TABLE OF CONTENTS

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ARTICLES

Civil Rights Enforcement in the Modern Healthcare System: Reinvigorating the Role of the Federal Government in the Aftermath of *Alexander v. Sandoval*

Sara Rosenbaum, J.D.*

Joel Teitelbaum, J.D., LL.M.†‡

On occasion, a decision by the United States Supreme Court in the area of federal civil rights law invites a profound rethinking of rights, remedies, and enforcement under federal law. Faced with such an invitation, the federal authorities charged with civil rights enforcement have often risen to the challenge and responded vigorously. For example, in 1999, the Supreme Court held in *Olmstead v. L.C.* that the medically unjustifiable institutionalization of persons with disabilities under publicly administered programs constitutes discrimination under the Americans with Disabilities Act.[1] The Court ordered that steps be taken toward

* Chair, Department of Health Policy and Hirsh Professor of Health Law and Policy, The George Washington University School of Public Health and Health Services.

† Assistant Research Professor of Health Policy and Managing Director, Hirsh Health Law and Policy Program, The George Washington University School of Public Health and Health Services. The authors are indebted to Grace Culley, Belinda Tilley, and Mandy Bartoshesky, candidates in the joint law-public health degree program at The George Washington University, for their research assistance in the preparation of this Article.

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1. 527 U.S. 581 (1999).

community integration "at a reasonable pace."[2] Within days of the decision, the Secretary of the Department of Health and Human Services (HHS) acknowledged the importance of the case in an unprecedented letter to the nation's governors;[3] within months, federal involvement by the Clinton Administration had dramatically expanded.[4] The Secretary instructed both the HHS Office for Civil Rights (OCR) and the Centers for Medicare and Medicaid Services (CMS; then the Health Care Financing Administration) to pursue active implementation strategies, which would include the issuance of interpretive guidelines, technical assistance to aid state compliance, expanded training of federal agency staff, and an aggressive program of internal assessment to determine the extent to which existing federal policies impeded community integration.[5] The incoming Bush Administration continued this national focus on disability rights through executive orders,[6] assessments of the performance of federal programs, and new initiatives to promote community integration.[7]

If the executive branch's follow-up to *Olmstead* stands out as a model of responsiveness, its reaction to the recent Supreme Court ruling in

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2. *Id.* at 605–06. *See also* Sara Rosenbaum, *The* Olmstead *Decision: Implications for State Health Policy*, HEALTH AFF., Sept./Oct. 2000, at 228. We note that *Olmstead*'s implications for private conduct relating to the provision of employer-sponsored health and disability benefits are under review by various federal courts. *See, e.g.*, Johnson v. K-Mart Corp., No. 99-14563, 2001 U.S. App. LEXIS 24923 (11th Cir. Dec. 19, 2001), *reh'g granted*, 273 F.3d 1035 (11th Cir. 2001).

3. Letter from Timothy M. Westmoreland, Director, Center for Medicaid and State Operations, Health Care Financing Administration, & Thomas Perez, Director, Office for Civil Rights, to State Medicaid Directors (Jan. 14, 2000), *available at* http://www.hhs.gov/ocr/olms0114.htm (last visited May 29, 2002).

4. From the time it was handed down, *Olmstead* was understood to be of great moment in the administration of public programs, as evidenced by the highly publicized reaction of federal and state officials. *See, e.g.*, Donna E. Shalala, Health Care Challenges for the New Millennium, Address at the National Conference of State Legislators (Jul. 28, 1999), *available at* http://www.hhs.gov/ocr/olmstead.htm (last visited May 29, 2002) (encouraging state legislators to invest the "time, effort, creativity and commitment" required to implement the *Olmstead* decision).

5. Kathleen A. Maloy, Alexandra Stewart & Sara Rosenbaum, Beyond *Olmstead v. L.C.*: An Assessment of HHS/OCR's Efforts to Implement a Community Integration Goal (May 2002) (unpublished manuscript, on file with the authors) (prepared for the HHS Office for Civil Rights).

6. *See, e.g.*, Exec. Order No. 13217, 66 Fed. Reg. 33,155 (June 19, 2001), *available at* http://www.whitehouse.gov/news/releases/2001/06/20010619.html (last visited May 29, 2002).

7. *Id.*

Alexander v. Sandoval[8] is just the opposite—a model of inaction and neglect. No case in recent memory has more urgently demanded the attention of the officials charged with the administration of civil rights laws in the context of federally funded programs. In *Sandoval*, a 5-4 majority held that individuals who allege disparate impact (*de facto*) discrimination under Title VI of the Civil Rights Act of 1964 (the Act),[9] which outlaws discrimination by programs receiving federal financial assistance, have no private cause of action to enforce their rights.[10] Although *Sandoval* left federal agencies with the exclusive province to enforce prohibitions against disparate-impact discrimination under Title VI, the response from HHS—the key enforcement agency for federally assisted health and human services programs—was virtual silence.[11] A search of news articles reporting on the decision failed to turn up a single statement from civil rights officials regarding the expanded importance of federal oversight obligations in the wake of *Sandoval*.[12] Similarly, the Bush Administration's

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8. 532 U.S. 275 (2001).

9. 42 U.S.C. § 2000a. Title VI, 42 U.S.C. § 2000d, prohibits discrimination on the basis of race, color, or national origin by programs and activities that receive federal financial assistance ("No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance.").

10. 532 U.S. at 293.

11. One noteworthy example of this silence is the Department of Justice's revision of policy guidance—since the time *Sandoval* was handed down—concerning the prohibition against national origin discrimination affecting persons with limited English proficiency (LEP). *See* Notice of Republication, Policy Guidance on the Prohibition Against National Origin Discrimination As It Affects Persons with Limited English Proficiency, 67 Fed. Reg. 4968 (Feb. 1, 2002). The revised guidance is notable for its utter lack of discussion in Section VIII of *Sandoval*'s implications for the Department's civil rights enforcement responsibilities. Moreover, the Department elsewhere asserts that compliance with its anti-discrimination directive is purely voluntary. *See* Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 67 Fed. Reg. 19,237 (Apr. 18, 2002), *available at* http://www.usdoj.gov/crt/cor/lep/DOJLEPGuidApr122002.htm (last visited May 29, 2002) (noting that "[t]he goal for Title VI and Title VI regulatory enforcement is to achieve voluntary compliance").

12. According to a search of Lexis-Nexis databases, in the first three months following the decisions, eighteen major newspapers ran *Olmstead* articles, while twenty ran *Sandoval* stories. Of all news outlets, eighty-two articles discussed the *Olmstead* decision, compared with eighty-five *Sandoval* stories. Nine months after each of the two rulings, again analyzing all news outlets, 137 articles covered *Olmstead*, while 117 discussed *Sandoval*. Putting aside the apparent similar newsworthiness of the two decisions, it is worth noting that there has

Fiscal Year 2003 budget request for civil rights enforcement in health care (the first presidential budget proposal following the *Sandoval* decision) contains no suggestion of the increased importance of federal civil rights enforcement activities following the decision.[13]

The failure of the federal government to respond vigorously to the *Sandoval* decision, as it vigorously responded to *Olmstead*, threatens to deepen a crisis of confidence regarding the willingness of society at large to decisively address one of the most fundamental problems in United States health policy—that of racial and ethnic discrimination.[14] The federal government's failure to respond to *Sandoval* grew more striking following the Spring 2002 release of the Institute of Medicine's (IOM) landmark study *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care*.[15] That study documented the pervasive nature of "racial or ethnic differences in the quality of healthcare that are not due to access-related factors or clinical needs, preferences and appropriateness of intervention."[16] The IOM study goes to the heart of the problem, namely the widespread and systemic discriminatory conduct within the United States health care system that begins at the point of entry and continues throughout the secondary and tertiary pathways of the system.[17] It is precisely this sort of systemic problem that Title VI was enacted to prevent.

This Article examines the *Sandoval* decision and its implications for federal civil rights enforcement activities in the modern health care system. Part I presents an overview of Title VI, examining the rights and obligations it creates as well as its federal enforcement and oversight

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been no suggestion we could find that the contrasting executive branch responses to *Sandoval* and *Olmstead* stemmed from the fact that somehow the net effect of the two cases in a health care context is different; both involve discrimination against a protected sub-population for reasons wholly unrelated to the appropriateness of care.

13. Indeed, HHS/OCR's budget request sought an overall increase that roughly approximated a nominal increase for inflation. *See* Office for Civil Rights, *FY2003 Budget, available at* http://www.hhs.gov/ocr/fy03budget.html (last visited May 29, 2002).

14. *See* discussion *infra* Part II.

15. INST. OF MED., UNEQUAL TREATMENT: CONFRONTING RACIAL AND ETHNIC DISPARITIES IN HEALTH CARE (Brian D. Smedley et al. eds., 2002) [hereinafter UNEQUAL TREATMENT].

16. *Id.* at 4.

17. For evidence corroborating the IOM findings, see, for example, HENRY J. KAISER FAMILY FOUND., KEY FACTS: RACE, ETHNICITY AND MEDICAL CARE (1999); MOREHOUSE MED. TREATMENT EFFECTIVENESS CTR., A SYNTHESIS OF THE LITERATURE: RACIAL AND ETHNIC DIFFERENCES IN ACCESS TO MEDICAL CARE (Robert M. Mayberry et al. eds., 1999); Kathryn A. Phillips et al., *Barriers to Care Among Racial/Ethnic Groups Under Managed Care*, HEALTH AFF., July/Aug. 2000, at 65.

structure. We also briefly review the history of private litigation attempting to enforce Title VI in a health care context. Part II examines the existing federal administrative system for enforcing Title VI and reviews evidence regarding the HHS Office for Civil Rights's ability to enforce anti-discrimination law. In Part III, we discuss *Sandoval* and examine the Supreme Court's reasoning in departing from longstanding principles of civil rights jurisprudence.

Finally, we argue in Part IV that regardless of whether Congress reverses *Sandoval* through legislation, there is an enormous need for a fundamental restructuring of federal civil rights oversight activities. With federal spending dominating a health system that is growing ever more complex, there is a compelling need to unequivocally grant civil rights enforcement responsibilities to the federal agencies with the power to make expenditure decisions. These agencies should not only investigate and sanction, but also set the standards for the entities that they oversee. This structural change is particularly important given that these agencies control the distribution of hundreds of billions of dollars to public and private entities ranging from state and local government agencies to the nation's leading teaching hospitals, research and training programs, and health care corporations.

I. AN OVERVIEW OF TITLE VI AND ITS ENFORCEMENT

The Civil Rights Act of 1964,[18] of which Title VI is a part, was a critical development in the evolution of American social policy. The Act created a broad remedial structure to end discrimination in employment, places of public accommodation, and programs and activities (including health care providers and programs) that receive federal financial assistance.[19] Because it derives from Congress' powers under the Spending Clause of the Constitution,[20] Title VI does not reach purely private conduct, such as the

18. Pub. L. No. 88-352, 78 Stat. 253 (codified as amended at 42 U.S.C. § 2000a (1994)).

19. Nearly thirty years after passage of the 1964 Act, the Americans with Disabilities Act of 1990 would classify private health care providers as places of public accommodation, a step that signaled a profound evolution in societal expectations of the health system and its basic accountability. *See* Americans with Disabilities Act, 42 U.S.C. § 12182 (1990); Bragdon v. Abbott, 524 U.S. 624 (1998).

20. U.S. CONST. art. I, § 8, cl. 1. We note parenthetically that Spending Clause legislation, including Title VI, is critical to the preservation and protection of civil rights given the current Supreme Court's inclination to strike down on federalism grounds congressional pronouncements based on the Commerce Clause. *See, e.g.*, U.S. v. Morrison, 529 U.S. 598 (2000); U.S. v. Lopez, 514 U.S. 549 (1995). Indeed, "[t]he Spending Clause is

activities of health professionals who do not directly participate in government insurance programs.[21] But the reach of federal funding in the U.S. health care system is so enormous that very little of the modern health care enterprise lies beyond the scope of Title VI.[22]

The legislative history of Title VI indicates that health care was prominent in the minds of its authors. The history also reveals that all forms of discrimination in health care—both deliberate acts of discrimination and conduct that unintentionally results in harm to racial minorities—were a driving force behind the law's enactment.[23]

Moreover, passage of the 1964 Act was contemporaneous with the judicial ruling in *Simpkins v. Moses H. Cone Memorial Hospital*,[24] which found unconstitutional a key portion of the Hospital Survey and Construction Act of 1946 (known as the Hill-Burton Act),[25] which had authorized the use of federal funds to construct and operate segregated health care facilities.[26] With the enactment of Medicare and Medicaid the following year, the federal government's power to use federal financial participation to force an end to discriminatory treatment was seemingly limitless.[27]

In this Part, we first review key terms under Title VI with an emphasis

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perhaps the clearest method of avoiding constitutional challenges to congressional acts under the Commerce Clause or Tenth Amendment." Julian Epstein, *Evolving Spheres of Federalism After* U.S. v. Lopez *and Other Cases*, 34 HARV. J. ON LEGIS. 525, 553 (1997) (footnotes omitted). It is for this reason that scholars have advocated that Congress use its spending power to expand the scope of its civil rights enforcement power. *See, e.g.*, Daniel O. Conkle, *Congressional Alternatives in the Wake of* City of Boerne v. Flores: *The (Limited) Role of Congress in Protecting Religious Freedom from State and Local Infringement*, 20 U. Ark. Little Rock L.J. 633, 668 (1998).

21. *See* Sidney D. Watson, *Reinvigorating Title VI: Defending Health Care Discrimination—It Shouldn't Be So Easy*, 58 FORDHAM L. REV. 939, 944 (1990).

22. Thomas E. Perez, *The Civil Rights Dimensions of Racial and Ethnic Disparities in Health Care, in* UNEQUAL TREATMENT, *supra* note 15, at 362–90.

23. CIVIL RIGHTS DIV., U.S. DEP'T OF JUSTICE, TITLE VI LEGAL MANUAL (2001), *available at* http://www.usdoj.gov/crt/cor/coord/vimanual.htm (last visited July 5, 2003); DAVID BARTON SMITH, HEALTH CARE DIVIDED: RACE AND HEALING A NATION (1999).

24. Simkins v. Moses H. Cone Mem'l Hosp., 323 F.2d 959 (4th Cir. 1963).

25. Pub. L. No. 88-443, § 3(a), 78 Stat. 447 (codified as amended at 42 U.S.C. §§ 291. (2003)).

26. SMITH, *supra* note 23, at 101–03.

27. Indeed, as David Barton Smith, *supra* note 23, recounts in his exceptional book detailing the history of this country's racially divided health care system, so powerful was the nexus between Title VI and Medicare that the existence of Title VI threatened Medicare's passage because of opposition by some Southern senators to such a huge expansion of civil rights authority into the health system. *Id.*

on their application to health care. We then describe the mechanisms for public enforcement of Title VI. Finally, we examine private enforcement under Title VI.

A. Key Terms in Title VI

The provisions of Title VI prohibit discrimination on the basis of race, color, or national origin by programs and activities that receive federal financial assistance. Section 601 of the Act provides that "[n]o person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance."[28] Section 602 "authorize[s] and direct[s]" federal agencies to "effectuate the provisions of section 601" by promulgating and enforcing "rules, regulations, or orders of general applicability."[29] The law thus imposes on federal agencies a duty to act, not merely the discretion to do so. As a result, federal regulations set forth an administrative enforcement mechanism that authorizes federal agencies to set non-discrimination standards, investigate claims of discrimination, and terminate federal assistance to any entity that is found to have violated the law.[30]

The term "discrimination" is not defined in Title VI; under the statute, each federal agency that oversees programs of federal financial assistance must promulgate regulatory standards—which would include a definition of discrimination—to enforce the law. Early efforts to produce a common set of standards regarding discrimination across all federal agencies offering federal financial assistance led to a series of twenty-two sets of rules that stemmed from a model initially developed for the U.S. Department of Health, Education and Welfare (the predecessor agency to HHS).[31] The rules, which remain in force and virtually unchanged, extend beyond acts of intentional discrimination and reach conduct and practices that, even if facially neutral, have a disproportionate adverse impact on members of minority groups. In the case of health and human services, federal regulations use in part the following broad language to identify prohibited activities:

A recipient, in determining the types of services, financial aid, or other

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28. Pub. L. No. 88-352, § 601, 78 Stat. 252 (codified at 42 U.S.C. § 2000d (2003)).

29. 42 U.S.C. § 2000d-1.

30. 28 C.F.R. §§ 42.101–.412 (2001); *see also* Guidelines for the Enforcement of Title VI, 28 C.F.R. § 50.3 (2001).

31. Watson, *supra* note 21, at 947-48.

> benefits, or facilities which will be provided under any such program, or the class of individuals to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program, or the class of individuals to be afforded an opportunity to participate in any such program, may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which *have the effect* of subjecting individuals to discrimination because of their race, color, or national origin, *or have the effect* of defeating or substantially impairing accomplishment of the objectives of the program as respect individuals of a particular race, color, or national origin.[32]

These standards were designed to target relevant conduct while still being sufficiently flexible to retain their force over time.[33] For example, in their prohibition of discrimination either directly or through contractual arrangements, the regulations would appear to apply not only to traditional health care entities such as hospitals, nursing homes, and other "brick and mortar" institutions,[34] but also to modern managed care entities that function as insuring intermediaries with contractually networked providers.[35] Despite the vast changes in the U.S. health system that have occurred since the promulgation of these regulations, it is evident that they retain sufficient vigor to reach all types of federally assisted agencies and entities operating directly or by contract, regardless of whether they are housed in single facilities or scattered across a community through far-flung service networks.

Because the American health care system is overwhelmingly privately owned and operated, it is essential in a discussion of Title VI to understand the meaning of the terms "federal financial assistance," "recipient," and "program or activity." The Department of Justice explains that "federal financial assistance includes more than money" and may include such benefits as the use of federal land and the lending of federal personnel.[36] Federal financial assistance does not include contracts of guarantee or insurance, or direct payments to individuals, but the term does include contracts that have as a purpose the provision of federal financial assistance.[37] For example, a contract between a state Medicaid program and

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32. 45 C.F.R. § 80.3(b)(2) (2001) (emphasis added).

33. Watson, *supra* note 21, at 947.

34. *See, e.g.*, NAACP v. Wilmington Med. Ctr., Inc., 491 F. Supp. 290 (D. Del. 1980).

35. *See* RAND E. ROSENBLATT ET AL., LAW AND THE AMERICAN HEALTH CARE SYSTEM 584 (1997).

36. CIVIL RIGHTS DIV., *supra* note 23, at 16–20.

37. *Id.*

a managed care organization to serve Medicaid beneficiaries may be covered by Title VI.[38] Other examples include federal payments to Medicare+Choice managed care organizations, payments to health professions teaching programs, and federal research grants.

Beyond the breadth of the term "federal financial assistance," the reach of Title VI is further expanded because of the related concepts of "recipient" and "program or activity." The Justice Department notes that under federal rules a "recipient" can be "any State, political subdivision of any State, or instrumentality of any State or political subdivision."[39] The term "recipient" also covers "any public or private agency, institution, or organization, or other entity . . . to whom federal financial assistance is extended. . . ."[40] The concept of "program or activity" has been interpreted broadly as well so that it subjects an entire entity to Title VI, not merely the portion that receives federal financial assistance.[41] Thus, for example, federal student loan payments to a university are sufficient to establish a nexus between Title VI and all university operations, not merely those activities specifically undertaken with, or in furtherance of, the student loan program. In other words, the presence of federal program beneficiaries within a larger enterprise that also serves private-pay individuals is sufficient to subject the entire enterprise to federal anti-discrimination law. The underlying theory of this interpretation of the law, reinforced by Congress in the Civil Rights Restoration Act of 1987,[42] is that when federal funds flow to a large enterprise, the funds help support the entire enterprise, not merely a specific element.

It was not an accident in the history of Title VI that Medicare payments to private physicians are not considered as federal financial participation. In his excellent history of Title VI and its enforcement in a health care context, David Barton Smith notes that, in the face of Southern opposition to the application of Title VI to Medicare, the Johnson Administration, in order to secure Medicare's enactment, effectively promised to exempt physicians from Title VI enforcement actions by classifying Medicare Part B payments as direct assistance to individuals, rather than as federal financial

38. Office for Civil Rights, U.S. Dep't of Health and Human Srvcs., *Fact Sheet, Your Rights Under Title VI of the Civil Rights Act of 1964, available at* http://www.dhhs.gov/ocr/title6.html (last visited May 29, 2002) (noting that Medicare and Medicaid may be programs covered by Title VI).

39. 28 C.F.R. § 42.102(f) (2001); CIVIL RIGHTS DIV., *supra* note 23, at 20.

40. 28 C.F.R. § 42.102(f) (2001).

41. CIVIL RIGHTS DIV., *supra* note 23, at 25.

42. Pub. L. No. 100-259, 102 Stat. 28 (1988) (codified as amended at 20 U.S.C. §§ 1681–88 (1994)).

assistance to physicians.[43] This promise effectively eliminated a principal basis of Title VI jurisdiction over the conduct of private physicians. The logic of this position flowed from Medicare's original structure as, by and large, an indemnifier of individual patients for payments made to private physicians for covered services. Medicare's evolution has, of course, eclipsed this original model; today, physicians overwhelmingly receive Medicare payments directly, and in its 2000 Limited English Proficiency guidelines, OCR classified Medicare payments as a form of federal financial assistance, suggesting an end to this longstanding policy of exemption for physicians.[44]

B. Public Enforcement of Title VI

Given the broad scope of Title VI, administrative agencies have developed mechanisms to enforce compliance with Title VI's terms. In this Section, we describe these mechanisms. In Part II, we embark upon a more focused look at the enforcement mechanisms specific to the health care context in an effort to expose their deficiencies.

An individual who chooses to use Title VI's administrative enforcement machinery begins the process by filing an administrative complaint with the appropriate federal agency.[45] Where federal health programs are at issue, this agency is the HHS Office for Civil Rights (OCR), which, under the organizational rules of the Department, is granted authority to investigate violations of civil rights law. Federal rules provide that an agency "will make a prompt investigation whenever a . . . complaint . . . indicates a possible failure to comply with [Title VI requirements]."[46] If an official investigation indicates a failure to comply, "the responsible Department official . . . will so inform the recipient and the matter will be resolved by informal means whenever possible."[47] If the agency determines that the matter cannot be resolved informally, then judicial action "will be taken."[48] On the other hand, if the official investigation concludes that no action is warranted, the agency must inform the complainant and recipient of this result.[49]

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43. SMITH, *supra* note 23, at 115–28.

44. Policy Guidance on the Title VI Prohibition Against National Origin Discrimination As It Affects Persons With Limited English Proficiency, 65 Fed. Reg. 52,762 (Aug. 30, 2000).

45. 28 C.F.R. § 42.107(b) (2001).

46. *Id.* § 42.107(c).

47. *Id.* § 42.107(d)(1).

48. *Id.*

49. *Id.* § 42.107(d)(2).

The power assigned to federal agencies under Title VI extends beyond the task of investigating individual complaints. Under the express terms of Section 602, this power includes the authority (if not a legally enforceable public duty)[50] to set rules of general applicability that provide recipients of federal financial assistance with standards for achieving compliance under the law. Under both the Act and normal principles of administrative law, federal agencies have the discretion to promulgate generally applicable rules of conduct that define the obligations and duties of recipients of federal financial assistance. To bolster their enforcement power, federal agencies require that all recipients of federal financial assistance file assurances of compliance with the terms of Title VI.[51]

Title VI administrative enforcement procedures thus vest federal agencies with considerable discretion to design, implement, and evaluate civil rights enforcement standards and procedures, with duties ranging from issuing policies to investigating specific incidents.[52]

C. Private Enforcement of Title VI

Like much of the legislation of its time, Title VI was silent on the issue of whether private individuals who had suffered discrimination by covered entities could bring lawsuits to enforce their rights under the law. However, until the *Sandoval* decision, many federal courts had inferred a private right of action under the law to enforce the legal protections contained in both the statute itself and its implementing regulations.[53] The

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50. Of course, whether individual claimants could actually enforce this duty is another matter. For example, in *Madison-Hughes v. Shalala*, 80 F.3d 1121 (6th Cir. 1996), plaintiffs were unsuccessful in a suit against the federal government in which they sought to compel the government to include queries as to the race and ethnic identity of patients on a standard billing form used by health care institutions seeking reimbursement from federally sponsored health programs.

51. 28 C.F.R. § 42.105(a) (2001).

52. The United States Commission on Civil Rights has extensively described the scope of this discretion in its 1999 study of discrimination in health care. 2 U.S. COMM'N ON CIVIL RIGHTS, THE HEALTH CARE CHALLENGE: ACKNOWLEDGING DISPARITY, CONFRONTING DISCRIMINATION, AND ENSURING EQUALITY 17–49 (1999). The report is discussed *infra* Part II.

53. Indeed, every federal Court of Appeals to address the question prior to *Sandoval* concluded that a private right of action exists to enforce the rights guaranteed both by the text of Title VI and by any regulations validly promulgated pursuant to that Title. *See, e.g.*, Powell v. Ridge, 189 F.3d 387, 400 (3d Cir. 1999); Ferguson v. Charleston, 186 F.3d 469 (4th Cir. 1999), *rev'd on other grounds*, 532 U.S. 67 (2001); Sandoval v. Hagan, 197 F.3d 484 (11th Cir. 1999); Chester Residents Concerned for Quality Living v. Seif, 132 F.3d 925, 936–37 (3d Cir. 1997), *vacated*, 524 U.S. 974 (1998); Buchanan v. Bolivar, 99 F.3d 1352, 1356 n.5

distinction between protections found in the statute and those created by regulations is important because the two reach distinct types of conduct. The statute prohibits disparate treatment, which encompasses claims of intentional discrimination. A disparate treatment claim requires proof of motive, which can be inferred from circumstances surrounding the defendant's conduct (for example, requiring all African-American or Latino patients to prepay certain tests or procedures that otherwise are furnished to patients on a "bill later" basis).

The second type of conduct, prohibited by the regulations implementing Title VI and termed "disproportionate adverse impact" discrimination, is the sort at issue in the *Sandoval* case. It focuses on conduct that is facially neutral but falls more heavily on members of minority groups and cannot be justified by the defendant.[54] Claims of this type involve allegations that a recipient of federal financial assistance, "in violation of federal regulations," has used a "neutral procedure or practice" that has a "disparate impact on protected individuals, and such practice lack[ed] a substantial legitimate justification."[55] In a disparate impact case, the focus is thus on the *consequences* of the conduct, rather than the recipient's intent.

As with other laws that proscribe certain conduct, Title VI enforcement turns on the basic elements of the claim, the permissible defenses, and the allocation of the burden of proof between the parties. Because Title VI and its regulations outlaw both intentional discrimination and facially neutral conduct having a disproportionate adverse impact, the defenses and burdens of enforcement depend on the nature of the claim.[56] Title VI health care cases have never been particularly common, nor particularly successful. Numerous reviews of the use of Title VI in health care discrimination cases have offered the same explanation: the manner in which burdens are allocated under Title VI litigation and the difficulty

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(6th Cir. 1996); Villanueva v. Carere, 85 F.3d 481, 486 (10th Cir. 1996); New York Urban League, Inc. v. New York, 71 F.3d 1031, 1036 (2d Cir. 1995); David K. v. Lane, 839 F.2d 1265, 1274 (7th Cir. 1988); Latinos Unidos De Chelsea v. Sec'y of Hous. & Urban Dev., 799 F.2d 774, 785 n.20 (1st Cir. 1986); Castaneda v. Pickard, 781 F.2d 456, 465 n.11 (5th Cir. 1986); Larry P. v. Riles, 793 F.2d 969, 981–82 (9th Cir. 1986).

54. Watson, *supra* note 21, at 948–49; CIVIL RIGHTS DIV., *supra* note 23, at 34.

55. CIVIL RIGHTS DIV., *supra* note 23, at 34.

56. *See generally* Daniel Hampton, *Title VI Challenges by Private Parties to the Location of Health Care Facilities: Toward a Just and Effective Action*, 37 B.C. L. REV. 517 (1996); Sara Rosenbaum et al., *U.S. Civil Rights Policy and Access to Health Care by Minority Americans: Implications for a Changing Health Care System*, 57 MED. CARE RES. & REV. 236 (2000).

plaintiffs face in meeting the burdens.[57]

In disparate treatment claims (i.e., claims of intentional discrimination), "smoking gun" evidence of discriminatory motive is rare, so plaintiffs typically rely on circumstantial evidence. Disparate treatment cases often involve a "three-step proof model" that focuses on "circumstantial evidence in an effort to uncover the defendant's true motive."[58] The three steps are the plaintiff's presentation of *prima facie* evidence that discrimination exists, the defendant's rebuttal of the evidence based on any legitimate reason for its existence, and finally the plaintiff's attempt to prove that the defendant's proffered basis is but a pretext cloaking a discriminatory motive. As with other state-of-mind offenses, proving motive (and therefore prevailing as a plaintiff) is extremely difficult.

In disproportionate adverse impact cases, the impact of the conduct and not the motive is at issue, and the goal is to identify and remove barriers that unnecessarily produce disproportionate adverse results for a protected minority group.[59] Again, there is a three-step test. The first step resembles that in a disproportionate treatment claim: A plaintiff makes out a *prima facie* case through statistical evidence that a facially neutral barrier has a disproportionate impact on a protected group. In health care, examples of these barriers include a defendant hospital's decision to place a limit on its number of Medicaid beds,[60] to relocate its facilities to a wealthier neighborhood,[61] or to refuse to participate in the Medicaid program altogether.[62] The defendant then has the burden of justifying the alleged discriminatory practice by arguing that it serves a legitimate goal. For example, in a non-participation case, a defendant might show that Medicaid rates are so low in relation to the cost and financial risks of patient care that participation would generate significant financial losses for the institution. In a relocation case, the defendant might show that a

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57. *See, e.g.*, Hampton, *supra* note 56; Rosenbaum et al., *supra* note 56; Watson, *supra* note 21.

58. Watson, *supra* note 21, at 956.

59. Watson, *supra* note 21. In a health care context, examples of such barriers include using patient co-payments as a condition of receiving treatment, or designing physician office hours based on patient insurance status (*e.g.*, by only permitting Medicaid beneficiaries access to a physician's office on particular days of the week or during particular times during the day).

60. *See, e.g.*, Linton v. Carney, 779 F. Supp. 925 (M.D. Tenn. 1990).

61. *See, e.g.*, Bryan v. Koch, 627 F.2d 612 (2d Cir. 1980); Wilmington Gen. Hosp. v. Manlove, 174 A.2d 135 (Del. 1961).

62. *See, e.g.*, Cook v. Ochsner Found. Hosp., 319 F. Supp. 603 (E.D. La. 1970).

move was necessary as a response to a basic shift in the institution's essential economic base. Similarly, a decision to close clinics in a poor neighborhood as part of a move might be defended as necessary to improve revenues and achieve greater operational efficiency.[63]

If the defendant makes the requisite showing of legitimate purpose, the plaintiff may rebut this defense by demonstrating a plausible alternative policy with less adverse disparate impact. While demonstrating the feasibility of a less adverse alternative is not as difficult as proving motive and pretext in a disparate treatment case, the burden on the plaintiff remains very steep. Since plaintiffs lack the business and marketing knowledge relevant to assessing defendants' choices, placing the burden of ascertaining the range of options on the plaintiff creates an enormous obstacle. This is particularly true in the case of private health care enterprises, where the responsibility to show the existence of realistic business alternatives requires a highly sophisticated analysis of business practices and access to huge amounts of data specific to the defendant's business.

To allow a recipient of federal assistance to defend *de facto* discriminatory practices as simply furthering a "legitimate" business goal (for example, the all-purpose legitimate goal of making an acceptable return on investment) means that plaintiffs are effectively placed in the position of having to contest the basic assumptions of the enterprise itself. In the absence of federal standards that describe a range of legitimate approaches and require conformity as a condition of federal funding, the courts have in effect assigned to private plaintiffs the task of second-guessing business decisions even though they lack access to the evidence needed to complete this task.[64]

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63. *See, e.g.*, Bryan v. Koch, 627 F.2d 612 (2d Cir. 1980); Cook v. Ochsner Found. Hosp., 319 F. Supp. 603 (E.D. La. 1970).

64. There is one example of an enforcement approach that involves the setting of prospective standards identifying the range of legitimate responses by federal recipients to their federal duties under Title VI. In 2000, the Health and Human Services Office for Civil Rights issued limited English proficiency guidelines that provided relatively detailed instructions to recipients of federal financial assistance (including agencies and health institutions) regarding approaches to compliance. Nondiscrimination Under Programs Receiving Federal Assistance Through the Department of Health and Human Services; Effectuation of Title VI of the Civil Rights Act of 1964, 45 C.F.R. pt. 80 (2000). The guidelines were immediately and aggressively challenged by a broad coalition of provider organizations and associations, but have remained in effect nonetheless. In its effort to both identify a major activity (i.e., the availability of services in a language other than English) on the part of federal financial assistance recipients and describe the range of responses to this

Plaintiffs in the few Title VI health care cases that have been litigated over the years have tended not to fare well.[65] In cases in which a plaintiff has been able to prove discriminatory impact on the basis of practices aimed at minority and non-minority patients receiving health care in the same geographic market, there have been victories. Thus, for example, separating hospital beds on the basis of insurance status or program in the same facility, or limiting the number of Medicaid beds in a single nursing facility, might amount to a successful case, since within the same service area there is an identifiable practice (i.e., separating patients by payer source) that has a disproportionate adverse impact on protected individuals. Yet even here it might be possible for a defendant to show a legitimate business reason for the practice.[66]

In cases involving market relocation or avoidance, plaintiffs have generally lost.[67] It is difficult to contest a defendant's decision to move because of underlying socioeconomic changes and shifts in neighborhoods; similarly, it is very difficult to force a business to relocate to a money-losing market. In health care, this mixing of financial opportunities with discrimination is complicated by the fact that minority patients disproportionately are uninsured or rely on Medicaid, a notoriously poor health care payer.[68] Were Medicaid a good payer, a decision to move away from or avoid serving Medicaid patients might be questioned. But where Medicaid pays poorly, the need to avoid financial loss arguably leaves defendants no alternative but to flee the market or shift costs onto other payers, which is hardly a sound business practice.

For all of the reasons discussed, particularly the heavy burdens plaintiffs face in making their cases, private enforcement of Title VI is extremely difficult. We now discuss whether public enforcement of civil rights law in the health care setting has met with greater success.

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duty that would be considered acceptable, OCR attempted to do what individual plaintiffs in civil rights actions cannot do, namely, underscore the availability of options for conducting business that are calculated to minimize adverse impacts. This example of proactive guidance from the government stands in stark contrast to the basic record of inaction.

65. Rosenbaum et al., *supra* note 56; Watson, *supra* note 21.

66. Perez, *supra* note 22.

67. Rosenbaum et al., *supra* note 56.

68. *See* Stephen Norton & Stephen Zuckerman, *Trends in Medicaid Physician Fees, 1993-1998*, HEALTH AFF., July/Aug. 2000, at 222.

II. THE CHALLENGE OF FEDERAL ENFORCEMENT OF TITLE VI

In this Part, we examine the scope and power of governmental enforcement by providing a brief review of where matters stood *vis-à-vis* Title VI enforcement at the time *Sandoval* was handed down.

In 1999—two years before the Supreme Court decided *Sandoval*—the United States Commission on Civil Rights (the Commission or USCCR) issued the results of a lengthy examination of U.S. civil rights enforcement in the area of health care.[69] The Commission was extremely harsh in describing the depths to which OCR had sunk by the end of the twentieth century. The Commission concluded that "the timid and ineffectual enforcement efforts of [OCR] have fostered, rather than combated, the discrimination that continues to infect the Nation's health care system. This is evident in the segregation, disparate treatment, and racism experienced by African Americans, Hispanic Americans, Native Americans, Asian Americans and Pacific Islanders, and members of other minority groups. . . ."[70]

The Commission was careful not to assign all the blame for discriminatory conditions to OCR.[71] It pointed out that since government-sanctioned segregation was abolished in the aftermath of the 1964 Civil Rights Act—and with it the most visible forms of discrimination—racial inequality in health care had never been a top national priority. As such, it found that civil rights enforcement was afforded relatively little emphasis and was not seen as an integral part of HHS's mission.[72] Similarly, the Commission determined that Congress and successive Presidents had essentially ignored OCR, failing to prioritize health care civil rights enforcement or offer any oversight or support. For example, as of 1999, Congress had not held an oversight hearing on OCR's civil rights enforcement activities since 1987.[73] Consequently, OCR was found to suffer from both a lack of guidance and severe resource constraints, thus

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69. 2 U.S. COMM'N ON CIVIL RIGHTS, *supra* note 52. The Commission is an independent, bipartisan agency first established by Congress in 1957. Its investigation of civil rights enforcement efforts by HHS was undertaken pursuant to Public Law 103-419 (1994), which, in part, reauthorized the Commission and directed it to study, collect information relating to, and make appraisals of federal laws and policies regarding discrimination or denials of equal protection of the laws. Until the 1999 report, the Commission had not conducted a comprehensive evaluation of HHS. 1 U.S. COMM'N ON CIVIL RIGHTS, *supra* note 52, at iii.

70. *Id.* at 274.

71. *See id.* at 276.

72. *Id.*

73. *Id.*

impeding competent implementation of its civil rights enforcement responsibilities. In 1999, OCR's budget represented just 0.0054 percent of the entire HHS budget, and OCR had no separate budget for Title VI enforcement.[74] Between 1980 and the date of the report, the number of full-time OCR employees had dropped by some sixty percent.[75]

At the same time, and even more striking in the context of *Sandoval*, the Commission laid considerable blame at OCR's feet. Even with lower expectations in light of limited resources, the Commission found that OCR showed shameful neglect of its responsibilities.[76] Most frustrating to the Commission was OCR's unwillingness to address or attack its deficiencies, choosing instead to act sluggishly and unresponsively to increasing racial inequalities in health care. The Commission found that OCR had developed no Title VI guidelines and few policy directives, that it lacked a thorough pre-award review process to ensure that prospective recipients of federal financial assistance were in compliance with the law, that it rarely conducted post-award desk audit reviews and comprehensive onsite compliance reviews, that it had a growing complaint backlog, and that it lacked an effective and comprehensive system for monitoring corrective action commitments.[77] In other words, OCR was utterly incapable of doing its job.

The Commission also described many concerns with OCR's complaint investigation process. It found OCR regulations for complaint evaluation vague and overly broad, offering little or no guidance for employees.[78] Furthermore, OCR was found to lack thorough and rigorous investigative techniques and methodologies, particularly in ascertaining the difference in quality of health care provided across racial and ethnic lines.[79] Of particular concern in light of *Sandoval*, OCR staff had no clear policy guidance on how to conduct disparate impact analyses, and was generally unable to identify a "nexus" between existing disparities and a health care practice or policy.[80]

OCR was also found to sometimes demonstrate inattention to or ignorance of Title VI issues. The Commission recounted one incident in which OCR became involved in a Title VI disparate impact case entitled

74. *Id.* at 292–93.
75. *Id.* at 27.
76. *See id.* at 276.
77. *See id.* at 240–45.
78. *Id.* at 173.
79. *Id.* at 184.
80. *Id.* at 184–85.

Mussington v. St. Luke's-Roosevelt Hospital Center.[81] At a community meeting about the case, one participant indicated that the hospital might have discriminated against Medicaid patients. Amazingly, the OCR investigator informed the audience that such discrimination was not illegal, according to an NAACP Legal Defense Fund attorney present at the meeting.[82]

From the Commission's viewpoint, however, perhaps the most distressing problem (and without doubt the most extraordinary of all the facts available to the Supreme Court at the time it decided *Sandoval*) is OCR's inability to effectively address and resolve complaints filed by alleged victims of race discrimination. Individuals who believe that they have been discriminated against on the basis of race, color, or national origin are entitled under federal regulations to file a complaint with OCR. Title VI regulations require OCR to establish procedures for the "prompt processing and disposition" of all complaints of discriminatory practices.[83] Yet despite this mandate, USCCR found that OCR "takes inordinate amounts of time to complete complaint investigations,"[84] with complaint files often open for three to six years. USSCR warned that,

> [u]nlike the civil rights enforcement agencies that address discrimination in education and employment, OCR is responsible for uncovering discrimination that may affect not just one's life opportunities but on [sic] something far more profound—individuals' health and physical well-being. In some cases, prompt investigation could be a matter of life and death.[85]

This recounting of the inner workings of OCR illustrates a few basic points. First, the Commission's description of the agency's funding and staffing difficulties suggests that the dreadful financial and operational conditions within OCR are a fixture on the landscape of government enforcement and not a recent development. As Smith notes in his history of Title VI, the very establishment of OCR as an agency separate from the agencies directly administering federally financed programs amounted to a deliberate attempt on the part of some members of Congress (in particular, powerful members of the appropriations committees) to eviscerate civil rights enforcement efforts.[86] This separation of agencies was

81. 824 F. Supp. 427 (S.D.N.Y. 1993), *aff'd*, 18 F.3d 1033 (2d Cir. 1994).

82. 2 U.S. COMM'N ON CIVIL RIGHTS, *supra* note 52, at 190.

83. 28 C.F.R. § 42.408(a) (2001).

84. 2 U.S. COMM'N ON CIVIL RIGHTS, *supra* note 52, at 189.

85. *Id.*

86. SMITH, *supra* note 23, at 164–66.

a direct response to active efforts by the Department of Health, Education, and Welfare to achieve civil rights compliance within the health care industry in the wake of Medicare's enactment.[87] Over time, the decision to centralize civil rights operations and remove civil rights enforcement from day-to-day program administration has had precisely its intended effect.

Second, to the extent that anyone expects that a renewed commitment to active government intervention in the face of health care inequality could occur through OCR, the Commission's analysis of the agency's structure and capability should dash this expectation. There are no standards of conduct in the area of health care—one of the largest sectors of the U.S. economy[88]—other than a handful of broadly crafted regulations that are nearly forty years old and a very small amount of informal policy guidance, even though OCR has the authority to craft specific standards.[89] There is no system for measuring the presence of discrimination. And there is no systematic enforcement strategy that could withstand most defenses raised by a recipient of federal financial assistance, particularly in light of the broad nature of the affirmative "legitimacy" defense. Under this defense, a defendant could show in *de facto* cases (both those brought by private litigants and by OCR) that even high levels of segregation and unequal treatment stem from a legitimate business need.[90]

But beyond the obvious need to maintain an office for civil rights that is not a positive embarrassment, a perhaps deeper question concerns the limits of what could be accomplished through a reinvigorated Title VI standard-setting and enforcement machinery, if such machinery were housed within OCR. The fact is that, even were OCR to be significantly expanded in size and resources, the agency still would be understood as having no real power over the thousands of basic, day-to-day decisions regarding the standards of performance that federally assisted entities must meet. Because OCR has never been given the formal task of administering federal funding programs (in the way, for example, that the HHS Health Resources and Services Administration administers the Community Health Center Program or CMS administers the Medicare

87. *Id.* For a similar view and excellent treatment of the need for litigation to address racial and ethnic disparities in health care, see Marianne Engelman Lado, *Unfinished Agenda: The Need for Civil Rights Litigation to Address Race Discrimination and Inequalities in Health Care Delivery*, 6 TEX. F. ON C.L. & C.R. 1 (2001).

88. Health care spending accounts for 14% of the United States's gross domestic product. Lado, *supra* note 87, at 10.

89. See, for example, the regulations regarding limited English proficiency, *supra* note 11; *supra* text accompanying note 44.

90. *See* Watson, *supra* note 21, at 962.

Program), its pronouncements over their standards of performance are understandably perceived as having only limited meaning. Furthermore, having worked closely with OCR officials over the years, it is our sense that many of them believe that even if the agency were given the personnel and resources to actively enforce its modest collection of standards in the health care arena, its activities would continue to be viewed as somehow separate and apart from the basic standards of performance guiding health spending, not only by the entities that receive federal funds, but by the sister agencies that administer the programs as well.

This sense of futility is underscored by a perusal of the thousands of pages of federal regulations applicable to federal health care financing programs. For example, although Title VI compliance is a condition of federal funding, this simple fact is not stated anywhere in federal regulations governing Medicare's conditions of participation. To offer one illustration, the Medicare conditions of participation for hospitals open with a threshold regulation that obligates participating facilities to be in compliance with "federal laws related to the health and safety of patients."[91] The fact that, in order to receive any federal funds, hospitals as a first matter must be in compliance with federal laws related to the equal treatment of patients regardless of race or national origin goes unmentioned. Even the Medicare regulation that establishes hospitals' legal obligation to honor "patients' rights" fails to make any mention of the right to equal treatment regardless of race or national origin.[92]

The same marked absence of any indication of the obligation to be in compliance with Title VI—or what that obligation means in a health care context—is evident throughout the hundreds of pages of Medicare conditions-of-participation regulations applicable to all forms of health care providers and entities.[93] Nor do the rules require that the entity attest to its compliance with Title VI at the time that it makes a claim for payment.[94]

Time and again, recipients of federal financial assistance issue policies that appear facially neutral (i.e., they make no mention of racial identification) but are capable of producing devastating racial effects. The

91. 42 C.F.R. § 482.11 (2002).

92. 42 C.F.R. § 482.13 (2002).

93. *See, e.g.*, Requirements Relating to Health Insurance Coverage, General Provisions, 45 C.F.R. § 114.103 (2002); Requirements Relating to Access and Renewability of Coverage, 45 C.F.R. § 146.113 (2002); Requirements for the Group Health Insurance Market, Exclusion of Plans and Enforcement Requirements, 45 C.F.R. § 146.180 (2002).

94. 42 C.F.R. §§ 424.30. (2002).

selection of markets is a clear area of concern, as the past two decades of litigation related to hospital closures and relocation underscore.[95] Yet in 2001, and with no discussion of the potential disproportionate effects on minority beneficiaries, the Bush Administration announced a new policy that would permit Medicare+Choice organizations to identify their service areas on a sub-county basis.[96] This policy, while clearly linked to an effort to hold on to a declining market, also appears to explicitly sanction redlining of racially identifiable portions of a community in favor of healthier and more affluent residents. The notion that race is linked to poor health and high cost is deeply embedded in the insurance industry despite years of efforts to prohibit racial profiling.[97]

Most striking perhaps from the standpoint of the modern health care system is the absence of any reference to the basic obligation to abide by Title VI regulations in the rules governing the sub-contractual arrangements maintained by covered entities such as hospitals, nursing homes, managed care organizations and other corporate health care providers. As noted previously, Title VI regulations reach not only entities but their contractors as well. This reach has become even more important in light of the formation of ever more complex corporate health care entities held together through a cascade of interlocking contracts. The absence of clear prohibitions within the Medicare rules against contracts with business partners that discriminate is striking. This is true not only because it is a specific standard that is directly compelled by basic civil rights law, but also because of the level of awareness within HHS today of the extent to which covered entities can use contracts with otherwise uncovered actors to avoid the purposes and intent of a federal law.[98]

The same observations can be made about federal rules governing Medicaid and the State Children's Health Insurance Program (SCHIP). The fact that compliance with Title VI is a basic condition of participation for any state agency, program, or health care provider receiving federal funding under these programs is simply absent from federal rules. Even

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95. *See, e.g.*, Bryan v. Koch, 492 F. Supp. 212 (S.D.N.Y. 1980); NAACP v. Wilmington Med. Ctr., Inc., 491 F. Supp. 290 (D. Del. 1980).

96. Hans R. Dutt et al., *The Financial Implications of HMOs' Partial County Carve-Out Option*, 14 MANAGED CARE INTERFACE 46 (2001).

97. Deborah A. Stone, *The Struggle for the Soul of Health Insurance*, 18 J. HEALTH POL., POL'Y & L. 287 (1993).

98. In fact, this theme of binding the contractual business partners of a covered enterprise has dominated the federal government's health care privacy rules. *See* Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 14,776 (proposed March 27, 2002).

worse, in the case of Medicaid there are situations in which CMS has actively condoned the segregation of Medicaid beneficiaries—who are of course disproportionately minority—into separate systems of care within a single health care enterprise.

The federal regulations governing the SCHIP program illustrate a broader failure on the part of federal agencies to think through the racial implications of federal spending standards. Generally speaking, SCHIP gives participating states two basic administration options. A participating state may elect to implement SCHIP as an extension of its Medicaid program, or it may cover some or all SCHIP-eligible children through a separate state plan with its own distinct eligibility, benefit, provider-participation, and other requirements. As of the end of 2001, approximately two-thirds of all states administered their SCHIP programs separately either in whole or in part (e.g., extending Medicaid coverage up to the federal poverty level for all children under 18 and enrolling near-poor children in a separate program).

The demographics of childhood poverty mean that in many states and communities, the poorest children (i.e., Medicaid children) are more likely to be minority children while the near-poor children (those potentially covered by SCHIP) are more likely to be non-minority. Whatever their race, children have the potential to move between the two programs as their family income fluctuates from year to year. Given the fluctuation in income that characterizes many low-income households, and the importance of continuity in pediatric care, one would imagine that, for both the prevention of bias in provider participation and the promotion of health quality, CMS would have addressed the issue of state contracting practices with health care providers and entities. In fact, the regulations are completely silent on the issue of whether a state agency can enter into agreements under its separate SCHIP program with entities that refuse to participate in Medicaid. The regulations do not even require states to be able to demonstrate that they have in place a series of standards and incentives to promote dual participation or discourage non-participation in Medicaid.

The most egregious example of rules that foment discrimination is a proposed rule, issued by the Bush Administration in August 2001,[99] that would reverse an earlier Medicaid managed care rule promulgated by the Clinton Administration. The earlier rule prohibited state agencies from

99. Medicaid Program; Medicaid Managed Care, 66 Fed. Reg. 43,614 (proposed Aug. 20, 2001), *available at* http://www.hcfa.gov/medicaid/cms2104p.pdf (last visited Mar. 30, 2003).

maintaining contracts with Medicaid managed care organizations and entities that maintained segregated provider networks (i.e., separate networks based on source of payment). The intent of this earlier rule was to prevent participating entities from excluding members from certain portions of their network (and at least by logical extension, as a means of discouraging managed care entities from contracting with health providers that refuse to treat Medicaid patients). This type of exclusionary and segregating practice bears striking similarities to the older and well-documented practices involving segregated hospital floors, segregated medical staffs, and segregated nursing home wings, all of which unquestioningly violate Title VI. Without explanation, the 2001 regulation proposed to simply eliminate the prohibition.

Similarly, the Clinton Administration's final Medicaid managed care regulations sought to address the problem of language and culture access in managed care by requiring participating entities in federal health programs to be able to demonstrate the existence of various approaches to cultural competency.[100] Yet the Bush Administration's 2002 Final Rule eliminated these relatively precise requirements in favor of virtually no standards other than a vague reference to cultural competence.[101] As with the segregated networks rule, this change was proposed with virtually no explanation in the Preamble to the proposal.[102]

A final example of the extent to which federal participation and payment rules ignore or even undermine Title VI obligations can be found in Medicaid rules applicable to provider payment. As a matter of federal law, a state Medicaid program must maintain provider payment levels that are sufficient to ensure reasonable access by beneficiaries, with the reasonableness of the access measured in terms of access to the same services by comparable populations.[103] The federal Medicaid equal-access regulations arguably have two statutory bases: the federal Medicaid statute that sets the standard, and Title VI, which reinforces these regulations because of Medicaid's disproportionate minority racial and ethnic composition. Despite the fact that inadequate beneficiary access to health providers is epidemic and the subject of widespread discussion,[104] CMS has

100. 42 C.F.R. § 438.10 (2000).

101. Medicaid Program; Medicaid Managed Care, 67 Fed. Reg. 40,989, 41,106 (June 14, 2002), codified at 42 C.F.R. § 438.206(c)(2).

102. Medicaid Program; Medicaid Managed Care, 67 Fed. Reg. 40,989 (June 14, 2002).

103. 42 U.S.C. § 1396a(a)(30) (2003).

104. *See, e.g.*, EDWIN PARK & LEIGHTON KU, CTR. ON BUDGET & POLICY PRIORITIES, ADMINISTRATION MEDICAID AND SCHIP WAIVER POLICY ENCOURAGES STATES TO SCALE BACK

never issued a written clarification stating that the obligation to ensure equal access stems not only from federal Medicaid law but also from the equality in treatment dimensions of civil rights law (i.e., Title VI) itself.

In sum, it is difficult to overstate the extent to which the major federal health care financing agencies, and CMS in particular, have ignored Title VI considerations in setting policy. Even where OCR has attempted to step in to fill the breach, its efforts have had little effect since the delegation of powers within HHS gives OCR no power to make program policy with respect to health care financing. This enormous paradox— the assignment of responsibility for enforcing federal civil rights laws applicable to federal spending to an agency that has no powers to set the standards for federal spending—results in a problem far worse than inaction. It effectively excuses the very agencies with day-to-day responsibility to keep federal spending in line with federal law. Even worse, this state of affairs encourages willful ignorance of civil rights laws in the setting of performance standards and in the establishment of procedures for measuring compliance.

III. *ALEXANDER V. SANDOVAL*

In spite of the already-significant hurdles facing both private and public Title VI enforcement, the United States Supreme Court's decision in *Alexander v. Sandoval*[105] sent shockwaves through the civil rights community.[106] By abrogating the right of individuals to bring private

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BENEFITS SIGNIFICANTLY AND INCREASE COST-SHARING FOR LOW-INCOME BENEFICIARIES (2001), *available at* http://www.cbpp.org/8-15-01health.htm (last visited Apr. 3, 2003); Bruce E. Landon & Arnold M. Epstein, *Quality Management Practices in Medicaid Managed Care: A National Survey of Medicaid and Commercial Health Plans Participating in the Medicaid Program*, 282 J. AM. MED. ASS'N 1769 (1999); Robert Pear, *Many on Medicaid Lack Drugs, Study Says*, N.Y. TIMES, Apr. 9, 2002, at A20.

105. 532 U.S. 275 (2001).

106. *See, e.g.*, Press Release, American Civil Liberties Union, Two Supreme Court Rulings Expand Police Powers and Limit Civil Rights Enforcement (Apr. 24, 2001), *available at* http://www.aclu.org/news/2001/n042401c.html (last visited Mar. 28, 2003) ("In one fell swoop, the Court has both increased the potential for racial profiling and diminished 30 years of civil rights law designed to protect victims of discrimination."); Press Release, Progressive Coalition for Equal Opportunity and Justice, Supreme Court Decision on English-Only Law a Blow to Civil Rights and Women of Color (Apr. 24, 2001), *available at* http://www.civilrights.org/library/detail.cfm?id=4892 (last visited Apr. 8, 2003) (noting that *Sandoval* represented "a major set back [sic] for those who want to combat discrimination in this country," and that the "decision has troubling implications for our civil rights laws in many areas").

actions under Title VI to enforce the disparate impact regulations, the decision effectively wiped out two decades of Title VI litigation.[107] While the decision left unanswered the question of whether a private right of action could be pursued under alternative legal theories in the case of public agencies,[108] it eviscerated actions against private entities that receive federal funds,[109] which in the case of health care is an enormous matter.

The *Sandoval* case began life as a relatively routine (in the sense that it typified Title VI cases) class action. The lawsuit was filed in December 1996 by non-English-speaking residents of Alabama, who claimed that the state's Department of Public Safety discriminated against them on the basis of national origin by refusing to offer drivers' licensing exams in any language other than English. The plaintiffs alleged that although Alabama's law was facially neutral—it did not explicitly prohibit non-English-speaking individuals from taking the licensing exam and therefore was not intentionally discriminatory—its *effect* was to discriminate against those individuals who hailed from countries where English was not spoken. Because the claim was one of discriminatory impact, it arose under the federal regulations promulgated pursuant to Title VI rather than under the statute itself (since the statute proscribes only intentional discrimination, while its implementing regulations prohibit conduct that is neutral in motive but discriminatory in effect). After the District Court for the Middle District of Alabama ruled that the English-only policy could not be enforced,[110] the United States Court of Appeals for the Eleventh Circuit affirmed the decision.[111] The U.S. Supreme Court then granted certiorari to the Director of Alabama's Department of Public Safety.

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107. As described *supra* in note 53, every federal circuit court of appeals to address the question in *Sandoval* concluded that a private right of action exists to enforce Title VI and its regulations.

108. The Court did not reach the question of whether individuals could sue for Title VI violations under 42 U.S.C. § 1983, which provides a cause of action against anyone who, acting under color of state law, causes deprivations of "rights . . . secured by the Constitution and laws." (In the wake of *Sandoval*, however, some lower federal courts have ruled that plaintiffs cannot use § 1983 to enforce Title VI rights. *See, e.g.*, Foster Children Bonnie L. v. Bush, 180 F. Supp. 2d 1321 (S.D. Fla. 2001) (plaintiffs' § 1983 claim could not survive *Sandoval*); South Camden v. New Jersey Dep't of Envtl. Prot., 274 F.3d 771 (3d Cir. 2001) (administrative regulation cannot create an interest enforceable under § 1983 unless the interest is already implicit in the statute authorizing the regulation)). Thus, even if such a suit were viable, only a portion of health care providers could be targeted under § 1983.

109. Alexander v. Sandoval, 532 U.S. 275 (2001).

110. Sandoval v. Hagan, 7 F. Supp. 2d 1234 (M.D. Ala. 1998).

111. Sandoval v. Hagan, 197 F.3d 484 (11th Cir. 1999).

Writing for the narrowest of majorities, Justice Scalia maintained that the text and structure of Title VI evidenced congressional intent to separate the means of enforcement in cases of intentional and *de facto* discrimination.[112] In particular, according to Scalia's reading, private enforcement of Title VI is available only for intentional discrimination. This reading is not obvious, however, given that Title VI makes no mention of private enforcement whatsoever.

The majority achieved this legal sleight-of-hand by reasoning that since the statute explicitly outlaws only intentional discrimination, the regulations cannot be seen as an extension of Section 601. They must instead be an extension of "the independent force"[113] of Section 602, which empowers federal administrative agencies to enforce the law through regulations. Having located the prohibition against *de facto* discrimination in Section 602, the Court holds that because this provision is limited to ensuring *agencies'* ability to effectuate Section 601, Congress could not have intended to include *private* enforcement rights as an option under Section 602. Justice Scalia argues that the plain language of Section 602 "focus[es] neither on the individuals protected nor even the funding recipients being regulated, but on the agencies that will do the regulating."[114] In sum, Section 602's focus on the regulatory process, coupled with the absence of explicit language creating a private right of action, was sufficient to satisfy the Court that Congress intended no private right of enforcement.

The Court's decision brushes aside any analysis of the context in which Title VI was enacted, declining with remarkable brevity the opportunity to examine Title VI's legislative history because "legal context matters only to the extent it clarifies text."[115] In fact, in one of the more insulting passages in any Court decision in recent memory, Justice Scalia frames the argument of the individuals who brought the action in terms of a drunk who has had one drink too many: "Respondents would have us revert in this case to the understanding of private causes of action that held sway 40 years ago when Title VI was enacted. . . . Having sworn off the habit of venturing beyond Congress's intent, we will not accept respondents'

112. 532 U.S. at 287–88.

113. *Id.* at 286.

114. *Id.* at 289.

115. 532 U.S. at 288. For examples of the Court's willingness to rigorously consider legal context in analyzing federal statutes, see *Merrill, Lynch, Pierce, Fenner & Smith, Inc. v. Curran*, 456 U.S. 353 (1981) (holding that Commodities Exchange Act provides implied right of action) and *Cannon v. Univ. of Chicago*, 441 U.S. 677 (1979) (holding that Title VI creates private right of action).

invitation to have one last drink."[116] In effect, the Court took the position that the entire history underlying congressional intent in enacting Title VI did not matter to its interpretation of the statute.

The Court's treatment of precedent was no more deferential. In considering the extensive Supreme Court case law in the area of civil rights enforcement, the Court failed to apply the hypercritical scrutiny to which it had subjected the text of Title VI, a failure for which it was roundly criticized in the dissent.[117] Justice Scalia refused to acknowledge that his approach was ad hoc, however, insisting that the "Court is bound by holdings, not language."[118]

The reasoning of the Court thus leaves persons who allege *de facto* discrimination in the position of having legal protections but no effective legal remedy other than the discretionary and grossly under-staffed federal enforcement machinery. This outcome—that there can be individual legal protections without adequate means of enforcement—is one that runs counter to long-standing principles of statutory interpretation regarding the existence of private rights of action.[119] The Court's decision to remove direct access to court as a remedy in *de facto* discrimination situations also runs counter to the approach taken by every federal appeals court in considering whether a private right of action exists to enforce regulations issued pursuant to Title VI, including the disparate impact regulations.[120]

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116. 532 U.S. at 287

117. For example: "In a decision unfounded in our precedent and hostile to decades of settled expectations, a majority of this Court carves out an important exception to the right of private action long recognized under Title VI." *Id.* at 294 (Stevens, J., dissenting); "The majority's statutory analysis does violence to both the text and the structure of Title VI." *Id.* at 304 (Stevens, J., dissenting); "In order to impose its own preferences as to the availability of judicial remedies, the Court today adopts a methodology that blinds itself to important evidence of congressional intent." *Id.* at 313 (Stevens, J., dissenting).

118. *Id.* at 282.

119. For example, it was not uncommon during the era of the Civil Rights Act's passage for courts to hold that private rights of action existed even when Congress created a statute with ambiguous or vague enforcement provisions (and, furthermore, to oftentimes do so without performing a detailed analysis of the statute's enforcement provisions). *See, e.g.*, Hewitt-Robins Inc. v. E. Freight-Ways, Inc., 371 U.S. 84 (1962) (implied right of action under Motor Carrier Act); Allen v. State Bd. of Elections, 393 U.S. 544 (1969) (Voting Rights Act of 1965); Susan J. Stabile, *The Role of Congressional Intent in Determining the Existence of Implied Private Rights of Action*, 71 NOTRE DAME L. REV. 861 (1996). *See also* Donald H. Zeigler, *Rights, Rights of Action, and Remedies: An Integrated Approach*, 76 WASH. L. REV. 67 (2001).

120. For decisions so holding most explicitly, *see, e.g.*, Sandoval v. Hagan, 197 F.3d 484

The dissent, authored by Justice Stevens and joined by Justices Souter, Ginsburg, and Breyer, assails the majority's holding as untenable, and displays an antagonism reserved for the most contentious of the Court's cases. Justice Stevens finds particular fault with three elements of the majority opinion: its "muddled" account of prior Supreme Court Title VI decisions, its "flawed and unconvincing" analysis related to the division of Sections 601 and 602, and its misinterpretation of an earlier Title IX decision key to the majority's opinion.[121]

Mainly, however, the dissent argues that although the statutory text of Title VI might be narrower in scope than its implementing regulations, there is nothing to suggest that Congress intended the statute to operate in isolation from the regulations; indeed, the very link between the prohibition of Section 601 and the assignment of standard-setting and enforcement duties in Section 602 argues against such a result.[122] Reviewing the history of the Civil Rights Act, Justice Stevens notes that the legislative design of Title VI countenanced a flexible approach to combating discrimination. Indeed, the very fact that the statute specifically instructs agencies to promulgate rules that effectuate legislative intent underscores the validity of extending private rights of action to any class of legal violation, not just certain types of misconduct. Specifically,

> the statute does not establish a static approach but instead empowers the relevant agencies to evaluate social circumstances to determine whether there is a need for stronger measures. Such an approach builds into the law flexibility, an ability to make nuanced assessments of complex social realities, and an admirable willingness to credit the possibility of progress.[123]

The dissent views the statute and regulations as "inseparably

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(11th Cir. 1999); Powell v. Ridge, 189 F.3d 387, 400 (3d Cir. 1999); Chester Residents Concerned for Quality Living v. Seif, 132 F.3d 925, 936–37 (3d Cir. 1997), *vacated*, 524 U.S. 974 (1998); David K. v. Lane, 839 F.2d 1265, 1274 (7th Cir. 1988). *See also* Ferguson v. Charleston, 186 F.3d 469 (4th Cir. 1999), *rev'd on other grounds*, 532 U.S. 67 (2001); Buchanan v. Bolivar, 99 F.3d 1352, 1356 n.5 (6th Cir. 1996); Villanueva v. Carere, 85 F.3d 481, 486 (10th Cir. 1996); New York Urban League, Inc. v. New York, 71 F.3d 1031, 1036 (2d Cir. 1995); Latinos Unidos De Chelsea v. Sec'y of Hous. & Urban Dev., 799 F.2d 774, 785 n.20 (1st Cir. 1986); Castaneda v. Pickard, 781 F.2d 456, 465 n.11 (5th Cir. 1986); Larry P. v. Riles, 793 F.2d 969, 981–82 (9th Cir. 1986). No court of appeals has ever reached a contrary conclusion.

121. 532 U.S. at 295 (Stevens, J., dissenting).

122. *Id.* at 303 (Stevens, J., dissenting).

123. *Id.* at 306 (Stevens, J., dissenting).

intertwined" into a flexible and sensible remedial scheme to ensure that recipients of federal aid do not discriminate against minorities, no matter the type of discrimination.[124] For this reason, the dissent finds it legally implausible to differentiate between private actions to enforce Section 601 and private actions to enforce Section 602.[125]

In sum, the *Sandoval* decision is a case of enormous legal consequence, and another in a series of Supreme Court cases that diverge from decades of civil rights history in order to achieve a result that is consistent with the modern Court's desire to withdraw the judicial system from disputes involving the alleged abrogation of individual legal rights by government actors.[126] Because Title VI also reaches private conduct by recipients of federal financial assistance, the case is of equal importance to instances in which the alleged wrong is committed by a private entity.

Of course, at first blush, it might appear that the Court's withdrawal of a private right of action to enforce the Title VI disparate treatment rule would be of little consequence in a health care context, in light of the relatively limited use of Title VI in the private health litigation context, the rarity of victory when cases are mounted, and the potential advantages of a strong federal enforcement presence.[127] But this conclusion overlooks the vital role that litigation—and the threat of litigation—has played in bringing about change through negotiated settlements even when an outright victory may not have been possible.[128] Furthermore, as we have

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124. *Id.* (Stevens, J., dissenting).

125. *Id.* at 310 (Stevens, J., dissenting).

126. *See, e.g.*, Bd. of Trs. v. Garrett, 531 U.S. 356 (2001) (holding that the Eleventh Amendment's sovereign immunity protections bar individuals from suing states that failed to provide disability accommodation). Furthermore, the *Sandoval* opinion evinces a willingness of a majority of the Court to depart from long-standing tradition in another context—that of broadly construing remedial civil rights statutes. *See, e.g.*, Golden State Transit Corp. v. City of Los Angeles, 493 U.S. 103, 105 (1989) (holding that § 1983 is to be broadly construed); Trafficante v. Metro. Life Ins. Co., 409 U.S. 205, 211–12 (1972) (holding that the Fair Housing Act is to be broadly construed). This departure includes the Court's efforts to obliterate implied private rights of action. See, for example, *Washington v. Davis*, 426 U.S. 229 (1976), and its progeny. It is also worth noting that the decision may also foreshadow a review of the validity of the disparate impact regulations themselves, since the Court only *assumes* for purposes of deciding *Sandoval* that the regulations are valid. 532 U.S. at 525.

127. *See* discussion *supra* Part II.

128. For example, negotiations in hospital relocation cases such as *Wilmington Gen. Hosp. v. Manlove*, 174 A.2d 135 (Del. 1961) and *Bryan v. Koch*, 627 F.2d 612 (2d Cir. 1980) resulted in crucial concessions over the establishment of satellite clinics, transportation to new

seen,[129] federal government enforcement capabilities where potential Title VI health care violations are concerned are so devastatingly constrained that it is difficult to overstate the futility of relying on the government to do its job in its current state.[130] These facts could not have been lost on the *Sandoval* majority, given the abundance of evidence from years of oversight investigations into government civil rights enforcement efforts (or the lack thereof).[131] This knowledge regarding the sorry state of affairs where civil rights enforcement is concerned makes the decision all the more unfortunate.[132]

Taken to its logical conclusion, the majority decision in *Sandoval* could be read as abrogating all private actions involving the enforcement of any congressionally sanctioned federal regulation that extends beyond the literal text of its parent statute.[133] This approach to statutory interpretation has no foundation in Supreme Court precedent but will likely be proffered by institutional defendants in a wide range of subsequent litigation, particularly in cases in which federal enforcement machinery is inadequate (see *supra* Part II) and the withdrawal of individual actions realistically means the denial of any remedy at all.

In fact, just two years after being handed down, *Sandoval*'s impact on civil rights litigation generally serves as a harbinger of the systematic deprivation of individual rights possible under the decision. Defendants in pending civil rights litigation have asked federal courts to dismiss claims and reconsider orders granting plaintiffs injunctive relief, and plaintiffs—unable to remedy alleged disparate impact discrimination through Section 602 enforcement—have moved to amend complaints against public defendants to add a Section 1983 claim. The *Sandoval* ruling has thus limited not only the civil rights claims adjudicated under Title VI[134] of the

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facilities, and other changes.

129. *See* discussion *supra* Part II.

130. SMITH, *supra* note 23; 2 UNEQUAL TREATMENT, *supra* note 15, at 3, 29–30.

131. 2 U.S. COMM'N ON CIVIL RIGHTS, *supra* note 52.

132. *See generally* Lado, *supra* note 87.

133. *See, e.g.*, Litman v. George Mason Univ., 156 F. Supp. 2d 579 (E.D. Va. 2001) (holding that *Sandoval* bars private enforcement of Title IX's anti-retaliation regulations, since Congress intended Title IX to be interpreted and enforced in the same manner as Title VI).

134. South Camden v. New Jersey Dep't of Envtl. Prot., 274 F.3d 771 (3d Cir. 2001) (using *Sandoval* as its guidepost and holding that an administrative regulation cannot create an interest enforceable under § 1983 unless the interest is already implicit in the statute authorizing the regulation); Foster Children Bonnie L. v. Bush, 180 F. Supp. 2d 1321 (S.D. Fla. 2001) (ruling that plaintiffs' § 1983 claim could not survive *Sandoval*, since holding that

Civil Rights Act, but also those adjudicated under Title IX of that Act,[135] the Americans with Disabilities Act (ADA),[136] and the Rehabilitation Act.[137] Although a full review of the case law emanating from those claims is beyond the scope of this Article, the results paint a disturbing picture.

IV. CONCLUSION

By eliminating the right of individuals to enforce their constitutional protection against facially neutral practices that have a disproportionate adverse impact, *Sandoval* inevitably focuses attention on the obligation of government to address this type of systemic discrimination. Thus, as sobering as the *Sandoval* decision is from a civil rights enforcement standpoint, it conceivably could have a significant positive effect if it causes policy makers to re-focus their attention on the role of federal enforcement in ensuring civil rights.

But it should not have taken the rescission of an individual right of action to incite a basic rethinking of the federal enforcement of civil rights laws. It is evident from even a cursory reading of the original Title VI disparate impact rules that they were aimed at preventing entire industries and programs from operating without considering the racial consequences of their conduct. This goal can upon occasion be reached through individual litigation on behalf of classes of individuals. But the task of forcing large interests to confront and remedy the racial harms that can flow from facially neutral practices is surely best achieved through

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the regulations are privately enforceable under § 1983 but not under § 602 would be equivalent to holding that Congress intended the disparate impact regulations to be enforceable against state actors, but not private entities).

135. Litman v. George Mason Univ., 156 F. Supp. 2d 579 (E.D. Va. 2001) (holding that *Sandoval* bars private enforcement of Title IX's anti-retaliation regulations, since Congress intended Title IX to be interpreted and enforced in the same manner as Title VI); Atkinson v. Lafayette Coll., No. 01-CV-2141, 2002 U.S. Dist. LEXIS 1432, at *8 (E.D. Pa. Jan. 29, 2002) (finding that in the wake of *Sandoval* there is no private right of action under Title IX to enforce its anti-retaliation regulations). A question left open in these cases, and not decided by the Supreme Court in *Sandoval*, is whether an agency may enforce the regulations against a state entity.

136. Access Living of Metro. Chicago v. Chicago Transit Auth., No. 00-C0770, 2001 U.S. Dist. LEXIS 6041 (N.D. Ill. May 9, 2001) (ruling that plaintiffs presented sufficient evidence to rebut defendant's motion for summary judgment but noting that, in light of *Sandoval*, plaintiffs would likely not have an enforceable disparate impact discrimination cause of action under the Americans with Disabilities Act).

137. *Id.*

concerted action by government agencies which can use their spending powers to generate systemic and structural changes.

To this end, it is inappropriate that the government assigns such an important task to a small and isolated federal agency like OCR, which has no day-to-day administrative authority over federal spending. Why should a state agency or a major health enterprise listen to what this isolated entity has to say, other than perhaps out of some abstract belief that federal civil rights laws are important? Nothing in the daily grind of ensuring that one's health care operations are in compliance with federal rules appears to tie Title VI requirements to the basic operating standards that a health program has to meet, particularly since the Title VI standards have never been clearly articulated in a health context.

For both practical and political reasons, we believe that the primary government tools for instigating deliberate efforts to achieve equality in health care must be the same agencies that are empowered to shape programs. As can be seen from the foregoing discussion, existing standards applicable to the federal health insurance programs are rife with examples of failures on the part of the federal government to view policy decisions through a Title VI lens. Some decisions positively undermine the systemic and structural goals of Title VI by inviting redlining, exclusion, segregation, and other types of discriminatory treatment.

Using the response to the *Olmstead* decision (in which the Supreme Court ruled that medically unjustifiable institutionalization of disabled individuals under public programs constituted illegal discrimination)[138] as an example, we believe that cross-agency commitment to civil rights enforcement is essential if the federal government is to achieve results. This cross-agency role begins with a clear statement from Congress that it is no longer acceptable to assign the daily obligation to ensure compliance with federal laws to a single weak and dysfunctional agency. Since (as David Barton Smith so eloquently shows) it was congressional pressure in the latter half of the 1960s that caused the diminution of enforcement activity,[139] an important first step in creating a new cross-agency commitment to civil rights enforcement lies with the current Congress, which should articulate an expectation that all agencies develop a viable approach to compliance. In the case of HHS, this means that, in the rules governing the agency's federal appropriation, there should be language that makes clear that lawmakers anticipate a Department-wide strategy for civil rights enforcement. Such a strategy would not be limited to

138. *See supra* text accompanying notes 2-3.

139. SMITH, *supra* note 23.

investigation of individual cases but would extend also to the development of prospective standards of conduct that guide programs and providers in understanding how civil rights regulations apply in a health care context.

Given the magnitude of the problem, the most sensible approach for the Department would be to follow the example that it set in *Olmstead*. In the aftermath of that Supreme Court decision, HHS leadership convened an interagency task force whose mandate went beyond figuring out ways to monitor and measure compliance with the decision. The goal of the HHS-wide working group in the case of *Olmstead* has been to move the world of federally assisted programs closer to the community integration goals of the Americans with Disabilities Act through a fundamental and systemic examination of existing federal policies. This effort to identify and address inadequate or flawed federal standards began with the Clinton Administration but has flowered under the Bush Administration, culminating in a series of policy statements, reports, technical assistance efforts, and other activities aimed not only at effectuating change but also at conveying the importance of change to recipients of federal funds.[140]

A parallel effort is no less important in the case of Title VI. In the post-*Sandoval* era especially, there is a need for a Department-wide effort that examines every aspect of the standards governing federal financial assistance to health programs and health care entities. In light of the market-based nature of the American health care system, a Department-wide review must focus on the basic mechanics of health care purchasing, and in particular on the elements of purchasing that are intrinsic to any transaction in health care today: market rules of entry (e.g., conditions of initial participation or grant awards for health professions training programs or biomedical research), contracting and performance standards (e.g., quality improvement criteria), and payment standards. These basic operating rules are precisely the type of "facially neutral" practices that can have a disproportionate adverse impact on racially identifiable subgroups, particularly in the case of practices that exclude or impede persons from accessing Medicaid or low-income Medicare programs. Given that certain systemic practices that are basic to structuring and operating the modern healthcare enterprise are prone to fall with disproportionate weight on groups that are correlated with race (e.g., Medicaid beneficiaries, low-

140. To be sure, disability rights advocates would take issue with an overly rosy picture of the progress made to date, and many would argue that the progress has been too slow and that successive administrations have not done enough to press for community integration reform. But when one compares the federal government's response to *Olmstead* to its post-*Sandoval* performance, the result is positively sobering.

income Medicare beneficiaries), we believe that particularly strong Departmental attention should be given to the features governing the *location* and *functioning* of health care entities. We describe below the sorts of questions HHS should consider in regulating these features:

1. *Market entry:*[141] What basic standards should be in place in any health care institution? In communities in which the Medicaid population is disproportionately minority, should an entity that seeks to participate in Medicare be expected to also participate in Medicaid? Should an entity be able to subdivide markets to avoid service areas that are disproportionately minority? Should Medicare+Choice entities be permitted to avoid certain communities and, if so, on the basis of what evidence? What reasonable alternatives must an entity seeking to control the extent of its market (either geographically or by payer source) be obligated to consider? What are the acceptable grounds for rejecting alternative and less potentially discriminatory approaches?

2. *Contracts with business partners:* What showings must a federally participating entity (whether a state agency or a private health care corporation) be required to make about its contractual business partners? Can an SCHIP agency do business with a health corporation that does not participate in Medicaid? Can an SCHIP-participating managed care organization contract with providers that refuse to treat Medicaid beneficiaries, and if so, under what conditions? Can a Medicare+Choice organization maintain contracts with providers that will not treat dually enrolled Medicare/Medicaid beneficiaries who need Medicaid to cover compulsory cost-sharing? What data must business partners provide about their conduct and practices?

3. *Payments:* What standards should apply to the payment practices of both public agencies and federally assisted health care corporations and entities? Should a state agency ever be able to pay at less than demonstrably actuarially reasonable rates for managed care enrollment, nursing home services, or physicians' services? If so, under what circumstances? Should a health care corporation that participates in federal programs be permitted to establish differential payment rates by payer source?

4. *Affirmative efforts to improve health quality for racially identifiable groups:* With the emphasis today on health care quality improvement and dissemination, should agencies and entities that receive federal funding be

141. These are the standards that determine whether an entity can enter a health care market at all (*e.g.*, conditions of participation for Medicare-participating hospitals, nursing facilities, managed care organizations, home health entities, and other providers).

required to demonstrate that they pursue quality improvement activities aimed at enhancing provider performance in the case of racially and culturally distinct subgroups of patients, particularly in the area of clinical decision-making practices? Should they be required to incorporate into their quality improvement strategies policies that reduce administrative and linguistic barriers to care and enhance patients' knowledge of their rights and roles in the care process?

5. *Health professions training programs:* Should recipients of federal health professions training grants and awards be expected to demonstrate evidence of active recruitment of minority candidates?[142] Should they be required to show that their curriculum includes efforts to increase the ability of health professionals to engage in appropriate treatment practices for patients who are members of racial and ethnic minorities?

6. *Biomedical research:* Should grantees have to demonstrate affirmative efforts to design clinical and other trials that test the impact of interventions on members of distinct racial and ethnic minority groups? Should recipients have to demonstrate an affirmative effort to include members of racial and ethnic minority groups in clinical trials?

By considering these questions and beginning to articulate clearer performance goals in a health context, and by inter-weaving Title VI compliance into federal program participation and grant administration standards, we believe three advantages could be gained. The first relates to eliminating distinctions between program compliance and civil rights compliance. The constitutional basis for Title VI (the Spending Clause) means that an entity cannot participate in a federal program if it is not in compliance with Title VI. By integrating the two sets of compliance requirements (program compliance and civil rights compliance), the government would erase the false distinction—and the ensuing confusion—that has arisen over the past three decades and would make it easier for the recipients of federal financial assistance to understand what is expected of them.

The second reason to incorporate Title VI standards into general program standards speaks to a basic reality that underlies the modern effort to achieve racial equality in health care. Because of the demographics of poverty, it is, as a practical matter, difficult to separate conduct with an adverse impact on the poor and publicly insured from racial discrimination. Incorporating Title VI compliance and health program participation standards would obviate the need to distinguish between income and race discrimination and allow federal agencies to

142. *See* UNEQUAL TREATMENT, *supra* note 15, app. B.

focus instead on layered reforms that do not parse the problem to a non-remediable point.

To appreciate the third advantage of incorporating Title VI compliance into general program standards, one must consider the gravity of a charge of racism. It is evident to those who are familiar with civil rights efforts that there is no more painful conversation than one involving race discrimination. Given the history and ugliness of racial discrimination in health care, the topic is an electrifying one, and an accusation of racism is especially painful in light of the strong fiduciary tradition that imbues health professionals with the notion that they act solely in the interest of their patients. The notion of "doing the right thing" is so basic to health care that when the system is accused of not doing the right thing, the results are extremely distressing.

We believe that by merging the legal basis of federal health care standards to encompass both program performance and civil rights compliance, the federal government could do much to transform the discussion to one that is grounded in both quality and equality and to simultaneously minimize the temptation to classify activities as programmatic or racial in nature. Given the nexus between race and income, federal standards that are grounded in both sets of concerns—i.e., program quality and racial equality—would be easier to grasp and accept. Merged standards also would eliminate the pressure to distinguish between race and income, at least on a prospective basis. Obviously, a legal action alleging that a recipient of federal financial assistance violated Title VI would continue to have to satisfy the elements of the claim, including the ability to show a nexus between the conduct that is complained of and a racially identifiable group. But our concern here is for prospective standards that move the system forward, not for facilitating legal actions.

In general, it no longer makes sense to divide the world of enforcement when the overall goal is the systemic improvement of program performance. Regulations built on two sets of laws—one tied to racial equality and the other to program performance and health quality—would make clear that a particular practice is desirable not only because it improves the racial equality of programs but also because it improves the quality of health care for persons who are the intended beneficiaries of the programs. By establishing both racial equality and program quality improvement as two inextricably linked goals (a direction that finds strong support in the IOM study),[143] the federal government would immeasurably strengthen its hand in the setting of prospective standards of conduct. The

143. *Id.*

final step in a federal effort to move systematically on issues of civil rights enforcement is compliance measurement. Clearly, if the government is to set standards that are meant in part to reflect racial equality goals, it must have a method for measuring compliance. Whether this is done through routine program reporting, specialized studies and surveys, periodic self-assessments of performance against a set of negotiated benchmarks, or some other means, there must be a way of measuring results and reporting on them. A whole industry that has grown up around benchmarking, performance measurement, performance reporting, and performance dissemination offers insights into the tools available for this type of compliance effort. If the federal government and other health purchasers can insist on accountability in health quality on the part of hospitals, nursing homes, and even physicians in private practice, then it is difficult to see why measures of racial justice in performance are any more controversial. To be sure, there are an enormous number of technical issues that arise in the development of a racial classification and reporting system,[144] but these technical difficulties are no reason not to develop the most feasible approach possible under technical constraints.

We have no illusion that upgrading federal involvement in civil rights enforcement will be free.[145] At the same time, the cost to the system of unequal treatment is vast, as the IOM has demonstrated.[146] Had the *Sandoval* case not been decided in the way that it was, we could perhaps continue to imagine that private actions are adequate to remedy the

144. For example, how would physician network accessibility be measured? How would the government implement reforms aimed at making sure hospitals receiving graduate medical education payments modified their practices to come into compliance with federal regulations?

145. Nor would we agree, however, with the argument that health care financing is a zero-sum game, such that resources directed toward new civil rights enforcement efforts in health care would somehow draw on existing health care expenditures. Indeed, the country has seemed quite willing over the past couple of decades to accept rather dramatic spending increases in health care. According to the federal government, national health expenditures have increased almost six-fold since 1980. *See* Ctrs. for Medicare and Medicaid Services, National Health Expenditure Table 1, *available at* http://www.cms.hhs.gov/statistics/nhe/historical/t1.asp (last visited May 29, 2002). This trend appears likely to continue, for example, in the form of a new prescription drug program for Medicare beneficiaries. We would also argue that it is not clear that additional enforcement efforts would drive up health care costs in real terms, since in the long run efforts associated with increased access to care might actually reduce overall costs to the health system.

146. *See generally* UNEQUAL TREATMENT, *supra* note 15.

problem of discrimination in health care. But *Sandoval* has put that delusion to rest once and for all, and now the only remaining question is whether the federal government will meet the challenge that has been thrust upon it.

Sex & Gender: The Politics, Policy, and Practice of Medical Research

Sarah K. Keitt, M.P.H.*

While women generally live longer than men,[1] they often do not live healthier.[2] Historically, women have suffered from a lack of medical information specific to their needs and problems.[3] This information gap is the result of policies and practices that excluded women from participating as research subjects in most clinical trials until the late 1980s. Women were initially excluded from participating in clinical trials due to neglect and, after the Thalidomide tragedy of the 1960s, misguided efforts at protection. It was not until the mid-1980s that the medical research community began to recognize that the information gap created by these policies had a detrimental effect on women's health and began to take action to fill this gap.[4]

This Article explores issues surrounding women's participation in clinical trials. Part I outlines the cultural and regulatory norms that for many years resulted in the exclusion of women from clinical trials. It includes a discussion of protectionist regulations, landmark legislation, and the backlash against the women's health movement. Part II provides

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* Sarah K. Keitt is a program manager with the Society for Women's Health Research. She would like to acknowledge and thank Dr. Florence P. Haseltine for her substantial contributions to this Article. Dr. Haseltine is currently the Director of the Center for Population Research at the National Institute of Child Health and Human Development and is the founder of the Society for Women's Health Research.

1. Robert N. Anderson, *United States Life Tables, 1997*, NAT'L VITAL STAT. REP., Dec. 13, 1999, at 1, 3.

2. BERNADINE HEALY, A NEW PRESCRIPTION FOR WOMEN'S HEALTH 16 (1995); Terrie T. Wetle & Richard J. Havlik, *Foreword* to THE WOMEN'S HEALTH AND AGING STUDY: HEALTH AND SOCIAL CHARACTERISTICS OF OLDER WOMEN WITH DISABILITY, at xii (Jack M. Guralnik et al. eds., 1995).

3. U.S. Pub. Health Serv., *Report of the Public Health Service Task Force on Women's Health Issues*, 100 PUB. HEALTH REP. 73 (1985).

4. *See also* Edward N. Brandt, Jr., *Some Thoughts About Women's Health and Its Evolution*, 1 J. GENDER-SPECIFIC MED. 48, 48-49 (1988) (discussing the establishment of a U.S. Department of Health and Human Services Talk Force to analyze and assess the information gap).

recommendations for improving the research process to allow for more equitable and scientifically sound research on the health issues that affect women. These recommendations include closer attention to the needs of female research participants, as well as novel methods of study design and data analysis.

I. THE HISTORY OF THE WOMEN'S HEALTH MOVEMENT

A. The Traditional Paradigm

Anyone who has taken a course in human biology, physiology, or pharmacology is familiar with the "Typical 70 Kilogram Man."[5] Our knowledge of human biology is based on this archetype as the standard human research subject. For decades, biologists and medical researchers approached the study of human biology from the point of view that whatever happened in the "70 Kilogram Man" was the norm, and that anything that differed from that norm, including female biology, was "atypical," or even abnormal.[6] A quick Medline search shows that this model is still in use; practice guidelines and research examples are often expressed in terms of the 70 kilogram male.[7]

Until recent years, most researchers belonged to one of two camps (and sometimes both): one group saw females as smaller versions of males and thus viewed the study of women as unnecessary; the other group believed that women were too complicated to study because their hormonal cycles made them difficult subjects and led to complicated data.[8] Research results from men were routinely incorporated into treatment guidelines for women, regardless of acknowledged male/female

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5. *See, e.g.*, ROBERT L. VICK, CONTEMPORARY MEDICAL PHYSIOLOGY (1984) (using the "70 Kilogram Man" as the standard throughout).

6. *See* HEALY, *supra* note 2, at 8.

7. *See, e.g.*, Robert Cartotto et al., *Minimizing Blood Loss in Burn Surgery*, 49 J. TRAUMA 1034 (2000); Mark V. Dahl & Alina G. Bridges, *Intravenous Immune Globulin: Fighting Antibodies with Antibodies*, 45 J. AM. ACAD. DERMATOLOGY 775 (2001); Mark A. Healey et al., *Irreversible Shock Is Not Irreversible: A New Model of Massive Hemorrhage and Resuscitation*, 50 J. TRAUMA 826 (2001); Wilbur Huang et al., *Pharmacology of Botulinum Toxin*, 43 J. AM. ACAD. DERMATOLOGY 249 (2000); Jerry W. Shay & Woodring E. Wright, *Aging: When Do Telomeres Matter?*, 291 SCIENCE 839 (2001).

8. Tracy L. Johnson & Elizabeth Fee, *Women's Health Research: An Introduction*, *in* WOMEN'S HEALTH RESEARCH: A MEDICAL AND POLICY PRIMER 3, 14-15 (Florence P. Haseltine & Beverly Greenberg Jacobsen eds., 1997) [hereinafter WOMEN'S HEALTH RESEARCH].

differences in body fat, hormones, and other physiological functions.

Policies aimed at protecting the fetus and women's reproductive potential added to this preference for male subjects. In 1962, the Kefauver-Harris Amendment, perhaps the most important piece of legislation regulating the conduct of clinical trials, was passed with the purpose of protecting children, pregnant women, and fetuses. The Kefauver-Harris amendment required drug manufacturers to demonstrate that new drugs were safe and effective via adequate and well-controlled clinical trials.[9] This legislation was passed in response to the thousands of babies born with severely deformed limbs as a result of *in utero* exposure to Thalidomide. Later, during the early 1970s, research revealed that the daughters of women who took diethylstilbestrol (DES) during pregnancy had an increased risk of vaginal cancer.[10] In 1977, the United States Food and Drug Administration (FDA) responded to these two events by issuing guidelines that required women of childbearing potential to be excluded from drug trials until teratogenicity data from animal studies of the drug were available.[11] The only exception to these guidelines was for drugs used in the treatment of life-threatening or serious diseases. Because teratogenicity studies were usually performed at the same time as clinical trials in humans, these guidelines had the effect of excluding women from most drug trials.[12] When the general acceptance of the male norm was coupled with images of deformed babies, the medical community did not question the exclusion.

B. The Women's Health Movement: A Sea Change in Public Policy

Despite their commendable purpose, the 1977 guidelines did more harm than good. In 1983, then-Assistant Secretary for Health Dr. Edward Brandt found that while the United States Public Health Service published a great deal of health information on menstruation, menopause,

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9. Drug (Kefauver-Harris) Amendments of 1962, Pub. L. No. 87-781; 76 Stat. 780 (codified as amended in scattered sections of 21 U.S.C.); *see also* Mark S. Schreiner & William J. Greeley, *Safe and Effective for Children?*, 141 AM. HEART J. 3, 3-5 (2001).

10. Arthur L. Herbst et al., *Adenocarcinoma of the Vagina: Association of Maternal Stilbestrol Therapy with Tumor Appearance in Young Women*, 284 NEW ENG. J. MED. 878 (1971).

11. U.S. DEP'T HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., HEW PUB. NO. 77-3040, GENERAL CONSIDERATIONS FOR THE CLINICAL EVALUATION OF DRUGS (1978).

12. Susan Flamm Honig, *Ethical Issues in Recruitment: Communicating the Risks to Women of Childbearing Potential*, *in* THE SOCIETY FOR WOMEN'S HEALTH RESEARCH, PROCEEDINGS FROM WOMEN AND CLINICAL RESEARCH: BREAKING THROUGH THE BARRIERS TO RECRUITMENT AND RETENTION 9, 9-11 (2001).

pregnancy, and breast diseases, there was a lack of information on other conditions, such as heart disease, that affect women. To address this situation, Dr. Brandt appointed a task force on women's health issues to develop an analysis of women's health activities and an agenda for further activities.[13] In 1985, the task force concluded that the lack of a research focus on women's health issues compromised the quality of health information available to women as well as the health care they received.[14] The report's findings prompted the National Institutes of Health (NIH) to develop guidelines urging the inclusion of women of child-bearing potential in federally funded clinical research.[15] Researchers and women's health advocates soon became aware, however, that the inclusion guidelines were not enforced and that women were still routinely excluded from clinical trials.[16]

In 1990, researchers and advocates concerned about the inclusion of women in medical research organized into what later became the Society for Women's Health Research.[17] At the urging of the Society, Congress ordered the General Accounting Office (GAO) to conduct a study into NIH's policies and practices regarding the inclusion of women. The resulting GAO report disclosed the lack of improvement in the inclusion of women in NIH-funded research. Specifically, the report found that the NIH policy had not been well communicated or understood within NIH or the research community, was applied inconsistently across institutes, and only applied to extramural research.[18] The GAO also found that despite their own published recommendations, NIH officials had done little to encourage the analysis of study data by sex. Finally, the 1990 GAO report concluded that there was no readily accessible source of data on the demographics of NIH study populations.[19] The 1990 GAO report signaled a

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13. Brandt, *supra* note 4.

14. *See* U.S. Public Health Service, *supra* note 3.

15. 15 NAT'L INST. HEALTH, NIH GUIDE FOR GRANTS AND CONTRACTS (1986) ("[T]he NIH urges applicants for grants and offerors for contracts to consider the inclusion of women in the study populations for all clinical research efforts. . . . If women are not included, a clear rationale should be provided for their exclusion.").

16. *Problems in Implementing the National Institutes of Health Policy on Women in Study Populations: Hearing Before the Subcomm. on Housing and Consumer Interest of the House Select Comm. on Aging*, 101st Cong. (1990) [hereinafter *Hearing*] (statement of Mark V. Nadel, Associate Director, U.S. Gen. Accounting Office).

17. *The Society for Women's Health Research: About the Society, Society History, at* http://www.womens-health.org/ (last visited Dec. 5, 2002).

18. *Hearing, supra* note 16.

19. *Id.*

landmark moment for women's health research. Researchers were put on notice that they would be held accountable for upholding previously enacted policies that encouraged the inclusion of women in clinical trials.

Public outrage over the implications of missing information on women fueled the work of congressional champions of the issue. A month after the release of the GAO report, the Congressional Caucus on Women's Issues introduced the Women's Health Equity Act of 1990 (WHEA).[20] This legislative response consisted of twenty separate bills designed to improve research on women's health issues, women's access to health care, and disease prevention services for women. WHEA's chief Senate sponsor, Senator Barbara Mikulski (D-MD), attached three provisions to legislation reauthorizing NIH funding which created an office specifically devoted to women's health research at NIH, required that women be included in clinical trials, and established five contraceptive and infertility research centers.[21] Of all the provisions included in the bill, only two—the Breast and Cervical Cancer Mortality Prevention Act and Medicare coverage for screening mammography—were passed at that time.[22]

Also as a result of the 1990 GAO report and the outcry it provoked in Congress, NIH instituted guidelines for grant submission that required the inclusion of women as research subjects unless there was a clear justification for their exclusion.[23] These guidelines became law in 1993 with the passage of the 1993 NIH Revitalization Act,[24] which contained language requiring the inclusion of women in medical research[25] and the analysis of resulting data by sex.[26] This language differs from the 1985 guidelines, as the earlier guidelines simply encouraged, but did not *require*, the inclusion of women in clinical trials. By requiring the inclusion of women, the new

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20. Women's Health Equity Act of 1990, H.R. 5397, 101st Cong.; Women's Health Equity Act of 1990, S. 2961, 101st Cong.

21. *Id.*

22. Lesley Primmer, *Women's Health Research: Congressional Action and Legislative Gains: 1990-1994, in* WOMEN'S HEALTH RESEARCH, *supra* note 8, at 308.

23. Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. 39,406 (July 22, 1993).

24. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14,508 (Mar. 28, 1994).

25. The 1994 NIH guidelines state that "it is the policy of NIH that women and members of minority groups and their subpopulations must be included in all . . . projects involving human subjects." *Id.* at 14,509.

26. The 1994 guidelines stated that "[f]or Phase III clinical trials, [the NIH must] ensure that women and minorities and their subpopulations must be included such that valid analyses of differences in intervention effect can be accomplished." *Id.* at 14,508.

legislation was a major policy shift in biomedical research. Scientists could no longer categorically deny women access to clinical trials; instead they had to provide a scientific argument to justify women's exclusion.

The 1990 GAO report on the inclusion of women in NIH-sponsored research was followed by a 1992 report on the practices of the FDA in approving prescription drugs. The 1992 report found that while women were sometimes included in drug trials, they were underrepresented.[27] The study reported that "for more than 60 percent of the drugs, the representation of women in the test population was less than the representation of women in the population with the corresponding disease."[28] Even when women were included in large numbers, data were not analyzed to determine if women's responses differed from those of men. Further, drug manufacturers often failed to study whether their drugs interacted with the different hormonal environment of a woman's body. The report concluded by recommending that the FDA should ensure that drug companies consistently include "sufficient numbers of women in drug testing to identify gender-related differences in drug response and that such differences are explored and studied."[29] As a result of this report, the FDA lifted its restriction regarding the inclusion of women of childbearing potential in clinical trials and formalized guidelines regarding the analysis of data by sex.[30]

C. Clinical Trials and the Pregnant Woman

The regulatory changes of the 1990s resulted in greater access to clinical trials for women. By the year 2000, the number of women in federally funded clinical trials was proportionate to their numbers in the general population.[31] The inclusion of pregnant women, however, remained an especially thorny issue. In 1975, the federal regulations governing the use of human subjects in research were amended to reflect a perceived need to afford special protection to fetuses and potential fetuses, effectively treating the fetus as a vulnerable research subject who could not

27. U.S. GEN. ACCOUNTING OFFICE, GAO-HRD-93-17, WOMEN'S HEALTH: FDA NEEDS TO ENSURE MORE STUDY OF GENDER DIFFERENCES IN PRESCRIPTION DRUGS TESTING (1992).

28. *Id.* at 2-3.

29. *Id.* at 12.

30. *See* Guideline for the Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs, 58 Fed. Reg. 39,406 (proposed July 22, 1993).

31. U.S. GEN. ACCOUNTING OFFICE, GAO/HEHS-00-96:2, WOMEN'S HEALTH: NIH HAS INCREASED ITS EFFORTS TO INCLUDE WOMEN IN RESEARCH (2000).

give consent.[32] This change had the result of diminishing women's autonomy in deciding whether to assume the risk of participation in a clinical trial, regardless of whether or not she was pregnant. In 1991, the emphasis shifted from fetal protection to respect for women's autonomy when the Supreme Court ruled in *UAW v. Johnson Controls, Inc.* that a woman has the right to be involved in decisions concerning fetal risk.[33] This ruling supported the Pregnancy Discrimination Act of 1978,[34] which stated that decisions about the welfare of future children should be left to the parents who conceive, bear, support, and raise them. In both instances, the Court and Congress supported a woman's ultimate right to make the decision about accepting risks that may be potentially harmful to her reproductive status.[35] Assuming that a woman is given appropriate risk information, one would assume that she is as capable of making decisions about participation in clinical trials as she is of making decisions about employment.

In May of 1998, during the Clinton administration, the United States Department of Health and Human Services (HHS) published a proposed change to federal regulations[36] that would have allowed pregnant women to be included in clinical trials.[37] Essential to this rule was the policy of *not* requiring paternal consent for a pregnant woman to participate in research.[38] In the past, paternal consent had been a barrier to the participation of woman or fetuses in research.[39] In reviewing the Proposed Rule, organizations such as the National Task Force on AIDS Drug Development, the Presidential Advisory Council on HIV/AIDS, and the Institute of Medicine's Committee on the Ethical and Legal Issues Relating

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32. Protection of Human Subjects, 40 Fed. Reg. 33,526 (Aug. 8, 1975) (to be codified at 45 C.F.R. pt. 46).

33. UAW v. Johnson Controls, Inc., 499 U.S. 187 (1991); *see also* Ruth B. Merkatz & Elyse I. Summers, *Including Women in Clinical Trials: Policy Changes at the Food and Drug Administration, in* WOMEN'S HEALTH RESEARCH, *supra* note 8, at 274.

34. 42 U.S.C. § 2000e(k) (2000).

35. *See* Merkatz, *supra* note 33, at 274.

36. 45 C.F.R. pt. 46.

37. Protection of Human Research Subjects, 63 Fed. Reg. 27,794 (proposed May 20, 1998) (to be codified at 45 C.F.R. pt. 46). This legislation reversed a 1977 ruling which excluded women of childbearing potential from participating in clinical trials. *See also* U.S. DEP'T HEALTH & HUMAN SERVS., *supra* note 11; Honig, *supra* note 12.

38. The issue of paternal consent will be discussed in more detail below. *See infra* Section II.D.

39. *See* Protection of Human Research Subjects, 63 Fed. Reg. 27,794 (proposed May 20, 1998) (to be codified at 45 C.F.R. pt. 46).

to Inclusion of Women in Clinical Studies, agreed unanimously that the participation of pregnant women in research should not be conditioned on paternal consent.[40] The Final Rule, which was published in January 2001, concluded "the decision making authority for research participation of the pregnant woman or fetus prior to delivery should rest with the pregnant woman."[41] By making the pregnant woman the sole decision-maker, the regulation based the participation of pregnant women in research on a policy of presumed inclusion, rather than presumed exclusion.

Scheduled to take effect in March 2001, this regulation was delayed as the incoming Bush administration considered several modifications, one of which specifically addressed paternal consent.[42] The proposed modification would have required a father's consent for participation in research that was directed solely at the fetus and that would not affect the mother's health. The father's consent, however, would not be needed for a woman to participate in research that would benefit her own health.[43]

This distinction is largely apocryphal as one cannot generally separate the health of the mother from that of the fetus.[44] As one policy expert stated, "Fetuses may be more vulnerable than adults, but no hazards affect exclusively fetuses."[45]

After reviewing public comment on the modification, HHS adopted the modification into the final replacement rule on November 13, 2001 and retained the language specifying that paternal consent would be required for participation in research directed solely at the fetus.[46] The final rule did add language specifying that paternal consent is not required in the case of rape or incest and that only maternal consent is needed for participation in research that may benefit *both* the mother and the fetus or only the mother. In cases where research is aimed only at the fetus, paternal consent is required for participation.

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40. Protection of Human Research Subjects, 66 Fed. Reg. 3879 (Jan. 17, 2001) (to be codified at 45 C.F.R. pt. 46).

41. *Id.* at 3880.

42. Protection of Human Research Subjects, 66 Fed. Reg. 35,576 (proposed July 6, 2001) (to be codified at 45 C.F.R. pt. 46).

43. *Id.*

44. *Id.* at 56,776.

45. Ruth Hubbard, *The Politics of Fetal/Maternal Conflict, in* POWER AND DECISION: THE SOCIAL CONTROL OF REPRODUCTION 311 (Gita Sen & Rachel C. Snow eds., 1994), *available at* http://www.hsph.harvard.edu/Organizations/healthnet/gender/docs/hubbard.html.

46. Protection of Human Research Subjects, 66 Fed. Reg. 56,775 (proposed Nov. 13, 2001) (to be codified at 45 C.F.R. pt. 46).

D. Criticism of the Women's Health Movement and the Response to that Criticism

As a result of legislation and policies to make medical research more widely available to women, the number of women included in clinical trials has increased. As mentioned above, a report issued by the GAO in 2000 found that women are being included in clinical trials at rates proportionate to their numbers in the general population.[47] The report found that "the review process for extramural research now treats the inclusion of women and minorities as a matter of scientific merit . . . and it appears that NIH staff and researchers are working to ensure that, when appropriate, study findings will apply to both women and men."[48]

With success, however, comes criticism. Critics cite the increasing numbers of female participants in NIH-funded clinical trials as evidence that attention to women's health has come at the expense of attention to men's health.[49] Many of these critics have based their arguments on the findings of a 2000 study by Curtis Meinert, which concluded that prior to 1993, women had *not* been excluded from clinical trials.[50] A small number of vocal opponents to the women's health movement saw the 2000 GAO report and Meinert's article as opportunities to lambaste policies aimed at promoting a women's health agenda.[51] However, the findings from this single study are contradicted by those of several other studies that did find a bias against the inclusion of women in clinical trials[52] but did not gain as

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47. *See* U.S. GEN. ACCOUNTING OFFICE, *supra* note 31.

48. *Id.* at 2.

49. EXPLORING THE BIOLOGICAL CONTRIBUTIONS TO HUMAN HEALTH: DOES SEX MATTER?, (Theresa M. Wizemann & Mary-Lou Pardue eds., 2001), *available at* http://bookshop.edu/books/0309072816/html; Edward E. Bartlett, *NIH Is Playing Fast and Loose with the Truth*, MEN'S HEALTH AM., *at* http://groups.yahoo.com/group/menshealth/message/157 (last visited on Dec. 4, 2002); Cathy Young, *Medical Gender Wars*, SALON, *available at* http://dir.salon.com/health/feature/2000/09/20/ womens_health/ (last visited on Dec. 4, 2002); Cathy Young, *It's Time To End the Gender Gap in Health Care*, BOSTON GLOBE, Nov. 15, 2000, at A27.

50. Curtis L. Meinert et al., *Gender Representation in Trials*, 21 CONTROLLED CLINICAL TRIALS, 462-75 (2000).

51. *See* EXPLORING THE BIOLOGICAL CONTRIBUTIONS TO HUMAN HEALTH, *supra* note 49; Satel, *supra* note 49; Young, *supra* note 49; Bartlett, *supra* note 49.

52. Kathryn Graff Low et al., *Women Participants in Research: Assessing Progress*, 22 WOMEN'S HEALTH 79-98 (1994); Mary McGrae McDermott et al., *Changes in Study Design, Gender Issues, and Other Characteristics of Clinical Research Published in Three Major Medical Journals from 1971 to 1991*, 10 J. GEN. INTERNAL MED. 13-18 (1995); Douglas L. Schmucker &

much exposure in the popular press as did Meinert's.

Meinert also asserts that "within broad limits, treatments shown to work in one gender group also work in the other gender group."[53] This conclusion was soundly refuted in the Institute of Medicine's 2001 landmark report, *Exploring the Biological Contributions to Human Health: Does Sex Matter?*.[54] In the mid-1990s, a consortium of public and private sponsors, led by the Society for Women's Health Research, initiated and sponsored the formation of the Institute of Medicine's (IOM) Committee on Understanding the Biology of Sex and Gender Differences. The Committee was charged with considering the biology of sex at the cellular, developmental, organ, organismal, and behavioral levels. The IOM report concluded that:

> There is now sufficient knowledge of the biological basis of sex differences to validate the scientific study of sex differences and to allow the generation of hypotheses. . . . Naturally occurring variations in sexual differentiation and development can provide unique opportunities to obtain a better understanding of basic differences and similarities between and within the sexes.[55]

Figure 1 provides a list of a few of the sex differences highlighted in the IOM report.

The exploration of sex differences in medical research is not purely an academic concern. Missing information on sex differences has serious health implications for women. A 2001 report by the GAO found that eight of ten prescription drugs that had been withdrawn from the United States market since January 1997 caused serious adverse reactions more often in women than in men.[56] Four of these drugs were prescribed with equal frequency to men and women, suggesting that the greater health risks in women were possibly due to physiological differences between women and men that predispose women to some drug-related health risks, including

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Elliot S. Vesell, *Underrepresentation of Women in Clinical Drug Trials*, 54 CLINICAL PHARMACOLOGY & THERAPEUTICS 11 (1993); Regina M. Vidaver et al., *Women Subjects in NIH-Funded Clinical Research Literature: Lack of Progress in Both Representation and Analysis by Sex*, 9 J. WOMEN'S HEALTH GENDER BASED MED. 495-504 (2000).

53. Curtis L. Meinert & Adele Kaplan Gilpin, *Estimation of Gender Bias in Clinical Trials*, 20 STAT. MED. 1153, 1163 (2001).

54. *See* EXPLORING THE BIOLOGICAL CONTRIBUTIONS TO HUMAN HEALTH, *supra* note 49.

55. *See id.* at 3.

56. U.S. GEN. ACCOUNTING OFFICE, GAO-01-286R, DRUG SAFETY: MOST DRUGS WITHDRAWN IN RECENT YEARS HAD GREATER HEALTH RISKS FOR WOMEN 2 (2001).

Torsades de Pointes (TdP), a potentially fatal cardiac arrhythmia (Table I).[57]

Other studies support the GAO findings. For example, one study found that the commonly prescribed antibiotic erythromycin causes TdP more often in women.[58] The investigators concluded that greater serum concentrations of erythromycin in women were not to blame for the increased risk of TdP; rather, the rate of erythromycin metabolism is higher in women, thereby mitigating the differences in body size and blood volume.[59] Some experimental studies have suggested that sex hormones, such as estrogen, can alter myocardial repolarization, potentially prolonging the QT interval,[60] leading to TdP.[61] Other studies, however, suggest that the effects of estrogen are not likely to be responsible for the gender differences seen in myocardial repolarization.[62] Conflicting findings such as these highlight the need for further research in the field of sex-based biology.

Sex differences in drug metabolism have serious implications for the drug development and approval process. For example, in one study of steroid-dependent Crohn's disease, researchers used separate parameters for drug clearance (the rate at which the body metabolizes a drug)—one for males and one for females.[63] They also used covariants such as lean body weight to take into account the volume of drug distribution. They found that for a given dose of the study drug, males in the study had a

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57. *Id.* at 2-4.

58. Milou-Daniel Drici et al., *Cardiac Actions of Erythromycin: Influence of Female Sex*, 280 JAMA 1774, 1774-76 (1998).

59. *Id.* at 1776.

60. The QT interval is a measurement made from the electrocardiogram (ECG or EKG). It reflects the duration of the electrical activity that controls contraction of the cells of the heart muscle. For more information, see Ariz. Ctr. for Educ. & Res. on Therapeutics, *Commonly Asked Questions*, *at* http://www.qtdrugs.org/consumers/ask-expert.htm (last visited Jan. 21, 2003).

61. Milou-Daniel Drici et al., *Sex Hormones Prolong the QT Interval and Downregulate Potassium Channel Expression in the Rabbit Heart*, 94 CIRCULATION 1471, 1473-74 (1996); M. Pragnell et al., *Estrogen Induction of a Small, Putative K+ Channel mRNA in Rat Uterus*, 4 NEURON 807 (1990).

62. Jennifer A. Larsen et al., *Effects of Hormone Replacement Therapy on QT Interval*, 82 AM. J. CARDIOLOGY 993, 993-95 (1998).

63. Helen Pentikis, Detecting PK Differences in Phase I trials (2001) (paper presented at Subgroup Analysis and Statistical Design for Detecting Sex Differences: Detecting Sex Differences in Clinical Trials, conference sponsored by the Society for Women's Health Research) (on file with author).

lower maximum concentration of the drug than did females. Further, they concluded that weight normalization for dosing did not provide for equal exposure for this particular drug and that dosing should have been stratified by sex. Despite this important information, the study sponsor did not want separate dosing recommendations for males and females for fear it would be more difficult to market the drug with differential dosing.[64] As this drug failed to show efficacy at a single dose, the study sponsor elected not to market it.[65]

In another study, a lipid protease inhibitor failed to show efficacy in reducing damage from infarcts of the brain.[66] When looking at the pharmacokinetic (PK) and pharmacology data in retrospect, however, there is reason to believe that the women in the study were simply underdosed. The clearance rate for the drug was 149 percent greater in women than in men, meaning that on average, for a given dose, women achieved only two-fifths the blood, tissue, and brain levels of the drug that men did. In this case, the study sponsor decided not to move forward with developing the drug and a potentially beneficial therapy was lost.[67]

As demonstrated by these examples, the inclusion of more women in clinical trials without appropriate analysis of data by sex serves political purposes but does little to improve our knowledge of women's health. The 2001 reports from the IOM and GAO emphasize that analyzing data by sex is critical for advancing our knowledge of human health.

II. POLICY SUGGESTIONS AND IDEAS FOR THE FUTURE

A. Improving Recruitment and Retention

Women are now increasingly included in clinical trials, but much can still be done to encourage women to volunteer for and remain in trials. Research has found that public misperceptions, mistrust of medical research, and fear of clinical trials are major barriers to participation in trials for both men and women. Potential subjects often believe that participating in a research trial means that they will receive general

64. *Id.*

65. *Id.*

66. Carl Peck, Detecting Sex Differences Ethically and Efficiently in Phase I/II Trials (2001) (paper presented at Subgroup Analysis and Statistical Design for Detecting Sex Differences: Detecting Sex Differences in Clinical Trials, conference sponsored by the Society for Women's Health Research) (on file with author).

67. *Id.*

medical care. They may be disappointed to learn that they are only receiving medical care related to the study. Additionally, participants may drop out of a study if they believe they are receiving a placebo or less efficacious form of a drug or therapy. The fear of numerous visits, unpleasant side effects, or complicated regimens that can interfere with, work or family responsibilities can also prevent women from enrolling in medical studies.[68] Examples of research misconduct, such as the infamous United States Public Health Service Syphilis Study (known as "The Tuskegee Study"[69]) have led to fear and distrust of the medical system, resulting in lower enrollment rates.[70] To address this problem, investigators and recruiters must be frank with participants about the specifics of a study, realistic about the expected costs and benefits from the trial, and focused on conducting a trial safely and ethically.

Researchers often cite the difficulty of recruiting and retaining female subjects in clinical trials as one reason why women are not sufficiently included in studies. Beyond the barriers mentioned above, there are additional barriers that are of special concern for women. These include lifestyle and logistical issues, concerns about participation risks, potentially onerous requirements for fetal protection, and unmanageable time commitments required by the study protocol.[71] Traditionally, women have been the primary caregivers for family members. As such, participation in a clinical trial may significantly impact a woman's ability to care for her family. Minimizing time and safety barriers for women can have a significant effect on increasing their participation in clinical trials.[72]

Overcoming lifestyle and logistical issues requires that investigators consider critical questions during the study planning and implementation phases such as:

- Has study protocol minimized the number of study visits?
- Is the site open evenings or weekends?
- Can the site provide childcare during study visits?
- Does the site offer convenient parking and access to public

68. Donna Rae Richardson, *The Retention of Women in Clinical Trials: Lifestyle Issues Unique to Women, in* THE SOCIETY FOR WOMEN'S HEALTH RESEARCH, PROCEEDINGS FROM WOMEN AND CLINICAL RESEARCH: BREAKING THROUGH THE BARRIERS TO RECRUITMENT AND RETENTION 22 (2001).

69. JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (1993).

70. *Id.*

71. Soc'y for Women's Health Res., The Participation of Women in Clinical Trials: A Review of the Literature. (Apr. 1999) (unpublished data, on file with author).

72. Richardson, *supra* note 68, at 23-24.

transportation?

- Is the site located in a safe area?
- How can long waiting times during visits be reduced or avoided?[73]

Further, investigators should be cognizant of the potential impact of a study on a woman's responsibilities in the home.[74]

Study sites that have successfully retained women have done so by paying close attention to women's needs and concerns. Female participants value the relationships they develop with study staff and appreciate staff attention to events in their lives. Fostering such a relationship can be done with little added expense by simply taking note of events that a study participant mentions during visits.[75] These may be family events such as births, illnesses or deaths, or an upcoming vacation or anniversary. Other strategies may include sending birthday cards or valentines to participants, or creating newsletters and other ways to maintain contact between study visits.[76] Even in populations of hard-to-reach women, attention to their special needs results in exceptional retention rates. In one study of an HIV prevention and vaccine trial, researchers had a retention rate of ninety-two percent after the first year of the study.[77] What makes this retention rate so exceptional is that the study population consisted of poor, disenfranchised women, many of whom had moved repeatedly, or were using illegal drugs.[78] The researchers attributed their success to the support they provided these women in the form of a shoulder to cry on, toiletries for the homeless and incarcerated, and referrals to social services for housing, drug treatment, domestic violence, welfare or other services. In addition, they concluded that study design requires one full-time staff person whose job was to focus solely on retention issues.[79]

To overcome public fears and misperceptions of medical research among both men and women, organizations and agencies have initiated

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73. *Id.*

74. *See* Soc'y for Women's Health Res., *supra* note 71.

75. *See* Richardson, *supra* note 68.

76. *Id.*

77. Pamela Brown-Peterside et al., *Retaining Hard-to-Reach Women in HIV Prevention and Vaccine Trials: Project ACHIEVE*, 91 AM. J. PUB. HEALTH 1377 (2001).

78. Pamela Brown-Peterside, *The Retention of Women in Clinical Trials: Outreach to the Hard-to-Reach*, *in* THE SOCIETY FOR WOMEN'S HEALTH RESEARCH, PROCEEDINGS FROM WOMEN AND CLINICAL RESEARCH: BREAKING THROUGH THE BARRIERS TO RECRUITMENT AND RETENTION 24 (2001).

79. *See* Brown-Peterside, *supra* note 77, at 1378.

public education efforts and organized on-line resources for locating studies. NIH maintains a database of all federally-funded research studies. Patients and potential study participants can search this database at www.clinicaltrials.gov. On-line listings of clinical trials and information on participating can also be found at www.womancando.org[80] and www.centerwatch.com. All three websites contain information about what clinical trials are, who can participate, and how to make a decision about participating.

There is early evidence that web-based education may increase enrollment rates. Results from a recent Harris Poll and Boston Consulting Group study show that that the more frequently a patient uses the Internet to seek health information, the stronger his/her response to "the call to action issued by health care companies."[81] The researchers found that "those who use the Internet frequently are two to three times more likely than infrequent users to take action that affects their diagnosis and treatment."[82] Logic would dictate that the more often patients use the Internet to research clinical trials, the more likely they are to participate.

It is important to note that strategies for promoting the recruitment and retention of women in clinical trials can be applied to other under-represented populations such as minorities and the elderly. Specifically, effective recruitment and retention strategies will take into account the knowledge, attitudes, and beliefs of potential study volunteers, as well as an assessment of potential barriers to continuing participation once a volunteer is enrolled. For example, extensive outreach by investigators to community leaders can help to overcome mistrust within minority communities.[83] Researchers must be aware that normal effects of aging (for

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80. The Society for Women's Health Research's "Some Things Only a Woman Can Do" public education campaign (www.womancando.org) provides tools for physicians and researchers to educate potential study volunteers about research and participation in studies. The campaign distributes printed information (available by calling a toll-free number), maintains an Internet site, and coordinates outreach to the print and broadcast media to reach women throughout the United States.

81. Harris Interactive, *eHealth Paradox: It's Harder to Reach Patients Online Than To Have an Effect on Them*, HARRIS INTERACTIVE NEWSL. (July 2, 2001), *available at* http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=326.

82. *Id.*

83. Katherine Pitkin Derose et al., *Dealing with Diversity: Recruiting Churches and Women for a Randomized Trial of Mammography Promotion*, 27 HEALTH EDUC. BEHAV. 632, 643-44 (2000); Shawkat Dhanani et al., *Community-based Strategies for Focus Group Recruitment of Minority Veterans*, 167 MIL. MED. 501, 504 (2002); Marion K. Slack et al., *Strategies Used by Interdisciplinary Rural Health Training Programs To Assure Community Responsiveness and Recruit*

example, vision problems and mobility issues), chronic disease, transportation needs, negotiations with caretakers such as family members, and physician involvement can all impact recruitment and retention of elderly subjects.[84] It has become obvious that a one-size-fits-all approach to recruitment and retention will limit a researcher's ability to recruit a diverse study population.

B. Informed Consent and the Use of Contraceptives

For any woman, pregnant or not, a thoughtful and honest informed consent process is critical to increasing the participation rate of women in clinical trials. During the informed consent process the research staff is responsible for informing a woman of potential risks to both her and her potential fetus and providing her with information about all available options in the event of pregnancy. A 1999 study found, however, that "investigators often omit fetal risk information from consent documents."[85] Without full disclosure of fetal risks, a woman of childbearing potential is unable to make a truly informed decision about her enrollment in a clinical study.[86]

Concern about fetal risk may also lead to enrollment requirements that pose an undue burden on female participants, such as the use of contraception methods that the participant may not find acceptable or affordable. Researchers and study sponsors often struggle with how to communicate risk effectively, and one means of reducing risk in cases with clear evidence of fetal risk, or with an unknown potential for risk, is to require women who are heterosexually active and who are not surgically sterile or postmenopausal to use effective contraception. This approach, however, limits access to trials for women who do not use birth control for economic, medical, moral, or religious reasons. Further, there may be limitations to what constitutes "effective" contraception. For example, hormonal contraception may alter the pharmacokinetics and pharmacodynamics of the drug being studied and may make it difficult to

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Practitioners, 16 J. INTERPROF. CARE 129 (2002).

84. Elizabeth A. McNeely & Sandra D. Clements, *Recruitment and Retention of the Older Adult into Research Studies*, 26 J. NEUROSURGERY NURSING 57, 58-59 (1994).

85. Marie T. Nolan et al., *Consent Documents, Reproductive Issues, and the Inclusion of Women in Clinical Trials*, 74 ACAD. MED. 275, 275 (1999).

86. Dale Hammerschmidt, *Ethical Issues in Recruitment: Navigating the Informed Consent Process Responsibly*, *in* THE SOCIETY FOR WOMEN'S HEALTH RESEARCH, PROCEEDINGS FROM WOMEN AND CLINICAL RESEARCH: BREAKING THROUGH THE BARRIERS TO RECRUITMENT AND RETENTION 12 (2001).

separate the side effects of the study medication from the side effects of hormonal contraception.[87] Certain drugs can also alter the effectiveness of hormonal contraceptives.[88] Unfortunately, non-hormonal contraceptive methods such as condoms, diaphragms, periodic abstinence, and withdrawal have failure rates between thirteen and twenty-eight percent.[89]

An important study found that informed consent documents routinely spelled out the requirement that female participants use contraception, but did not provide adequate justification for such a requirement.[90] When a study does require the use of contraception, the explanations for this requirement should be offered in a manner that is respectful of a woman's autonomy in deciding which contraception methods to use. Women for whom contraceptives would be an unnecessary burden (for example, religious women who have taken vows of celibacy, women whose partners have been surgically sterilized, and lesbians) should not be required to use them. If the study involves compulsory pregnancy testing, this requirement should be clearly explained to women during the consent process.[91]

C. Pregnancy and the Clinical Trial

Because women of reproductive potential are now included in clinical trials, there is the potential for some of these women to become pregnant while participating in a study. Pregnancy during a clinical trial opens up new concerns and risks—including practical issues such as the unknown effects of pregnancy on the pharmacokinetics and pharmacodynamics of a drug, and the ethics of continuing the administration of a study medication with unknown reproductive risks. However, the 1994 report from the IOM concluded that the lack of information regarding safe treatment options for pregnant women has its own set of concerns and risks. The Committee recommended that "NIH strongly encourage and facilitate clinical research to advance the medical management of pre-existing medical conditions in women who become pregnant (e.g., lupus), medical conditions of pregnancy (e.g., gestational diabetes), and

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87. 1 WOMEN AND HEALTH RESEARCH 185 (Anna C. Mastroianni et al. eds., 1994), *available at* http://www.nap.edu/books/030904992X/html/.

88. Mark S. Yerby, *Special Considerations for Women with Epilepsy*, 20 PHARMACOTHERAPY 159S, 159S (2000).

89. Haishan Fu et al., *Contraceptive Failure Rates: New Estimates from the 1995 National Survey of Family Growth*, 31 FAM. PLAN. PERSP. 56, 56 (1999).

90. Joanna Cain et al., *Contraceptive Requirements for Clinical Research*, 95 OBSTETRICS & GYNECOLOGY 861, 861 (2000).

91. *See* Hammerschmidt, *supra* note 86, at 12.

conditions that threaten the successful course of pregnancy (e.g., pre-term labor)."[92] As outlined in the Belmont Report, the principal of respect for persons requires that research subjects be given the opportunity to choose what will and will not happen to them.[93] Therefore, a truly informed participant, aware of the potential risks to her and to her fetus, should be allowed to make her own decisions about continuing in a study. It is more unethical to deny her the autonomy to make her own medical decisions than it is to force her to quit in the name of fetal health.

D. Paternal Consent

The regulation discussed above requiring paternal consent before a pregnant woman can participate in a trial aimed at the health of the fetus[94] is based on the assumption that one can separate the mother's health from that of the fetus. Arguments for requiring paternal consent were summarized in a 1994 IOM report:

> The committee recognizes that the husbands of pregnant women, as well as future fathers who are not husbands, have an interest in the health of their children and that these men may have a deep emotional attachment toward their offspring prior to birth. Until a child is born however, the future father can only protect the health of the potential child by controlling the decisions and actions of the woman.[95]

The IOM concluded that "[t]o give men the authority to veto the decisions of their wives or partners to participate in research grants men unacceptable power over women."[96] This position is also supported by the Scientific and Ethical Review Group (SERG) of the World Health Organization, which stated, "A requirement of partner agreement or authorization for an individual to participate in research violates the autonomy of research subjects and their right to confidentiality."[97] By

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92. WOMEN AND HEALTH RESEARCH, *supra* note 87, at 16.

93. Nat'l Comm'n for the Prot. of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Apr. 18, 1979), http://ohsr.od.nih.gov/mpa/belmont.php3#xethical.

94. Protection of Human Research Subjects, 66 Fed. Reg. 35,576 (proposed July 6, 2001) (to be codified at 45 C.F.R. pt. 46).

95. WOMEN AND HEALTH RESEARCH, *supra* note 87, at 197.

96. *Id.*

97. World Health Org., *Guidelines on Reproductive Health Research and Partners' Agreement*, *in* PREPARING A PROJECT PROPOSAL, GUIDELINES AND FORMS (3rd ed. 2002), *available at* http://www.who.int/reproductive-health/hrp/guidelines_partners.en.html.

requiring paternal consent for participation in medical research, one is denying a woman the autonomy to make decisions about her health and about what is to be done to her body.

E. Improving Statistical Design in Clinical Trials and the Need for Accurate Drug Labeling

As discussed above,[98] sex differences in drug trials may be missed in early phase clinical trials because women are not included in numbers great enough to detect statistically significant differences in drug effects. So how can researchers avoid making such statistical errors in the analysis of clinical trial data? One way is to include enough women to have a sample size with enough power to be able to detect statistically significant sex differences. Trials this size, however, are generally cost-prohibitive.[99] Industry experts fear that escalating costs for clinical trials will have the effect of stalling medical research, as private companies will not be able to recoup research and development costs.[100]

But there are alternatives to large, costly trials. Dr. Carl Peck of Georgetown University recently proposed a method for conducting Phase I clinical trials in a manner that is both ethical and cost efficient. Safety and dosing information is determined in Phase I trials. These early trials generally have a small sample size (between ten and twenty subjects) and are usually conducted on men.[101] Peck proposes testing an investigational drug first in a small number of men and then testing it in a smaller number of women to determine if the women's results vary from those of the men. Using Bayesian analysis methods to compare the distribution of these results, [102] one could then determine if the females' distribution of drug responses differed from that of the males. If it did, then one would need to conduct a separate study in women to determine appropriate dosing and efficacy data. If their distributions were the same, one could then proceed to Phase II trials under the assumption that there were no sex differences in the metabolism of the drug.[103]

Innovative approaches to statistical analysis such as this can pave the

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98. *See* Peck, *supra* note 66; Pentikis, *supra* note 63; discussion *infra* Section II.D.

99. *See* Peck, *supra* note 66.

100. Tom Hollan, *What Women Want: Taking Sex Differences Seriously in Clinical Trials*, 1 CLINICAL RESEARCHER 24 (2001).

101. *See* Peck, *supra* note 66.

102. For an explanation of Bayesian analysis, see Will Hively, *The Mathematics of Making Up Your Mind*, 1996 *Discover* 90, *available at* http://www.discover.com/archive/index.html.

103. *See* Hollan, *supra* note 103, at 26.

way for drug sponsors to conduct clinical research that is relevant to women, without significantly increasing drug development costs.[104] Action, however, must also be taken in order to ensure that once sex differences are detected, information about these differences makes its way into drug labeling. It is easier to market a drug that has a one-size-fits-all dosing regimen.[105] Currently, there are very few incentives, and no requirements, for drug companies to have different dosing regimens or patient information sheets for men and women. Even when pharmacokinetic and safety data are available, the FDA does not require this information to be included in product labeling.[106]

A recent study by the FDA demonstrates the pressing nature of the drug labeling problem. The study examined the labeling for new drugs approved between 1995 and 1999. Of the 185 product labels analyzed for this study, twenty-two percent of the labels stated that there were sex differences for the drug. Ten percent stated that no studies were performed, studies were inadequate, retrospective review showed no differences, or that the product was not indicated in a specific gender. Thirty-two percent of the labels had no statements about sex.[107] Of the forty-one products for which the labels did describe sex differences, most (ninety percent) were pharmacokinetic. Twelve percent were safety differences and five percent were related to efficacy.[108] Of all 185 products reviewed, not one reported a change in dosage based on sex differences—despite the fact that thirty-seven of these products had known sex differences in their PK properties.[109]

F. Pharmacogenomics

Learning more about sex differences is just one step toward improving health care for both men and women. The sex of a patient may soon become a critical piece of information used by clinicians in deciding which antidepressant, cardiac drug, or painkiller to prescribe.[110] These exciting

104. *See* Peck, *supra* note 66.

105. *Id.*

106. B. Evelyn et al., *Women's Participation in Clinical Trials and Gender Related Labeling: A Review of New Molecular Entities Approved 1995-1999* (2001), *available at* http://www.fda.gov/cder/reports/womens_health/women_clin_trials.html (last visited Mar. 24, 2003).

107. *Id.* at 11.

108. *Id.* at 13.

109. *Id.*

110. Deborah Gesensway, *Reasons for Sex-Specific and Gender-Specific Study of Health Topics,*

discoveries are the building blocks for even greater advances in the field of medicine. The nascent field of pharmacogenomics, the science of examining the inherited variations in genes and how these variations can be used to predict an individual's response to a drug,[111] holds the promise of allowing clinicians to tailor drug therapies to the individual patient, not just to women or men. Advances in the field have led to new approaches to treating disorders common in women, such as heart disease and breast cancer.[112]

Pharmacogenomics may also reduce the incidence of adverse drug reactions (ADRs) in both women and men. Some of these ADRs could be prevented by changing prescribing practices for patients with a known genetic mutation that negatively impacts treatment outcomes.[113] For women, pharmacogenomics holds the promise of reducing the incidence of cerebral-vein thrombosis (blood clots), a common ADR associated with the use of oral contraceptives. Studies have shown that women who have the G20210A mutation for the prothrombin gene have ten times the risk of developing a blood clot as do women who do not have this mutation.[114] For all woman, taking oral contraceptives increases the risk of developing a blood clot by a factor of approximately twenty. It has now been shown that, in women who take oral contraceptives *and* have the prothrombin mutation, the relative risk of thrombosis is increased to nearly 150.[115] In the future, physicians may screen women for this and other genetic mutations before they are prescribed oral contraceptives. Women with susceptible genetic mutations would then have the option of using other contraceptive and therapeutic regimens. This is just one example of how pharmacogenomics may be used to improve the health of women. As the field matures, pharmacogenomics will offer the opportunity to better understand the pathogenesis of diseases and to improve sub-optimal drug

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135 ANNALS INTERNAL MED. 935 (2001).

111. Nat'l Ctr. for Biotechnology Info., Nat'l Inst. of Health, *One Size Does Not Fit All: The Promise of Pharmacogenomics* (Feb. 13, 2003), *at* http://www2.ncbi.nlm.nih.gov/About/primer/pharm.html.

112. Francis S. Collins & Victor A. McKusick, *Implications of the Human Genome Project for Medical Science*, 285 JAMA 540 (2001); Francis S. Collins, *Medical and Societal Consequences of the Human Genome Project*, 341 NEW ENG. J. MED. 28 (1999).

113. Kathryn A. Phillip et al., *Potential Role of Pharmacogenomics in Reducing Adverse Drug Reactions: A Systematic Review*, 286 JAMA 2270 (2001).

114. I. Martinelli et al., *High Risk of Cerebral-Vein Thrombosis in Carriers of a Prothrombin-Gene Mutation and in Users of Oral Contraceptives*, 352 NEW ENG. J. MED. 1793 (1998).

115. *Id.*

therapies for each sex.[116]

III. CONCLUSION

As the nascent field of pharmacogenomics demonstrates, and the 2001 IOM report confirms, it is crucial for researchers to look for differences in their study populations—whether they are differences related to gender or differences between individuals. However, researchers will not be able to detect these differences if study populations do not include appropriate numbers of women and men of all ages and ethnicities.

The inclusion of women in clinical trials has been a major force in the advancement of biomedical research. Paternalistic policies of the 1960s and 1970s gave way under pressure from the burgeoning women's health movement. which instigated landmark reports by the U.S. Public Health Service[117] and the United States General Accounting Office.[118] These reports led to changes in regulations regarding the inclusion of women in federally funded research.[119] As a result, by the late 1990s, record numbers of women were participating in medical studies. The data from these studies has finally resulted in the male norm of medical research being dislodged. Investigators have come to realize that recruiting and retaining women in research studies requires special attention to the unique needs of women. The IOM has recognized the field of sex-based biology as a valid scientific field of study.[120] Experts are urging the pharmaceutical industry to collect pharmacokinetic and pharmacodynamic data for women as well as men.[121] Statisticians and researchers are investigating novel methods for conducting sex analysis of research data without bankrupting the system with unwieldy study sizes.[122]

Despite these advances, many issues remain regarding the inclusion of women in clinical trials. Investigators still grapple with ethical issues regarding paternal consent and the inclusion of pregnant women in clinical trials. Even when it is collected, information about important sex

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116. Francis S. Collins & Alan E. Guttmacher, *Genetics Moves into the Medical Mainstream*, 286 JAMA 2322 (2001).

117. *See* U.S. Pub. Health Serv., *supra* note 3.

118. *See Hearing*, *supra* note 16.

119. Protection of Human Research Subjects, 66 Fed. Reg. 56,775 (proposed Nov. 13, 2001) (to be codified at 45 C.F.R. pt. 46).

120. *See* EXPLORING THE BIOLOGICAL CONTRIBUTIONS TO HUMAN HEALTH, *supra* note 49.

121. *See* Hollan, *supra* note 103.

122. *See* Peck, *supra* note 66.

differences often does not make its way into drug labeling[123] or into the medical literature.[124] There are signs, however, that this is changing. The FDA is proposing major revisions in the format of the content of package inserts to include information about sex differences,[125] and several prominent journals have begun requiring authors to include sex analysis in their manuscripts. *The Journal of the National Cancer Institute (JNCI)* specifically states in its information for authors that "Where appropriate, clinical and epidemiologic studies should be analyzed to see if there is an effect of sex or any of the major ethnic groups. If there is no effect, it should be so stated in Results."[126]

The wording of the editorial policy of the *JNCI* is particularly noteworthy because it specifically states that negative results must be reported. This is the antithesis of the more common practice of suppressing negative results.[127] It should be noted that several studies have found that publication bias (failure to publish negative findings) is initiated by the investigator and is not due to editorial decisions.[128] The authors found that most unpublished negative findings remained so because the investigators thought the results were uninteresting or they did not have enough time to publish them. By requiring investigators to include sex analysis results, even negative ones, in their manuscripts, journals such as *JNCI* are reinforcing the message of the 2001 IOM report: Sex does matter.

In the past fifteen years, women have made great strides in their participation in clinical trials. As the barriers to appropriate representation

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123. *See* EVELYN, *supra* note 109.

124. *See* Vidaver, *supra* note 52.

125. U.S. DEP'T HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, CTR. FOR BIOLOGICS EVALUATION & RESEARCH, GUIDANCE FOR INDUSTRY: CONTENT AND FORMAT OF THE ADVERSE REACTIONS SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUGS AND BIOLOGICS (2000) (draft guidance), *available at* http://www.fda.gov/cder/guidance/1888dft.pdf; *see also* Robert L. Woosley, *Drug Labeling Revisions: Guaranteed To Fail?*, 284 JAMA 3047, 3048 (2000).

126. Nat'l Cancer Inst., *Information for Authors for the Journal of the National Cancer Institute*, http://jncicancerspectrum.oupjournals.org/misc/jnci/ifora2.dtl (updated Mar. 13, 2003).

127. Kay Dickersin, *How Important Is Publication Bias? A Synthesis of Available Data*, 9 AIDS EDUC. & PREVENTION 15 (Supp. A 1997); Philippa J. Easterbrook et al., *Publication Bias in Clinical Research*, 337 LANCET 867 (1991).

128. Kay Dickersin & Yuan I. Min, *Publication Bias: The Problem that Won't Go Away*, 703 ANNALS N.Y. ACAD. SCI. 135 (1993); Kay Dickersin et al., *Factors Influencing Publication of Research Results: Follow-up of Applications Submitted to Two Institutional Review Boards*, 267 *JAMA* 374 (1992).

of women in medical research are being removed and more women volunteer for medical studies, scientists are discovering important sex differences that may lead to improved therapies and prevention strategies for both men and women. More importantly, the greater inclusion of women in clinical trails has led to more equitable research practices and has begun to narrow the information gap regarding women's health.

Figure 1. Examples of Sex Differences Beyond the Reproductive System.

Differences in Immune Function:

Females have a more aggressive immune response to infectious challenges, but are also more likely than males to develop autoimmune diseases.

Differences in Symptoms, Type and Onset of Cardiovascular Disease:

Men experience heart attacks, on average, 10 years earlier and have a better early survival rate than women. Symptoms of heart attack are also different in men and women. Women more often experience shortness of breath, fatigue, and nausea, while men more often experience crushing chest pain.

Differences in Response to Toxins:

Women are at 1.2- to 1.7-fold higher risk than men for all major types of lung cancer at every level of exposure to cigarette smoke.

Differences in Brain Organization:

Men rely on the inferior frontal gyrus to carry out language tasks. Women use both the left and right inferior gyrus to carry out the same task. Both men and women perform the task equally accurately and rapidly.

Adapted from "Box 1-2: Examples of Sex Difference Beyond the Reproductive System" in Wizemann, *supra* note 53 at 22-23.

Table I. Prescription Drugs Withdrawn from the United States Market, Jan. 1, 1997 Through Dec. 31, 2000.

Drug Name	Type of Drug	Primary Health Risk
Prescription Drugs With Evidence of Greater Health Risks in Women		
Drugs Prescribed with Equal Frequency to Men and Women		
Seldane (terfenadine)	Antihistamine	Torsades de Pointes
Posicor (mibefradil dihydrochloride)	Cardiovascular	Lowered heart rate in elderly women and adverse interactions with 26 other drugs
Hismanal (astemizole)	Antihistamine	Torsades de Pointes
Propulsid (cisparide monohydrate)	Gastrointestinal	Torsades de Pointes
Drugs Prescribed More Frequently to Women		
Pondimin (fenfluramine hydrochloride)	Appetite suppressant	Vavular heart disease
Redux (dexyfenfluramine hydrochloride)	Appetite suppressant	Vavular heart disease
Rezulin (troglitazone)	Diabetic	Liver failure
Lotronex (alosteron hydrochloride)	Gastrointestinal	Ischemic colitis (intestinal inflammation due to lack of blood flow)
Prescription Drugs Without Evidence of Greater Health Risks for Women		
Raxar (grepafloxacin hydrochloride)	Antibiotic	Torsades de Pointes
Duract (bromfenac sodium)	Analgesic and anesthetic	Liver failure

From U.S. Gen. Accounting Office, GAO-01-286R, Drug Safety: Most Drugs Withdrawn in Recent Years Had Greater Health Risks for Women 2 (2001).

COMMENTARY

Advocating for a Medicare Prescription Drug Benefit

John Rother, J.D.*

> *The health of a people is really the foundation upon which all their happiness and all their power as a state depend.*
>
> —Benjamin Disraeli, 1877

Efforts to enact a prescription drug benefit in Medicare date back more than forty years. Since then, drugs have continuously grown in importance; they have also grown in cost. Design and enactment of a Medicare drug benefit is therefore one of the most challenging health policy tasks before Congress. Many policy trade-offs have to be brokered, powerful interests acknowledged, budget limits respected, and public expectations rewarded. Ideology and partisan considerations also play a prominent role. As the benefit finally nears becoming law, as it inevitably must, the ongoing tension between adequacy and cost-containment has begun to play out in earnest. In all, the Medicare prescription drug debate serves as a microcosm of the competing forces that make the American health care system so challenging to reformers.

AARP (formerly the American Association of Retired Persons) made enactment of a voluntary, adequate, and affordable prescription drug benefit its top legislative priority for the past several years. This Commentary reviews the needs that have given urgency to this effort, the policy and political considerations surrounding the debate, and the advocacy strategy that AARP chose to achieve enactment of this benefit.

As this Commentary goes to press, the U.S. Senate and House of

* Policy and Strategy Director, AARP

Representatives have each passed Medicare prescription drug legislation. The conference committee, however, has just begun its work. The legislation's final form remains unknown.

NEED FOR COVERAGE: FINANCIAL BURDENS

Together, Medicare and Social Security were created to provide financial security to Americans in their later years. But there is no economic security for older Americans without comprehensive medical coverage, and there is no comprehensive medical coverage without prescription drug benefits.

Medicare beneficiaries make up approximately 15% of the population, yet account for about 40% of U.S. prescription drug spending.[1] Almost a third of Medicare beneficiaries—roughly 13 million older and disabled Americans—have no prescription drug coverage at all. And about 40% of Medicare beneficiaries lack coverage at some point in the year.[2] Millions of others have only partial or unstable coverage.[3] This amounts to a staggering financial burden on millions of older Americans and persons with disabilities. An estimated 80% of Medicare beneficiaries use a prescription drug every day and, on average, fill or refill a prescription 24 times a year.[4] According to the Congressional Budget Office (CBO), prescription drug spending for each Medicare beneficiary will exceed $3000, on average, by 2006.[5] The average Medicare beneficiary spends more out-of-pocket on prescription medications than on physician visits, medical supplies and vision services combined.[6]

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1. *Projections of Medicare and Prescription Drug Spending: Hearing Before the S. Comm. on Fin.*, 107th Cong. (2002) [hereinafter *Hearing*] (statement of Daniel L. Crippen, Director, Cong. Budget Office), *available at* http://www.cbo.gov/showdoc.cfm?index=3304&sequence=0 (last visited July 7, 2003).

2. Mary Laschober et al., *Trends in Medicare Supplemental Insurance and Prescription Drug Coverage, 1996-1999*, HEALTH AFFAIRS, Feb. 27, 2002, at W136, *at* http://www.healthaffairs.org/WebExclusives/Laschober_Web_Excl_022702.htm (last visited July 7, 2003).

3. DAVID J. GROSS, MEDICARE BENEFICIARIES AND PRESCRIPTION DRUGS: COST AND COVERAGE (AARP Public Policy Inst., Data Dig. No. 77, 2002), *available at* http://research.aarp.org/health/dd77_rx.pdf (last visited July 7, 2003).

4. John A. Poisal & Lauren Murray, Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage, HEALTH AFFAIRS, Mar./Apr. 2001, at 77.

5. This is an average based on Congressional Budget Office projections. *Hearing*, *supra* note 1, tbl.4.

6. DAVID GROSS & NORMANDY BRANGAN, OUT-OF-POCKET SPENDING ON HEALTH CARE BY

Elders with no drug coverage lack the comprehensive health benefits enjoyed by most insured Americans. They also are forced to pay top dollar for the prescriptions they buy because they are not eligible for the price discounts negotiated by insurers, managed care companies, and government health plans. In 1998, for example, Medicare beneficiaries who lacked drug coverage filled 31% fewer prescriptions than did beneficiaries with drug coverage, but spent an average of 40% more out-of-pocket on prescription drugs.[7]

NEED FOR COVERAGE: HEALTH IMPLICATIONS

According to recent studies, Medicare beneficiaries lacking drug coverage fill about 30 percent fewer prescriptions than do those with coverage.[8] A recent eight-state survey reported that 22% of older Americans said they did not fill a prescription because it was too expensive, or skipped doses of their medications to make them last longer; this number rose to 35% for elders who lacked prescription drug coverage.[9]

Chronic health problems common to the elderly often require medications that can total hundreds of dollars a month. Absent Medicare prescription coverage, many who lack drug coverage or who have inadequate coverage must choose between the drugs they need to stay healthy and other life necessities. For example, nearly one-third of the Medicare-eligible with diabetes, but without drug coverage, skipped doses or did not fill a prescription. Similarly, about a third of those with heart disease and without drug coverage reported skipping doses and 25% did not fill a prescription because of cost.[10]

There are serious health consequences to this kind of behavior: Chronically ill lower-income Medicare beneficiaries who don't take medications as prescribed are more frequently hospitalized, more likely to

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MEDICARE BENEFICIARIES AGE 65 AND OLDER: 1999 PROJECTIONS (AARP Public Policy Inst. Publication, In Brief No. 41, 1999).

7. John A. Poisal & Lauren Murray, *Growing Differences Between Medicare Beneficiaries With and Without Drug Coverage*, HEALTH AFFAIRS, Mar./Apr. 2001, at 74, 80-81.

8. *Id.* at 80.

9. Press Release, The Henry J. Kaiser Foundation, New Survey of Seniors in Eight States Finds Nearly One in Four Skipping Doses Or Not Filling Prescriptions Due to Cost (July 31, 2002), http://www.kff.org/content/2002/6049/NewsRelease.pdf (last visited July 7, 2003).

10. Dana Gelb Safran et al., *Prescription Drug Coverage And Seniors: How Well Are States Closing The Gap?*, HEALTH AFFAIRS, July 31,2002, at http://www.healthaffairs.org/WebExclusives/2105Safran.pdf (last visited July 7, 2003).

be admitted to nursing homes, and suffer more dire health outcomes.[11]

EXISTING SOURCES OF DRUG COVERAGE

Prescription drug expenditures are the fastest growing component of health care spending. According to the Centers for Medicare & Medicaid Services (CMS), total spending on prescription medications is projected to rise 13.4% in the United States this year to $182.1 billion, or 11.6% of the nation's $1.66 trillion in health spending.[12]

These costs are forcing insurers and employers to reduce benefits. Many companies today are reducing or eliminating retiree health benefits—the primary source of comprehensive drug coverage for the Medicare-eligible. According to a recent study by the Kaiser Family Fund, only 21% of companies with more than 200 employees provided health benefits to Medicare-age retirees in 2001, down from 31% just five years ago.[13]

Meanwhile, the private insurance market is proving dangerously volatile for Medicare beneficiaries. Faced with ballooning costs, many plans available through Medicare+Choice (the Medicare program that allows beneficiaries to opt into private plans) are increasing premiums and scaling back drug benefits. In 2003, 66.1% of plans offer some type of drug coverage in a basic plan, down from 73.4% in 1999.[14] Moreover, the number of plans that do provide coverage, but limit that coverage to

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11. See, e.g., Jan Blustein, Drug Coverage and Drug Purchases by Medicare Beneficiaries with Hypertension, HEALTH AFFAIRS, Mar./Apr. 2000, at 219; Stephen B. Soumerai, Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes, 325 NEW ENG. J. MED. 1072 (1991); Stephen B. Soumerai et al., Effects of Limiting Medicaid Drug-Reimbursement Benefits on the Use of Psychotropic Agents and Acute Mental Health Services by Patients With Schizophrenia, 331 NEW ENG. J. MED. 650 (1994).

12. CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH CARE EXPENDITURES PROJECTIONS TABLES, tbls.1 & 11, http://cms.hhs.gov/statistics/nhe/projections-2002/ (last visited July 7, 2003)

13. AARP Public Policy Inst., Employer Health Benefits: 2002 Annual Survey 144, 147 (2003); Kaiser Fam. Found. et al., Erosion of Private Health Insurance Coverage for Retirees: Findings From the 2000 and 2001 Retiree Health and Prescription Drug Coverage Survey 2 (2002).

14. It is important to note that these figures apply to any type of Medicare+Choice plan, not necessarily an HMO and, in 2003, 41.4% of plans with some prescription drug coverage covered generic drugs only. Eighty-five percent of plans offering 'generic coverage only' had an unlimited generic benefit. LORI ACHMAN & MARSHA GOLD, MATHEMATICA POLICY RES., INC., MEDICARE+CHOICE PLANS CONTINUE TO SHIFT MORE COSTS TO ENROLLEES (2003).

"generic drugs only," almost tripled just between 2001 and 2002 (51% vs. 18%).[15] As a result, those Medicare beneficiaries who need medications available only in brand-name forms have no coverage for those drugs.[16]

Other Medicare+Choice plans are abandoning the Medicare market entirely, leaving tens of thousands of patients who relied on the plans for prescription coverage without recourse. Medicare+Choice plans serving 215,000 enrollees withdrew from the Medicare program or reduced their service areas effective January 2003, bringing to 2.4 million the number of beneficiaries who have been dropped by Medicare+Choice plans since 1999.[17]

While some older Americans purchase additional insurance, known as Medigap policies, to cover prescription medications, these plans can be prohibitively expensive and offer only limited benefits.

The combined effect of these problems is that the need for a prescription drug benefit under Medicare is greater than ever.

BENEFIT DESIGN ISSUES

AARP is committed to pursuing a Medicare prescription drug plan that is voluntary, reliable, affordable, provides adequate benefits, and is available to all beneficiaries. Political and financial constraints, however, pose significant challenges to achieving these goals.

Consumer acceptance of any prescription drug plan is critical. Consider the case of the Medicare Catastrophic Coverage Act of 1988, an effort by Congress in the late 1980s to protect beneficiaries from

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15. LORI ACHMAN & MARSHA GOLD, THE COMMONWEALTH FUND, MEDICARE+CHOICE: BENEFICIARIES WILL FACE HIGHER COST-SHARING IN 2002 (2002), tbl.3, http://www.cmwf.org/programs/medfutur/achmangold_M+Ccostshar2002_533.pdf (last visited July 7, 2003).

16. *Id.*

17. CTRS. FOR MEDICARE & MEDICAID SERVS., CY 2002 NONRENEWAL REPORT BY STATE, COUNTY, PLAN, http://www.cms.gov/healthplans/nonrenewal/markprintedoutnew.asp (last visited July 7, 2003); CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE+CHOICE NONRENEWAL REPORTS CY 2001, http://www.cms.gov/healthplans/nonrenewal/reports2001.asp (last visited July 7, 2003); CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE+CHOICE NONRENEWAL REPORTS CY 2003, http://cms.hhs.gov/healthplans/nonrenewal/reports2003.asp (last visited July 7, 2003); MEDPAC, REPORT TO CONGRESS, MARCH 2000, http://www.medpac.gov/publications/congressional_reports/Mar00 Table of Contents.pdf (last visited July 7, 2003).

"catastrophic" medical bills not covered by Medicare.[18] The goal was to provide a safety net for those with the highest out-of-pocket medical expenses. But the legislation drew fire from many of the very beneficiaries it was enacted to help—in part because lawmakers made premiums mandatory and added an income-related premium of up to $800 per year, even for those older Americans who already had drug coverage through employer health benefits or other privately-purchased insurance plans.

Rallying behind the slogan "Repeal the Seniors-Only Surtax," opponents waged a successful protest even as public opinion polls showed that most seniors with low-to-modest incomes supported the legislation. The catastrophic bill was repealed before it could be implemented.

That experience taught Congress an important lesson: Public support is essential. For Medicare beneficiaries, any new benefit must be both affordable and voluntary. But as lawmakers have discovered, it is difficult to provide a voluntary comprehensive prescription plan that includes the benefits older Americans expect at a price they can afford.

Older Americans will only buy into the program if they feel they are saving money, which is difficult to do if the program is covering the cost of insuring both low-income beneficiaries and the "high-cost" patients with expenses beyond four or five thousand dollars a year.

For a viable program, premiums must be reasonably priced to attract middle class and relatively healthy beneficiaries. Otherwise, only high-risk beneficiaries—including patients with chronic conditions or higher-than-average drug costs—will buy in to the plan—a situation known as "adverse selection." If primarily high-cost beneficiaries bought in, an insurance "death spiral" could ensue, as premiums spiraled upward, and only those with the most expensive medical needs remained in the plan. If the cost of care exceeded the premiums collected and continuously forced increases in premiums, the plan would eventually fail.

Unfortunately, without federal support, the proposals under consideration could be priced far higher than most older Americans are willing or able to pay. Therefore, the only way to make a Medicare prescription benefit economically feasible is to factor in a significant federal contribution—a challenging prospect given current budgetary constraints.

CONGRESSIONAL DEBATE

In June of 2002, the United States House of Representatives passed a

18. Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 110-360, 102 Stat. 683.

$310 billion (over ten years) Medicare prescription drug bill that relied primarily on at-risk private insurers to administer the benefit. It also contained a significant gap in the benefit that critics dubbed the "doughnut hole." In July of 2002, the Senate tried and failed four times with four separate bills to muster the sixty votes necessary to pass its own version of a Medicare drug plan. Ninety-nine Senators voted for competing versions of a benefit, but could not reach a bipartisan compromise to reach the sixty-vote threshold required in the Senate to overcome points of order.

Despite this failure, Senators implicitly reached agreement on several key points, most notably, a commitment to fund the program with at least $400 billion over ten years—still an amount less than many consider necessary for a meaningful benefit. In addition, there was bipartisan agreement to offer coverage to all Medicare beneficiaries, to subsidize costs for low-income beneficiaries and those with the highest drug costs, and to cap the amount beneficiaries would have to spend out-of-pocket at approximately $4,000 a year.

But partisan and policy disputes ultimately killed the chance for legislative compromise in the Senate in 2002. At issue were three primary points of contention:

1. *Benefit design*: The "doughnut hole" gap in benefit coverage would have affected almost one third of Medicare beneficiaries who have drug costs above $3,450 per year. Republicans were unwilling to allocate the funding necessary to close that gap, while Democrats generally saw it as a barrier to beneficiary acceptance and incompatible with the goal of financial protection that is the rationale for a benefit.

2. *Who bears risk*: Democrats generally believe that government should run the program and bear the risk of cost overruns, just as Medicare currently accepts cost overruns for other parts of the healthcare system. Republicans prefer to put delivery in the hands of private insurers, who would compete for the enrollment of beneficiaries. They believe that such entities could be more flexible in achieving cost savings and, because they would be at financial risk, would have a strong incentive to do so. Democrats counter that relying on private insurers would only add overhead costs and could leave beneficiaries vulnerable if profits suffer and companies pull out of the market.

3. *Asset test*: Republican proposals impose both an asset test and an income test on beneficiaries who want to qualify for more generous low-income assistance, primarily as a means of saving money. Democrats generally view this as stigmatizing and a barrier to enrollment, and, as a matter of principle, do not want to introduce asset tests into a social

insurance program.

Last fall, Medicare prescription coverage proved a potent political issue in congressional campaigns across the country. In fact, almost all successful candidates pledged to enact a benefit in 2003. As a result, Congress convened in January with the understanding that it had to produce a benefit.

In addition to the issues mentioned above, the 108th Congress faces a heightened need for even tougher cost containment mechanisms, as well as a push for broader Medicare reforms, to accompany a drug benefit. The election gave Republicans control of the Senate and a greater margin in the House. President Bush designated $400 billion in his annual budget proposal for Medicare reform and a prescription drug benefit. Bipartisan legislation in the Senate (S.1) passed in the early hours of June 28th. The House followed hours later, passing H.R.1 by a single vote. Both bills combined a modest and voluntary prescription drug benefit with various "structural reforms" that increased the role of the private sector in Medicare. Both bills made changes to current benefits in Part B, and increased rural provider payment rates. Finally both bills structured the prescription drug benefit to primarily assist lower-income beneficiaries and those with the highest level of drug expenses.

As this Commentary goes to press, AARP has commented extensively on both bills and has written a detailed letter to the conferees expressing substantive concerns and recommendations. AARP is withholding judgment on a conference report, pending resolution of these items. The issues addressed in this Commentary remain central to the final legislative debate, with AARP's advocacy more intensive than ever in promoting an affordable, universal and workable benefit program.

COST CONTAINMENT STRATEGIES

Beyond the promise of an added benefit is the issue of how to keep it affordable over time, especially when drug costs are projected to increase at double-digit rates. A range of initiatives has been proposed. One such measure is a prescription discount card proposed by the Bush administration. Health and Human Services officials estimate that the card would save 10%-13% on eligible cardholders' out-of-pocket prescription costs, or an average of $170 per year. Government funding would not provide these discounts. It is anticipated that decreases would largely be possible from discounts Pharmacy Benefit Managers (PBMs) will negotiate from pharmacies and, less likely, from drug manufacturers.

Additional cost savings will be necessary. The reality is that any

comprehensive plan requires hard choices. The only way to have a sustainable drug benefit is to put in place mechanisms that contain costs and keep premiums affordable for beneficiaries.

Prescription prices in the United States are driven in part by the desire by drug manufacturers to recoup quickly their research, development, and capital costs—an investment now rewarded with twenty-year patents on new drugs that limit competition and delay the introduction of less-expensive generic alternatives. For this reason, among others, many in Congress have been reluctant to impose price controls, common in other countries, on pharmaceuticals. One way to control costs is through pharmacy benefit managers (PBMs), which negotiate discounts with drug manufacturers and pharmacies, and channel more prescription business through low-cost mail-order pharmacies.

A cost-sensitive prescription drug plan must also promote wider use of less expensive generic drugs where medically appropriate. Generics now account for 42% of all prescriptions filled, but potentially offer much greater savings: The Food and Drug Administration (FDA) estimates that nearly 60% of the most common brand name medications have cheaper generic equivalents, a figure expected to rise as patents on popular drugs expire over the next few years. In July of 2002, the United States Senate debated legislation (known as McCain/Schumer) that would have reformed federal patent law to promote price competitions and allow faster market access to generics. The bill would have closed loopholes in United States patent law that have allowed manufacturers to delay the introduction of generics to compete with name-brand drugs. According to an estimate by the CBO, the legislation would have reduced total spending on prescription drugs by $60 billion over the next ten years. The bill was approved by the Senate in 2002 but died in the House of Representatives. A modified version, with less savings, was approved in 2003 and included in the Medicare legislation by both the Senate and the House.

In addition, many states are implementing "preferred drug lists" (PDLs) and other measures to expand the use of generics and lower-cost brand-name drugs in their Medicaid programs. This could motivate manufacturers to reduce prices in order to remain competitive. This approach uses techniques applied by PBMs in the private sector to identify the most effective medication at the least cost. PDLs have substantially lowered state Medicaid drug expenditures and have prevented states from adopting more draconian cuts in their Medicaid programs, such as limiting eligibility.

But these approaches are not without controversy. Drug manufacturers are fighting many cost-control measures, and PhRMA, a

pharmaceutical trade group, has filed suit in federal court to block Medicaid PDLs.[19] PhRMA contends that such programs illegally restrict access to drugs. Many retail pharmacies oppose PBMs, claiming that pharmacy benefit managers set reimbursement rates to pharmacies too low to cover the cost of services they provide, and rely on mail-order pharmacies that could drive traffic away from community drugstores.

Finally, any successful cost-containment initiative must address value. Some drugs produce little additional benefit for great additional cost. There is to date little research to determine the comparative efficacy of particular drugs. This is missing information that could direct cost control approaches to lower overall costs without lowering health benefits. Developing such studies is expensive, but needs to be a national priority. Funding for efficacy research could be repaid several times over in the long term by focusing coverage expenditures on appropriate and effective medications.

MEDICARE STRUCTURAL REFORM

A second issue before the 108th Congress is broader Medicare reform. Many insurance analysts believe that a voluntary, stand-alone prescription drug product is not viable because only the sickest beneficiaries would be certain to apply. An alternative is to place a drug benefit in the context of broader insurance benefit packages that would be associated with broader Medicare reforms. Under this approach, beneficiaries could choose to enroll in a "high option" set of Medicare plans that trade higher premiums for an improved benefit package. Republican health leaders have long favored a greater role for private plans in Medicare. They view a prescription drug benefit as the "carrot" that will permit broader restructuring than would otherwise be politically possible.

Medicare structural reform, however, complicates both the design issues and the politics of achieving a drug benefit. Design issues take into account the need to reform the entire Medicare benefit structure, complicating the risk of pooling relationships between the original Medicare program and any new alternatives. Established ways of reimbursing providers for care may be affected, and reforms are likely to add to the total costs of a legislative proposal, at least for the near future. These issues had the potential to make or break the prescription drug drive to enactment in 2003. Like most other aspects of healthcare, the interrelationships among all aspects of financing, delivery, cost-

19. *See, e.g.*, Pharm. Research & Mfrs. of Am. v. Walsh, 123 S. Ct. 1855 (2003).

containment and consumer acceptance make Medicare policy-making especially difficult.

AARP'S ADVOCACY STRATEGY

AARP is the voice of the beneficiary, so we adopted a consumer-driven strategy. We have used all of the advocacy tools available to us to keep the concerns and views of beneficiaries before policy-makers, to present preferred solutions to the design and political challenges involved, and to keep the legislative momentum moving forward. We see ourselves as the key bridge between the political parties. We also act as a principal "validator" to the public for the worthiness of various proposals.

Our fundamental strategy has been to apply enough pressure on the Congress and the industry to break the legislative and political logjam. Given the budget constraints set by the White House, the proposed program was unlikely to be seen as adequate. Out of a projected total nationwide expenditure for prescription drugs of 1.8 trillion over the next ten years, the program would cover less than one-quarter of costs. Nevertheless, if a solid foundation was established, it could be built upon in future years. If assistance was targeted to lower-income beneficiaries and those with high expenses, the most pressing immediate needs would be met. Waiting for a more favorable budget allowance in future years seemed hazardous at best.

AARP played a crucial role in this campaign, mainly due to the clout of our thirty-five million members. We also developed a unique set of advocacy tools to employ in this effort. The challenges inherent in this effort required that all of these tools be used effectively in order to mount a successful campaign.

To support our ongoing advocacy strategy, we:

- Sponsor an active program of consumer polling and focus groups;
- Employ sophisticated economic policy analysis and modeling, including actuarial models and budgetary forecasting tools;
- Call upon our grassroots base and thousands of dedicated community-based volunteer advocates;
- Host candidate debates and town meetings during elections, although we do not fundraise for candidates or endorse them;
- Compile voters' guides based on candidate responses to our questions and distribute them to our members;
- Publish a monthly newspaper that features regular reporting on the progress of the campaign and on the urgency of the

problems. This newspaper goes to all AARP members, making it the largest circulation newspaper in the country;

- Sponsor radio interviews and television news spots that are broadly distributed to stations;
- Litigate to keep pressure on the industry to limit anti-consumer practices, and to make sure that laws are interpreted and enforced consistent with their intent;
- Advocate for state-based pharmaceutical assistance while the congressional debate continues. We believe that the state experience can contribute to the development of good policy, whether on cost-containment or the administrative arrangements involved in administering the benefit. To support this effort, AARP has staffed offices in every state;
- Join coalitions with other interested parties, such as business leaders, insurers, and governors. These coalitions are especially helpful in formulating consistent advocacy messages from a range of perspectives, and in building a broader base of support for particular aspects of legislation; and
- Engage in face-to-face lobbying in both the Congress and the Executive Branch to communicate about all of this work, to exchange ideas, and to respond to the ideas of others. Although our small handful of lobbyists who work on this issue are greatly outnumbered by the paid lobbying efforts of the pharmaceutical industry and other interests, it is the grassroots, analytical, and communications structure that supports those lobbyists that gives their work the impact that it has.

This advocacy strategy in 2003 was grounded in a sense of urgency. While design, political, and budgetary challenges are always serious, it is crucial to remember that delay also has a price. For many disabled and older Americans, this is not just a matter of dollars, it is also a matter of access to the drugs they need to stay healthy and stay alive. Nearly forty years ago, President Lyndon Johnson signed Medicare into law, promising that "no longer will older Americans be denied the healing miracle of modern medicine." Today, prescription medications are a crucial component to that healing miracle. Without prescription benefits, the promise of elders' access to the miracles of modern medicine is not fulfilled.

CASE STUDY

Question:

What role should research universities play in ensuring access to essential medicines in the developing world?

The human devastation wrought by the AIDS epidemic has focused attention on the desperate need for essential medicines in the developing world. Recently, research universities in the United States have been pressured to take actions to increase access to essential medicines. Universities play a central role in the development of new medicines, and control important medical patents. Their commitment to serving the public raises important questions about what measures they can and should take to see their creations shared around the world.

RESPONSES:

The Responsibility of Research Universities to Promote Access to Essential Medicines

Ellen F.M. 't Hoen, LL.M.*

INTRODUCTION

One-third of the world's population lacks access to essential medicines. In the poorest parts of Africa and Asia, this figure climbs to one-half. This global health and medicines crisis is the result of increased microbial resistance to older medicines, discontinued production of unprofitable existing medicines, and the prohibitive price of many drugs. In addition, very few new drugs are being developed to tackle major diseases affecting people in poor countries. Many other factors also contribute to the problem of limited access to essential medicines, including logistical supply and storage problems, substandard drug quality, and the inappropriate selection and use of drugs.[1]

This piece focuses on the role universities can play in helping to improve access to medicines in developing countries. Most basic medical research in the United States takes place at universities. Universities can take steps to increase the amount of research relevant to health in the developing world. Universities also hold patents on many important medicines. By managing this intellectual property (IP) responsibly, universities can do much to ensure access to medical innovations in developing countries.

SUSTAINABLE ACCESS TO MEDICINES: A LONG WAY OFF

Infectious diseases kill over ten million people each year, with the majority of these deaths occurring in the developing world.[2] The leading causes of illness and death in Africa, Asia, and South America—regions

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* Ellen 't Hoen is the Policy Advocacy and Research Coordinator of the Campaign for Access to Essential Medicines of Médecins Sans Frontières.

1. Bernard Pécoul et al., *Access to Essential Drugs in Poor Countries: A Lost Battle?*, 281 JAMA 361-67 (1999).

2. WHO, THE WORLD HEALTH REPORT 2002, at 186-87 (2002).

that account for four-fifths of the world's population—are HIV/AIDS, respiratory infections, malaria, and tuberculosis.

In particular, the magnitude of the AIDS crisis has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat disease or alleviate suffering. Each day, nearly eight thousand people die of AIDS in the developing world.[3] One key factor preventing access to medicines in poor countries is the high price of new drugs. Prohibitive drug prices are often the result of IP protection, which usually takes the form of a patent. The owners of IP have a responsibility to consider measures to ensure that IP does not become an unacceptable barrier to appropriate health care in developing countries.

The high price of antiretrovirals—the class of drugs prescribed to treat HIV/AIDS—prevents many in developing countries from using these drugs. While in recent years, some pharmaceutical companies have responded to growing public pressure to lower the prices of certain AIDS medicines for developing countries, their efforts have been neither systematic nor sufficient. For example, until January 2003, more than three years after the need for access to medicines made world headlines at the World Trade Organization's (WTO) Seattle conference, one pharmaceutical company was charging $2,000 a year more in Guatemala than in Switzerland for its AIDS drug. Only after months of public pressure did the price of the drug come down in Guatemala.[4]

The pharmaceutical industry usually justifies high prices for medicines by pointing to the high costs of drug research and development (R&D). But many antiretroviral medicines were initially developed by public research institutes—including universities—and not by pharmaceutical companies. Public research institutes have heavily contributed to the development of many of the most important AIDS drugs, including zidovudine, stavudine, zalcitabine, abacavir, and a number of protease inhibitors.[5]

Stavudine (also known as d4T) is an important nucleoside reverse

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3. UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC, at 125, 129, 133 (2000), http://www.unaids.org/epidemic_update/report/Epi_report.pdf (Mar. 24, 2002). This document outlines the statistics utilized to reach the generally recognized figure of eight thousand deaths per day due to AIDS in the developing world.

4. Associated Press, *Roche Cuts Price of AIDS Drug to Nations* (Feb. 13, 2003), *available at* http://www.aegis.com/news/ap/2003/AP030220.html (last visited May 14, 2003).

5. Pierre Chirac et al., *AIDS: Patent Rights Versus Patient's Rights*, 356 THE LANCET 502 (2000).

transcriptase inhibitor used in antiretroviral combination therapy to treat HIV/AIDS. Stavudine was developed by researchers at Yale University, which holds the patent on the drug. Yale licensed the stavudine patent to Bristol-Myers Squibb (BMS), which currently sells stavudine under the brand name Zerit. Zerit has been a great commercial success for both BMS and Yale. In 2000 Yale earned over $40 million in royalties from the stavudine license.[6]

In March 2001, researchers and students campaigned on the Yale campus, demanding that Yale not enforce its stavudine patent in South Africa so that generic versions of the drug could be used. In South Africa at that time, the price of the generic version of stavudine was thirty-four times less than the price of BMS' brand name Zerit. Yale professor Dr. William Prusoff, who, with the late Dr. Tai-Shun Lin, demonstrated the value of stavudine in treating AIDS, stated publicly, "People shouldn't die for economic reasons, because they can't afford the drug."[7]

Under pressure from researchers, students, and access advocates, Yale renegotiated its license with BMS to ensure the availability of generic versions of stavudine (d4T) in developing countries.[8] This action showed that research institutions like Yale can play a central role in improving access to their innovations. In light of this power, it is imperative that universities and other research institutions be aware of the global implications of their patent and licensing policies.

DRUG ACCESS AND R&D: TWO SIDES OF THE SAME COIN

Developing countries account for four-fifths of the world's population, but less than ten percent of the global pharmaceutical market. Because the development of medicines is almost entirely profit-driven, investment in R&D related to the health needs of people in developing countries has come to a near standstill.[9]

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6. YALE UNIVERSITY OFFICE OF COOPERATIVE RESEARCH, 1999-2000 ANNUAL REPORT (2000), http://www.yale.edu/ocr/images/docs/ocr_report_99-00.pdf (last visited July 16, 2003).

7. Philippe Demenet, The High Cost of Living: Yale Shares Profits from AIDS Drugs, Le Monde Diplomatique, Feb. 2002, http://mondediplo.com/2002/02/04stavudine (last visited May 13, 2003). For further details see the Consumer Project on Technology page on stavudine at http://www.cptech.org/ip/health/d4T.html.

8. Julian Borger & Sarah Boseley, *Campus Revolt Challenges Yale over $40m AIDS Drug*, THE GUARDIAN (Manchester, U.K.), Mar. 13, 2001.

9. Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 THE LANCET 2188 (2002).

As a result, many of the diseases common in the developing world remain difficult to treat, while others are completely untreatable. For example, there is a growing need for new medicines to combat resistant strains of malaria and tuberculosis, to replace the ineffective and toxic drugs for sleeping sickness and Chagas disease. and to find treatments for diseases like dengue fever and Buruli ulcer that are currently almost untreatable.

The rationale of the patent system is to stimulate R&D by offering a temporary monopoly in exchange for beneficial innovation. Medical research aims to contribute to the advancement of human health, but in reality, it is primarily people in wealthy countries who benefit from medical progress. Ninety-seven percent of the patents held worldwide are in the hands of individuals and companies in industrialized countries, and eighty percent of the patents granted in developing countries belong to residents of industrial countries.[10]

World Bank estimates suggest that developing countries will be the net losers in an increasingly global patent system.[11] The implementation of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights is expected to further inflate drug prices, while increased R&D investment, despite higher levels of IP protection, is not expected.[12] Certainly, strict IP laws are unlikely to stimulate investment in non-profitable areas such as tropical diseases.

Market forces will not solve the access and R&D crisis. Therefore, the public sector, including universities and public research institutes, must step in where the market fails. The activities of the public sector should be guided by global health needs, and IP should be managed with the intent of increasing access to medicines and stimulating further research.

MARKET PROSPECTS DO NOT EQUAL HEALTH NEEDS

Investments in health-related R&D tends to gravitate towards illnesses

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10. U. N. DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 68 (1999), *available at* http://hdr.undp.org/reports/global/1999/en/ (last visited May 13, 2003).

11. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 21 (2002), *available at* http://www.iprcommission.org/graphic/documents/final_report.htm (last visited May 13, 2003).

12. Access to Essential Medicines Campaign and the Drugs for Neglected Diseases Working Group, Médecins Sans Frontières, Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases 10-18 (2001), *available at* http://www.msf.org/source/access/2001/fatal/fatal.pdf (last visited Mar. 24, 2002).

or symptoms that offer the greatest potential return on investment, regardless of actual health needs. When it comes to priority-setting for R&D in the health field, money talks louder than needs. Pharmaceutical innovation does not necessarily equal therapeutic innovation. An assessment of 2,257 new products that were brought to the health market in France between 1981 and 2000 shows that sixty-three percent of new products were "me-too" drugs (those that offer no therapeutic gain over existing drugs). Only seven products (0.13%) represented real therapeutic breakthroughs.[13] In the United States, less than five percent of the drugs introduced by the top twenty-five pharmaceutical companies were therapeutic advances. Of these, seventy percent were developed with government involvement.[14] While sixty-eight percent of the 1,393 new chemical entities registered world wide for marketing over the last twenty-five years were classified as "me-too" drugs, only one percent were for tropical diseases and tuberculosis, diseases that together account for over eleven percent of the worldwide disease burden.[15]

Almost all R&D activities are currently undertaken in the industrialized world. Ensuring R&D for neglected diseases in the developing world will require a strong commitment by all actors involved, including research institutions and universities in wealthy countries.

However, academic research is increasingly guided towards avenues that may yield profitable returns. Moreover, those activities that do result in progress in the field of neglected disease are often not taken up by the private sector and translated into products useful to patients in developing countries. This is shown most strikingly in the cases of sleeping sickness and leishmaniasis. These parasitic diseases cause significant illness and death in the developing world and urgent health tools are needed. Scientists have long studied these parasites and know a great deal about their molecular biology, immunology, and genetics. Yet, despite an urgent need for new medical tools, many pharmaceutical companies are not working to develop new diagnostics, medicines, or vaccines for these diseases.[16]

A PUBLIC RESPONSIBILITY BEYOND BORDERS: THE ROLE OF UNIVERSITIES

A Yale initiative to bring together a group of experts in public health,

13. *A Look Back at 2000*, 10 PRESCRIRE INTERNATIONAL 52, 52-54 (2001).
14. U. N. DEVELOPMENT PROGRAMME, *supra* note 9, at 69.
15. Trouiller et al., *supra* note 8, at 2189.
16. *Id.* at 2190.

IP management, and university policy on September 25, 2002, signaled a willingness to address the role of universities in promoting access to essential medicines. The group discussed what universities as IP holders can do to promote access to essential medicines and medical technologies in developing countries. The report from that meeting identified the crucial role that universities can play in the development of new medicines and medical technologies, stressing the need to create and implement best practices in this area.[17]

The decisions universities make when patenting and licensing their technologies can help determine whether individuals in developing countries have access to the end products of university research. University research is "upstream" in the development process, meaning that universities have potential early leverage, though they rarely know in advance whether or not a product will result in a marketable technology useful in developing countries. This suggests the importance of establishing a policy framework upfront and then ensuring its consistent application.

Those attending the Yale meeting generally agreed upon the following principles to guide universities in establishing a framework for making patenting and licensing decisions:

- University research is intended to advance the common public good, a primary element of which is the advancement of health;
- Global public health concerns need to be an important part of patenting and licensing decisions;
- The success of patenting and licensing programs should be measured according to their impact upon public health;
- University IP policies should be implemented in a manner supportive of developing countries' rights to protect public health and, in particular, to promote access to medicines for all; and
- Technology transfer to develop capacity in developing countries is an important part of universities' mandate to advance knowledge and the social good.

Universities should consider different strategies to implement these principles, including not patenting or allowing their licensees to patent in developing countries, and issuing non-exclusive licenses for developing country markets.

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17. Yale Ctr. for Interdisciplinary Research on AIDS, Access to Essential Medicines and University Research: Building Best Practices (2002), http://cira.med.yale.edu/whats_new/Essential%20meds,%20final%20report.doc (last visited July 16, 2003).

Universities must also be aware of the effect that an IP strategy will have on innovation. In some cases, exclusive rights to sell a drug in the developing world may be the only way to encourage research because no other market exists for the drug. However, because developing country markets are small and provide limited financial incentive for research, there is cause to think such cases will be rare.

Changes in university practice will require collective action and leadership. Participants at the Yale meeting were clear that where universities act together they can successfully establish norms and implement best practices. In a recent positive step, an assembly of the American Medical Students Association (AMSA) adopted a resolution urging universities to follow the principles discussed at the Yale meeting when making patenting and licensing decisions that potentially impact access to essential medicines and medical technologies worldwide.

It is encouraging to see that universities and researchers in wealthy countries are increasingly aware of global health needs and are working to ensure that the fruits of medical progress are not withheld from people in developing countries. Biomedical research in university laboratories should indeed be guided by policies that take global health needs into account.

Universities should also review their existing research incentives. For example, researchers should not be rewarded solely for publication or patenting, but also for ensuring that innovations actually reach the people who need access to them. Western universities have an obligation to take a global perspective and look beyond market opportunities in the United States and Europe when considering research priorities.

CONCLUSION

The Yale initiative on "Access to Essential Medicines and University Research: Building Best Practices" deserves follow-up within the public research sector. The meeting concluded that changes in university practice will require collective action and leadership and acknowledged that universities can act together to successfully establish norms and implement best practices. This enterprise must also take an international dimension. Increasingly, research activities are becoming global, as are the initiatives to tackle the R&D divide.

John Barton, Professor of Law at Stanford University and Chair of the U.K. Commission in Intellectual Property Rights, has proposed a treaty to

preserve the global scientific and technology commons.[18] He argues that science and technology require a commons of data, ideas, and insight, and that all scientists will benefit from having access to the work of their predecessors. Such a commons should be global. Existing restrictions to creating a commons—such as licensing regulations that favor nationals and the global trend to expand the scope of IP protection to include basic ideas, procedures, methodologies, and research tools—need to be overcome. This requires an international treaty to create a global scientific and technology commons. This treaty could include a commitment ensuring that the benefits of publicly funded research are made available to all and not just to nationals of a few wealthy countries.

Médecins Sans Frontières (known in the U.S. as Doctors Without Borders), together with other organizations, is exploring the feasibility of a new Essential Health Technology R&D Convention to address international R&D priorities, and to ensure the development of and access to new essential medicines, vaccines, diagnostics, and equipment. Such a convention would:

- Define a needs-driven international R&D priority agenda;
- Secure commitments from all countries to contribute to R&D for health;
- Establish a financing system for sharing the burden of the cost of this R&D;
- Define appropriate funding and incentive mechanisms for governments to fulfill their commitments to essential health technology R&D.
- Establish and strengthen international mechanisms for exchanging and transferring research results, knowledge, and technology; and
- Ensure that developing countries play a central role in public R&D, through North-South and South-South collaboration, and through the conduct of R&D in disease-endemic countries.

It is crucial that universities and other research institutions engage in these international debates and developments. The increasing awareness among researchers that millions are not reaping the benefits of medical and scientific progress must be translated into concrete action and benefits for those in greatest need.

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18. John H. Barton, Preserving the Global Scientific and Technological Commons, Address at the International Centre for Trade and Sustainable Development, U.N. Conference on Trade and Development Policy Dialogue on a Proposal for an International Science and Technology Treaty (Apr. 11, 2003) (transcript available at http://www.ictsd.org/dlogue/docs/tech_transfer_dialogue.pdf).

The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries

Lita Nelsen*

Universities that attempt to use patents arising from academic research to make medical treatments available in developing countries are caught in a paradox of the patent system. Simply put, if all the medicines and vaccines needed in developing countries existed today, one would wish the patent system to disappear. The absence of patents on medicines and vaccines would presumably allow maximum competition and drive prices down, thereby maximizing affordability and availability.

In reality, adequate treatments and preventatives do not exist for many diseases common to the developing world. If one wishes to encourage industry to use its skills and resources in the discovery, development, testing, quality control, and distribution of new drugs and vaccines, patent protection may be necessary to provide the incentive for industrial participation. Few, if any, companies will start on the long trail of new drug discovery and development unless they can depend on patent protection from competition should a drug prove successful. Thus, we come to the conclusion that patents are neither inherently bad nor inherently good for this purpose. Like all tools, they must be used wisely.

Research institutions such as universities, medical schools, and other non-profits engaged in biological and medical research (collectively referred to as "universities" in this piece) have a special role to play in the use of patents for the development and distribution of drugs and vaccines for developing countries. These institutions are often the main source for the core technologies and lead compounds that are developed into drugs and vaccines. The primary ways in which universities disseminate their discoveries are through publication and the training of students. But since the passage of the Bayh-Dole Act in 1980,[1] U.S. research institutions have

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* Lita Nelsen is the director of the Technology Licensing Office at the Massachusetts Institute of Technology.

1. Act of Dec. 12, 1980, Pub. L. No. 96-517, 94 Stat. 3015-3028 (codified as amended at

also used patents and licensing to transfer inventions arising from their research into the marketplace.

Again, it seems paradoxical that patents—which are legally a way to exclude others from appropriating one's inventions—could be used by universities whose primary purpose is to disseminate knowledge. But this paradox is readily resolved. Knowledge itself is disseminated by universities via publication, but the commercial use of some of that knowledge is restricted by patents to companies to whom the universities grant licenses. The public purpose of this patenting and licensing activity is to encourage early investment in new university findings to translate these findings into products for public consumption. The incentive for investment is sometimes provided by "exclusive licensing"—that is, the restriction of the commercial use of the patent to only one company.

Why would a university choose to grant a single exclusive license rather than multiple non-exclusive licenses to multiple companies? University research is usually at so fundamental a level ("embryonic" is a common term) that investment in development involves substantial risk—neither the technical practicability nor the market acceptability of the invention is proven. More inventions will fail than will reach the market, particularly in the medical field. In order for a company to be willing to take on the risk of developing an early stage technology, it may demand protection from its potential competitors via the exclusive use of the patent. This is especially important in the medical field, where development and, in particular, clinical trials, require very large investments.

Naturally, universities also hope for some financial return from their patents, but, contrary to widely held beliefs, this return is seldom large. On average, American universities receive licensing royalties equivalent to approximately two-to-four percent of their research budgets.[2] Most universities believe that the primary purpose of their technology transfer activities is to induce investment in university technology by private firms to bring products based on the technology to the public. A second goal at many universities is to aid local economic development by encouraging the creation of startup companies based on licenses to use their technology.

Despite the avowed public-minded purposes of their technology transfer activities, universities have recently come under criticism for using patents in a way that does (or could) inhibit the distribution of medicines

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35 U.S.C. §§ 200-211, 301-307 (1994)).

2. Summary of AUTM Licensing Survey FY 2001. *Available at* http://www.autm.net/surveys/01/01summarypublicversion.pdf (last visited July 2, 2003).

to developing countries at accessible costs. Universities often grant exclusive licenses to first-world pharmaceutical companies in order to provide the incentive for these companies to invest in developing the products. However, by insisting on enforcing these patents in developing countries, the pharmaceutical companies may prevent local companies from producing and selling the drugs at affordable prices, thus effectively denying life-saving drugs to poor people in these countries.

In the context of non-profit research institutions, such cases are very rare (in part because the fraction of medically-related patents owned by such institutions is small). However, the visibility of such cases, coupled with the universities' consciousness of public responsibility, is causing university technology transfer offices to make changes in their licensing practices for patents relevant to health care in developing countries. Awareness of these issues is new, and techniques for addressing the problem are only emerging. As yet, there is no consensus concerning "best practices." The remainder of this piece addresses some potential solutions.

RAISING AWARENESS IN THE UNIVERSITY COMMUNITY

The first task is to raise awareness of these issues in the university community as a whole. Increasing technology transfer officers' consciousness of developing-country health care needs and their universities' responsibilities to the public should help prevent the inadvertent granting of exclusive licenses without building in protection for developing-country needs. Senior administrators and researchers will become more ready to accept licensing terms that, while somewhat less profitable, address the needs of developing countries. Finally, a consistent policy from universities on these issues will raise awareness in the companies with which they deal, making these companies more readily accepting of licensing terms that address these issues.

In North America, the Association of University Technology Managers ("AUTM") has begun publicizing this issue to its members. More than ninety percent of technology transfer professionals working at non-profit research institutions in the United States and Canada belong to AUTM, and there are more than 100 members from other countries. Their 2003 annual meeting included the first AUTM workshop on health care needs for developing countries. A Special Interest Group was formed and at next year's Annual Meeting an intensive educational program will be run. AUTM also intends to compile from its members a collection of "best practice" policies and licensing terms to distribute.

A new international organization, the Center for the Management of Intellectual Property in Health Research ("MIHR"), originally formed by

the Rockefeller Foundation and now based in London, is working to educate research institutions in developing countries about intellectual property in health research, and with AUTM to spread awareness to research institutions in first-world countries. Additionally, MIHR is also developing practice manuals and will eventually develop a collection of "best practices" with the intent to distribute them widely both in the United States and worldwide.

CREATING PATENTING AND LICENSING STRATEGIES WHICH ADDRESS THE NEEDS OF DEVELOPING COUNTRIES

1. Where to File Patents

Usually, when a research institution patents and licenses out a technology, it can—if it insists—continue to own the patent after licensing. (This is the practice in most American universities.) Universities can then contract with the licensee company to control in which countries the patent will be filed. The best strategy regarding where to file a patent, however, is not easy to determine.

a. Prohibition-on-Filing Strategy.

Where the drug or vaccine in question has a large first-world market, one strategy is to prohibit the patent from being filed in developing countries. Presumably, most of the licensee's profits, with or without developing country patents, will come from first-world markets. The loss of revenue from developing countries (which could not afford to purchase large quantities of the medicines at first-world prices anyway) would be negligible and the licensee would, presumably, not be substantially disadvantaged by the strategy.[3] The absence of patents in the developing world would allow "generic" competitors to produce drugs in those countries at low prices.

This strategy will be effective only if:

(i) The first-world market for the medicine is large. If the first-world market is only a specialty "travelers' market" and the

3. The proposition that the effect on incentives for R&D of patenting drugs in poor countries depends on the relative size of the market for the drug in poor versus rich countries is well supported in the literature. *See* J. O. Lanjouw, *A Patent Proposal for Global Diseases, in* 2001 ANNUAL WORLD BANK CONFERENCE ON DEVELOPMENT ECONOMICS 189 (Pleskovic et al. eds., 2002).

primary demand for the medicine is in developing countries (malaria vaccines are a good example), this strategy will not be acceptable to the licensee company;

(ii) The drug or vaccine is relatively easy to manufacture and does not rely on any special knowledge from the licensee company. This is more likely with simple chemical drugs than with biological drugs (including vaccines). If the techniques needed for production and purification of complex biological drugs are beyond the capabilities of developing countries, permitting them to appropriate the patented technology will be of little help;

(iii) The research institution owns the core patent for the drug or vaccine and other, "secondary," patents owned by the licensee are not critical to the development and manufacture of the medicine. If such secondary patents are critical and the licensee chooses to file them in developing countries, then attempts by the university to provide their own technology "freely" may be moot. If secondary patents prevent the distribution of a drug, then the only effect of not enforcing a primary patent is to shelter the university from criticism. Theoretically, it is possible for the university to demand in its licensing agreement that no such secondary patents be filed in developing countries. But it is doubtful that the university will have sufficient negotiating power to make that demand, particularly if the university's invention, at the time it is licensed, is still far from becoming a marketable product; and

(iv) Both the developing countries and first-world countries in which the licensee sells the product will take effective legal measures to prevent importation of the presumably cheaper generic drug back into the first-world markets of the licensee.

b. When Patent Filing in Developing Countries May Be Beneficial for Access.

When the demand for a drug or vaccine exists primarily in developing countries and products that meet the demand satisfactorily do not yet exist, the primary problem is one of developing a sufficiently profitable market to provide an incentive for the private sector to invest in the discovery and development of the medicine. Absent a profitable market, only governments or non-profit non-governmental organizations (NGOs) are likely to fund the research, manufacturing, development, and clinical testing required to create a new drug; and they have very limited resources to do so.

Patents may provide an incentive for the private sector to invest in drugs for the developing world by aggregating the developing world market into one single market large enough to warrant investment by an exclusive licensee. The success of this strategy relies upon:

(i) The availability of sufficient resources to buy the product once it is developed: Governments and NGOs may have to step in to supply the money for purchase by the public sectors of the poorer developing countries, particularly if there is no private "travelers' market" from which higher prices can be extracted;

(ii) Adequate systems for quality control and regulatory approval that assure consistent high-quality products in the absence of first-world regulatory control over the product;

(iii) Belief that the legal systems of non-manufacturing countries will be strong and consistent enough to allow the supplier to enforce its patent rights; and

(iv) The willingness of governments and NGOs to accept prices sufficiently high that suppliers can recoup research and development costs.

2. Licensing Strategies

Universities and other research institutions have the most control over the use of their inventions at the time of licensing. It is before each invention is licensed that a university can best ensure that the license will be used to advance—or at least not to hinder—efforts to meet the health care needs of developing countries.

The first decision for a university is what kind of license it will grant for the invention. A license may be fully exclusive, exclusive but limited by type of product, exclusive but limited by geographical territory, or nonexclusive. Two extreme cases are illustrative:

- Where the invention is a tool for discovery that does not need significant additional development to be useful, nonexclusive licensing is probably most appropriate for first-world use, while foregoing filing of patents on the same invention in developing countries.[4]
- Where the patent covers the core invention of a potential new drug or vaccine requiring years and tens, if not hundreds, of million

4. Many universities will require their patents not be asserted against other non-profit research institutions, thus allowing free access by such institutions in all countries. The purpose of this is to ensure that research in non-profit institutions is not inhibited.

dollars of investment, an exclusive license may be the best strategy.

The second case—exclusive licensing—puts a major responsibility on the university to negotiate license clauses that ensure both development of the product and its rapid distribution to developing countries at accessible prices. Consciousness of the need to do this is new to the university technology transfer community. Though "best practices" have not yet been established, strategies have evolved from experience (including a few situations that, in retrospect, were clearly mistakes and have become "learning experiences"). Some of these experimental strategies include:

(i) *Development milestones*: A university may require, as a condition of the company maintaining a license, that the company devote at least a set minimum amount of resources to develop the technology. It may also require certain "success milestones," e.g., performing clinical trials by a certain date, getting the product on the market by a certain later date, etc. However, success milestones are particularly difficult to negotiate for technology in very early stages, where both the company and the university are conscious of many unpredictable technical hurdles in the product's development, making it difficult to demand set dates for success;

(ii) *Requirement of delivery of products for developing countries*: A university may require that the company begin the testing and distribution of products in developing countries simultaneously, or at least within a very short time frame after, introducing them in first-world countries. This is particularly important for vaccines, where the "trickle down theory" has sometimes deprived developing countries of suitable products for decades;

(iii) *Control over pricing in developing countries*: Prices can be set at a small percentage of cost; and

(iv) *Compulsory sublicensing*: A university may require that, if the company cannot deliver a product or cannot deliver it at an acceptable price, then it must sublicense the patent to others. Where manufacture of the product is simple, this strategy may work, but where the product requires substantial company knowledge and background technology, the "victory" in forcing a sublicense of the patent alone may be pyrrhic. This is particularly true for complex biological drugs and many vaccines. Thus, the university must negotiate clauses that make sublicensing as attractive as possible to the company so that the company will cooperate fully in the venture. A recent article by

> Friedman et al. in *The Lancet* describes such a strategy by the Pharmacia Company. [5] The company enthusiastically sublicenses its patent, along with its know-how, and exerts a degree of control over the quality of the product. The benefits to the company are primarily reputational, with a justifiable pride in the good that is done. But it is also defensive—protecting the company from criticism it may receive for not meeting the needs of the poor in developing countries.

These are just a few of the strategies that universities and other research institutions may try in their quest to provide access to new medicines in developing countries. Each strategy has been tried to some extent in the past, but all are relatively new and will need refinement in the fire of negotiations between research institutions and companies—along with new approaches that will develop in the future. None will be effective unless both research institutions and companies become more aware of their obligations to help those in developing countries. And none will survive unless they meet the needs of both the research institutions and companies in developing new technologies for human health needs.

5. Michael A. Friedman et al., *Out-Licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries*, 361 THE LANCET 341, 344 (2003).

Public Health as Statecraft and Soul-Craft

Bruce Jennings, M.A.*

Public Health Law: Power, Duty, Restraint. **By Lawrence O. Gostin. Berkeley: University of California Press, and New York: Milbank Memorial Fund, 2001. Pp. 491**

Public Health Law and Ethics: A Reader. **Edited by Lawrence O. Gostin. Berkeley: University of California Press, and New York: Milbank Memorial Fund, 2002. Pp. 523.**

A book review should not use clichés like *tour de force*, but I can't think of another phrase that does justice to the magnificent achievement of Lawrence Gostin in these two volumes. They belong on the shelf of every reader of this Journal and indeed of everyone whose work or interests touch on the law, ethics, healthcare, and public health policy and practice. When *Public Health Law*[1] was published in 2000, it instantly became the standard-setting, comprehensive treatise on the subject. The appearance last year of *Public Health Law and Ethics*,[2] a companion reader designed to facilitate teaching as well as scholarship, provides a good occasion to consider this body of work as a whole and the broad significance it holds for the philosophical foundations and future directions of public health as

* Bruce Jennings is Senior Research Scholar at The Hastings Center in Garrison, NY and teaches ethics at the Yale School of Public Health.

1. LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT (2000) [hereinafter PUBLIC HEALTH LAW]

2. LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW AND ETHICS: A READER (2002) [hereinafter PUBLIC HEALTH LAW AND ETHICS]

a profession and as an instrument of public policy. In particular, Gostin's work indicates just how important it is to understand the place of public health law and ethics within the framework of liberalism as a public philosophy.

It is rare in these days of burgeoning information for a scholar to master one field thoroughly, let alone three or four. Gostin is at home in public health law, constitutional law, and administrative law; not to mention the epidemiological, social scientific, and historical aspects of public health research and practice; not to mention his more-than-competent mastery of ethics and social theory. Moreover, in the case of these companion volumes, the whole is greater than the sum of the parts. Either volume alone would have been an extraordinary contribution. Read and used together, they complement and supplement one another and create an extraordinary whole.

A glance at each volume's table of contents reveals similar structures. Gostin begins with the theoretical foundations of public health law, policy, and practice. In these sections he draws widely from law, ethics, and social theory. Along the way, he gives a lucid explication of the development of constitutional law and reasoning regarding the state's role in social, health, and welfare matters. The remainder of each volume is composed of a series of chapters organized around various areas and functions of public health. Topics include public health surveillance, communication and health promotion activities, the control of infectious disease (including mandatory vaccination and quarantine), and the use of economic measures and tort law as regulatory tools in public health. Knitting together this broad range of activities and topics is the guiding theme of the tension between individual rights and the common good.

There were some notable omissions in *Public Health Law* when it appeared, and their significance has grown over time. One is public health research, and particularly questions about human rights and cultural diversity, which are often raised in research projects conducted in developing countries. Another is the growing area of public health genetics. A third is the area of chronic illness and the aging society as matters of public health concern. And of course, because the book was published well before 9/11, there is little explicit discussion of bioterrorism. *Public Health Law and Ethics* redresses many of these omissions, including public health genetics and bioterrorism, and hence makes the material more comprehensive and more up-to-date than the earlier volume.

Public Health Law and Ethics contains an extensive sampling from public health case law, especially opinions from the U.S. Supreme Court.

For this reason, the book is a virtual compendium of important legal documents in the history of public health in America. These documents run the gamut from affirmations of state power to defenses of individual liberty. Gostin's analysis traverses the space between *Gibbons v. Ogden* (1824)[3] in which Chief Justice John Marshall included public health activities under the authority of the "police powers" of the state,[4] and *Jacobson v. Massachusetts* (1905),[5] which sets out the limits of the police power and the public health authority and which Gostin calls "the most important Supreme Court opinion in the history of American public health law."[6] It also tracks the distance between the *Report of the Sanitary Commission of Massachusetts*, written by Lemuel Shattuck (1850) who is eloquent about the duty (and the authority) of government to assure the health of the populace,[7] and *DeShaney v. Winnebago County Department of Social Services* (1989)[8] in which, as Gostin characterizes it, the Court "expresses a vision of a 'negative' constitution where the judiciary is highly reluctant to impose on government an affirmative duty to safeguard the well-being of its citizens."[9]

Gostin calls *Public Health Law and Ethics* a "Reader," but it is actually much more than that. Its opening sections give a fuller treatment of various approaches to ethical theory so that the discussion broadens out beyond the constitutional law analysis of the earlier book. Also in each section of the book (both those on theoretical foundations and those on particular public health issues like surveillance, health promotion, and infectious disease prevention), Gostin takes the trouble to lay out the conceptual, political, and historical groundwork before presenting the reprinted selections from court decisions, policy documents, and academic books and articles. This is an ingenious way to organize an anthology, and it works particularly well for teaching purposes. As a result, *Public Health Law and Ethics* can stand alone (but it shouldn't), and it can be used by itself in a course. Indeed the books are supported by a web site (www.publichealthlaw.net/reader), which provides the latest case law, reports and articles to update the material in the book. Links to other web sites are also helpful to teachers and students in courses on public health

3. Gibbons v. Ogden, 22 U.S. 1 (1824).
4. PUBLIC HEALTH LAW AND ETHICS, *supra* note 2, at 185.
5. Jacobson v. Massachusetts, 197 U.S. 11 (1905).
6. PUBLIC HEALTH LAW AND ETHICS, *supra* note 2, at 206.
7. *Id.* at 24-27.
8. DeShaney v. Winnebago County Dep't of Social Servs., 489 U.S. 189 (1989).
9. PUBLIC HEALTH LAW AND ETHICS, *supra* note 2, at 169.

law and ethics.

The books can be read apart; read them together, though, and what you find is a fascinating interplay between two of Gostin's voices—the voice of the legal theorist in the first volume and the voice of teacher, historian, and contextualizer in the second. You also get Gostin's own mind and intelligence in juxtaposition with those of Supreme Court Justices and other thinkers past and present who vie with him in these pages. A good example, already mentioned, is the way Gostin positions himself between Chief Justice Rehnquist writing for the majority in *DeShaney*, and Justice Blackmun, who wrote a strong dissent in that case.[10] Another example is the way Gostin sets out the tension between the prevailing view in the field of public health and the ideology of free-market libertarians.[11]

For Gostin the adjective "public" in public health is no mere modifier, and it does not simply refer to the fact that we are talking about the health of a lot of people. The concept of the public—and closely related notions such as community, membership, justice, solidarity, and what otherwise separate individuals and groups may have in common—is both a problem to be defined in these books and a constituent feature of the very subject matter itself. The paradox that animates much of Gostin's inquiry is that there could be no public health unless there is already a public; and that there can be no public if there is no public health.

Health is a primary social good; we want and need it no matter what else we may want and need; it is a prerequisite for pursuing, attaining, and enjoying any and all the other goods and interests that are important to human life. Health is something individuals and societies need regardless of whatever else it is they want. So it follows that one can hardly have a democratic society, or a robust civic life for citizens, unless individuals are well enough to be active, engage in common activities with others, and the like. A society made up of individuals too weak and frail in body, or too jaundiced and fearful in mind, to engage in the activities that comprise a civic society would not be a community of citizens but at best a collectivity of subjects. As Gostin puts it, "[w]ithout minimum levels of health, populations cannot fully engage in the social interactions of a community, participate in the political process, generate wealth and assume economic prosperity, and provide for common defense and security."[12]

There is a difference between measures undertaken to protect the health of a large number of citizens who are acting with a sense of

10. *DeShaney*, 489 U.S. 189.

11. PUBLIC HEALTH LAW AND ETHICS, *supra* note 2, at 229-233.

12. PUBLIC HEALTH LAW, *supra* note 1, at 8.

common obligation in support of authoritative institutions—a "public"—and the measures (no matter how effective) to promote health imposed by tyrants on a powerless, subjugated population of people who have no political rights or civic status. There can be no public health (properly speaking) in such a context because public health "can be achieved only by collective action, not by individual endeavor. . . . Meaningful protection and assurance of the population's health require communal effort."[13] Again, Gostin points out that "the quintessential feature of public health is its concentration on communal well-being. . . ."[14] And finally, "the communal efforts of the body politic to protect and promote the population's health represent a central theoretical tenet of what we call public health law."[15]

In contemporary American political culture, with its predominate libertarian and individualistic ethos, it is difficult to grasp the conception of the political, the public, the civic, or the communal for which Gostin is searching. One of the things that makes these volumes so interesting is that someone like Gostin, who has shown himself through his previous work to be an ardent champion of civil liberties and human rights, should face off against the question of what is public about public health in such a serious, albeit sometimes tentative and searching, way. The kind of liberalism that exerts considerable intellectual influence in these books, a generous, progressive liberalism of tolerance and the protection of individual privacy and self-determination against the will of the majority or the power of government, can so easily privatize public health by reducing the normative notion of a public to the statistical concept of a population. And as someone once remarked, in the field of public health, p-values have often seemed more important than ethical or civic values.

While fully aware of the intellectual power, moral appeal, and political importance of this liberal tradition, Gostin makes an honest attempt to place it properly as one element among several in the dynamic value conflicts that arise in the face of public health policies and public health law. Although this notion is present in both of these volumes, I believe it comes through most clearly in *Public Health Law and Ethics.* Consider the following important formulation of what is really at stake in public health ethics:

> Few public health experts advocate denial of truly fundamental

13. *Id.* at 7-8.
14. *Id.* at 12.
15. *Id.* at 8.

> individual liberties in the name of paternalism. In the public health model, individual interests in autonomy, privacy, liberty, and property are taken seriously, but they do not invariably trump community health benefits. The public health approach, therefore, differs from modern liberality primarily in its preferences for balancing; public health favors community benefits, whereas liberalism favors liberty interests. Characterizing public health as a utilitarian sacrifice of fundamental personal interests is as unfair as characterizing liberalism as a sacrifice of vital communal interests.[16]

This is a more nuanced and sophisticated understanding of both liberalism and communitarianism than one generally finds, and perhaps marks some movement for Gostin away from views he himself expressed a decade ago. One trait that drives Gostin in this more communitarian direction is his intellectual honesty and fidelity to the record of American constitutional history and jurisprudence. Public health is one area in which taking the law seriously means having something like a concept of the public that is a normative notion and not just a statistical one. Using his voice as an educator, Gostin helps us to understand this concept and the reasoning behind it, even if we (and he) are made morally uncomfortable by the degree of legitimate authority it vests in our body politic and in the hands of the wielders of statecraft.

This also shows Gostin the theorist at his best. Rather than moving from a former liberalism to a newer communitarianism or even authoritarianism, he endeavors to call into question this very dichotomy. He does this not by denying that individualistic and communally-oriented values often conflict. Instead he does it by questioning the notion that there is a zero-sum relation between these values at all times. He challenges the idea that, to the extent that the social good of public health is served by placing restraints on choice and behavior, individual interests and liberty must necessarily be sacrificed.

To visit the theoretical terrain Gostin explores is again to traffic in seeming paradox: although some of my interests as an individual may be overridden by public health measures is it not the case that other interests which are just as much mine and just as authentic are promoted thereby? As Charles Taylor observed some time ago,[17] modern day communitarian theory is mainly a new chapter in the intellectual history of Anglo-American liberalism, much like guild socialism and democratic socialism

16. PUBLIC HEALTH LAW AND ETHICS, *supra* note 2, at 13.

17. CHARLES TAYLOR, PHILOSOPHICAL ARGUMENTS 181-203 (Harvard University Press 1995).

before it. It is not really a throwback to authoritarian, pre-liberal conservatism. It is an attempt to rescue what is still living and valuable in liberal theory in the face of a continuing failure of liberal governance and practice in the context of capitalist society. Although he never talks explicitly about such matters, Gostin is fully aware of the contemporary terrain of political theory and knows where on that map he wants to stand.

If I have a criticism to make of these books, it is not that Gostin too boldly embarks on this more difficult, more nuanced response to the framing of clashes between liberal or libertarian and communitarian values. It is that his quest for the right language, the right rhetoric (in the best sense of the term) is not completely successful. Throughout the richness of this masterful thousand page symphony of his, he does not, at least to my ear, get the communitarian tonality quite right. What separates liberals from communitarians *au fond* is not a proclivity to balance individual and social interests in different directions. They differ more fundamentally because they see political and moral reality differently. One's moral balance in hard cases derives ultimately from one's social ontology. For communitarians that social ontology is fundamentally relational; for liberals it is individualistic. Given this, where should we go from here? I suggest a detour from legal scholarship and jurisprudence and a more direct foray into philosophy. Communitarian theory is much more compelling at devising critiques of excessive individualism and social atomism than it is of making its own positive, constructive moral case. In fact, communitarian theorists would do well to familiarize themselves with public health because it is a fecund venue for constructive exploration and positive theory-building.

The public is not separate and distinct from the privates that make it up. It is not some realm of collective being that stands over and above the reasons, hopes, and desires of ordinary persons in everyday life. There are times in public health controversies when by losing one wins. I may have enjoyed the freedom to smoke in a restaurant, but I can't honestly say that my overall freedom has been diminished by the loss of this liberty because not only are risks to my own health reduced (and perhaps the health of others in the room) but by obeying the ban I now have a different set of possible relationships and identities with others open to me. My self-presentation and my relationships are no longer mediated by the fact that I am smoking; new possibilities come to the fore in my interactions, and new freedoms emerge that I hadn't even thought of before.

Public health law, policy, and practice are not only about protecting populations and individuals from risk and harm, nor even about more actively promoting health and well-being. Public health is also about

nurturing and enriching the moral imagination, to empathize with the needs of others, to define oneself in terms of reciprocity and solidarity with others, and to reconcile a public identity as a citizen with responsibilities with a private identity as a person with interests. Public health is not only about statecraft, it is also about soul-craft.

A reader can lose himself or herself in the thousand pages of Lawrence Gostin's wonderful books and not reemerge for days or weeks. I recommend the trip. You come out the other side having learned an enormous amount.

Globalization and Its Unhealthy Consequences for the Developing World

Susan D. Foster, Ph.D.*

***Health Policy in a Globalising World.* Edited by Kelley Lee, Kent Buse, and Suzanne Fustukian. New York: Cambridge University Press, 2002. Pp. 331.**

In late 1999, tens of thousands of activists descended on Seattle to protest the World Trade Organization (WTO) and, in particular, its impact on workers and worker health.[1] As technological developments and economic changes have led to increasing globalization, the impact of globalization on workers and workers' health has become a prominent concern for academics as well as activists. The recent book *Health Policy in a Globalising World* presents an excellent collection of essays devoted to this and other topics related to globalization and its influence on public health. The resulting compilation is a useful resource for students and teachers of health policy and international heath.

The editors begin the book with an introduction to global health policy,[2] and then provide a series of essays, each of which discusses a different aspect of that policy. To understand the scope of the collection, it is important to understand how the essays' authors define globalization. Globalization is defined as "processes that are changing the nature of human interaction across a wide range of spheres including the social, cultural, political, economic, technological, and ecological."[3] Reflecting this "wide range of spheres," the topics covered in these essays include the

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* Susan Foster is the Chair of the Department of International Health at the Boston University School of Public Health.

1. *See* Mark Suzman, *While Support for the Principle of Free Trade Remains Strong, Attitudes Toward It Are More Ambivalent*, FIN. TIMES (London), Nov. 29, 1999, at World Trade 3.

2. The authors distinguish between "international health" and "global health." While international health relates essentially to matters between states or regions, global health deals with issues that are "transborder in cause or effect" and not confined to any country or group of countries.

3. Kelley Lee et al., *An Introduction to Global Health Policy, in* HEALTH POLICY IN A GLOBALISING WORLD 6 (Kelley Lee et al. eds., 2002).

implications of multilateral trade agreements; the growing enthusiasm for public/private partnerships; health care financing reform; cost-effectiveness and priority-setting; violence against women and reproductive health; the globalization of approaches to the treatment of tuberculosis; aging and health policy; worker's health and safety; and finally globalization, conflict, and the humanitarian response.

One of the great virtues of the book is the diversity of topics covered, which enables each reader to find chapters of particular interest to him or her. In fact, after I finished reading the introductory chapter, I could not help but skip ahead to the chapter which seemed most relevant to the current world situation—Chapter Thirteen, *Globalisation, Conflict, and the Humanitarian Response*, by Anthony Zwi et al. To fully appreciate the significance of this topic, it is important to understand how globalization and conflict interact. In particular, Zwi et al. argue that globalization contributes significantly to the existence of conflicts around the world by shifting power both "from states to markets, but also from weak states to strong states."[4] Additionally, within countries, the pressure brought about by the World Bank and the International Monetary Fund's Structural Adjustment Programs, or SAPs, has produced what Zwi et al. term "residual state[s]."[5]

These "residual state[s]" are often unable to contain or curtail violence within their borders. Even worse, they are sometimes based on "structural violence," which involves unequal and unfair distributions of resources and services. The World Bank contributes to the formation of residual states by continuing to insist on economic policies consistent with a "globalized world economy" wherein the state is no longer a "provider," but rather a "facilitator and regulator."[6] But truly weak states are not in a position either to facilitate or regulate.

The authors make several significant observations about this important topic. First, they note that insufficient attention has been paid in recent conflicts to "prevent[ing] or mitigat[ing] significant human rights abuses . . . [and] to the links between external and internal non-state actors, such as private companies and diaspora communities, that can play

4. Antony Zwi et al., *Globalisation, Conflict and the Humanitarian Response, in* HEALTH POLICY IN A GLOBALISING WORLD 235 (Kelley Lee et al. eds., 2002) (quoting Andrew Hurrell, *Security and Inequality, in* INEQUALITY, GLOBALIZATION, AND WORLD POLITICS 248-72 (Andrew Hurrell & Ngaire Woods eds., 1999)).

5. *Id.* at 235.

6. *Id.* at 236.

a major role in supporting violence."[7] The authors also observe that ethnic identity is playing a growing role in conflict. Specifically, they quote a paper by political scientists Ronnie Lipschutz and Beverly Crawford of the University of California at Berkeley, entitled *"Ethnic conflict" Isn't*, stating, "so-called ethnic conflicts are reflections of failing social contracts between different groups as global economic forces place governments under immense pressure to promote greater economic efficiencies and exploitation of local resources."[8]

Conflicts have winners and losers. Typically, the losers are already poor and marginalized while those who benefit are in a position to manipulate markets or seize assets. The winners consequently have an interest in perpetuating conflict. The impact of conflict on public health includes the high mortality rates caused by the conflict itself as well as mortality caused by displacement both internally and across borders. Moreover, the mental health impact of trauma, torture and stress is enormous. Often the conflict results in damage to the health services infrastructure. This damage can occur through actual destruction of physical and human resources, or from the diversion of funds away from health purposes to the military.

Conflict situations are not the only settings in which the impact of globalization on public health can be observed. Chapter Two, *The Public Health Implications of Multilateral Trade Agreements*, by M. Kent Ranson et al., provides a discussion of how trade agreements and economic globalization are affecting public health. This chapter focuses on the WTO and begins by introducing the WTO's basic premise, that "human welfare will increase through economic growth based on trade liberalization . . . . From a public health perspective, this desirable goal requires linking the benefits of the global trading system to sound social policies."[9] That key link, as the chapter demonstrates, remains to be forged. Disturbingly, not only has the link not been made, but a number of strong states and actors have opposed making it. In her provocative article "Globalization," Tina Rosenberg of the *New York Times* comments that she thought the anti-WTO protesters "were simply being sentimental; after all, the masters of the universe must know what they are doing. But that was before I studied the agreements that regulate global trade. . . . I no longer think the masters of

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7. *Id.* at 230.

8. *Id.* at 231.

9. M. Kent Ranson et al., *The Public Health Implications of Multilateral Trade Agreements*, *in* HEALTH POLICY IN A GLOBALISING WORLD 18 (Kelley Lee et al. eds., 2002) (citing Nick Drager, *Making Trade Work for Public Health*, 319 BRIT. MED. J. 1214 (1999)).

the universe know what they are doing."[10] This chapter, with its emphasis on the need for a link between the benefits of a global trading system and sound social policy, provides a strong beginning to the book because subsequent chapters devote attention to the agreements—and, more importantly, the *interpretations* of those agreements—that will be required to put those social policies into operation.

The solid description of the on-going policy discussions concerning health care financing reform in Chapter Six, *Global Policy Networks: The Propagation of Health Care Financing Reform Since the 1980s*, by Kelley Lee and Hilary Goodman, is an example of this attention. This chapter focuses on the formation of a "transnational policy elite" with two hubs in Washington and London.[11] In this chapter, the authors describe an "early transatlantic divide" between the Washington hub and the London hub.[12] While the Washington hub has links to the World Bank and USAID, the London hub, largely based at the London School of Hygiene & Tropical Medicine is funded by the United Kingdom government and has links to the World Health Organization, and the United Nations Children's Fund (UNICEF). The main issue on which these two hubs differ is user fees. While the Washington hub is a strong proponent of such fees, the London hub has raised equity concerns. The authors trace this divide to "differences in the underlying values and principles that shape the US and European health care systems," with the Europeans viewing health care as a "social good" which should be available to all regardless of ability to pay. In contrast, in the United States, health care continues to be viewed as primarily the responsibility of the individual and a private consumption good.[13]

Chapter Eight, *Cost-effectiveness Analysis and Priority-setting: Global Approach without Local Meaning?*, by Lilani Kumaranayake and Damian Walker, turns to a more pragmatic issue in health policy. It examines the applications of cost-effectiveness analysis (CEA) and presents a thoughtful commentary on the use of the Disability-Adjusted Life Year, or DALY. This commentary will be of interest not just to economists, but also to anyone who has wrestled with the use of CEA for health priority setting. The tool

10. Tina Rosenberg, *Globalization*, N.Y. TIMES, Aug. 18, 2002, at 28.

11. This book is largely the work of researchers with ties to, or based at, the London School of Hygiene and Tropical Medicine, the institution where this reviewer obtained her PhD and spent ten years as a faculty member.

12. Kelley Lee & Hilary Goodman, *Global Policy Networks: The Propagation of Health Care Financing Reform Since the 1980s, in* HEALTH POLICY IN A GLOBALISING WORLD 114 (Kelley Lee et al. eds., 2002).

13. *Id.*

presents many limitations, such as poor local data and difficulties applying that data to different settings. But despite these limitations, the tool is used to determine global priorities. In reviewing this use, the authors sensibly conclude, "we must be aware of not expecting too much from the tool . . . rather than aiming for precision, which both the data and tool are not designed for."[14] They further note that CEA "does not take the politics out of decision-making . . . but is an element in the process of overall-priority setting, rather than a mechanistic way to select alternatives."[15]

While some of the chapters focus on more general issues of health policy and public health, others turn to more specific concerns. In Chapter Nine, *Global Rhetoric and Individual Realities: Linking Violence Against Women and Reproductive Health,* for example, Susannah Mayhew and Charlotte Watts look specifically at the issues of reproductive health and violence against women. They review the global attempts to reduce the horrific levels of different forms of violence against women. The authors cite figures indicating that, around the world, between twenty and fifty percent of women report having been physically assaulted by "an intimate male partner" at least once in their lives.[16] Moreover, partner violence occurs in all countries, and transcends socio-economic and cultural boundaries. Of course, violence against women includes not only rape and sexual assault by partners, but also trafficking in women, forced prostitution, and violence and rape that is "perpetrated or condoned by the state, such as rape in war."[17] Violence against women is indeed universal. Recent studies indicate that in the United States, the leading cause of death of pregnant women is not complications of pregnancy itself, but murder.[18]

The authors' discussion of the global debate on this issue is valuable and focused. They stress that the Reagan administration's "hard right-wing line on population" forced the groups that would otherwise have focused on violence against women to align with groups promoting family

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14. Lilani Kumaranayake & Damian Walker, *Cost Effectiveness Analysis and Priority-Setting: Global Approach Without Local Meaning?, in* HEALTH POLICY IN A GLOBALISING WORLD 155 (Kelley Lee et al. eds., 2002).

15. *Id.*

16. Susannah H. Mayhew & Charlotte Watts, *Global Rhetoric and Individual Realities: Linking Violence Against Women and Reproductive Health, in* HEALTH POLICY IN A GLOBALISING WORLD 161 (Kelley Lee et al. eds., 2002).

17. *Id.* at 160 (quoting WORLD HEALTH ORGANIZATION WHO/FRH/WHD/97.8, VIOLENCE AGAINST WOMEN (1997)).

18. Mary Papenfuss, *Murder Most Foul,* SALON.COM (Feb. 27, 2003), *at* http://archive.salon.com/news/feature/2003/02/27/pregnancy_death/index_np.html (last visited June 25, 2003).

planning, so as to prevent further restrictions on availability of contraceptive services.[19] It seems that the same phenomenon is repeating itself now—the threat of limiting access to family planning and contraception, including abortion, diverts attention from the wider issue of violence against women in all settings.

Chapter 12, *Workers' Health and Safety in a Globalizing World*, by Suzanne Fustukian et al., addresses the important issue of occupational health. Most readers will recall that concerns about worker health were among the main rallying cries at the anti-globalization protests in Seattle. This is one of the most useful chapters in the book, and since it provides a survey of this important issue in just twenty pages, it is necessarily packed with information. The chapter begins with a review of the data on workers' health around the world and catalogs the causes of problems in this area. According to the authors, these causes include the lack of health and safety standards, the concentration of poor migrants in the most dangerous jobs, and the transfer of dangerous technologies to areas where there is little awareness of the dangers they pose, or where enforcement of existing standards is minimal. The use of female and child labor in the even less regulated informal sector puts them beyond the reach of international organizational efforts that usually target formal, export industries. Workers in developing countries are often particularly vulnerable to the practices of multinational and transnational countries that are deliberately targeting countries with a large labor force and poor regulation.

As one example of this problem, the authors cite the notorious Union Carbide disaster in Bhopal, India, in 1984. In that case, double standards in terms of design, equipment and maintenance, as well as deficiencies in operational practices, meant that the workers and surrounding population were put at significant risk. However, as the subsequent investigation showed, the Indian authorities were complicit in the low standards maintained by this subsidiary of a large multinational company. The authors describe how most low- and middle-income countries are content to leave labor standards issues up to the largely toothless International Labor Organization (ILO), rather than an organization such as the WTO, which has genuine "teeth."[20] These countries fear losing the industry altogether in a world where the multinationals are able to quickly shift their operations from one country to a more welcoming environment elsewhere.

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19. Mayhew & Watts, *supra* note 16, at 173.

20. Fustukian et al., *Workers' Health and Safety in a Globalizing World*, *in* HEALTH POLICY IN A GLOBALISING WORLD 223 (Kelley Lee et al. eds., 2002).

As should be evident from the earlier discussion, this book has much to say on many important topics related to global health. Nonetheless, it leaves much unsaid as well. There are several areas to which the editors might have usefully devoted some attention. For example, an examination of the attempts to agree on measures to improve the environment and slow global climate change, with particular attention to the politics around the Kyoto protocol, would have been welcome. So, too, would have been reviews of the attempts to set up a tribunal to hear accusations of war crimes and of the efforts to agree to a global ban on landmines. I would also have expected more on the changing roles of UN agencies, such as the United Nations Fund for Population Activities (UNFPA), and on the influence of U.S. domestic politics on reproductive health.

Although Lilani Kumaranayake and Sally Lake nicely cover the issue of patent protection and the impact of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), a chapter devoted to the controversies surrounding pharmaceutical distribution, pricing, and access would have been a timely complement to Kumaranayake and Lake's contribution. Other issues which are closely linked with globalization, but which are not covered in any depth, include the global trade in illegal drugs, trafficking in women, and international attempts to control the distribution and marketing of tobacco products. According to the WHO, by 2020, "tobacco use will cause over 12% of all deaths globally." Moreover, "tobacco will cause more deaths worldwide than HIV, tuberculosis, maternal mortality, motor vehicle accidents, suicide and homicide *combined.*"[21] The World Bank projects that "[i]f current smoking trends persist, the number of tobacco-related deaths worldwide will soar from 3 million a year today to 10 million a year in 2020, with 70 percent of the deaths occurring in the developing world."[22] Given these staggering figures, this topic seems to be a significant omission from this important book.

But perhaps the most surprising omission is the absence of a chapter on the HIV/AIDS epidemic, which is not only the most important global health issue of our time, but also the issue that most embodies the

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21. WORLD HEALTH ORGANIZATION, THE TOBACCO EPIDEMIC: A CRISIS OF STARTLING DIMENSIONS (1998), *at* http://www.who.int/archives/ntday/ntday98/ad98e_3.htm (last visited June 25, 2003).

22. THE WORLD BANK GROUP, DEVELOPMENT EDUCATION PROGRAM, BEYOND ECONOMIC GROWTH: MEETING THE CHALLENGES OF GLOBAL DEVELOPMENT (2000), *at* http://www.worldbank.org/depweb/beyond/global/chapter8.html (last visited June 25, 2003).

challenges raised by globalization. The HIV/AIDS epidemic has been affected by the ease of travel which allowed its spread to all corners of the globe; the international trafficking of women and children which facilitates sexual transmission of HIV and its penetration into new communities; the global mobilization around issues of access to treatment and medicines; and, most recently, the struggle for funding of HIV/AIDS initiatives which calls into question the role, and for some even the relevance, of the United Nations and its agencies in dealing with this pandemic.

Despite these omissions, what *is* here is a very useful and thoughtful collection of works on many of the most pressing global health issues of the day. The essays themselves are insightful, and the editors helpfully provide a policy framework to tie them all together. Globalization is here to stay; it is "the dominant material and social force of our time."[23] This collection should prove valuable to those interested in following the implications of globalization for health and health policy, particularly in the developing world, as well as to specialists in international policy who want to know more about how globalization affects issues of public health. As globalization brings peoples from across the world closer and closer together, so too does it necessitate the bringing together of previously isolated academic and policy disciplines. This book, discussing many of the most important topics at the intersection of international relations, international political economy, and public health, helps to fill that need.

23. PAUL LUBECK, ANTINOMIES OF ISLAMIC MOVEMENTS UNDER GLOBALIZATION (Ctr. for Global, Int'l, & Reg'l Stud., CGIRS Working Paper Series No. 99-1, 1999).