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## Bioethics Policy: Looking Beyond the Power of Sovereign Governments (Foreword)

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# HOUSTON LAW REVIEW

## FOREWORD

### BIOETHICS POLICY: LOOKING BEYOND THE POWER OF SOVEREIGN GOVERNMENTS

*Robert Schwartz\**

Lawyers are trained to think in terms of power exercised by a sovereign—an institution authorized to enforce a procedurally appropriate decision with coercive force.<sup>1</sup> Generally, lawyers have a broad notion of what constitutes a sovereign. In the United States, for example, this notion includes the federal government, state governments, most tribal units, traditional territorial governments and their agencies—e.g., school boards, local public park districts, water run-off management districts, and flea abatement boards—and a host of other institutions. As a result, it is difficult for lawyers to recognize that policy also may emanate from other institutions that possess only persuasive authority, not coercive power.

Of course, it makes sense for lawyers to focus on the implementation of law through sovereign power. The criminal law has

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1. Although the word "sovereign" has been attributed a number of meanings, it includes the characteristics of independence and authority, unbridled except by internal sources. See BLACK'S LAW DICTIONARY 1395 (6th ed. 1990) (defining sovereign as "[a] . . . state in which independent and supreme authority is vested . . .").

virtually no meaning outside of such power,<sup>2</sup> and everything from health policy<sup>3</sup> to arts policy<sup>4</sup> is, at least in part, made through the exercise of sovereign power. It may turn out, however, that in bioethics,<sup>5</sup> which is permeated with values that vary from person to person, family to family, and group to group,<sup>6</sup> authorities that seek to persuade, cajole, and shame can do more to create effective policy than those that exercise coercive power.

It is not surprising that lawyers have attempted to analyze bioethics policy by focusing on the exercise of governmental authority. Within the law, issues surrounding research on human subjects have been perceived primarily as regulatory issues for national governments.<sup>7</sup> Similarly, legislatures from the Netherlands<sup>8</sup> to the Northern Territory<sup>9</sup> have expended a great deal

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2. Though we sometimes talk about edification and other functions of the criminal law, it is difficult to find a curriculum that does not focus on the coercive power of that law. For while the law may intend to "awaken . . . voluntary inclination toward a certain cause of action," it does so primarily through its ultimately coercive effect. See YVES R. SIMON, *PHILOSOPHY OF DEMOCRATIC GOVERNMENT* 109-10 (1951) (restating Thomas Aquinas's theory that through coercion, governments create "good habits" in wrongdoers).

3. The American health care system is regulated by literally thousands of federal and state statutes and regulations, and nearly half of it is financed by government-appropriated dollars. See BARRY R. FURROW ET AL., *HEALTH LAW* chs. 11-14 (1995) (discussing government regulation of both public and private health care financing mechanisms and stating that the government paid 42% of all health care costs in 1990).

4. In the United States, arts policy is to a large degree dictated by the substantive rules for grant funding by the National Endowment for the Arts (NEA). See *Bella Lewitzky Dance Found. v. Frohnmayer*, 754 F. Supp. 774, 783 (C.D. Cal. 1991) (noting that NEA funding maintains substantial influence in the United States art world). For an account of how the United States Congress established arts policy over the past year, see Cassandra Burrell, *Budget Cuts Blamed for Hurting Art*, ROCKY MOUNT. NEWS, May 9, 1996, at A44 (reporting that congressional Republicans "succeeded in shaking up the endowment and cutting its \$167.4 million budget for 1995").

5. The term "bioethics" includes the principle-based discussion of public policy issues arising out of the biological development of human beings and their relationships. See 1 *ENCYCLOPEDIA OF BIOETHICS* xix (Warren T. Reich ed., 1978).

6. See *id.*; cf. Kevin Wm. Wildes, *Particularism in Bioethics: Balancing Secular and Religious Concerns*, 53 MD. L. REV. 1220, 1220 (1994) (stating that controversies arise in the field of bioethics "because there are different views concerning . . . how medicine should be practiced").

7. For the regulations in force in the United States, see 21 C.F.R. §§ 56.101-.124 (1996), the regulations promulgated by the Department of Health and Human Resources, and parallel regulations issued by other agencies. For a general account of government regulation of medical research, see ROBERT J. LEVINE, *ETHICS AND REGULATION OF CLINICAL RESEARCH* (2d ed. 1986).

8. The society-wide debate over physician-assisted death has been reflected in the Dutch legislature and, more recently, the legislative definition of the appropriate methods of physician-assisted death. For a discussion of this debate from an international law perspective rather than a bioethics perspective, see Julia Belian, Comment, *Deference to Doctors in Dutch Euthanasia Law*, 10 EMORY INT'L L.J. 255 (1996).

of energy over the past few years debating the merits and appropriate limitations of a formal legal recognition of physician-assisted death. In parts of Africa, national governments and their local subdivisions have confronted the practice of female genital surgery<sup>10</sup> and caused some countries to abolish the practice.<sup>11</sup> Virtually every government in the world has been confronted with the need for sovereign intervention to affect distribution of health care resources or the regulation of the market that provides for such distribution.<sup>12</sup> These are serious issues upon which sovereign governments attempt to bring their knowledge of science, their national values, their social resources, and their good sense to bear in establishing enforceable law.

In a sense, we are watching the laboratory of the nations at work in developing bioethics policy. Many governments are watching the Dutch experience with physician-assisted death, as they also keep an eye on the experiences in Oregon,<sup>13</sup>

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9. In 1995, the Northern Territory became the first Australian legislature to legalize physician-assisted death. See Rights of the Terminally Ill Act, No. 12 (1995) (NT). For an account of the legislative process that led to this development, and a description of the international interest in this law, see Philip Shenon, *Australian Doctors Get Right to Assist Suicide*, N.Y. TIMES, July 28, 1995, at A8. An interesting compilation of different national responses to this issue is found in *Legal Systems Handle Euthanasia Differently Around the Globe*, L.A. TIMES, Mar. 14, 1993, at A9.

10. For one recent account of the global debate over female genital surgery, see Sandra D. Lane & Robert A. Rubinstein, *Judging the Other: Responding to Traditional Female Genital Surgeries*, HASTINGS CENTER REP., May-June 1996, at 31. For a discussion of the medical, legal, and ethical considerations involved, see Nahid Toubia, *Female Circumcision as a Public Health Issue*, 331 NEW ENG. J. MED. 712 (1994).

11. See Lane & Rubinstein, *supra* note 10, at 36-37. Parliaments in Sweden, the United Kingdom, and the Netherlands have passed legislation prohibiting female circumcision. See *id.* at 35. See generally Elise A. Sochart, *Agenda Setting, the Role of Groups and the Legislative Process: The Prohibition of Female Circumcision in Britain*, 41 PARLIAMENTARY AFF. 508 (1988).

12. See Robert H. Blank, *Rationing Medicine: A Comparative Analysis*, 21 W. ST. U. L. REV. 11, 11 (1993) ("No developed nation will be spared from difficult decisions concerning the allocation of health care resources.").

13. The Oregon Death With Dignity Act was codified in 1994. See OR. REV. STAT. ANN. §§ 127.800-.895 (Supp. 1996). The Act would permit physician-assisted suicide, but not euthanasia, under limited circumstances. See *id.* (requiring, among other things, confirmation of a diagnosis that a requesting patient suffers from a terminal disease). However, an injunction against the application of the Act was issued in *Lee v. Oregon*, 869 F. Supp. 1491, 1503 (D. Or. 1994).

Subsequently, in *Lee v. Oregon*, 891 F. Supp. 1429 (D. Or. 1995), the Act was held unconstitutional because it violated the Equal Protection Clause of the Fourteenth Amendment. See *id.* at 1438. More recently, the United States Supreme Court heard arguments challenging the constitutionality of state prohibitions of physician-assisted suicide. See Steve Lash, *Justices Wrestle with Whether Constitution Protects Doctor Assisted Suicide*, WEST LEG. NEWS, Jan. 9, 1997, available in 1997 WL 14249 (reporting on challenges to Washington and New York statutes that

the Northern Territory,<sup>14</sup> and a host of other legislatures, including many of the United States, that are contemplating bills that would permit physician-assisted death under certain circumstances.<sup>15</sup> Similarly, African nations are watching developments in other nations that have decided to use their sovereign power to eliminate the practice of female genital surgery.<sup>16</sup> Countries are watching others experiment with different legal devices designed to make pharmaceuticals more available to members of their society.<sup>17</sup> Much of the world is also watching the remarkable variety of health care financing mechanisms that have been established over the last half century.<sup>18</sup> For example, the American focus on making the market work within health care through the creation of managed competition<sup>19</sup> has provided a substantial influence on health care systems from the United Kingdom, where reform has created an "internal market" within the national health system,<sup>20</sup> to Cambodia, where market mechanisms are being considered as a way to provide incentives for the creation of a national health care system from scratch.<sup>21</sup>

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prohibit physician-assisted suicide and noting that the Supreme Court will announce a decision by summer 1997).

14. Refer to note 9 *supra*.

15. For a discussion of the physician-assisted death initiatives being considered by the legislatures of Michigan, Nevada, New Hampshire, Rhode Island, and Virginia, see Kevin M. Stansbury, Note, 31 LAND & WATER L. REV. 623, 637 n.132 (1996).

16. Refer to notes 10-11 *supra* and accompanying text.

17. In fact, some countries have joined together formally to address the "scientific, cultural, and technical problems that obstruct drug development and importation" in an attempt to increase the availability of pharmaceuticals to their respective citizens. See Joseph G. Contrera, Comment, *The Food and Drug Administration and the International Conference on Harmonization: How Harmonious Will International Pharmaceutical Regulations Become?*, 8 ADMIN. L.J. AM. U. 927, 929 (1995) (reporting on the Second International Conference on Harmonization and the participation therein by the European Union, the United States, and Japan).

18. For a thorough account of the various financing systems employed in Canada, Europe, and the United States, see Uwe E. Reinhardt, *Reforming the Health Care System: The Universal Dilemma*, 19 AM. J.L. & MED. 21 (1993).

19. See Robert Pear, *Clintons Should Address Health Care One Issue at a Time, Experts Suggest*, N.Y. TIMES, Oct. 10, 1994, at B7 (reporting that "the mainstream coalition," a bipartisan group of senators that included Bob Dole, proposed health care legislation based on managed competition). For an account of the impact of managed competition on the debate over health care reform in the United States, see Paul M. Ellwood et al., *The Jackson Hole Initiatives for a Twenty-First Century American Health Care System*, 1 HEALTH ECON. 149 (1992).

20. See Frances H. Miller, *Denial of Health Care and Informed Consent in English and American Law*, 18 AM. J.L. & MED. 37, 52-54 (1992) (discussing the effects on Britain's National Health Service). For an interesting political account of this development, see Steve Lohr, *Free-Market Health System: New Thatcher Goal for Britain*, N.Y. TIMES, Feb. 1, 1989, at A1.

21. See generally WORLD HEALTH ORGANIZATION, STRENGTHENING HEALTH

As the thoughtful Articles in this Symposium prove, however, legal scholars are beginning to recognize that enforcement by sovereign authority is not the best way to address many of these issues. There are devices—even formal legal devices—that will allow us to develop better bioethics policy than we could achieve through the enforcement of the law. Consider the situation in Michigan, where three separate juries, each hearing a separate criminal case against Dr. Jack Kevorkian, showed us that sometimes the majority does not want to enforce the law—even though that same majority is reluctant to change that effectively unenforceable law through the use of its democratic institutions.<sup>22</sup> While juries were acquitting Dr. Kevorkian, the Michigan legislature decided that his conduct should remain criminal.<sup>23</sup> The conversation about physician-assisted death that resulted from the Kevorkian cases may lead us to a social consensus on that issue of bioethics policy; new enforceable laws—whether they attempt to prohibit physician-assisted death, as in Michigan, or permit it under some circumstances, as in Oregon—are far less likely to resolve the underlying social issue. Even the distribution of health care resources, including pharmaceuticals, might improve if it is removed from the clutches of the sovereign and delegated to other institutions, such as the market.

The goal of health and bioethics policy generally is to maximize the quality of health of those touched by the policy. But health is not the only value that we prize, and it is not the only value that is touched by health policy. To the extent that any such policy also touches cultural identity, national sovereignty, local integrity and decision making, international trade and international intercourse of all kinds, or the international image of governments, the policy must be a compromise that recognizes all of these values. In fact, many of these values—the cultural identity of minorities, for example—are not the prevailing values in a democratic nation. Values of individual families are more likely to be expressed in a policy if those families are involved in making the policy, and policies that affect particular ethnic

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SERVICES (1994).

22. See Jack Lessenberry, *Kevorkian Indicted on Charges of Helping in Three Suicides*, N.Y. TIMES, Nov. 1, 1996, at A32 (reporting that Dr. Kevorkian was acquitted three times on assisted suicide charges).

23. The Michigan legislature created the crime of assistance to suicide in 1992, but it carried with it a sunset provision; the sunset provision has since expired. See MICH. COMP. LAWS ANN. § 752.1027 (Supp. 1996). For a brief description of Dr. Kevorkian's travails in the Michigan courts, and for a discussion of how the Michigan legislature and courts addressed the issue, see BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS AND PROBLEMS 283-85 (Supp. 1996).

groups are more likely to be satisfactory if those ethnic groups are sources of the policy. In a world where political boundaries are arbitrary, policies articulated by sovereign nations may be enforceable but they are not, per se, justifiable. We may be better off with more rationally created and justifiable policies, even if they are not so cleanly enforceable. Further, by placing the responsibility for health and bioethics policy decision making in those that have the power to persuade and convince, but not to enforce—by placing decision making in bodies that are not sovereign—we may avoid some of the abuse that comes with giving power over such fundamental issues to already powerful governments. Additionally, we may create a diversity of decision making that will allow for better, more universal, and more consistent policies around the globe.

All of the Articles in this Symposium recognize that the health of our community may be advanced more substantially if policy making is in the hands, as least in part, of unofficial, non-sovereign bodies with no real power of enforcement. First, Professor Lars Noah explains the potential effects of the North American Free Trade Agreement (NAFTA) on the trade in pharmaceuticals.<sup>24</sup> Professor Noah's thorough account provides us with a story of how bioethics policy will be made, effectively, outside of sovereign governments. As Professor Noah explains, NAFTA, which provides stronger intellectual property rights and enforcement mechanisms,<sup>25</sup> lowers tariffs,<sup>26</sup> formally permits open bidding across North America,<sup>27</sup> and governs cross-border purchases (which thus could affect the gray market),<sup>28</sup> is unlikely to substantially alter the current trade in pharmaceuticals throughout this continent.<sup>29</sup> However, Professor Noah's approach, which is based upon the presumption that such issues should be resolved in the market, suggests that the distribution of pharmaceuticals throughout North America (and, presumably, the world) may be advanced if we allow the international market in those drugs to develop fully, and leave the governments to the comparatively narrower task of protecting the intellectual property rights of those developing the pharmaceuticals.

Allyn L. Taylor's contribution to this Symposium provides us with an exceptionally clear description of how the International

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24. See Lars Noah, *NAFTA's Impact on the Trade in Pharmaceuticals*, 33 HOUS. L. REV. 1293 (1997).

25. See *id.* at 1297-1302.

26. See *id.* at 1309.

27. See *id.* at 1311-15.

28. See *id.*

29. See *id.* at 1314-15.

Health Regulations (IHR, or Regulations) could help contain the spread of infectious diseases.<sup>30</sup> The Regulations, which originated in the World Health Organizations International Sanitary Regulations in 1951 and were last revised in 1981, have not proven adequate to deal with infectious disease transmission over the past few years.<sup>31</sup> Consequently, Ms. Taylor suggests that the IHR be rewritten to create an independent agency of the World Health Organization (or the World Health Assembly) that will not partake of any sovereignty of any of the members of the World Health Organization, and will not have any of the authority of the World Health Organization itself.<sup>32</sup> Rather, it will have the power to provide assistance when it is requested, to seek information, and to congratulate or shame those who do (or fail to) live up to the regulations.<sup>33</sup> The power of sovereign nations is not sufficient to resolve this problem in a world fractured by arbitrary international boundaries that are unrespected by pathogens, but that does not mean our effort to control disease must fail. It simply means that we must look elsewhere to persuade sovereign nations into compliance.

In their contribution to this Symposium, Ms. Le Bris, Professor Knoppers, and Ms. Luther remind us that there are several sources of bioethics decision making that do not partake of sovereign power.<sup>34</sup> The participation of these diverse nonsovereign decision makers in the global bioethics debate, the authors argue, will facilitate policies that are more "adaptive and evolutionary" than those that typically evolve from traditional linear consensus building.<sup>35</sup> The authors do not seek to supplant the traditional positive principles of bioethics, however. They simply believe that combinations of these nonsovereign decision makers are more flexible and more able than governments to accommodate the nonlinear policy development that health and bioethics policy necessitates.<sup>36</sup>

While the first three Articles deal, directly or indirectly, with international (or, at least, multinational) law, Professor Henry Greely's Article does not.<sup>37</sup> His suggestion is that some

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30. See Allyn L. Taylor, *Controlling the Global Spread of Infectious Diseases: Toward a Reinforced Role for the International Health Regulations*, 33 HOUS. L. REV. 1327 (1997).

31. See *id.* at 1341-46.

32. See *id.* at 1346-52.

33. See *id.* at 1352-60.

34. See Sonia Le Bris, Bartha Maria Knoppers, Lori Luther, *International Bioethics, Human Genetics, and Normativity*, 33 HOUS. L. REV. 1363, 1364-74 (1997).

35. See *id.* at 1393-95.

36. See *id.* at 1392-95.

37. See Henry T. Greely, *The Control of Genetic Research: Involving the*

bioethics policy—at the least, policy regarding the maintenance of genetic information—ought to be set by “groups between” the individual,<sup>38</sup> who is generally recognized by law as the one with authority to grant consent to research upon his body (and, presumably, his genome),<sup>39</sup> and the sovereign state, which makes and enforces that law and has the independent authority to regulate bioethics and, more particularly, genetics research policy.<sup>40</sup> Professor Greely’s concern arises out of his participation in the Human Genome Diversity Project (HGDP), a particularly exciting undertaking that plans to obtain, catalog, and maintain genome samples from hundreds of different sources around the world.<sup>41</sup>

The proposed Model Ethical Protocol for Collecting DNA Samples from the North American Regional Committee Human Genome Diversity Project, which is also included in this Symposium,<sup>42</sup> provides a description of how some of these “groups between” can be defined, and what might constitute “a culturally appropriate” authority to grant consent on the groups’ behalf.<sup>43</sup> But how are the decisions of these groups to be enforced? They do not have the legal status of individuals, nor do they have the legal authority of sovereign governments, for the most part. As Professor Greely points out, they will be enforced by the private institutions that choose to be bound by them.<sup>44</sup> For example, the HGDP proposes that it not collect or maintain any DNA samples that do not meet the requirements of the proposed Model Protocol.<sup>45</sup> Professor Greely’s proposed method of enforcement is remarkably similar to Ms. Taylor’s method of enforcement of the IHR. When an Institutional Review Board or a funding agency refuses to make a reasonable effort to define the “group between” and discover “a culturally appropriate” authority to consent on behalf of that group, others, including the HGDP, will make sure the community knows of this transgression.<sup>46</sup> Shame and public

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“Groups Between,” 33 HOUS. L. REV. 1397 (1997).

38. See *id.* at 1408-13.

39. See *id.* at 1405-08.

40. See *id.* at 1399-1405.

41. See *id.* at 1414.

42. See *Proposed Model Ethical Protocol for Collecting DNA Samples*, 33 HOUS. L. REV. 1431 (1997) [hereinafter *Model Protocol*].

43. See *id.* at 1443-47.

44. See Greely, *supra* note 37, at 1414-20.

45. See *Model Protocol*, *supra* note 42, at 1436.

46. See Greely, *supra* note 37, at 1425; *Model Protocol*, *supra* note 42, at 1437-38.

approbation are the weapons available to those that wish to enforce the guidelines; there may be no better way of enforcing the principles of bioethics.

Together, the four Articles in this Symposium demonstrate the strength of bioethics institutions that do not grow out of sovereign governments. Perhaps we have entered an era where the value of engaging nonsovereign institutions in policy making is seen as valuable across disciplinary lines. These authors, for example, apply their theories to the market for pharmaceuticals, the International Health Regulations, and the collection of genetic information. The challenge for the bioethics community is to take the principles developed here and to apply them to other pressing issues, including physician-assisted death, female genital surgery, the request for futile medical care, designing proper regulation for a managed care system, and, perhaps, providing a just and equitable distribution of health care resources in this country and around the world.