Vanderbilt Law Review

Volume 45
Issue 4 *Issue 4 - May 1992*

Article 3

5-1992

Introduction: Caring for the Nation--Current Issues in Health Care Reform

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SPECIAL PROJECT

Caring for the Nation—Current Issues in Health Care Reform

INTRODUCTION

Health care reform is once again on the "front burner" of American politics. With health care costs in the United States rising at three times the rate of inflation and an increasing portion of the population falling through the cracks of the current health care delivery system,[1] legislators, health care professionals, and the population at large now have little difficulty agreeing that the system is badly in need of reform.

1. Victor Cohn, *How Can We Fix a Broken System?*, Wash. Post, Nat'l Weekly Ed. 6, 6 (Feb. 3-9, 1992). Current estimates indicate that over 35 million Americans, about 15% of the population, are uninsured. Approximately the same number of Americans are underinsured. Both figures continue to rise. Only 42% of the poor receive health care coverage through Medicaid. Id. According to one report, "[b]etween 1980 and 1988, the number of privately insured fell by nearly 5 million." Joe White, *Democrats Can and Should Push on Health Care. . .*, Wash. Post, Nat'l Weekly Ed. 9, 9 (Sept. 30-Oct. 6, 1991). Twenty-five percent of all Americans have lost health insurance for some period in the last two years. Cohn, Wash. Post, Nat'l Weekly Ed. at 6 (Feb. 3-9, 1992).

This consensus, however, falls apart when discussion turns to what needs to be fixed and how to fix it. Federal legislators currently have over twenty health bills pending before them,[2] and state governments, tired of waiting for a consistently elusive federal solution, have begun seeking their own solutions to health care problems.[3]

While perhaps the current focus on health care reform is unsurprising in light of election year politics, there is compelling evidence that Americans are rightly concerned about the state of health care in this country.[4] The United States is now one of only two major industrialized nations that have yet to implement some form of universal health care system for their citizens.[5] Despite possession of the most advanced medical technology and the most highly skilled medical personnel in the world, the United States consistently rates well below other countries in life expectancy, infant mortality, and low birth weight.[6] Rapidly rising costs and the growing number of uninsured and underinsured undoubtedly contribute to these gloomy statistics by limiting the access of many citizens to even basic health care.[7] Administrative inefficiency, waste, and health care fraud compound the problem by needlessly con-

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2. Cohn, Wash. Post Nat'l Weekly Ed. at 6 (Feb. 3-9, 1992). These health care reform proposals have taken several forms. "Pay or play" advocates suggest requiring employers either to provide basic health coverage to their employees or to make contributions to a public fund through which governments would pay for coverage. Additional public funds would pay for basic coverage for those not covered under employer mandates. Universal health care proposals call for the institution of a government-managed, national health insurance system. Those favoring incremental reform tend to suggest the gradual implementation of measures such as tax credits and government vouchers to help individuals pay for private health coverage, the use of risk pools to lower premiums, extending current Medicaid coverage, and encouraging the use of managed care. See id. at 7; see also Henry Aaron, . . . *But There Are No Easy Answers*, Wash. Post, Nat'l Weekly Ed. 10, 10 (Sept. 30-Oct. 6, 1991).

3. At its annual meeting last summer, the National Governor's Association (NGA) gave top priority to the health care issue. Skeptical that any federal solution to the health care crisis is forthcoming any time soon, the governors on the NGA Health Care Task Force proposed action on the state level. Robert Shogan, *Governors Urge New Approach to Health Care Reform*, L.A. Times A18 (Aug. 18, 1991). The State of Oregon has recently passed legislation that, if fully implemented, would revamp the entire Oregon health care system. See Note, *The Oregon Basic Health Services Act: A Model for State Reform?*, 45 Vand. L. Rev. 977, 988-97 (1992). The portions of the plan that affect the allocation of federal Medicaid funds currently are awaiting the necessary waivers from the federal government. Id. at 997.

4. A recent poll indicates that 76% of American voters consider health care one of several important issues. Eleven percent considered health care the most important issue. See Cohn, Wash. Post, Nat'l Weekly Ed. at 6 (Feb. 3-9, 1992) (cited in note 1).

5. B. D. Colen, *Strong Medicine*, 23 Health 32, 32 (May 1991).

6. The Health Care Crisis and the American Family, Hearing Before the Senate Committee on Labor and Human Resources, 102d Cong., 1st Sess. 64 (1991) (reprinting *The Crisis in Health Insurance, Pt. 2*, Consumer Rep. at 1 (Sept. 1990)). The United States ranks twelfth among all nations in life expectancy, twenty-second in infant mortality (ranking from lowest percentage to highest percentage), and twenty-fourth in low birth weight (ranking from best to worst). Id.

7. See Cohn, Wash. Post, Nat'l Weekly Ed. at 6 (Feb. 3-9, 1992) (cited in note 1).

suming limited health care funds, both private and public.[8] It is little wonder that the cry for reform has become so universal and so persistent.

Although ensuring that all Americans have access to at least basic physical health care properly has risen to the forefront of the current health care debate, other important health care reform issues often seem to get lost in the process. For example, millions of Americans suffer with some form of mental illness at least once in their lives, yet as few as twenty percent receive professional care for their illnesses.[9] Other societal problems—such as homelessness, crime, and substance abuse—stem, in part, from untreated and inadequately treated mental illness.[10] As with physical health care, piecemeal public and private funding programs may contribute greatly to the problem of limited access to adequate care. Unlike physical health care, however, the stigmatization that often accompanies mental illness exacerbates the difficulty of arriving at workable solutions to the mental health care access problem.[11]

The mentally ill are not the only group to suffer additional burdens in obtaining adequate care due to their pariah status among the population. Although those incarcerated in this country's prisons are the only portion of the population constitutionally entitled to medical care at government expense, the quality and quantity of care this group receives well may be less than adequate.[12] Many of the lawsuits filed by prisoners against the state or federal authorities responsible for their

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8. Experts estimate that fraud and abuse in the health care system cost Americans as much as $50 to $80 billion per year. Gordon Witkin et al., *Health Care Fraud*, U.S. News & World Rep. 34, 34 (Feb. 24, 1992). In 1991, the General Accounting Office estimated that the implementation of a national health insurance system could reduce current administrative costs by $67 billion. White, Wash. Post, Nat'l Weekly Ed. at 9 (Sept. 30-Oct. 6, 1991) (cited in note 1).

9. Statement of Lewis L. Judd, M.D., Chairman of the National Mental Health Leadership Forum, at a public hearing on the homeless and the mentally ill, quoted in Deborah S. Pinkney, *Public Hearing Focuses on Homeless Mentally Ill*, American Medical News 2, 2 (Sept. 23/30, 1991). See also Note, *The Pariah Patient: The Lack of Funding for Mental Health Care*, 45 Vand. L. Rev. 951, 953-55 (1992) (citing various mental health statistics).

10. For example, arrest rates among the mentally ill are consistently higher than those among the general population. See Rael J. Isaac and Virginia C. Armat, *Madness in the Streets: How Psychiatry & the Law Abandoned the Mentally Ill* 271 (Free Press, 1990). Between 38% and 56% of the homeless are afflicted with some form of mental illness. Pamela J. Fisher, *Alcohol, Drug Abuse and Mental Health Problems Among Homeless Persons: A Review of the Literature, 1989-1990* 72 (U.S. Dep't of Health and Human Services, 1991).

11. See Note, *The Pariah Patient*, 45 Vand. L. Rev. at 972-75 (cited in note 9).

12. See *Estelle v. Gamble*, 429 U.S. 97, 103 (1976) (recognizing a prisoner's right to challenge the adequacy of health care received in prison under the Eighth Amendment and 42 U.S.C. § 1983 and noting that the government has an "obligation to provide medical care for those whom it is punishing by incarceration"). In *Gamble*, the Court held that "deliberate indifference" was the appropriate standard for reviewing prisoners' claims of inadequate health care. Id. at 104.

incarceration are based on claims of inadequate health care,[13] and the standard of health care in this country's prisons often draws criticism from commentators.[14] Despite this criticism, prison health care funding remains an unpopular cause among the public and, hence, a low priority item in governmental budget planning.[15] In addition, within the prison system itself, health care, as a nonsecurity function, receives a low priority in the distribution of limited funds.[16] Furthermore, although prisoners have recourse to the courts in challenging the adequacy of care, review under the "deliberate indifference" standard currently applied by the courts often places an impossible burden of proof on the complaining prisoner[17] and may do little to encourage any broad reform in prison health care. With the increasing unavailability of adequate health care to the general population, the lack of public receptiveness to prisoners' complaints[18] is likely to continue if not increase.

Limited funding often plays a central role in preventing access to adequate health care. Yet, the receipt of adequate care is not completely dependent upon the ability of the individual or society to fund that care. Adequate care also depends upon the quality and accuracy of medical research. The DES crisis[19] and the recent dispute over the

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13. See Robert Dvorchak, *Medicine Behind Bars: Quality Care is Elusive, Despite Lawsuits: Hostile Public, Shortage of Good Doctors and Nurses Worsen Prison Problem*, L.A. Times 2 (June 18, 1989).

14. See Phil Gunby, *Health Care Reforms Still Needed in the Nation's Prisons*, 245 JAMA 211 (1981); Jim Doyle, *Judge Holds SF in Contempt*, San Fran. Chronicle A8 (Jan. 25, 1990); Elizabeth Levitan Spaid, *Advocates Urge Better Conditions for Women Inmates*, Christian Science Monitor 9 (May 29, 1991).

15. See Ciba Foundation, *Symposium on Medical Care of Prisoners and Detainees* 40 (Associated Scientific Publishers, 1973) (noting that prisons "stand[] as a relatively low claimant" for public funds).

16. See Eric Neisser, *Is There a Doctor in the Joint? The Search for Constitutional Standards for Prisoner Health Care*, 63 Va. L. Rev. 921, 936-37 (1977).

17. See *Wilson v. Seiter*, 111 S. Ct. 2321, 2330 (1991) (White concurring) (noting that the intent element of the deliberate indifference standard "likely will prove impossible to apply in many cases").

18. See William P. Isele, *Constitutional Issues of the Prisoner's Right to Health Care*, in Office of Development, Testing, and Dissemination, National Institute of Law Enforcement and Criminal Justice, and United States Department of Justice, *Health Care in Correctional Institutions—MANUAL* 21 (1979).

19. Between 1943 and 1971, an estimated three million pregnant women were treated with diethylstilbestrol (DES). Upon discovery that DES had operated as a carcinogen for offspring whose mothers were treated with DES during their pregnancies, the FDA banned the use of DES in 1971. Edward Saunders and Jeanne See Saunders, *Drug Therapy in Pregnancy: The Lesson of Diethylstilbestrol, Thalidomide, and Bendictin*, 11 Health Care for Women Int'l, 423, 424-24 (1990). Researchers did not test DES on animals for teratogenic potential, nor did they run dose-ranging studies. Only at the last state of clinical testing were women used in the trials. See Roberta Apfel and Susan Fisher, *Do No Harm: DES and the Dilemmas of Modern Medicine* 21 (Yale, 1984).

safety of silicone breast implants[20] exemplify the hazards presented by the failure to test health care products thoroughly prior to their approval for general use. One currently developing area of controversy in the field of medical research is the methodology used by pharmaceutical companies in conducting clinical drug trials. Traditionally, these manufacturers have excluded fertile women from the majority of clinical drug trials, often with adverse consequences to women.[21] Most significantly, the practice of excluding women from clinical trials results in incomplete knowledge of the potential dangers and negative side effects on women of drugs tested in this fashion.[22] While manufacturers justify this exclusion on various grounds, financial as well as medical,[23] many in the medical community have come to doubt the soundness of this practice.[24] The exclusion also raises a variety of legal issues, just now gaining recognition in the federal agencies that regulate the testing practices of drug manufacturers.[25] The extent to which these agencies will be willing to require the reform of current clinical trial procedures, however, remains to be seen.

This Special Project addresses four issues of significance to the current debate on health care reform. The Special Project begins with an examination of the practice of excluding fertile women from clinical drug trials and the negative effect this practice has had on women's health care. The Project reviews the current efforts—congressional, administrative and private—to change this practice and explores some of the legal ramifications the failure to alter the practice may hold for both administrative agencies and pharmaceutical manufacturers. The Project suggests that appropriate action by the federal administrative

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20. The FDA has recently received evidence that 3% to 10% of breast implants rupture sometime after implantation. Previously, manufacturers had claimed that ruptures occurred in only 1% of implants. In addition, some experts now believe silicone implant leaks may be linked to an immune system disorder and to lupus erythematosus. Under a new FDA recommendation, unrestricted use of silicone implants will be limited to women seeking reconstructive surgery. Women who seek implantation for purely cosmetic reasons would have to participate in clinical trials to receive them. See Steven Findlay, *New limits, more questions*, U.S. News & World Rep. 61 (March 2, 1992).

21. Women suffer proportionally more negative side effects from the use of pharmaceuticals. Jean Hamilton and Barbara Parry, *Sex-Related Differences in Clinical Drug Response: Implications for Women's Health*, J. Am. Women's Ass'n 126, 129 (Sept./Oct. 1983).

22. Id.

23. See Council on Ethical and Judicial Affairs, *Gender Disparities in Clinical Decision Making*, 266 JAMA 559, 559 (1991).

24. See, for example, id; Paul Cotton, *Is There Still Too Much Extrapolation From Data on Middle-aged White Men?*, 263 JAMA 1049, 1049 (1990). Wendy Chavkin and Harold Fox, Letter to the Editor, 264 JAMA 973-74 (1990); Hamilton and Parry, J. Am. Med. Women's Ass'n at 129 (cited in note 21).

25. See Note, *The Disfranchisement of Fertile Women in Clinical Trials: The Legal Ramifications of and Solutions for Rectifying the Knowledge Gap*, 45 Vand. L. Rev. 877, 895-907 (1992).

agencies responsible for regulating drug testing procedures could do much to rectify the unnecessary exclusion of women from clinical trials.

The Special Project then turns to the issue of prison health care and questions the appropriateness of the continued use of the "deliberate indifference" standard for reviewing prisoner complaints of inadequate health care. After outlining the development of the deliberate indifference standard and evaluating its inadequacy in correcting current deficiencies in the prison health care system, the Project suggests the adoption of a gross negligence standard as a more appropriate means of reviewing constitutional challenges to prison health care.

Next, the Special Project examines the current state of mental health care funding in the United States. The Project points to the inadequacy of the current piecemeal approach to funding—both public and private—and the effect stigmatization continues to have in this important area. The Project also suggests various methods by which the private funding of mental health care might be increased, including the expansion of federal laws requiring hospitals and physicians to provide emergency care and a limitation on the reach of mental illness benefit-limitation clauses under both state common law and federal statutes.

The Special Project concludes with an examination and evaluation of the innovative and controversial Oregon Basic Health Services Act (OBHSA).[26] OBHSA proposes a complete restructuring of the current health care system in Oregon, including the use of mandated employer-sponsored health care and state health-risk pools. The most controversial aspect of OBHSA, however, is its revamping of Medicaid allocation, using a system of rationed health services. OBHSA would guarantee that virtually all Oregon residents would have true access to at least basic health care, but its implementation also would mean that residents presently receiving Medicaid would suffer the loss of some benefits. Although the OBHSA currently is awaiting the federal waivers necessary to its full implementation, eighteen states already have begun to develop programs modeled on the Oregon plan, thus increasing its importance in the call for health care reform.

The degree of attention currently focused on health care issues is long overdue, and reform finally appears to be on the horizon. Recognizing the depth and multi-leveled nature of the health care crisis in the United States is an important first step in providing adequate health care to all Americans. Thoughtful resolution of the issues that are the subject of this Special Project could do much to change the

26. See Oregon Senate Bills 27, 534, and 935.

current poor state of health care in the United States and to help ensure that change, if and when it comes, will be change for the better.

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* The Editor dedicates this Special Project to her parents, Jack and Clarissa Powley, without whose love, support, encouragement, and friendship the rocky road of returning to school in midlife would have heen much harder to travel and much lonelier along the way. The Editor's gratitude for their continuing good health and the wish that all citizens of this country could enjoy the same did much to inspire the selection of the Special Project topic. The Editor also wishes to acknowledge the significant contributions made to this Special Project by her colleagues Alvaro Anillo, Susan Hurd, Stacey Jarrell, and Benjamin Vernia. My thanks to all of you.