-03824-PD (No. 12-3824) (E.D. Pa., Nov. 21, 2012).

229. *Abbott Labs. v. Teva Pharm. USA, Inc.*, 432 F. Supp. 2d 408, 434 (D. Del. 2006) (denying a motion to dismiss).

230. *State Regulations on Generic Substitution*, 22 PHARMACIST'S LETTER/PRESCRIBER'S LETTER 220901 (2006) (updated Apr. 2009), [http://pharmacistsletter.therapeuticresearch.com/\(X\(1\)S\(ngouagz3ngdjz5qk1vti2045\)\)/pl/ArticlePDF.aspx?cs=yml&s=PL&DocumentFileID=1499&DetailID=220901&SegmentID=1186](http://pharmacistsletter.therapeuticresearch.com/(X(1)S(ngouagz3ngdjz5qk1vti2045))/pl/ArticlePDF.aspx?cs=yml&s=PL&DocumentFileID=1499&DetailID=220901&SegmentID=1186).

promote such a switchback, although there may be financial pressures from insurers or other payors once they become savvy to the stratagem and if the new version's use cannot be justified by additional benefits.

Dose formulation or other changes in the listed drug are distinct from similar strategies in other industries in that they can entitle the patent holder to a second thirty-month stay of generic competition if a Paragraph IV challenge is brought against the new product. In the 1990s, brand-name manufacturers began to obtain multiple thirty-month stays on a single product before Congress generally barred that practice with the MMA of 2003.²³¹ The provisions of the MMA, however, do not extend to an altered dosage, dosage form, or method of administration, since those are considered to result in a "new drug," as is combining two existing drugs into a single dosage form or altering the proportions of those drugs as compared to an existing combination.²³² A drug for which the labeling is revised to indicate use for a different disease—or for the same disease in a different part of the body—could also be considered a "new drug" under FDA regulations.²³³

Even absent an additional thirty-month stay, a shift to a new version will create delay by forcing the generic manufacturer to submit a second ANDA for the new product.²³⁴ Under the 2012 Generic Drug User Fee goals, the FDA will seek to act on ninety percent of ANDAs within ten months by the year 2017.²³⁵ But reformulation and ANDA preparation time must be added to this figure. While it is possible for the generic firm to market its copy of the old product under its own brand and encourage doctors to prescribe it directly, this is not a role that generics are well-equipped to undertake. In cases in which the brand-name manufacturer voluntarily withdraws the original drug from the U.S. market, the ANDA applicant will have to petition the FDA for a determination that the

231. Pub. L. No. 108-173, § 1101(a)(2)(A)(ii)(I), 117 Stat. 2066, 2449 (codified at 21 U.S.C. § 355(j)(5)(B)(iii) (2012)); *id.* § 1101(b)(2)(B)(i), 117 Stat. 2453 (codified at 21 U.S.C. § 355(c)(3)(C) (2012)); *see also Draft Guidance for Industry: Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Questions and Answers*, FOOD & DRUG ADMIN. 8 (2004), <http://www.fda.gov/ohrms/dockets/dockets/04d0460/04d-0460-gdl0001.pdf> [hereinafter *Questions and Answers*] (noting that "in most cases . . . no more than one 30-month stay" is permitted).

232. 21 C.F.R. § 310.3(h) (2014).

233. *Id.*; *see also* 21 C.F.R. § 314.92(a)(1) (2014) ("For determining the suitability of an abbreviated new drug application, the term 'same as' means identical in active ingredient(s), dosage form, strength, route of administration, and conditions of use . . .").

234. In some cases, the generic applicant may submit an amendment or supplement, such as where the ANDA seeks approval for different strengths of the same listed drug. *Questions and Answers*, *supra* note 231, at 3.

235. 158 CONG. REC. S8291 (daily ed. Dec. 20, 2012).

drug was not withdrawn for safety or effectiveness reasons,²³⁶ which may result in delay²³⁷ or even litigation to sort out the issue.²³⁸

A number of commentators have taken a permissive view of changing dose formulations or other pharmaceutically relevant features of the listed drug, often on the theoretically plausible (but largely unsubstantiated) basis that new versions could possess advantages that their predecessors do not.²³⁹ One suggested that the practice be allowed so long as the old drug is left on the market or the new one offers significant improvement.²⁴⁰ Another went further, suggesting that the practice be deemed per se legal so long as a valid patent supports the new product.²⁴¹ One pair of antitrust attorneys pointed out that this is merely one form of life-cycle management, which firms have undertaken for decades and which is a normal part of development and innovation.²⁴² They note that, in practice, courts have tended to find violations of the antitrust laws only where consumers are coerced into a choice, such as where the old version is removed from the market.²⁴³

The patent laws are intended to lay the groundwork for vigorous competition after the expiration of the patent term, and patentable product changes are therefore expected to create a new period of exclusivity for the modified form. The Hatch-Waxman Act, however, grew out of a special need in the

236. *E.g.*, 21 C.F.R. § 314.92(a)(1) (2014) (“If a listed drug has been voluntarily withdrawn . . . sale by its manufacturer, a person who wishes to submit an abbreviated new drug application for the drug shall comply with § 314.122.”); 21 C.F.R. § 314.122(a) (2014) (requiring submission of a petition to determine whether listed drug was withdrawn for safety or effectiveness reasons).

237. *See* 21 C.F.R. § 314.93(e)(1)(v) (2014) (noting that the petition may be disapproved if the agency has not yet determined whether the voluntary withdrawal from sale is for safety or effectiveness reasons); Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 262-63 (2012) (discussing delays in the petition process that culminated in a 2007 law requiring the FDA to respond within 180 days).

238. *Cumberland Pharm. Inc. v. FDA*, 981 F. Supp. 2d 38 (D.D.C. 2013). Moreover, withdrawal of the older branded drug may lead the FDA to designate a generic company as the RLD holder, which one court has held subjects the generic company to failure-to-warn liability normally borne only by brand manufacturers. *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80, 96 (Pa. Super. Ct. 2013), *appeal denied*, 99 A.3d 926 (Pa. 2014).

239. *See, e.g.*, Daniel A. Crane, *Provigil: A Commentary*, 3 HASTINGS SCI. & TECH. L.J. 453, 455 (2011).

240. Alan Devlin, *Exclusionary Strategies in the Hatch-Waxman Act*, 2007 MICH. ST. L. REV. 631, 681 (2007).

241. Michelle L. Ethier, *Permissible Product Hopping: Why a Per Se Legal Rule Barring Antitrust Liability is Necessary to Protect Future Innovation in the Pharmaceutical Industry*, 3 AKRON INTELL. PROP. J. 323, 324 (2009). To obtain a new 30-month stay for the new drug, at least one Orange Book-listed patent must exist in order to create a basis for a Paragraph IV certification.

242. Silber & Kuritz, *supra* note 225, at 3.

243. *Id.*

pharmaceutical market stemming from the fact that the expiration of the patent period alone could not adequately promote generic competition due to the high transaction costs associated with pharmaceutical introductions. While the ANDA process reduces these costs substantially, costs remain high, both in terms of dollar value and months of delay. For this reason, changes in dose formulations or other similar changes in the listed drug should be viewed skeptically. This will ensure that generic drugs can freely compete at the expiration of both patent and regulatory exclusivity periods, and will thwart what the FTC recently described as techniques used to “game the regulatory structure”²⁴⁴ on the part of brand-name manufacturers. Courts, the FTC, and even the FDA should closely scrutinize practices for which the primary purpose is to frustrate generic competition as generic competition for that product nears. These practices include voluntarily withdrawing a brand-name drug for reasons other than safety or efficacy or changing the number of milligrams of active ingredient in a formulation in ways that do not correspond to therapeutic demands. While discerning a company’s “purpose” in taking some action may be difficult, timing can provide an important clue. In light of the dramatic success and increasing market share of generics, scrutiny by the FTC and courts rather than statutory amendment should be sufficient to effectuate the purposes of the Hatch-Waxman Act with respect to this business practice. Should trends reverse and a clear pattern of abuse go uncorrected by the courts, statutory amendment might be a better means of reform.

5. Refusal to Provide Material for Purpose of Establishing Bioequivalence

Unintended consequences of legislation are not limited to oddities like “reverse” payments, well-timed switching of the dose formulation, or slight changes to other pharmaceutically relevant components of the listed drug. Another strategy brand-name manufacturers recently used to protect their market share was to take deliberate steps to prevent generic firms from obtaining samples of their branded products to conduct the bioequivalence testing envisioned under the Hatch-Waxman Act. Although the FDA takes a flexible approach to the determination of bioequivalence, generic approval as an AB-rated bioequivalent drug generally requires comparative testing of the generic against the innovator drug.²⁴⁵ The acquisition of a certain amount of brand-name

244. Brief for FTC as Amicus Curiae, *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-3824 (E.D. Pa. Nov. 21, 2012); *see also* 1 HERBERT HOVENKAMP ET AL., IP AND ANTITRUST § 15.3 (2d ed. Supps. 2010–2013) (discussing reverse payment settlements, authorized generics, conduct designed to eliminate 180-day exclusivity, misrepresentations to the FDA, sham FDA citizen petitions, and product hopping).

245. *See, e.g.*, Complaint at 9-10, *Mylan Pharm. Inc. v. Celgene Corp.*, No. 2:14-cv-02094

product is therefore usually a prerequisite to generic approval.²⁴⁶

However, over the past several years, the FTC has been investigating allegations by some generic manufacturers that brand-name firms are deliberately withholding access to their products for the purpose of preventing bioequivalence testing.²⁴⁷ In 2009, generic firms reported that Celgene refused to sell them samples of thalidomide (Thalomid), the infamous drug associated with birth defects in the 1950s, which was approved in 1998 and 2006 to treat leprosy and a form of cancer called multiple myeloma, respectively.²⁴⁸ Gilead has been accused of including provisions in its supply chain contracts that restrict the distribution of ambrisentan (Letairis), a pulmonary artery hypertension drug, to generic manufacturers.²⁴⁹ Similar practices were challenged in court under the antitrust laws against Actelion, the company that manufactures bosentan (Tracleer), another pulmonary artery hypertension product, and miglustat (Zavesca), a treatment for a form of the rare genetic deficiency Gaucher disease.²⁵⁰ The FTC filed an amicus brief supporting the position of the generic manufacturers,²⁵¹ but the case recently settled with an undisclosed outcome.

There are sometimes legitimate safety reasons to restrict sales of patented

(D.N.J. Apr. 3, 2014) (“In order to perform the necessary bioequivalence testing between a proposed generic product and the RLD, the generic manufacturer needs to obtain samples of the RLD.”); *Draft Guidance for Industry on Bioequivalence Studies with Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application; Availability*, FOOD & DRUG ADMIN. 3 (2013), <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm377465.pdf> (“[FDA] recommend[s] that applicants perform a two-period, two-sequence, two-treatment, single-dose, crossover study In this design, each study subject should receive each treatment (test, and RLD [i.e., reference listed drug]) in random order.”); *see also id.* at 6 (“[FDA] usually recommend[s] a . . . two-treatment . . . crossover study for fed BE [i.e., bioequivalence] studies.”); *Guidance for Industry on Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations*, FOOD & DRUG ADMIN. 6 (2003), <http://www.fda.gov/downloads/Drugs/Guidances/ucm070124.pdf> (“A typical [bioequivalence] study is conducted as a crossover study.”); *Guidance for Industry: Statistical Approaches to Establishing Bioequivalence*, FOOD & DRUG ADMIN. 7 (2001), <http://www.fda.gov/downloads/Drugs/Guidances/ucm070244.pdf> (referring to “the standard two-formulation . . . crossover design”).

246. Even if the branded drug is covered by a patent, a special provision provides an exemption from patent infringement litigation for otherwise infringing uses that are “reasonably related to the development of information” for FDA approval, therefore allowing bioequivalence testing prior to patent expiration. 35 U.S.C. § 271(e)(1) (2012).

247. Brief for FTC as Amicus Curiae, *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743-NLH-AMD, at 2 (D.N.J. Mar. 11, 2013).

248. Katie Thomas, *Game Plan Against Generics*, N.Y. TIMES, Apr. 15, 2013, at B1.

249. *Id.*

250. *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 1:12-cv-05743-NLH-AMD, 2013 WL 5524078 (D.N.J. Sept. 6, 2013).

251. Brief for FTC as Amicus Curiae, *supra* note 228, at 2.

pharmaceuticals. In 2007, the Food and Drug Administration Amendments Act (FDAAA) gave the FDA power to require drugs to be distributed through controlled channels as part of its Risk Evaluation and Mitigation Strategies (REMS) provision.²⁵² Foreseeing the potential to use this provision to frustrate generic entry, Congress specifically prohibited companies from using REMS to “block or delay approval” of an ANDA.²⁵³ However, the legislation did not address restrictions on distribution unrelated to REMS, nor did it affirmatively require brand-name companies to sell their products to generics. Nevertheless, deliberate attempts to frustrate the operation of the Hatch-Waxman Act’s bioequivalence provisions are likely to be viewed skeptically by courts. If the judiciary does not restrain this tactic, amending the Hatch-Waxman Act to ensure access may be a reasonable solution. The FDA recently issued guidance intended to assist the generic industry in obtaining samples of brand products subject to restricted distribution systems.²⁵⁴ It is too early to determine whether this guidance will have any positive impact.

B. Ensuring Continued Safety of Generic Drugs

A second major challenge to the Hatch-Waxman regime involves interpretation of the statute by the Supreme Court in a way that fundamentally, if unintentionally, has altered the interchangeability of generics and brands. Both Hatch-Waxman and state generic substitution laws depend on the assumption that generic products are medically equivalent to their brand-name versions. As discussed above, decades of evidence demonstrate that the safety and efficacy profiles of generic and branded drugs are equivalent. In 2011, however, the Supreme Court held in *Pliva, Inc. v. Mensing* that patients injured by a generic drug could not bring suit against the manufacturer for failing to include an adequate warning on the label.²⁵⁵ This was because the FDA interpreted the Hatch-Waxman Act to require generic manufacturers to display a label that is the same as the brand name label at all times.²⁵⁶ The FDA’s goal may have been to

252. Pub. L. 110-85, 121 Stat. 823, 926 (codified as amended at 21 U.S.C. § 355-1 (2012)).

253. 21 U.S.C § 355-1(f)(8) (2012).

254. *Draft Guidance: How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD*, FOOD & DRUG ADMIN. (2014), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425662.pdf>.

255. 131 S. Ct. 2567, 2582 (2011). *Mensing*’s holding was reinforced in another Supreme Court case in 2013, *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013).

256. 21 U.S.C. § 355(J)(2)(A)(v) (2012); Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

ensure that the drugs were as interchangeable as possible. Because the Court found that the Hatch-Waxman Act did not provide a clear pathway for generic manufacturers to independently change their label, generic manufacturers could not be liable under state law for failing to change it. Brand-name drug manufacturers, by contrast, could be liable for failing to conform to their state-law duties to provide adequate labeling and update their labeling proactively, because the FDA had provided a pathway to do that under the FDCA.²⁵⁷

The practical impact of the *Mensing* holding, however, is a reduction in safety oversight for, and an increased threat to, the interchangeability of generic drugs. Post-*Mensing*, there is little incentive for generic manufacturers to undertake pharmacovigilance or other programs intended to promote learning about the adverse effects of generic drugs. In the past, serious new safety issues have been identified after generic versions of a drug become available. A recent review led by Public Citizen identified dozens of drugs that had black box warnings—the most prominent sort of warning that the FDA can impose on a product—added after the generic version of the product was available.²⁵⁸ But many of these new warnings have been identified fortuitously by government-funded observational research or years of litigation led by injured plaintiffs.²⁵⁹ If generic manufacturers are not subject to lawsuit by virtue of their label not being updated to reflect ongoing learning about safe use of a drug, then they have no incentive to lead the studies that might contribute to such learning and uncover late-arising safety hazards. Because only brand-name manufacturers bear this responsibility, active learning about prescription drugs under the *Mensing* regime essentially stops after generics hit the market and brand-name manufacturers' market penetration drops precipitously (or they exit the market altogether).²⁶⁰

In addition to its negative effects on public health, *Mensing* gave patients reason to be wary of accepting low-cost generic drugs that were pharmaceutically and clinically equivalent: if they were injured by side effects that were inadequately described in the label, they would find it more difficult to obtain compensation from the manufacturer. *Mensing* also undermines interchangeability in a second, complementary fashion. After 2011, physicians

257. *Wyeth v. Levine*, 555 U.S. 555 (2009).

258. *Generic Drug Labeling: A Report on Serious Warnings Added to Approved Drugs and on Generic Drugs Marketed Without a Brand-Name Equivalent*, PUB. CITIZEN 4 (2013), <http://www.citizen.org/documents/2138.pdf>.

259. Aaron S. Kesselheim et al., *Risk, Responsibility, and Generic Drugs*, 367(18) NEW ENG. J. MED. 1679, 1680 (2012) [hereinafter *Risk, Responsibility, and Generic Drugs*].

260. See Henry Grabowski et al., *Recent Trends in Brand-Name and Generic Drug Competition*, J. MED. ETHICS 1, 6 (2013) (After only a single year of generic competition, “brands retained an average of only 16%” of unit sales.); see also *id.* at 7 fig.4 (illustrating that both the speed and extent of market share loss to generic entrants has increased between 1999 and 2012).

deciding whether to prescribe brand-name or generic drugs for their patients now faced an ethical conundrum. Should they prescribe the generic (or allow substitution), on the basis that most patients will appreciate the lower price and that they have an ethical responsibility to be prudent stewards of healthcare resources, or should they prescribe the brand-name drug so as to preserve a patient's ability to obtain compensation should injury result? Or, would the physician be obligated to make a case-by-case determination, taking into account factors such as the likelihood and magnitude of potential harm and the patient's financial position, including insurance coverage? Even more disconcerting, *Mensing* questions the ethics of generic substitution laws, threatening to erode the prodigious gains in generic market share over the past thirty years. *Mensing* was met with stunned bewilderment in the press²⁶¹ and elicited pleas for reform by commentators.²⁶²

Recognizing the oddity created by the *Mensing* holding, the Supreme Court offered that "Congress and the FDA retain the authority to change the law and regulations if they so desire."²⁶³ Lawmakers responded by introducing legislation,²⁶⁴ but it has not passed. The FDA also acted on the Supreme Court's invitation, issuing proposed regulations in late 2013 that would permit ANDA holders to distribute revised product labeling that differs, temporarily, from the brand-name version's labeling.²⁶⁵ However, a dispersed community of generic manufacturers may not be well positioned to monitor and respond to safety concerns.²⁶⁶ Even brand-name manufacturers channel resources away from pharmacovigilance of their products once the products go off-patent. A more promising approach would be to centralize the collection and analysis of safety data about generic drugs at the FDA, which would coordinate the creation of a consensus label. Injured plaintiffs could be compensated out of a fund generated from a small tax on generic drug sales,²⁶⁷ using the National Childhood Vaccine Injury Act's provision for the establishment of a National Vaccine Injury

261. See e.g., Katie Thomas, *Generic Drugs Prove Resistant to Damage Suits*, N.Y. TIMES, Mar. 20, 2012, at A1.

262. See e.g., Leonard H. Glantz & George J. Annas, *Impossible? Outlawing State Safety Laws for Generic Drugs*, 365 NEW ENG. J. MED. 681 (2011); *Citizen Petition of August 29, 2011* PUB. CITIZEN (2011), <http://www.citizen.org/documents/1965.pdf>.

263. *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2582 (2011).

264. *Risk, Responsibility, and Generic Drugs*, *supra* note 259, at 1679.

265. Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601).

266. *Risk, Responsibility, and Generic Drugs*, *supra* note 259, at 1680.

267. Aaron S. Kesselheim et al., *Who Is Now Responsible for Discovering and Warning About Adverse Effects of Generic Drugs?*, 310 JAMA 1023, 1024 (2013).

Compensation Program²⁶⁸ as a model. These steps would help to ensure adequate patient warnings, provide compensation to injured plaintiffs, and, most importantly for present purposes, restore both medical equivalence and ethical equipoise to the choice between brand-name products and their generic equivalents.

V. CONCLUSION

In the robust generic drug market in the United States, generics make up a dominant and rising share of prescriptions, and generic prices are low in the United States when compared with prices in other developed countries.²⁶⁹ This success is attributable to a number of features of the Hatch-Waxman Act that facilitate and encourage the introduction of new generic drugs and help to promote price competition once those drugs are approved. The 180-day generic exclusivity period offered to the first generic to challenge a pharmaceutical patent creates a financial incentive to bring generic drugs to market as early as possible, and potentially clears away weak patents so that other generic firms can enter the market at the end of the exclusivity period. By statutorily deeming the act of filing with the FDA to constitute constructive patent infringement, the Paragraph IV system provides a means to obtain a judicial determination of patent validity at relatively low risk, avoiding the need to “bet the farm”²⁷⁰ by entering the market and risking treble damages for intentional infringement. The bioequivalence pathway created by the Hatch-Waxman Act allows generic firms to obtain approval by showing acceptable serum concentrations based on data from a few dozen subjects, avoiding the need to conduct duplicative and costly full-scale clinical trials of hundreds or even thousands of subjects. Finally, DPS laws facilitate the dispensing of the generic drugs that are approved, providing a needed element in a system where insurance might otherwise inappropriately dampen price competition. As a result, scores of generic drugs are widely available for as little as \$4 for a thirty-day supply at stores such as Wal-Mart and Target,²⁷¹ and dozens of new generics are approved each month.

268. Pub. L. No. 99-660, Title III, § 311(a), 100 Stat. 3755, 3758 (1986) (codified as amended at 42 U.S.C. § 300aa-10 (2012)).

269. Danzon & Furukawa, *supra* note 5, at 528.

270. *See* MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 129 (2007) (noting the importance to potential defendants of being able to obtain judicial resolution of patent matters without having to “bet the farm” by actually infringing the patent and risking treble damages).

271. *See* *Save Big on Hundreds of Generic Drugs*, TARGET, <http://www.target.com/pharmacy/generics-alphabetic> (last visited Apr. 18, 2015); *Retail Prescription Program Drug List*, WALMART (2013), <http://i.walmart.com/i/if/hmp/fusion/genericdruglist.pdf>.

Despite this generally positive record of success, a number of challenges to the continued effectiveness of the Hatch-Waxman Act have emerged that require legislative, regulatory, or judicial attention. Some of these developments consist of the deliberate reactions of industry players that are attempting to maximize profitability within the constraints of the Hatch-Waxman Act, while others have been technological or legal developments that have threatened to render the Act less effective or less relevant. Much like taxpaying entities alter their behavior in response to new tax laws, players in the brand-name and generic drug industries have rationally responded to the Hatch-Waxman legislation in a number of ways that may not be socially productive. Such responses include: amassing large numbers of patents that can be used to trigger a thirty-month stay; using the threat of authorized generics as a potentially anti-competitive lever to settle Paragraph IV challenges; and hopping to new products without a substantial clinical justification in order to obtain additional thirty-month stays. At the same time, the Supreme Court decision in *Pliva v. Mensing* has called into question the future clinical and ethical interchangeability of generic and brand-name drugs.

With three decades of experience to guide the way, numerous policy refinements could address these challenges and thereby help to fulfill the Hatch-Waxman Act's original purpose. Congress should consider amending the Act to prohibit the introduction of authorized generics during the 180-day period. Courts and the FTC should scrutinize attempts by brand-name firms to engage in formulation changes or to prevent generic companies from obtaining needed test products unless it can be shown that these actions have a genuine clinical justification. Clinical equivalence and ethical equipoise should be restored by abrogating *Pliva v. Mensing* either via legislation or regulation,²⁷² and considering whether compensation for harms might better be provided by a government-funded program analogous to that available for vaccine injuries. Additional funding may be needed to educate patients and healthcare professionals regarding generic equivalence and to generate additional data in those areas where evidence of equivalence is not sufficiently robust.

The Hatch-Waxman Act has transformed the pharmaceutical marketplace

272. Following *Mensing*, the FDA proposed regulations that would permit ANDA holders to revise their product labels such that they differ in certain respects, on a temporary basis, from the label in the RLD. See Supplemental Application Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. pts. 314, 601). Although this would likely preserve the ability of patients to bring failure-to-warn claims against generic manufacturers and thereby help to restore clinical and ethical equipoise, the proposed regulation has been criticized for its potential to lead to reduced generic drug availability due to liability costs and uncertainties. See Erin M. Bosman et al., *FDA Proposed Rule in Flux?*, MORRISON & FOERSTER LLP (2015), <http://www.mofo.com/~media/Files/ClientAlert/2015/02/150218FDAProposedRule.pdf>.

over the last thirty years, and its influence around the world will only increase as trade agreements are developed and similar legislation is enacted in other countries. The importance of the law to setting the appropriate balance between pioneering innovation and a vibrant generic drugs market warrants continued vigilance in light of evolving circumstances. With attention to the issues raised in this Article, modest reshaping of the law can help assure the continued success of the Hatch-Waxman Act for decades to come.

In the Nick of Time: Using the Reasonable Promptness Provision to Challenge Medicaid Spending Cutbacks

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Abstract:

Because agency enforcement of the Medicaid statute against non-compliant states is utterly impractical, Medicaid providers and beneficiaries have relied on § 1983 litigation to protect themselves against the harmful effects of state cutbacks on Medicaid spending by privately enforcing two particular provisions of the Medicaid statute against the states. However, because of several legislative and judicial decisions, private litigants can no longer use these provisions to challenge low Medicaid reimbursement rates. This Note proposes and evaluates an alternative method of resisting state Medicaid spending cutbacks: enforcing the Reasonable Promptness Provision of the Medicaid statute through § 1983.

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INTRODUCTION

Much scholarly attention has been paid to the disturbing but increasingly apparent notion that Medicaid is “metamorphosing into a right without a remedy.”¹ Because federal agency enforcement against the states for violations of the Medicaid statute is impractical and therefore never utilized, enforcement of the Medicaid statute has primarily been effectuated by private litigants through § 1983 suits.² However, decisions made by Congress and the federal courts have constrained the ability of private litigants to challenge states for violating the Medicaid statute.³

Nowhere has this trend been more problematic than in the context of Medicaid reimbursement rates. The extent to which Medicaid beneficiaries can access health services depends crucially on the level of provider participation in Medicaid.⁴ However, Medicaid reimbursement rates are the primary determinants of provider participation levels.⁵ Thus, if states can cut reimbursement rates in violation of the Medicaid statute with impunity, Medicaid beneficiaries will suffer the harmful effects of impeded access to necessary health services. Currently, the ability of Medicaid providers and beneficiaries to challenge low Medicaid reimbursement levels through litigation is uncertain at best, which spells trouble for the health outcomes of our poorest and most vulnerable citizens and legal permanent residents.

This Note details how the current inability to challenge low Medicaid payment rates came about; it then identifies and evaluates a potential solution to this problem. Part I explains in more detail why private Medicaid enforcement is vital to the health and well-being of Medicaid beneficiaries. Part II discusses the ways in which prior litigants have challenged low reimbursement levels and describes how these avenues have been foreclosed by Congress and the courts. Part III provides an account of two new tactics that litigants have employed to successfully challenge low Medicaid reimbursement rates. Finally, Part IV evaluates the viability of one of those strategies: suing under the Reasonable Promptness Provision of the Medicaid statute.

1. Nicole Huberfeld, *Bizarre Love Triangle: The Spending Clause, Section 1983, and Medicaid Entitlements*, 42 U.C. DAVIS L. REV. 413, 417 (2008); see, e.g., Rosemary B. Guiltinan, Note, *Enforcing a Critical Entitlement: Preemption Claims as an Alternative Way to Protect Medicaid Recipients' Access to Healthcare*, 51 B.C. L. REV. 1583, 1600 (2010).

2. See *infra* Part I.

3. See *infra* Part II.

4. See Sean Jessee, Comment, *Fulfilling the Promise of the Medicaid Act: Why the Equal Access Clause Creates Privately Enforceable Rights*, 58 EMORY L.J. 791, 796 (2009).

5. *Id.*

I. MEDICAID AND SECTION 1983: THE IMPORTANCE OF PRIVATE MEDICAID ENFORCEMENT

Established in 1965 under Title XIX of the Social Security Act,⁶ Medicaid is a medical assistance program that has become the largest source of health insurance for low-income people.⁷ Medicaid currently provides services and support to sixty-six million people, including thirty-two million children and sixteen million elderly and disabled persons.⁸ The federal government and the states fund Medicaid jointly;⁹ the federal government “matches” state Medicaid expenditures according to a formula based on a state’s average personal income relative to the national average.¹⁰ States are not required to participate in Medicaid, but states that choose to do so must structure and administer their plans in compliance with the Medicaid statute and federal regulations.¹¹ Among other things, states must cover certain populations and services in their Medicaid plans.¹² Beyond these requirements, states are allowed flexibility in choosing additional benefits and populations to cover, as well as methods of delivery and payment.¹³

At the federal level, the Centers for Medicaid and Medicare Services (CMS) within the Department of Health and Human Services (HHS) is responsible for overseeing and administering Medicaid.¹⁴ States must submit Medicaid plans to CMS for approval, and if a state wants to implement policies that deviate from federal Medicaid requirements, it must apply for a “waiver.”¹⁵

CMS is also charged with monitoring and assuring state compliance with the federal Medicaid requirements.¹⁶ However, CMS’s formal oversight has not been an adequate means of ensuring that states actually comply with the requirements

6. For a discussion on Medicaid’s history, see Sara Rosenbaum, *Medicaid at Forty: Revisiting Structure and Meaning in a Post-Deficit Reduction Act Era*, 9 J. HEALTH CARE L. & POL’Y 5, 8-24 (2006).

7. *Federal Core Requirements and State Options in Medicaid: Current Policies and Key Issues*, KAISER FAM. FOUND. 1 (2011), <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8174.pdf> [hereinafter *Federal Core Requirements*].

8. Vernon Smith et al., *Medicaid in a Historic Time of Transformation: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2013 and 2014*, KAISER FAM. FOUND. 7 (2013), <http://kaiserfamilyfoundation.files.wordpress.com/2013/10/8498-medicaid-in-a-historic-time-of-transformation.pdf>.

9. *Federal Core Requirements*, *supra* note 7, at 1.

10. Smith et al., *supra* note 8, at 7.

11. 42 U.S.C. § 1396 (2012).

12. 42 U.S.C. § 1396a(a)(10) (2012).

13. *Federal Core Requirements*, *supra* note 7, at 1.

14. *Id.* at 3.

15. *Id.*

16. *Id.*

set forth in the Medicaid statute and regulations, primarily because of the limited range of enforcement mechanisms available to CMS and HHS. After CMS approves a state's Medicaid plan, the only course of action that HHS can take if a state does not comply with federal requirements is to withhold part or all of the federal matching payment from that state.¹⁷ This enforcement mechanism is entirely impractical and counterproductive. States usually fail to comply with federal Medicaid requirements by cutting reimbursement rates and services because of budgetary shortfalls. Thus, withholding Medicaid funding from noncompliant states would only work to exacerbate the problem that caused the noncompliance by further diminishing the states' ability to provide Medicaid services. This would ultimately make things worse for Medicaid beneficiaries, who are the very group of people harmed by noncompliance in the first place.¹⁸ Unsurprisingly, HHS has never used this mechanism to withhold federal Medicaid funding from a noncompliant state.

The infeasibility and imprudence of HHS's sole means of enforcing state compliance with Medicaid requirements highlights the importance of alternative enforcement mechanisms. In particular, Medicaid beneficiaries and providers have frequently resorted to federal litigation to compel states to comply with the Medicaid statute and regulations,¹⁹ especially under 42 U.S.C. § 1983.²⁰ In *Wilder v. Virginia Hospital Association*, the Supreme Court held for the first time that a provision of the Medicaid statute created a right that was enforceable under § 1983.²¹ Since *Wilder*, federal circuit courts have found various other provisions of the Medicaid statute to confer rights to beneficiaries and providers that are enforceable under § 1983.²² In the past decade, suits seeking to enforce Medicaid provisions have been the most prevalent type of case brought under § 1983.²³ In

17. 42 U.S.C. § 1396c (2012); see also Mark A. Ison, *Two Wrongs Don't Make A Right: Medicaid, Section 1983, and the Cost of an Enforceable Right to Health Care*, 56 VAND. L. REV. 1479, 1511 (2003) ("[T]he sole external enforcement mechanism is the termination or reduction of federal payments to States failing to comply substantially with Medicaid provisions.").

18. See Sasha Samberg-Champion, Note, *How to Read Gonzaga: Laying the Seeds of a Coherent Section 1983 Jurisprudence*, 103 COLUM. L. REV. 1838, 1839 (2003).

19. See Brief of Former HHS Officials as Amici Curiae in Support of Respondents at 12-13, *Douglas v. Indep. Living Ctr. of S. Cal.*, 132 S. Ct. 1204 (2012) (Nos. 09-958, 09-1158, & 10-283).

20. 42 U.S.C. § 1983 (2012). Section 1983 allows citizens to bring civil suits against state officials for violations of federal rights. In *Maine v. Thiboutot*, 448 U.S. 1, 4 (1980), the Supreme Court held that citizens could bring § 1983 lawsuits for violations of rights created by federal statutes in addition to rights protected by the Constitution.

21. 496 U.S. 498, 509-10 (1990).

22. E.g. *Doe v. Kidd*, 501 F.3d 348, 356 (4th Cir. 2007) (holding that the "reasonable promptness" provision, 42 U.S.C. 1396a(a)(8), is enforceable under § 1983); *S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 607 (5th Cir. 2004) (holding that 42 U.S.C. 1396a(a)(10) (2012), is enforceable under § 1983).

23. See Devi M. Rao, Note, *"Making Medical Assistance Available": Enforcing the Medicaid*

the past twelve years alone, the Courts of Appeals have ruled on the enforceability of twenty-three different Medicaid provisions under § 1983 in forty-one different cases.²⁴ The frequency with which Medicaid beneficiaries and providers bring § 1983 suits against states underscores the crucial role that § 1983 litigation plays in ensuring that beneficiaries obtain the care and services guaranteed to them by CMS-approved state plans and the federal Medicaid requirements.

II. CHALLENGING LOW MEDICAID REIMBURSEMENT RATES: DAYS OF GLORY PAST

In particular, Medicaid providers and beneficiaries have relied on § 1983 litigation to protect themselves against the deleterious effects of state cutbacks on Medicaid spending. Recent economic downturns have caused state tax revenues to fall and Medicaid enrollments to surge.²⁵ In response to this troublesome combination of events, many states have implemented Medicaid spending cutbacks, commonly in the form of reduced reimbursement rates to providers. For example, in 2009, during the most recent recession, thirty-nine states reduced or froze Medicaid reimbursement rates.²⁶ Between 2001 and 2004, *every* state reduced or froze reimbursement rates in response to the previous economic recession.²⁷ Considering the fact that Medicaid reimbursement rates have historically been significantly lower than both Medicare and private insurance rates,²⁸ these rate reductions carry a substantial risk of harm to Medicaid beneficiaries because the level of provider participation in Medicaid depends crucially on reimbursement rates.²⁹ The proportion of physicians who accept Medicaid patients is greater in states with higher Medicaid reimbursement rates

Act's Availability Provision Through § 1983 Litigation, 109 COLUM. L. REV. 1440, 1460 (2009).

24. JANE PERKINS & SARAH SOMERS, NAT'L HEALTH LAW PROGRAM, ISSUE BRIEF: PRIVATE ENFORCEMENT OF THE MEDICAID ACT PURSUANT TO 42 U.S.C. § 1983 6 (2013).

25. See Kaiser Comm'n on Medicaid & the Uninsured, *Medicaid's Continuing Crunch In a Recession: A Mid-Year Update for State FY 2010 and Preview for FY 2011*, KAISER FAM. FOUND. 1, 5 (2010), <http://www.kff.org/medicaid/upload/8049.pdf>.

26. Kaiser Comm'n on Medicaid & the Uninsured, *The Crunch Continues: Medicaid Spending, Coverage and Policy in the Midst of a Recession*, KAISER FAM. FOUND. 30 (2009), <http://www.kff.org/medicaid/upload/7985.pdf>.

27. *Id.* at 6.

28. See Kaiser Comm'n on Medicaid & the Uninsured, *Headed for a Crunch: An Update on Medicaid Spending, Coverage and Policy Heading into an Economic Downturn: Results from a 50-State Medicaid Budget Survey for State Fiscal Years 2008 and 2009*, KAISER FAM. FOUND. 30 (2008), <http://www.kff.org/medicaid/upload/7815.pdf> [hereinafter *Headed for a Crunch*].

29. *Id.* at 30.

relative to states with lower rates,³⁰ and physicians cite low reimbursement rates as the primary reason for not accepting Medicaid patients.³¹ When fewer physicians and providers participate in Medicaid, the risk of impaired access to care for Medicaid beneficiaries increases.

Many Medicaid beneficiaries and providers have brought § 1983 lawsuits to challenge low reimbursement levels and rate reductions as violations of the Medicaid statute.³² In the past, litigants primarily utilized two specific Medicaid provisions in their attempts to force states to increase reimbursement rates: the Boren Amendment and the Equal Access Provision.³³ However, recent decisions by Congress and the courts, respectively, have foreclosed both avenues of recourse to plaintiffs seeking to challenge low reimbursement levels.

A. The Repeal of the Boren Amendment

The Boren Amendment provided, in relevant part, that:

[A] State plan for medical assistance must . . . provide . . . for payment . . . of the hospital services, nursing facility services, and services in an intermediate care facility for the mentally retarded . . . through the use of rates (determined in accordance with the methods and standards developed by the State . . .) which the State finds, and makes assurances satisfactory to the Secretary, are reasonable and adequate to meet the costs which must be incurred by efficiently and economically operated facilities in order to provide care and services in conformity with applicable State and Federal laws, regulations, and quality and safety standards and to assure that individuals eligible for medical assistance have reasonable access (taking into account geographic location and reasonable travel time) to inpatient hospital services of adequate quality³⁴

Enacted in 1980, the Boren Amendment was, “in its inception and implementation, an effort to reduce federal and state expenditures.”³⁵ The Boren

30. Stephen Zuckerman et al., *Changes in Medicaid Physician Fees, 1998-2003: Implications for Physician Participation*, HEALTH AFF. W4-381 (June 23, 2004), <http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.374v1>.

31. *Headed for a Crunch*, *supra* note 28, at 30.

32. See Brietta R. Clark, *Medicaid Access, Rate Setting and Payment Suits: How the Obama Administration is Undermining its own Health Reform Goals*, 55 HOW. L.J. 771, 831 (2012).

33. 42 U.S.C. § 1396a(a)(30) (2012).

34. 42 U.S.C. § 1396a(a)(13) (1994), *amended by* Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4712(c), 111 Stat. 509.

35. Malcolm J. Harkins III, *Be Careful What You Ask For: The Repeal of the Boren Amendment and Continuing Federal Responsibility to Assure that State Medicaid Programs Pay for Cost Effective Quality Nursing Facility Care*, 4 J. HEALTH CARE L. & POL’Y 159, 174 (2001).

Amendment made one procedural and one substantive change to the Medicaid statute. Before 1980, the Secretary of HHS was responsible for determining whether state Medicaid payment plans satisfied federal standards (the procedural status quo), and state payment methods and standards were required to result in reasonable cost-related payments (the substantive status quo).³⁶ The Boren Amendment shifted the responsibility of determining whether state payment plans complied with federal standards to the states. The Amendment also shifted the focus from payment methods to aggregate payment rates, requiring only that payment rates be reasonable and adequate and doing away with the prior requirement that they be cost-related.³⁷

Even before the Supreme Court held that § 1983 conferred Medicaid providers a private right of action to enforce the Boren Amendment,³⁸ the federal circuit courts were in almost unanimous agreement that the Boren Amendment was enforceable under § 1983.³⁹ Most providers who sued states under the Boren Amendment alleged both a procedural violation (that a state did not make a bona fide finding that its plan would meet federal standards before implementing the plan), and a substantive violation (that a state plan's reimbursement rates were not reasonable and adequate).⁴⁰ Though courts differed in their interpretations of what states were required to do to make "findings" that their plans would meet federal standards, once a court found that a state failed to make proper findings, that state's payment methodology would almost certainly be invalidated without further inquiry into whether the reimbursement rates were ultimately reasonable and adequate.⁴¹ A state found to have satisfied the procedural requirement of the Boren Amendment would enjoy relatively more deferential treatment in a court's substantive inquiries.⁴² Providers had the burden of proving that reimbursement rates fell outside a "zone of reasonableness,"⁴³ which sometimes required a showing that Medicaid payments did not cover the costs of a substantial proportion of providers.⁴⁴

Medicaid providers utilized the Boren Amendment to pressure states to raise their reimbursement rates⁴⁵ with considerable success until 1997, when the

36. *Id.* at 169-70.

37. *Id.*

38. *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 509-10 (1990).

39. *See Harkins, supra* note 35, at 179.

40. *Id.* at 181.

41. *Id.* at 182-83.

42. *Id.* at 183.

43. *See, e.g., Portland Residence, Inc. v. Steffen*, 34 F.3d 669, 672 (8th Cir. 1994).

44. *See Harkins, supra* note 35, at 184 n.123.

45. *See U.S. GOV'T ACCOUNTABILITY OFFICE, GAO/HEHS-95-122, MEDICAID: SPENDING PRESSURES DRIVE STATES TOWARD PROGRAM RETENTION*, 53 (1995) ("Provider suits brought under

Amendment was repealed.⁴⁶ States in general, and the National Governors Association in particular, pushed for the repeal, claiming that the Boren Amendment denied states fiscal and administrative discretion to control costs in the face of rising health care costs, and that the Amendment prevented states from exploiting market competition to secure lower prices for Medicaid services.⁴⁷ The repeal's legislative history indicates that Congress specifically intended to take away the ability of Medicaid providers to sue states under § 1983 because of low reimbursement levels.⁴⁸ The Balanced Budget Act of 1997 repealed the Boren Amendment⁴⁹ and replaced it with a requirement that states use a public process to set reimbursement rates,⁵⁰ thereby eliminating one channel through which beneficiaries and providers could attempt to compel states to raise Medicaid payment levels.

B. The Vitiating of the Equal Access Provision

In addition to the Boren Amendment, Medicaid providers and beneficiaries also used the Equal Access Provision to bring § 1983 suits challenging low Medicaid reimbursement levels. The Equal Access Provision requires state Medicaid plans to ensure that payment rates are “sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area.”⁵¹ The inclusion of this provision in the Medicaid statute suggests that Congress was specifically trying to prevent states from cutting reimbursement levels in the face of budgetary shortfalls.⁵² In the 1990s, federal circuit courts generally allowed litigants to bring § 1983 suits to enforce the Equal Access Provision,⁵³ and even some providers successfully brought § 1983

the Boren Amendment, 42 U.S.C. § 1396a(13), have been a major factor pressuring states to increase payment rates. . . . Particularly in recent years, states have been dogged by provider lawsuits forcing them to better justify or raise their Medicaid payment rates to hospitals and nursing homes.”).

46. See Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4712(c), 111 Stat. 509; Guiltinan, *supra* note 1, at 1598.

47. See Harkins, *supra* note 35, at 189.

48. See H.R. REP. NO. 105-149, at 591 (1997) (“It is the Committee's intention that, following enactment of this Act, neither this nor any other provision of [42 U.S.C. § 1396a] will be interpreted as establishing a cause of action for hospitals and nursing facilities relative to the adequacy of the rates they receive.”).

49. Pub. L. No. 105-33, § 4712(c), 111 Stat. 509 (1997).

50. 42 U.S.C. § 1396a(a)(13) (2012).

51. 42 U.S.C. § 1396a(a)(30) (2012).

52. See Abigail R. Moncrieff, Comment, *Payments to Medicaid Doctors: Interpreting the “Equal Access” Provision*, 73 U. CHI. L. REV. 673, 674 (2006).

53. See, e.g., *Visiting Nurse Ass’n of North Shore v. Bullen*, 93 F.3d 997, 1005 (1st Cir.

claims arguing that state officials violated the Equal Access Provision by setting Medicaid reimbursement rates too low.⁵⁴ Unfortunately, this mechanism for keeping states honest with regards to Medicaid payment levels has also been neutralized, primarily by two cases that are part of the Supreme Court's recent § 1983 jurisprudence.

In the 1997 case *Blessing v. Freestone*, the Court held that Title IV-D of the Social Security Act, which details the eligibility requirements for child support services, does not give individuals a federal right to force a state agency to comply with its provisions.⁵⁵ In reaching this holding, the Court delineated a three-part test for determining whether a federal statute creates a private right that is enforceable under § 1983: "First, Congress must have intended that the provision in question benefit the plaintiff"; second, the potential federal right must not be so "vague and amorphous" that its enforcement would strain the courts; and third, "the statute must unambiguously impose a binding obligation on the States."⁵⁶

The Court elaborated upon this three-part test just five years later in *Gonzaga University v. Doe*.⁵⁷ In deciding that the Family Educational Rights and Privacy Act (FERPA) did not confer a federal right enforceable under § 1983,⁵⁸ the Court attempted to clarify the first prong of the three-part test it established in *Blessing*. The *Gonzaga* Court stressed that only rights, and not vague "benefits" or "interests," are enforceable through § 1983, and thus in order to satisfy the first prong of the test a statute must "unambiguously" confer a right.⁵⁹ The Court applied a textual analysis for determining whether a statute confers a right, emphasizing that the statute must contain "rights-creating" language that is "phrased in terms of the person benefited"⁶⁰ as opposed to language with "an aggregate, not individual, focus."⁶¹ By setting forth a more limited set of criteria for determining the existence of statutory rights, the Court narrowed the range of statutes that confer privately enforceable rights, thereby diminishing the availability of § 1983 as a means of suing state officials for violations of federal

1996); *Methodist Hosp., Inc. v. Sullivan*, 91 F.3d 1026, 1028-29 (7th Cir. 1996); *Ark. Med. Soc'y, Inc. v. Reynolds*, 6 F.3d 519, 522 (8th Cir. 1993).

54. See *Reynolds*, 6 F.3d at 531 (holding that a rate reduction by Arkansas's Medicaid plan violated the Equal Access Provision). But see *Sullivan*, 91 F.3d at 1029-30 (holding that plaintiffs did not show that Indiana's Medicaid reimbursement rates violated the Equal Access Provision).

55. 520 U.S. 329, 332 (1997).

56. *Id.* at 340-41.

57. 536 U.S. 273 (2002).

58. *Id.* at 276.

59. *Id.* at 282-83.

60. *Id.* at 284.

61. *Id.* at 290.

statutes.

The federal circuit courts have applied *Blessing* and *Gonzaga* to render the Equal Access Provision unenforceable. Every circuit court but one that has considered the enforceability of the Equal Access Provision under § 1983 after *Gonzaga* has found it unenforceable by Medicaid providers,⁶² and most of them have also found it unenforceable by beneficiaries.⁶³ The circuit courts have variously held that the Equal Access Provision was not intended to benefit Medicaid providers,⁶⁴ that it lacks “rights creating language,”⁶⁵ and that it has an “aggregate and systemic” rather than an “individualized” focus.⁶⁶ In short, the Supreme Court’s § 1983 jurisprudence has precluded enforcement of the Equal Access Provision against the states under § 1983.

Several plaintiffs have attempted to work around the § 1983 barrier by bringing federal preemption claims, alleging that state laws that conflict with the Medicaid statute violate the Supremacy Clause of the United States Constitution.⁶⁷ Some circuit courts have employed the Supremacy Clause to invalidate state laws for conflicting with the Medicaid statute,⁶⁸ and the Supreme Court recently assumed without explicitly stating that Medicaid beneficiaries had an implied right of action under the Supremacy Clause to enforce an anti-lien provision of the Medicaid statute.⁶⁹ It looked like the Court would have the chance to decide whether the Equal Access Provision in particular could be enforced through the Supremacy Clause in *Douglas v. Independent Living Center of Southern California, Inc.*,⁷⁰ but because of a change in circumstances,⁷¹ the

62. *Equal Access for El Paso v. Hawkins*, 509 F.3d 697 (5th Cir. 2007); *Mandy R. ex rel. Mr. and Mrs. R. v. Owens*, 464 F.3d 1139 (10th Cir. 2006); *Westside Mothers v. Olszewski*, 454 F.3d 532 (6th Cir. 2006); *Sanchez v. Johnson*, 416 F.3d 1051 (9th Cir. 2005); *Long Term Care Pharm. Alliance v. Ferguson*, 362 F.3d 50 (1st Cir. 2004); *Pa. Pharm. Ass’n v. Houstoun*, 283 F.3d 531 (3d Cir. 2002). *But see* *Pediatric Specialty Care, Inc. v. Ark. Dep’t of Human Servs.*, 443 F.3d 1005 (8th Cir. 2006) (holding that the Equal Access Provision is enforceable under § 1983), *vacated sub nom. Selig v. Pediatric Specialty Care, Inc.*, 551 U.S. 1142 (2007).

63. *Equal Access for El Paso*, 509 F.3d at 697; *Mandy R. ex rel. Mr. and Mrs. R.*, 464 F.3d at 1139; *Westside Mothers*, 454 F.3d at 532; *Sanchez*, 416 F.3d at 1051. *But see* *Pa. Pharm. Ass’n*, 283 F.3d at 544 (stating in dicta that Medicaid beneficiaries are “potential private plaintiffs”).

64. *See, e.g., Pa. Pharm. Ass’n*, 283 F.3d at 540.

65. *See, e.g., Long Term Care Pharm. Alliance*, 362 F.3d at 57.

66. *See, e.g., Equal Access for El Paso*, 509 F.3d at 704.

67. U.S. CONST. art VI, cl. 2; *see* Rochelle Bobroff, *Medicaid Preemption Remedy Survives Supreme Court Challenge*, 46 CLEARINGHOUSE REV. 35, 35 (2012) (“As access to federal courts narrows, Medicaid beneficiaries increasingly rely on preemption claims as the basis for litigation to challenge state laws that conflict with the Medicaid statute.”).

68. *See* *Lankford v. Sherman*, 451 F.3d 496 (8th Cir. 2006); *Planned Parenthood of Houston & Se. Tex. v. Sanchez*, 403 F.3d 324 (5th Cir. 2005).

69. *Wos v. E.M.A.*, 133 S. Ct. 1391 (2013).

70. 132 S. Ct. 1204 (2012).

Court avoided the issue by vacating and remanding to the Ninth Circuit.⁷² However, Chief Justice Roberts, writing for four dissenters, insisted that the plaintiffs—a group of Medicaid providers—did not have a cause of action under the Supremacy Clause to enforce the Equal Access Provision against California. The Chief Justice reasoned that, because the Medicaid statute gives CMS—and only CMS—the responsibility to enforce the requirements of the statute against the states, allowing providers to sue under the Supremacy Clause would conflict with congressional intent to vest sole enforcement authority in CMS.⁷³

The Chief Justice's reasoning in *Douglas* foreshadowed the ultimate demise of the Equal Access Provision as a means of challenging state Medicaid cutbacks through private rights of action. In *Armstrong v. Exceptional Child Center, Inc.*,⁷⁴ a divided Court held that providers of residential habilitation services to Medicaid enrollees did not have a private cause of action through the Equal Access Provision to enjoin Idaho's Department of Health and Welfare from setting Medicaid reimbursement rates at improperly low levels.⁷⁵ Specifically, Justice Scalia, writing for the majority, explained that the Supremacy Clause itself does not contain a private right of action,⁷⁶ and that although litigants can generally obtain private rights of action through the *equitable* power of courts to enjoin unconstitutional actions by state or federal officers, the Medicaid statute implicitly precludes equitable relief in the case of the Equal Access Provision.⁷⁷

Justice Scalia proffered two factors that “establish Congress's ‘intent to foreclose’ equitable relief”⁷⁸ in the Equal Access Provision context. First, he cited the fact that the “sole remedy Congress provided for a State's failure to comply with Medicaid's requirements” is the withholding of Medicaid funding by HHS.⁷⁹ Second, he emphasized the “judicially unadministrable nature” of the Equal Access Provision's text, asserting that it would be difficult to imagine a “broader and less specific” requirement.⁸⁰ These two features combined constituted sufficient evidence, in the majority's eyes, that Congress “wanted to make the agency remedy that it provided exclusive,” thereby thwarting the

71. CMS initially disapproved of California's State Plan Amendments (SPAs), through which California wished to implement cuts to its Medicaid reimbursement rates. However, after California withdrew some of the cuts, CMS approved the remaining cuts about one month after oral arguments. *Id.* at 1209.

72. *Id.* at 1208.

73. *Id.* at 1211-12 (Roberts, C.J., dissenting).

74. 135 S. Ct. 1378 (2015).

75. *Id.* at 1388.

76. *Id.* at 1384.

77. *Id.* at 1385.

78. *Id.* (citation omitted).

79. *Id.*

80. *Id.*

courts' equitable power to allow private enforcement of the Equal Access Provision.⁸¹ In short, it seems that the Court, through its decision in *Armstrong*, has all but eliminated any possibility for private litigants to utilize the Equal Access Provision to challenge state cutbacks on Medicaid reimbursement rates.

III. A NEW HOPE? TWO POTENTIAL WORKAROUNDS

With the Boren Amendment repealed and the private enforceability of the Equal Access Provision eviscerated by the Court, what other possible means do Medicaid beneficiaries or providers have to protect themselves against harmful cuts to reimbursement rates? For starters, there is a specific provision within the Medicaid statute that addresses payment methodology and reimbursement rates for services provided by federally qualified health centers (FQHCs) and rural health clinics (RHCs),⁸² and some of these providers have utilized this provision to compel states to raise reimbursement rates under § 1983. Additionally, one consumer health advocacy group was able to force a state to raise its payment rates on behalf of a set of Medicaid beneficiaries using the Reasonable Promptness Provision,⁸³ another requirement in the Medicaid statute. This tactic has only been attempted once in a federal court,⁸⁴ but it may be worthwhile to consider it as a potential alternative mechanism for suing states for higher payment levels. Thus, the bulk of the remainder of this Note will examine the Reasonable Promptness Provision as a tool for challenging state cutbacks on Medicaid reimbursement rates.

A. Section 1396a(a)(bb): Relief for FQHCs and RHCs

Section 1396a(a)(bb) sets forth the methodology that states must use to calculate payments levels to FQHCs and RHCs.⁸⁵ The provisions under this section were introduced by the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA),⁸⁶ and they allow for two primary methods of reimbursement. The first is a "prospective payment system" under which states must calculate reimbursement rates based on the previous year's average costs, augmented by the percentage increase in the Medicare

81. *Id.* (quoting *Gonzaga University v. Doe*, 536 U.S. 273, 292 (2002)).

82. 42 U.S.C. § 1396a(a)(bb) (2012).

83. 42 U.S.C. § 1396a(a)(8) (2012).

84. *Health Care for All v. Romney (Health Care for All II)*, No. Civ.A. 00-10833-RWZ, 2005 WL 1660677 (D. Mass. July 14, 2005).

85. 42 U.S.C. § 1396a(a)(bb) (2012).

86. Pub. L. No. 106-554, § 1(a)(6), 114 Stat. 2763 (codified as amended in scattered sections of 42 U.S.C.).

Economic Index and adjusted for any change in the scope of services offered by a particular clinic.⁸⁷ The second is an “alternative payment system” that allows states more flexibility, as long as the state and the clinic agree on the system and the resulting rates are at least equal to those under the prospective payment system.⁸⁸

Lower federal courts have held that § 1396a(a)(bb) confers statutory rights that are enforceable under § 1983.⁸⁹ In particular, courts have allowed FQHCs and RHCs to bring § 1983 suits challenging reimbursement rates as lower than required by § 1396a(bb).⁹⁰ Section 1396a(bb) is very specific with regards to the methodology by which payments to FQHCs and RHCs must be calculated, rendering deviations from the required rates very clear and easy to prove. Therefore, suing states under § 1983 for violating § 1396a(bb) of the Medicaid statute seems to be an effective mechanism through which FQHCs and RHCs can ensure receipt of the federally required levels of payment for the services that they provide.

B. The Reasonable Promptness Provision

In *Health Care for All v. Romney*,⁹¹ a consumer health advocacy organization brought a § 1983 lawsuit against Massachusetts officials on behalf of a group of Medicaid beneficiaries for an alleged violation of the Reasonable Promptness Provision. This provision requires state plans to “provide that all individuals wishing to make application for medical assistance under the plan shall have opportunity to do so, and that such assistance shall be furnished with reasonable promptness to all eligible individuals.”⁹² The plaintiffs successfully convinced the District Court for the District of Massachusetts that by providing insufficient reimbursement to Medicaid dental care providers, Massachusetts violated the Reasonable Promptness Provision. The court found the low payment levels to be one of the primary causes for the unreasonable delays that juvenile Medicaid beneficiaries experienced in accessing dental services.⁹³

The plaintiffs originally sued under both the Reasonable Promptness

87. 42 U.S.C. § 1396a(a)(bb)(2)-(3) (2012).

88. 42 U.S.C. § 1396a(a)(bb)(6) (2012).

89. *See, e.g.,* N.J. Primary Care Ass’n v. N.J. Dep’t of Human Servs., 722 F.3d 527 (3d Cir. 2013); Rio Grande Cmty. Health Ctr., Inc. v. Rullan, 397 F.3d 56 (1st Cir. 2005).

90. *See, e.g.,* Pee Dee Health Care, P.A. v. Sanford, 509 F.3d 204 (4th Cir. 2007); Cmty. Health Care Ass’n of N.Y. v. N.Y. State Dep’t of Health, 921 F.Supp.2d 130 (S.D.N.Y. 2013).

91. *Health Care for All v. Romney*, No. Civ.A. 00-10833-RWZ, 2005 WL 1660677 (D. Mass. July 14, 2005).

92. 42 U.S.C. § 1396a(a)(8) (2012).

93. *Health Care for All II*, 2005 WL 1660677 at *15.

Provision and the Equal Access Provision, but a previous decision handed down by the same court held that Health Care for All did not have a private cause of action to enforce the Equal Access Provision under § 1983.⁹⁴ In the subsequent decision, the court then found that the juvenile Medicaid beneficiaries experienced “extraordinary difficulty in obtaining timely dental services” at two stages.⁹⁵ First, the beneficiaries struggled to find dental care providers who accepted MassHealth (the Massachusetts Medicaid program) patients, in part because the MassHealth provider lists were not updated frequently enough to accurately reflect the fact that more and more dental care providers were refusing to accept MassHealth patients.⁹⁶ In their complaint, the beneficiaries alleged that after their usual providers stopped accepting MassHealth patients, they spent many hours calling providers on the list, cold-calling other private providers, and seeking word-of-mouth referrals.⁹⁷ Many of the beneficiaries could not locate any available providers; as a result, these beneficiaries either went without treatment or paid out-of-pocket for services that should have been covered by MassHealth.⁹⁸ Furthermore, those beneficiaries who were fortunate enough to locate dental providers who still accepted MassHealth patients faced substantial waiting periods. The court found that beneficiaries with non-emergency conditions had to wait anywhere between two months and a year for an actual appointment after locating a participating provider.⁹⁹

The *Health Care for All* court held that these significant obstacles and delays constituted a violation of the Reasonable Promptness Provision.¹⁰⁰ Additionally, the court asserted that “the difficulties encountered by enrollees who sought dental appointments resulted from a shortage of dentists participating in MassHealth.”¹⁰¹ The plaintiffs were able to convince the court that the shortage of participating dentists was caused by low reimbursement rates,¹⁰² leading the court to hold that the low reimbursement rates themselves constituted a violation of the Reasonable Promptness Provision.¹⁰³ The court then ordered the parties to

94. *Health Care for All v. Romney (Health Care for All I)*, No. Civ.A. 00-10833-RWZ, 2004 WL 3088654, at *2 (D. Mass. Oct. 1, 2004).

95. *Health Care for All II*, 2005 WL 1660677 at *10.

96. See Third Amended Complaint at 12-20, *Health Care for All v. Romney*, No. Civ.A. 00-10833-RWZ, 2004 WL 5468533 (D. Mass. July 14, 2005).

97. *Id.* at 12-20; see *Health Care for All II*, 2005 WL 1660677 at *10.

98. *Health Care for All II*, 2005 WL 1660677 at *10.

99. *Id.* at *10.

100. *Id.* at *15.

101. *Id.* at *11.

102. *Id.* (“[P]laintiffs’ evidence persuasively demonstrates that MassHealth established reimbursement levels so low that private dentists could not afford to treat enrollees who, thus, either received dental care only after much delay or not at all.”).

103. *Id.* at *15 (“Plaintiffs have demonstrated that defendants violated sections of the

attempt to develop a joint remedial program, which resulted in an agreement that required Massachusetts to increase dental payment levels for services furnished to beneficiaries under twenty-one by at least \$13.74 million. The program also required Massachusetts to pay dental care providers for certain procedures for which MassHealth had not previously provided reimbursements—such as root canals on second molars.¹⁰⁴

IV. EVALUATING THE REASONABLE PROMPTNESS PROVISION AS A MEANS OF CHALLENGING LOW REIMBURSEMENT RATES

The success of the *Health Care for All* plaintiffs suggests that suing states under the Reasonable Promptness Provision may be a viable option for similarly-situated beneficiaries seeking to challenge low Medicaid reimbursement rates. One appealing feature of the Reasonable Promptness Provision is that it has been held to be enforceable under § 1983 by all federal circuit courts that have considered its enforceability,¹⁰⁵ indicating that its text is sufficient to overcome the *Blessing* and *Gonzaga* hurdles. However, the fact that the Reasonable Promptness Provision has only been utilized once to challenge low Medicaid reimbursement levels in the federal courts suggests some reluctance on the part of plaintiffs to use the Reasonable Promptness Provision for this purpose. Plaintiffs may be reluctant for various reasons; there may be other barriers to deploying the Reasonable Promptness Provision, or perhaps certain uncommon or extreme conditions must exist for courts to find a violation of the provision. Below, I discuss four factors that may affect the feasibility of utilizing the Reasonable Promptness Provision to compel reimbursement rate increases.

A. The Reasonable Promptness Provision Is Only Enforceable by Medicaid Beneficiaries

One characteristic of the Reasonable Promptness Provision that might explain why it has not been used frequently to challenge low payment levels is that it only seems to confer statutory rights to Medicaid beneficiaries, and not

Medicaid Act that require prompt provision of services . . . and that these violations resulted, in part, from insufficient reimbursement.”).

104. First Joint Report on Proposed Remedial Program at 3-7, *Health Care for All v. Romney*, No. Civ.A. 00-10833-RWZ, 2005 WL 5913277 (D. Mass. July 14, 2005).

105. *Romano v. Greenstein*, 721 F.3d 373 (5th Cir. 2013); *Doe v. Kidd*, 501 F.3d 348 (4th Cir. 2007); *Sabree v. Richman*, 367 F.3d 180 (3d Cir. 2004); *Bryson v. Shumway*, 308 F.3d 79 (1st Cir. 2002); *Doe v. Chiles*, 136 F.3d 709 (11th Cir. 1999); *see also* *Bertrand v. Maram*, 495 F.3d 452 (7th Cir. 2007) (assuming that the Reasonable Promptness provision confers statutory rights enforceable under § 1983 without explicitly deciding the issue).

providers. To satisfy the first prong of the *Blessing* three-part test, the provision that confers the asserted statutory right must “benefit the plaintiff.”¹⁰⁶ The Reasonable Promptness Provision requires states to provide medical assistance that “shall be furnished with reasonable promptness to all eligible individuals.”¹⁰⁷ It is clear from this text that the provision confers a right to Medicaid beneficiaries only; it does not directly benefit Medicaid providers. The federal courts that have considered this issue have held that Medicaid providers cannot enforce the Reasonable Promptness Provision under § 1983.¹⁰⁸

If the goal is to challenge low reimbursement rates, it might be problematic if only Medicaid beneficiaries can bring § 1983 suits to enforce the Reasonable Promptness provision. Compared to health care providers, Medicaid beneficiaries are generally much less able, and therefore much less likely, to initiate lawsuits because they have relatively fewer resources. Additionally, Medicaid beneficiaries are less likely to be able to overcome the collective action problem; the “costs” of low Medicaid provider payment levels to beneficiaries (in the form of reduced access to medical services) are diffuse, so for any individual beneficiary, the cost of litigating likely outweighs the uncertain benefit of increased access to medical services. Furthermore, because a successful suit to compel increased reimbursement rates would benefit all Medicaid beneficiaries, there is also a free-rider problem. Each individual beneficiary is better off letting some other beneficiary incur the costs of litigation because, if the suit is successful, all beneficiaries who did not partake in the litigation can reap the same benefits stemming from the suit’s outcome without having incurred any litigation costs. This makes it even more unlikely that any one beneficiary will initiate a lawsuit. These obstacles highlight the importance of consumer health advocacy groups and other organizations like Health Care for All that advocate on behalf of Medicaid beneficiaries. These organizations make up for the beneficiaries’ lack of monetary resources, and they also help overcome the collective action problem by bringing beneficiaries together and lowering the litigation costs to each individual beneficiary.

On the other hand, all of the problems discussed above apply to § 1983 suits that attempt to enforce other Medicaid provisions that only confer rights to beneficiaries, as well as to Reasonable Promptness suits that are not aimed at challenging low reimbursement rates. Yet, neither of these types of suits has been

106. *Blessing v. Freestone*, 520 U.S. 329, 340 (1997).

107. 42 U.S.C. § 1396a(a)(8) (2012).

108. *See, e.g., Women’s Hosp. Found. v. Townsend*, No. 07-711-JJB-DLD, 2008 WL 2743284, at *10 (M.D. La. July 10, 2008); *Bio-Med. Applications of NC, Inc. v. Elec. Data Sys. Corp.*, 412 F.Supp.2d 549, 554 (E.D.N.C. 2006).

in short supply in the federal courts.¹⁰⁹ For example, the Minimum Services Provision, which requires states to provide certain categories and types of “medical assistance” to Medicaid beneficiaries,¹¹⁰ has been utilized by many plaintiff beneficiaries in many federal § 1983 lawsuits to sue states for neglecting to provide required services.¹¹¹ This disparity suggests that the infrequency with which Reasonable Promptness suits are brought to challenge low reimbursement levels is not due solely to the fact that only beneficiaries can enforce the Reasonable Promptness Provision.

B. It is Difficult for Plaintiffs to Prove that Low Medicaid Reimbursement Rates Themselves Violate the Reasonable Promptness Provisions

Perhaps the potential difficulty in using the Reasonable Promptness Provision to challenge low payment levels lies not in the fact that only beneficiaries can enforce the Reasonable Promptness Provision, but rather in the difficulties that beneficiaries might face in proving that low reimbursement rates are the proximate cause of unreasonable delays in accessing Medicaid services. It might be the case that health providers, who certainly have more knowledge than beneficiaries (and perhaps consumer health advocacy groups) about the health care delivery system, would be better equipped to prove that low reimbursement rates cause more providers to refuse Medicaid patients, thereby creating barriers to accessing Medicaid services. If this is true, beneficiary plaintiffs seeking to challenge low reimbursement rates under the Reasonable Promptness Provision would probably benefit from finding ways to incorporate provider knowledge and expertise into their litigation efforts.

This is exactly what the *Health Care for All* plaintiffs did as part of their successful efforts to prove that low dental reimbursement rates caused the unreasonably prompt provision of juvenile dental services. First, the plaintiffs cited a 2000 Report of the Special Legislative Commission on Oral Health,¹¹² which was commissioned by the Massachusetts legislature, to support the propositions that low dental provider participation in MassHealth impeded access to dental health services and that low MassHealth reimbursement rates for dental

109. See Huberfeld, *supra* note 1, at 445-46 (discussing how the circuit courts have handled § 1983 suits under the Minimum Services and Reasonable Promptness provisions).

110. 42 U.S.C. §1396a(a)(10) (2012).

111. See, e.g., *Watson v. Weeks*, 436 F.3d 1152 (9th Cir. 2006); *S.D. ex rel. Dickson v. Hood*, 391 F.3d 581 (5th Cir. 2004).

112. *The Oral Health Crisis of Massachusetts: Report of the Special Legislative Commission on Oral Health: Executive Summary* (2000), <http://www.bphc.org/whatwedo/physical-health/oral-health/PublishingImages/Pages/Oral-Health-Resources/Oral%20Health%20Crisis%20in%20MA%20report%202000.pdf>.

services were the primary cause of the low participation rate.¹¹³ Specifically, they cited the Commission's finding that only fourteen percent of the 4,500 dentists in Massachusetts accepted MassHealth, and that this proportion was likely going to shrink even further as more dentists left MassHealth due to low payment levels.¹¹⁴ They also cited the Commission's finding, regarding the shortage of MassHealth dentists, that "[o]ne of the most significant factors is the longstanding inadequacy of the MassHealth fee schedule. Present reimbursement rates are so dramatically below current market levels that dentists who choose to treat MassHealth patients receive fees that cover only about 75% of their direct costs of providing the service."¹¹⁵

The plaintiffs offered testimony from several dental providers to substantiate their claim that low reimbursement rates created barriers to access for beneficiaries. One provider, a former Dentist-in-Chief of the Children's Hospital Dental Clinic (CHDC), explained that CHDC operated at a loss because of low MassHealth payment levels.¹¹⁶ Another provider testified that he and the vast majority of other providers with private practices refuse to accept MassHealth patients because doing so would force them to operate at a loss.¹¹⁷ The plaintiffs' strategy worked beautifully; the court commented that the "plaintiffs' evidence persuasively demonstrates that MassHealth established reimbursement levels so low that private dentists could not afford to treat enrollees who, thus, either received dental care only after much delay or not at all."¹¹⁸ The court then held that these low reimbursement levels constituted a violation of the Reasonable Promptness Provision.¹¹⁹

The strategies employed by the *Health Care for All* plaintiffs suggest a role for providers to play in challenging low payment rates as violations of the Reasonable Promptness Provision. Though they cannot personally bring § 1983 suits under the Provision, providers can assist beneficiaries by testifying about the effects of low rates on provider participation in Medicaid. Doing so would actually be in their interest, as both providers and beneficiaries would benefit from higher Medicaid reimbursement levels. However, while the *Health Care for All* strategy was successful, it may be quite expensive to replicate; securing extensive provider testimony may be time and resource intensive. Furthermore, *Health Care for All* leaves uncertain the amount of evidence that is sufficient to

113. *Health Care for All v. Romney*, No. Civ.A. 00-10833-RWZ, 2005 WL 1660677, at *3 (D. Mass. July 14, 2005).

114. *Id.*

115. *Health Care for All II*, 2005 WL 1660677, at *4.

116. *Id.*

117. *Id.* at *5.

118. *Id.* at *11.

119. *Id.*

prove causation. It is unclear whether future plaintiffs could rely solely on the testimony of providers, or whether citation to some sort of report or study is necessary. If the latter were the case, and if in a given litigation context there were no pre-existing studies to which the plaintiffs could refer, then the high burden of proof might render the Reasonable Promptness Provision infeasible as a means of challenging low reimbursement levels.

Finally, it is important to note that in order to prompt a state to raise reimbursement rates, plaintiffs do not necessarily have to prove that the state is violating the Reasonable Promptness Provision specifically by setting reimbursement rates too low. That is, as long as a plaintiff proves a Reasonable Promptness violation on the part of a state, there is some chance that the state will raise its payment levels to Medicaid providers in response. For example, if a state is ordered to remedy a Reasonable Promptness violation by decreasing wait times, the state might choose to comply with this order by raising reimbursement rates so that more providers are willing to serve Medicaid beneficiaries. However, when compared to piecemeal litigation involving scattered plaintiffs challenging long wait times for vastly different Medicaid services, a successful direct challenge increases the likelihood of system-wide changes in reimbursement rates.

C. The Definition of "Medical Assistance" in the Medicaid Statute

One relatively recent trend in some circuits regarding the interpretation of the term "medical assistance" in the Medicaid statute might have foreclosed some Reasonable Promptness suits in those circuits and caused reluctance to sue under the Reasonable Promptness Provision in others. The Reasonable Promptness Provision obliges states to provide "medical assistance" with "reasonable promptness."¹²⁰ In *Bruggeman ex rel. Bruggeman v. Blagojevich*,¹²¹ Judge Richard Posner understood "medical assistance" as referring to "*financial* assistance rather than . . . actual medical *services*." In other words, Judge Posner reasoned that the Reasonable Promptness Provision only requires states to provide "funds to eligible individuals," rather than actual medical services, promptly.¹²² In Judge Posner's view, because Medicaid is "a payment scheme, not a scheme for state-provided medical assistance," requiring states to provide prompt treatment would constitute an inappropriate "direct regulation of medical services."¹²³ However, this assertion was mere dicta. Judge Posner used other

120. 42 U.S.C. § 1396a(a)(8) (2012).

121. 324 F.3d 906, 910 (7th Cir. 2003).

122. *Id.*

123. *Id.*

reasoning to hold that Illinois's Medicaid plan was not in violation of the Reasonable Promptness Provision, and the discussion regarding the definition of "medical assistance" was only used to bolster his position. Specifically, Judge Posner stated that "even if" his previous reasoning was not valid, the plaintiffs' theory of the case would be "a considerable stretch" because of his view of the definition of "medical assistance."¹²⁴

The Fifth, Sixth, and Tenth Circuits followed suit by holding that "medical assistance" refers only to financial assistance for medical services, and not to the medical services themselves.¹²⁵ Some district courts in other circuits also followed this trend.¹²⁶ Though many of these decisions cited *Bruggeman*, all of them relied primarily on the definition of "medical assistance" provided in the definitions section of the Medicaid statute, which states that "medical assistance means payment of part or all of the cost of the following care and services,"¹²⁷ to reach their holdings.

This definition of "medical assistance" is fatal to almost all Reasonable Promptness suits. Under this interpretation, both the level of reimbursement to Medicaid providers and the promptness with which beneficiaries receive care are wholly irrelevant; so long as a state ensures that *some* amount of reimbursement—even an amount below the cost of providing care—reaches providers promptly, that state will have satisfied the Reasonable Promptness requirement. Indeed, the District Court for the District of Massachusetts recognized the unsavory consequences of such an interpretation of "medical assistance" in *Health Care for All v. Romney*. In response to the state's argument that "medical assistance" should be read to mean only payment for medical services, the court called the state's reading "myopic," asserting that "[t]imely payment for services does little to benefit enrollees who cannot find a provider willing to accept such payment. Because payment for services necessarily presumes delivery of services, state Medicaid programs may indirectly impede medical assistance through practices and protocols that delay the delivery of services."¹²⁸

124. *Id.*

125. *Equal Access for El Paso, Inc. v. Hawkins*, 562 F.3d 724 (5th Cir. 2009); *Mandy R. ex rel. Mr. and Mrs. R. v. Owens*, 464 F.3d 1139 (10th Cir. 2006); *Westside Mothers v. Olszewski*, 454 F.3d 532 (6th Cir. 2006).

126. *See, e.g., Disability Rights N.J., Inc. v. Velez*, Civil No. 05-4723 (AET), 2010 WL 3862536 (D.N.J. Sept. 24, 2010); *Doe v. Kidd*, Civil Action No. 3:03-1918-MBS, 2010 WL 419922 (D.S.C. Jan. 29, 2010).

127. 42 U.S.C. § 1396d(a) (2006).

128. *Health Care for All v. Romney*, No. Civ.A. 00-10833-RWZ, 2005 WL 1660677, at *9 (D. Mass. July 14, 2005).

Fortunately, the Patient Protection and Affordable Care Act (ACA)¹²⁹ seems to have addressed this problem by amending the definitions section of the Medicaid statute. The section now defines “medical assistance” as “payment of part or all of the cost of the following care and services *or the care and services themselves, or both.*”¹³⁰ Additionally, a House Committee Report accompanying the amendment emphasized that (1) the longstanding definition of “medical assistance” has always been *both* payment for services and the services themselves; (2) that recent court opinions construing “medical assistance” to mean only payment for services run contrary to longstanding practice and render some sections of Title XIX absurd; and (3) that the purpose of the amendment was to “correct any misunderstandings as to the meaning of the term” and to “conform this definition to the longstanding administrative use and understanding of the term.”¹³¹

Because the courts that construed “medical assistance” to mean mere payment relied primarily on the text of the definitions section of the Medicaid statute, the amendment should give plaintiffs the ability to convince those courts to overrule their erroneous constructions. In fact, one set of plaintiffs succeeded in getting a district court to change its erroneous construction after filing for reconsideration and arguing that “an intervening change in controlling law” (the amendment of the definitions section) required the court to adjust its previous interpretation of “medical assistance.”¹³² Additionally, all post-ACA federal court decisions that construed “medical assistance” to mean no more than payment did not take the amended definitions section into account.¹³³ Thus, it seems likely that the ACA’s amendment to the definitions section of the Medicaid statute has revived and reinforced the viability of the Reasonable Promptness Provision as a means of challenging low Medicaid reimbursement levels.

D. What is Reasonably Prompt?

Finally, plaintiffs might be deterred from using the Reasonable Promptness Provision to sue states for unreasonably low payment rates by the criteria that courts use to determine what constitutes “reasonable promptness.” Perhaps a court would only find a violation of the Reasonable Promptness Provision when

129. Pub. L. No. 111-148, 124 Stat. 119 (2010).

130. 42 U.S.C. § 1396d(a) (2012) (emphasis added).

131. H.R. REP. NO. 111-299, pt. 1, at 649-50 (2009).

132. *Disability Rights N.J., Inc. v. Velez*, Civil No. 05-4723 (AET), 2010 WL 5055820, at *2 (D.N.J. Dec. 2, 2010).

133. *E.g. Phoenix Memorial Hosp. v. Sebelius*, 622 F.3d 1219, 1226 (9th Cir. 2010); *Covenant Health Sys. v. Sebelius*, 820 F. Supp. 2d 4, 9 (D.D.C. 2011).

delays in the delivery of services are extreme. Reluctance to bring § 1983 suits under the provision may also stem from uncertainty as to what kinds of criteria courts will utilize to decide whether services have been provided with reasonable promptness. An examination of the regulations and case law related to the Reasonable Promptness Provision suggests that the second explanation is not unreasonable.

One would think that a provision as vague and open-textured as the Reasonable Promptness Provision would be accompanied by regulations issued to clarify what constitutes “reasonable promptness,” but it turns out that there are less than a handful of regulations related to the Provision, and only one of them provides significant guidance for litigants, courts, and states.¹³⁴ Among other requirements, 42 C.F.R. § 435.912 sets forth timeliness standards for states for determining Medicaid eligibility: it forbids states from taking longer than forty-five and ninety days to determine the eligibility of non-disabled applicants and disabled applicants, respectively, and it also forbids states from using time standards as “a waiting period before determining eligibility.”¹³⁵ 42 C.F.R. § 435.930 requires states to “[f]urnish Medicaid promptly to beneficiaries without any delay caused by the agency's administrative procedures” and to continue furnishing Medicaid to “all eligible individuals until they are found to be ineligible.”¹³⁶ Finally, 42 C.F.R. § 441.56(e) requires state agencies responsible for administering Medicaid to set timeliness standards for the provision of Early Periodic Screening, Diagnostic, and Treatment (EPSDT) services that meet “reasonable standards of medical and dental practice.”¹³⁷ State agencies must consult with “recognized medical and dental organizations involved in child health care” before setting these standards, and must ensure timely initiation of treatment that generally does not exceed six months after a request for screening services.¹³⁸ The dearth of regulations clarifying the meaning of “reasonable promptness” might be explained by the fact that what constitutes reasonably prompt provision of care is completely dependent on what condition the care is supposed to be treating. Because illnesses and conditions vary so widely, any set of regulations aimed at defining “reasonable promptness” would have to provide a different standard for at least every category of illness or condition.

Presumably, 42 C.F.R. § 441.56(e) provides some guidance for plaintiffs attempting to sue states for unreasonable delays in the provision of EPSDT services. If a state fails to establish timeliness standards, consult with medical

134. 42 C.F.R. § 441.56(e) (2013).

135. 42 C.F.R. § 435.912 (2013).

136. 42 C.F.R. § 435.930 (2013).

137. 42 C.F.R. § 441.56(e) (2013).

138. *Id.*

and dental professionals before establishing those standards, or provide initial treatment within six months of a request, then it clearly violates the regulation. However, the fact that the plaintiffs in *Health Care for All* did not invoke 42 C.F.R. § 441.56(e) is puzzling. This suggests some sort of confusion about the regulation's role in defining "reasonable promptness" in the context of EPSDT services. Those plaintiffs brought suit because juvenile Medicaid beneficiaries faced enormous delays in receiving dental services, which fall under the EPSDT umbrella. Yet, they did not argue that Massachusetts was in violation of 42 C.F.R. § 441.56(e). It could be the case that Massachusetts did in fact set timeliness standards after consulting with the appropriate professionals, and that the plaintiffs were trying to prove that Massachusetts was violating the Reasonable Promptness Provision *despite* satisfying the requirements of 42 C.F.R. § 441.56(e), but none of this is explicitly discussed or addressed by either party or the court.

Adding to this confusion, at least one federal district court has applied the 42 C.F.R. § 441.56(e) requirements to the provision of non-EPSDT services. In that case,¹³⁹ the District Court for the Eastern District of Pennsylvania acknowledged that the regulation only specifically implements EPSDT services. It does not cover behavioral health rehabilitative (BHR) services, which were the services at issue. But the court then decided that "in the absence of another guide by which to base timeliness, the Court may compare the Defendant's provision of services against this standard," and found the state to be in violation of the Reasonable Promptness Provision because it did not establish timeliness standards for BHR services after adequate consultation with medical providers.¹⁴⁰

Another federal district court made a similarly odd move by applying the ninety-day limit on eligibility determinations for disabled Medicaid applicants found in 42 C.F.R. § 435.911 to the actual provision of care to disabled Medicaid recipients. In *Boulet v. Celluci*, the District Court for the District of Massachusetts explicitly stated that "[w]hile this regulation is focused on eligibility determinations rather than the actual provision of services, it still gives some guidance to courts attempting to decide what time periods may be considered reasonably prompt in the larger context."¹⁴¹ The court went on to find that Massachusetts violated the Reasonable Promptness Provision by subjecting Medicaid enrollees to unreasonably long waiting periods, and ordered the state to provide the services to each beneficiary no later than ninety days after the beneficiary was placed on the waiting list.¹⁴² However, in a later decision, the

139. *Kirk T. v. Houstoun*, No. 99-3253, 2000 WL 830731 (E.D. Pa. June 27, 2000).

140. *Id.* at *2-3.

141. 107 F. Supp. 2d 61, 73 (D. Mass. 2000).

142. *Id.* at 80.

District Court for the Eastern District of New York declined to follow *Boulet's* application of the regulation's ninety-day limit, asserting that applying this limit would be "completely arbitrary because the record contains no information suggesting that the magic number ninety bears any relation to what is reasonable in this case."¹⁴³

The Reasonable Promptness case law that does not involve federal rules and regulations is just as haphazard and, ultimately, unilluminating. Some early court decisions held that *any* delay in the provision of services, or any use of waiting lists, constituted a violation of the Reasonable Promptness Provision.¹⁴⁴ In the case that is most often cited for this proposition, *Sobky v. Smoley*,¹⁴⁵ the District Court for the Eastern District of California applied the borrowed statute doctrine to reach this conclusion. The court first observed that the Reasonable Promptness Provision was borrowed from a similar provision with almost the exact same wording in the Aid to Families with Dependent Children (AFDC) portion of the Social Security Act.¹⁴⁶ The court then pointed to the Supreme Court's decision in *Jefferson v. Hackney*, which construed the borrowed provision in the AFDC program to forbid waiting lists. The Supreme Court relied on legislative history to hold that "the statute was intended to prevent the States from denying benefits, even temporarily, to a person who has been found fully qualified for aid."¹⁴⁷ Finally, the *Sobky* court reasoned from this chain of events that the Reasonable Promptness Provision in the Medicaid statute must also prohibit states from implementing any waiting lists or delays.¹⁴⁸ More recent court decisions have also held that waiting periods of several years or longer are obvious violations of the Reasonable Promptness Provision.¹⁴⁹

Recently, courts seem to be more reluctant to construe the Reasonable Promptness Provision as prohibiting all delays or waiting lists. Few of the recent cases even cite *Sobky*, let alone use its reasoning. Perhaps courts or litigants have come to think that the Medicaid program is so different from the AFDC program

143. Alexander A. *ex rel. Barr v. Novello*, Civ.A. No. 99-CV-8418, 210 F.R.D. 27, 38 (E.D.N.Y. Sept. 12, 2002).

144. *See, e.g., Boulet*, 107 F. Supp. 2d at 79; *Sobky v. Smoley*, 855 F. Supp. 1123, 1149 (E.D. Cal. 1994). In *Boulet*, the court concedes that "the state must only provide services in facilities if those facilities are available." *Boulet*, 107 F. Supp. 2d at 79.

145. 855 F. Supp. 1123 (E.D. Cal. 1994).

146. 42 U.S.C. § 602(a)(10)(A) (1994).

147. *Sobky*, 855 F. Supp. at 1148 (quoting *Jefferson v. Hackney*, 406 U.S. 535, 545 (1972)).

148. *Sobky*, 855 F. Supp. at 1148.

149. *Doe v. Chiles*, 136 F.3d 709, 717 (11th Cir. 1998) ("It is axiomatic that delays of several years . . . are far outside the realm of reasonableness."); *Boulet v. Cellucci*, 107 F. Supp. 2d 61, 80 (D. Mass. 2000) ("Here, where some of the delays extend more than a decade, I have little trouble finding that the defendants have not been reasonably prompt if facilities are available for offering the requested services.").

that their respective “reasonable promptness” provisions are not *in pari materia*. One district court made this point explicitly; in refusing to apply the borrowed statute doctrine to construe the Reasonable Promptness Provision to prohibit any delay, the court observed that “[a]lthough distribution of welfare money, which was an issue in *Jefferson*, can be expected to occur without delays, immediate placement in [residential treatment facilities] upon finding of eligibility does not appear to be reasonable or practical.”¹⁵⁰

The courts seem to have developed a separate set of criteria for determining whether “waiver” services are being provided with reasonable promptness. Unlike the services that the Medicaid statute requires states to provide,¹⁵¹ “waiver” services—like Home and Community-Based Services (HCBS) programs for beneficiaries with developmental disabilities—are allowed to have a “cap.”¹⁵² This means that states are allowed to establish a fixed number of “slots” to allocate among the entire beneficiary population, so long as that fixed number is above a minimum number specified by CMS. Each beneficiary who gets a slot receives the services provided by the waiver program. Beneficiaries who do not receive slots are put on a waiting list.¹⁵³ Thus far, the courts have held that in order to comply with the Reasonable Promptness Provision in the context of waiver services, states must allocate empty slots without delay and provide waiver services to those who receive slots without delay.¹⁵⁴ In other words, states are under no obligation to increase the number of slots for waiver services, nor are they required to shorten the waiting periods of those waiting for waiver slots—even if the waiting periods span multiple years.¹⁵⁵

As demonstrated above, the regulations and case law related to the Reasonable Promptness Provision do not provide a clear answer to the question of what constitutes a violation of reasonable promptness. Perhaps the case law suggests that a plaintiff’s best bet is to draw upon specific numbers from objective and minimally relevant sources, like the ninety-day figure from the eligibility determination regulation. However, one district court opinion suggests another strategy. In *Oklahoma Chapter of American Academy of Pediatrics (OKAAP) v. Fogarty*, the District Court for the Northern District of Oklahoma found that the plaintiffs offered “substantial evidence that the delays in treatment

150. Alexander A. *ex rel. Barr v. Novello*, Civ.A. No. 99–CV–8418, 210 F.R.D. 27, 37 (E.D.N.Y. Sept. 12, 2002).

151. 42 U.S.C. § 1396a (2012).

152. *See Susan J. v. Riley*, 616 F. Supp. 2d 1219, 1239 (M.D. Ala. 2009).

153. *See id.* at 1241 & n.17 (citing *Mandy R. v. Owens*, 464 F.3d 1139 (10th Cir. 2006)).

154. *See, e.g., Susan J.*, 616 F. Supp. 2d at 1241; *Lewis v. N.M. Dep’t of Health*, 275 F. Supp. 2d 1319, 1346 (D.N.M. 2003); *Makin ex rel. Russell v. Hawaii*, 114 F. Supp. 2d 1017, 1030 (D. Haw. 1999).

155. *See sources cited supra* note 149.

for children with specific conditions are medically inappropriate.”¹⁵⁶ This evidence convinced the court that the system-wide delays constituted a violation of the Reasonable Promptness Provision.¹⁵⁷ *OKAAP*, along with the timeliness standards based on “reasonable standards of medical and dental practice” required by 42 C.F.R. § 441.56(e), suggest that a plaintiff might be able to convince a court that a state is violating the Reasonable Promptness Provision by proving that beneficiaries are having to endure delays that are *medically inappropriate*. This standard could be the most commonsensical and thus intuitively appealing one to judges. It also offers flexibility, as it can be applied to all conditions and illnesses. Finally, the “medically inappropriate” standard would create another role for providers to play in suits aimed at forcing states to raise their Medicaid reimbursement rates: they could provide testimony regarding the medical consequences of the delays stemming from low reimbursement levels, thereby helping plaintiffs prove that those delays, and by extension those low reimbursement rates, constitute violations of the Reasonable Promptness Provision.

CONCLUSION

In today’s economic climate, as Medicaid enrollment expands and state coffers dwindle, finding a way to prevent states from skimping on Medicaid is crucial for the health and well-being of our most vulnerable and politically powerless citizens and residents. Given the current status of § 1983 jurisprudence and the uncertainty surrounding Medicaid preemption claims, utilizing the Reasonable Promptness Provision to challenge low Medicaid reimbursement rates may be just the workaround the doctor ordered.

156. 366 F. Supp. 2d 1050, 1109 (N.D. Okla. 2005).

157. *Id.*

The Quest for Global Justice in Health: A Review of *Global Health Law* by Lawrence O. Gostin

Octavio Gómez-Dantés^{*} & Julio Frenk^{}**

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INTRODUCTION

We are witnessing the emergence of a new world health order. Health occupies an increasingly relevant place in the global agenda. An unprecedented health transition is leading to a new model characterized by expanded international and national funding for health and the involvement of a growing pluralism of actors.

During the twentieth century, the life expectancy of the world population increased more than it had in all previous centuries combined. In 1900, global life expectancy averaged just over a mere thirty years.¹ By 1990, it had more than doubled to sixty-four years, and now may surpass seventy years.² Of course, there are huge disparities among countries: life expectancy at birth in Japan is eighty-three years, while in Sierra Leone it is forty-five.³

We have also seen a major shift in the dominant patterns of disease. Chronic non-communicable disorders (NCDs) in adults have replaced acute infections in children as a relatively dominant cause of death globally. The increasing importance of chronic diseases explains another salient characteristic of the health transition: the rising role of disability in the global health profile. "Health problems," according to a recent Global Burden of Disease Report, "are increasingly defined not by what kills us, but what ails us."⁴

The prominence of health in the global agenda has changed as well. Health issues have moved from the realm of "low politics," commonly associated with development concerns, to that of "high politics," usually associated with national and global security issues.⁵ Health issues increasingly contribute to economic

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1. *Health, History and Hard Choices: Funding Dilemmas in a Fast-Changing World*, WORLD HEALTH ORG. 7 (2006), http://www.who.int/global_health_histories/seminars/presentation07.pdf.

2. *World Health Statistics 2014: A Wealth of Information on Global Public Health*, WORLD HEALTH ORG. 68 (2014), apps.who.int/iris/bitstream/10665/112738/1/9789240692671_eng.pdf.

3. *Life Expectancy at Birth, Total (Years)*, WORLD BANK, <http://data.worldbank.org/indicator/SP.DYN.LE00.IN> (last visited Apr. 22, 2015) (listing country-by-country life expectancy data through 2012).

4. *The Global Burden of Disease: Generating Evidence, Guiding Policy*, UNIV. OF WASH. INST. FOR HEALTH METRICS & EVALUATION 44 (2013), http://www.healthdata.org/sites/default/files/files/policy_report/2013/GBD_GeneratingEvidence/IHME_GBD_GeneratingEvidence_FullReport.pdf.

5. David P. Fidler, *Health as Foreign Policy: Between Principle and Power*, 7 WHITEHEAD J. DIPL. & INT'L REL. 179, 180 (2005).

growth and development, national and global security, and human rights promotion.

The growing perceived importance of health explains the unparalleled sums of international and national funds that are flowing into this sector. International assistance for health grew from \$5 billion (in U.S. dollars) in 1990 to almost \$30 billion in 2012, while government health expenditures in developing countries increased from \$128 billion in 1995 to over \$400 billion in 2010.⁶

There has also been a recent proliferation of actors in the global health arena: the World Health Organization (WHO) and other United Nations (U.N.) agencies, development banks, bilateral agencies, global health initiatives, philanthropic organizations, global nongovernmental organizations (NGOs), professional associations, transnational corporations, research funders, and academic institutions.

Given this complex context, it is critically important to use novel perspectives when discussing the nature and scope of global health. This is exactly what Lawrence O. Gostin achieves in his recent book, *Global Health Law*. This outstanding volume views global health through the lens of international law. However, its vast breadth and innovative approach allow it to transcend a strictly legal framework. It appeals not only to legal and public health specialists, but also to “the informed public that cares about global health with justice.”⁷ The book’s launching is particularly timely since negotiations around the post-2015 Development Agenda are reaching their final stage. These negotiations intend to define a new development framework that will succeed the Millennium Development Goals.⁸

The topic of this book is in good hands. Gostin is one of the pioneers and leading figures in the field of global health law.⁹ His credentials are impeccable. He has published some of the most influential papers on global health law.¹⁰ At Georgetown University, he holds the highest academic rank of University Professor and serves as the Founding O’Neill Chair in Global Health Law. In

6. *Financing Global Health 2012: The End of the Golden Age?*, UNIV. OF WASH. INST. FOR HEALTH METRICS & EVALUATION 56 tbl.B1 (2012), http://www.healthdata.org/sites/default/files/files/policy_report/2012/FGH/IHME_FGH2012_FullReportHighResolution.pdf.

7. LAWRENCE O. GOSTIN, *GLOBAL HEALTH LAW* xvi (2014).

8. *See Millennium Development Goals and Post-2015 Development Agenda*, UNITED NATIONS ECON. & SOC. COUNCIL, <http://www.un.org/en/ecosoc/about/mdg.shtml> (last visited Mar. 13, 2015).

9. Global health law should be distinguished from international law. *See infra* Part II.

10. *See, e.g.*, Lawrence O. Gostin, *World Health Law: Toward a New Conception of Global Health Governance for the 21st Century*, 5 YALE J. HEALTH POL’Y L. & ETHICS 413 (2005); Lawrence O. Gostin & Devi Sridhar, *Global Health and the Law*, 370 NEW ENG. J. MED. 1732 (2014); Lawrence O. Gostin & Allyn L. Taylor, *Global Health Law: A Definition and Grand Challenges*, 1 PUB. HEALTH ETHICS 53 (2008).

addition, he is professor of Law and Public Health at the Johns Hopkins Bloomberg School of Public Health. He is also the Faculty Director of the O'Neill Institute for National and Global Health Law and Director of the WHO Collaborating Center on Public Health Law and Human Rights. In recent years, Gostin has been leading a call for a Framework Convention on Global Health modeled on the successful design and implementation of the Framework Convention on Tobacco Control (FCTC).

Global Health Law has a clear guiding question: How can international law contribute to improve global governance in order to offer equal opportunities to live healthy and productive lives everywhere? The book has three explicit goals: (i) to define global health law within the field of global governance for health; (ii) to describe and analyze the major sources of global health law and their institutional frameworks; and (iii) to discuss several themes—health equity, global solidarity, health in all policies, multiple regimes, good governance, health-promoting priorities, and right to health—that are critical for global health in the twenty-first century. Using a critical approach and a thoughtful style, Gostin addresses this guiding question and these goals in the book's four parts.

I. THE MAIN CHALLENGE OF GLOBAL JUSTICE AND THE DEFINITION OF GLOBAL HEALTH LAW

This ambitious book opens with a discussion of the main challenges of global justice in health and the core concepts of global health law. For Gostin, the main challenge of global justice in health is the global recognition and effective exercise of the right to health. Recognition of such a right could help reduce the existing health gap between the rich and the poor, which according to Gostin, has seen negligible signs of improvement. "Despite unprecedented engagement," he says, "the international community has not fundamentally changed the reality for the world's least advantaged people."¹¹ Realistic as this appraisal may sound, the health conditions of the global poor deserve a more balanced discussion. The most recent global health initiatives have rendered important, but still insufficient, achievements that have benefited primarily the poor and vulnerable. A few examples:

- The expansion of the global coverage of immunizations produced a seventy-five percent decrease in measles deaths (from an estimated 544,200 to 145,700 annually) between 2000 and 2013.¹²

11. GOSTIN, *supra* note 7, at 14.

12. *Measles: Fact Sheet No. 286*, WORLD HEALTH ORG., <http://www.who.int/mediacentre/factsheets/fs286/en> (last updated Feb. 2015).

- The number of global deaths due to malaria declined from almost one million in 2000 to 584,000 in 2012 thanks to increased use of insecticide-treated bed nets, earlier diagnoses, and expanded access to more effective drugs.¹³
- The number of AIDS-related deaths has diminished from 2.3 million globally in 2001 to 1.6 million in 2012 due to a significant increase in access to preventive services and antiretroviral therapy.¹⁴

A discussion of how global health conditions have evolved requires reliable metrics and information systems to measure improvements. It also demands a clear understanding of what would constitute a “fundamental change” in the lives of the world’s poorest people. Interestingly, a recent *Lancet* Commission Report discussed the possibility of reducing the burden of common infections, nutritional deficiencies, and maternal and child disorders in most high-mortality developing countries by 2035. The Commission articulated a goal of reaching current morbidity rates in the best performing middle-income nations, such as Chile, Costa Rica, and Cuba.¹⁵ Gostin may consider this to be a reasonable timeframe and achievement.

To meet the major challenges of global justice in health, Gostin argues that we need to define: (i) the goods and services that the right to health should guarantee; (ii) a state’s duty to meet the health needs of its population; (iii) the responsibilities of a wealthy state to promote the health of poor people beyond its borders; and (iv) the governance strategies necessary to improve the performance of global health institutions and the health conditions of the global population. It is only through law, he adds, that we can define the entitlements to health services that individuals and populations may claim. Legal instruments will also be needed to establish and enforce corresponding state obligations and transform the prospects for good health—especially for the poor and vulnerable.

“Health aid” is key in answering these questions. This concept is usually associated with the idea of charity provided by rich countries to poor nations in order to meet problems supposedly characteristic of the developing world. The convergence of world population health needs with increasing global interdependence is forcing us to move beyond this reductionist idea of charity. Instead, health aid should be conceived as collaborative, where the international

13. *10 Facts on Malaria*, WORLD HEALTH ORG. 2, http://www.who.int/features/factfiles/malaria/malaria_facts/en (last updated Dec. 2014).

14. *Fact Sheet*, UNAIDS, <http://www.unaids.org/en/resources/campaigns/globalreport2013/factsheet> (last visited Apr. 11, 2015).

15. Dean T. Jamison et al., *Global Health 2035: A World Converging Within a Generation*, 382 LANCET 1898, 1900-01 (2013).

community builds capacity to collectively respond to common threats.¹⁶ “Conceptualizing international assistance as ‘aid,’” says Gostin, “masks the deeper truth that human health is a globally shared responsibility, reflecting common risks and vulnerabilities—an obligation of health justice that demands a fair contribution from everyone.”¹⁷ The recent Ebola crisis evinces the extent to which a global response is a shared moral imperative. The global response sought to protect the populations not only of Guinea, Liberia, Sierra Leone and neighboring African countries, but also the population of the Western world.

After discussing the framework of joint responsibility under which the challenge of global health justice should be addressed, Gostin analyzes the global health profile, or “globalized health hazards.” This term encompasses the transnational spread of infectious diseases, the increasing prevalence of NCDs, and the global expansion of disability. “Globalized health hazards” also include the underlying processes that explain these phenomena (travel, trade, migration, aging, urbanization, motorization, environmental degradation). This conventional classification of global health needs and their determinants focuses only on health losses and risks. However, the conventional classification Gostin supports fails to discuss the “globalized health opportunities” that global law should help promote. These opportunities include the spread of health-related knowledge and practices that enhance health and wellbeing.

In chapter three, Gostin discusses the first of the book’s three central goals: defining global health law within the field of global governance for health. His definition is comprehensive: “The study and practice of international law—both hard law (e.g., treaties that bind states) and soft instruments (e.g., codes of practice negotiated by states)—that shapes norms, processes, and institutions to attain the highest attainable standard of physical and mental health for the world’s population.”¹⁸ Gostin’s conception of global health law assumes health to be a fundamental human entitlement. He modifies the definition of health put forth by WHO: “A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.”¹⁹ Gostin echoes a growing consensus that healthcare is a right. However, he goes on to insist that global health law should help guarantee equal opportunities to live a healthy life. This notion includes access not only to personal and public health services, but also to

16. Julio Frenk et al., *From Sovereignty to Solidarity: A Renewed Concept of Global Health for an Era of Complex Interdependence*, 383 LANCET 94, 94 (2014).

17. GOSTIN, *supra* note 7, at 19.

18. GOSTIN, *supra* note 7, at 59.

19. WHO *Definition of Health*, WORLD HEALTH ORG., <http://www.who.int/about/definition/en/print.html> (last visited Mar. 13, 2015).

clean water, sanitary services, adequate nutrition, and other determinants of health.

Notably, Gostin avoids the use of three terms that are included in the WHO definition of health: “state,” “complete,” and “social wellbeing.” In a paper published in the *Journal of Public Health Policy* in 2014, we objected to the use of these terms for at least three reasons.²⁰ First, the word “state” conveys the idea of permanence or immovability. Critics tend to view health more as a dynamic condition with continuous adjustments to the changing demands of the physical and social environment.²¹ A second important objection is the use of the term “complete” when referring to wellbeing. At a time when chronic illness increasingly dominates the epidemiologic landscape, the emphasis on total “physical, mental and social wellbeing” seems unrealistic. Finally, we object to the WHO’s expanded definition of health, which includes not only physical and mental health, but also social wellbeing. This impractically broadens the scope of responsibility of healthcare providers.

An important topic that Gostin touches only briefly in discussing his definition of “global health law” is the difference between the concept and the theory of “international health law.” The Health Law and Justice Program of American University’s Washington College of Law states that global health law not only encompasses international health law, but also extends beyond it in three ways. First, international health law focuses on health-specific agreements while global health law examines a broader collection of laws that affect but are not necessarily focused on health. Second, international law focuses on agreements among nation-states that attempt to influence governmental behavior, while global health law also addresses the rights and obligations of nongovernmental actors. Third, international health law focuses mostly on international agreements, while global health law also considers the impact of national and local laws on global health.²² This distinction is implicit in part two of *Global Health Law*.

II. INSTITUTIONAL FRAMEWORKS OF GLOBAL HEALTH LAW

According to Gostin, international law applies mainly to states and has three main sources: (i) treaties, which are international agreements between states; (ii) customary international law, which refers to legal norms that have been

20. Julio Frenk & Octavio Gómez-Dantés, *Designing a Framework for the Concept of Health*, 35 J. PUB. HEALTH POL’Y 401 (2014).

21. RENÉ DUBOS, *MAN ADAPTING* xvii (11th prt. 1975).

22. Health Law & Justice Program, *What Is Health Law?*, AM. UNIV. WASH. COLL. OF LAW, http://www.wcl.american.edu/health/health_law_info.cfm (last visited Apr. 11, 2015).

established by general and consistent state practice; and (iii) general principles of law, a vague body of law that emphasizes broad principles of domestic or municipal law that are recognized in the legal systems of civilized nations.

Rich as international law may be, it has two serious limitations related to its state-centric orientation. One, as mentioned above, is its narrow potential to govern non-state actors, including individuals, NGOs, foundations, and private enterprises, some of which have a dominating presence in the global health arena. The second limitation is its mostly voluntary nature. As Gostin says, "In signing and ratifying treaties, which are the primary source of health law, states establish international legal rules by consenting to them. There is often no supranational authority to monitor, adjudicate, and enforce international law against states."²³

Conceptually, Gostin places global health law not, as expected, within "global health governance" but within "global governance for health." At the beginning of his book he states the following: "The former principally describes the norms and institutions within the health sector, while the latter is more encompassing, extending beyond the health sector."²⁴ This allows him to establish a platform for the promotion of "healthy policies" or "health in all policies" through international law, something he considers critical for global health.

In terms of institutions, global health has become, as Gostin attests, increasingly pluralistic. Traditionally, the vehicles for mobilizing international collective action had been the U.N. health agencies—most notably the WHO. However, in recent years the range of actors involved in global health has expanded to include development banks, international NGOs, academic institutions, and philanthropic organizations. This institutional diversification has generated novel public-private alliances among the traditional agencies of the U.N. system and other important global actors, including multinational private corporations. The result is a diversity of what could be called "quasi-multilateral" organizations. Salient among them are the Global Alliance for Vaccines and Immunization and the Global Fund to Fight Aids, Tuberculosis and Malaria.

Such pluralism positively reflects the growing importance of health in the global agenda. Until now, the broad variety of actors had not been able to develop an effective global health system with a capacity for concerted action. To deal effectively with the challenges posed by globalization, global health actors must solve what has been described as a sovereignty paradox.²⁵ Paradoxically, in a world of sovereign nation-states, health continues to be

23. GOSTIN, *supra* note 7, at 64.

24. *Id.* at xii.

25. Dean T. Jamison et al., *International Collective Action in Health: Objectives, Functions and Rationale*, 351 LANCET 514, 515 (1998).

primarily a national responsibility. Yet, the determinants of health and the means to fulfill that responsibility are increasingly global. Because of the international transfer of health risks, so too are the consequences of failing to fulfill that responsibility. No individual country, no matter how powerful, can unilaterally generate an effective response to most global challenges. The 2009 Swine Flu pandemic demonstrated the importance of international cooperation in avoiding the reintroduction of this disease into America once the outbreak in the United States was under control.

The way to solve this paradox is not for nation-states to give up, but rather to *share* their sovereignty in order to mobilize international collective action in a way that engages all actors. This, in turn, requires a transformation of the institutional architecture for global health. The basis for this transformation should be a clear allocation of functions to the multiplicity of actors concerned with global health that preserves some sort of global coordination through the main multilateral health agencies.

According to Gostin, these institutions should be guided by five values of good governance. It would be difficult to disagree with his list of values: honesty, transparency, deliberative decision-making, effective performance, and accountability.

The WHO's importance in the institutional framework of global health merits a full chapter. "There is no substitute for the WHO, with its incomparable normative powers and influence," Gostin states.²⁶ However, he also argues that this institution is facing a crisis of leadership, expressed above all in its decreasing capacity to respond to global emergencies. This crisis demands reform, which should include at least the following eight very reasonable proposals. The WHO should: (i) encourage members to become shareholders, "foregoing a measure of sovereignty for the global common good";²⁷ (ii) transform the Organization's internal culture from technical excellence to global leadership; (iii) give voice to stakeholders and harness the creativity of non-state actors; (iv) improve its governance through transparency, performance, and accountability; (v) exert its institutional authority as a normative organization; (vi) increase organizational coherence to ensure a unified voice and policy across headquarters, regions, and countries; (vii) ensure funding that is predictable, sustainable, and scalable to needs; and (viii) exercise leadership in global governance for health by exerting influence within and beyond the health sector.

Gostin discusses four other global actors in detail: the World Bank, the Global Fund, the GAVI Alliance, and the Bill & Melinda Gates Foundation. According to him, these institutions "bring a host of benefits—more funding, an

26. GOSTIN, *supra* note 7, at 89.

27. *Id.* at 115.

enhanced voice for civil society, and innovative ideas—but also a mismatch between health needs and available funds, a fractured approach to health planning and financing, and inadequate leadership and accountability.”²⁸ The arguments presented in this part of the book are somewhat lopsided, especially in regard to the World Bank and the Gates Foundation. The World Bank and its *World Development Report 1993: Investing in Health* are depicted as paradigmatic sources of the neoliberal health policies of the 1990s, which had “a devastating impact on public health.”²⁹ Little praise is offered for the conceptual and methodological contributions that this Report, qualified by *The Lancet* as a landmark document, brought to the health arena.³⁰ Gostin criticizes the Gates Foundation’s passion for technical innovations and points to the problems of governance and accountability that such a powerful actor creates. Fair as these criticisms may sound, this unbalanced discussion unjustly minimizes the impact this philanthropic organization has had on the health conditions of the poor, particularly through its support of efforts such as global immunization and research on diseases of the poor.

III. INTERNATIONAL LAW AND GLOBAL HEALTH

Part three of *Global Health Law* starts with a discussion of the core sources of law in global health—the two major WHO normative treaties (the International Health Regulations (IHR) and the FCTC) and the international human rights law regime—and ends with a thorough analysis of the relationship between trade and health.

The IHR, which govern global health security and remain one of the world’s most widely adopted treaties, date back to the nineteenth century and were last revised in 2005. The IHR aim primarily “to prevent, protect against, control and provide a public health response to the international spread of disease.”³¹ They also deal with the relationship between health, international trade, and human rights. Salient in the discussion of the IHR are the lessons learned from the Swine Flu pandemic, which offered what until recently was the only significant test of

28. *Id.* at 129.

29. *Id.* at 140.

30. Richard Horton & Selina Lo, *Investing in Health: Why, What, and Three Reflections*, 382 LANCET 1859 (2013).

31. *International Health Regulations (2005)*, WORLD HEALTH ORG. 10 (2008), whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf.

the IHR's effectiveness. Gostin concludes that this global emergency showed improvements in global governance, but also revealed important fault lines. For example, many nations failed to adopt certain WHO science-based recommendations regarding trade sanctions, travel restrictions, and coercive public health powers. The recent Ebola outbreak also tested the IHR. The Ebola crisis exposed the inability of global governance arrangements to build the health system envisioned by these regulations. Such a system would require countries "to develop capabilities to detect, assess, report, and respond to global health emergencies."³²

The WHO's most recent treaty is the FCTC. Gostin discusses the damaging effects of tobacco; the strategies of the tobacco industry to promote tobacco consumption; the response of the medical establishment and civil society to "Big Tobacco's dishonesty and deceit"; and, finally, the FCTC itself, "the most innovative international health treaty ever adopted by the World Health Assembly."³³ The chapter ends with a fascinating examination of the strategies for a "tobacco-free world," including a ban on the commercial sale of cigarettes reminiscent of the alcohol prohibition in the United States in the 1920s.

While Gostin analyzes the human rights law regime with a dual focus on civil/political and economic/social rights, his discussion centers on the right to health, which "encompasses health care, public health, and the underlying determinants of health."³⁴ This discussion includes an additional appraisal of the definition of the right to health, as well as its appearance in national constitutions and in litigation. Gostin addresses the debate over the legal interpretation of this right, which was once dismissed by a U.S. Court of Appeals as being part of a group of rights that are "devoid of articulable or discernible standards and regulations."³⁵ Gostin argues that "national litigation demonstrates the justiciability of health rights despite their progressive nature and budgetary implications," and mentions that the most successful cases have involved access to essential services and medicines.³⁶ Regrettably, the budgetary impacts of some of these cases, especially in Brazil and Colombia, are not sufficiently documented. No mention is made of the increasing participation of the pharmaceutical industry in financing some of these lawsuits, especially those in which access to extremely costly medication for uncommon diseases is involved.

32. Lawrence O. Gostin, *Ebola: Towards an International Health Systems Fund*, 384 LANCET e49 (2014).

33. GOSTIN, *supra* note 7, at 209.

34. *Id.* at 259.

35. *Flores v. S. Peru Copper Corp.*, 414 F.3d 233, 255 (2d Cir. 2005) (quoting *Beanal v. Freeport-McMoran, Inc.*, 197 F.3d 161, 167 (5th Cir. 1999)).

36. GOSTIN, *supra* note 7, at 264.

The third part of the book ends with an analysis of the effects of international trade on health and a description of the trade in health services. Emphasis is put on the impacts of trade liberalization on health and the reasonable concern that in this process, the interests of rich countries and multinational corporations may be prioritized over the health and lives of the people of the Global South. Gostin highlights the need for accessible essential vaccines and medicines, and advocates for the inclusion of domestic public health as a priority for the World Trade Organization. Indeed, he concludes that the global discussion should strike a balance between trade and health. “A fair and vibrant trade system would raise everyone’s standard of living, which would benefit global health and development,” he says.³⁷ “At the same time,” he adds, “a healthy population is more creative and productive, which bodes well for trade and investment.”³⁸

IV. THE QUEST FOR GLOBAL SOCIAL JUSTICE

The final part of this book is devoted to four crucial topics of global health—the HIV/AIDS pandemic, international migration of health workers, pandemic influenza, and the ‘silent’ pandemic of NCDs—and to an exciting and comprehensive reflection on the road to a world with global health justice.

The chapter “Imagining Global Health with Justice” attempts to respond to three strategic questions: (i) To what level of health should we aspire and with what provision of health-related services? (ii) What would global health justice look like? and (iii) What would it take to achieve global health with justice?

Gostin wisely states that no government or institution can guarantee complete physical and mental wellbeing. What governments can guarantee—and that should be the goal of global health—are the conditions in which people can be healthy. This requires public health or community services, essential personal health services accessible to all, and interventions that address the socioeconomic determinants of health.

In trying to answer the second question, Gostin brings up a topic also raised by the WHO framework for assessing health system performance: the need to improve not only the general level of population health but also its distribution.³⁹ Gostin states that health institutions have focused on the general level of major health indicators, such as life expectancy and infant and maternal mortality. He

37. *Id.* at 301.

38. *Id.*

39. Christopher J.L. Murray & Julio Frenk, *A Framework for Assessing the Performance of Health Systems*, 78 BULL. WORLD HEALTH ORG. 717 (2000).

rightly argues that we should move beyond this approach to close the gaps that exist in health conditions between the well-off and the poor. “Global health with justice,” he says, “demands that society embed fairness into the environment in which people live and equitably allocate services, with particular attention to the needs of the most disadvantaged.”⁴⁰ Gwatkin and Ergo captured this idea when they coined the concept of “progressive universalism,” which refers to the expansion of comprehensive health services through the implementation of measures that benefit the poor first.⁴¹ According to these two authors, the Family Health Program in Brazil and *Seguro Popular* in Mexico were both designed to increase coverage first among disadvantaged groups instead of taking the traditional approach of serving the rich, who are easier to reach.

Finally, in answering the third question, Gostin states that good governance is critical to achieving global health with justice. Good governance includes establishing clear and rigorous targets, monitoring progress, and ensuring accountability for results.

Global Health Law ends with a discussion of Gostin’s ambitious proposal for a Framework Convention on Global Health. The design of this framework could draw upon the much-praised FCTC. The goal of this novel Convention would be gradually to create the conditions to guarantee the effective exercise of the right to health and to reduce health inequities. Gostin’s framework would represent a “New Deal” for global health.

In sum, *Global Health Law* is a book that will likely become a classic. It provides an ordered, thoughtful, and comprehensive approach to a nascent field of scholarship and practice. In this regard it will be particularly useful for education. It affords useful insights into global governance challenges. Most importantly, it offers reasonable policy and legal answers to the practical dilemmas faced by those interested in improving global health with a special focus on the timeless aspiration for social justice.

40. GOSTIN, *supra* note 7, at 413.

41. Davidson R. Gwatkin & Alex Ergo, *Universal Health Coverage: Friend or Foe of Health Equity?*, 377 LANCET 2160, 2161 (2011).