ON THE COVER
Growing Pains
(oil on canvas)
by Andrea Tom,
Brown University of Medicine.

EDITOR’S NOTE
Defining a "Patients’ Bill of Rights" for the Next Century
Stefan C. Weiss

AS THE MILLENNIUM APPROACHES, THE HEALTH CARE DELIVERY SYSTEM IN THE United States remains in a period of transformation. The commercialization of medicine has challenged the professional dominance of physicians.

Corporate organizations emerged under the assumption that the principles that defined US industry were applicable to health care. They offered efficiency through vertical and horizontal integration. Initially, tremendous cost reductions were achieved. Organizing provider services into competitive networks resulted in the lowest rate of health care expenditure growth in seven years: 4.4%. The market was ostensibly beginning to solve the problems of a system that had experienced explosive inflation and failed to provide services to the entire population.

The introduction of an active third party, however, fragmented fundamental relationships. Because physicians have a virtual monopoly over medical practice, they can exert enormous influence. This includes the right to define what constitutes a disease and how to treat it. Consequently, overuse of resources became a primary cost-driver. Managers were required to intercede in treatment decisions to control spending. The final denial rate of physician recommendations was no more than 3% overall and 1% for hospitalization and surgical requests. However, some of those failures to treat were the basis for the woeful tales retold to Congress this past summer.

Our health care system delivers 4 million babies, witnesses 762 million visits to physicians, and facilitates 539 million days in the hospital. But it does so at a cost of $1 trillion, 13.6% of the gross domestic product. A “patients’ bill of rights” is about establishing a situation in which all members of the community can seek professional services and receive high-quality care at reasonable costs. By defining a standard of care, it promotes the development of innovative, cost-effective organizations that focus on clinical quality improvements, patient satisfaction, and access to information.

This month, MSJAMA considers the meaning of a “patients’ bill of rights” from several viewpoints. Throughout the history of this country, physician-legislators have been active in securing rights in health care. This unique US claim to rights appears rooted in a culture of independence. In 1998, when the President of the United States issued an executive order defining a set of standards for treating individuals in federal health plans, he incited the political system to address the revolutionary changes in the health care delivery system. The resultant congressional efforts, however, became more of an attempt to secure consumer rights than patient rights. Furthermore, these political discussions focused on increased regulations to protect those with insurance and made little mention of how to solve the problem of the uninsured.

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BENJAMIN DISRAELI EXPLAINED THAT CHANGE IS INEVITABLE IN a progressive country. Over the last few decades, the US health care system has witnessed dramatic progress in medical technologies and treatment, a dramatic rise in health care costs, and a dramatic shift in the system to managed care. Since 1990, the number of US citizens enrolled in managed care has nearly doubled. Now, a majority receive health care benefits from a managed care organization.

When done right, managed care can provide a seamless system of care delivery from prevention to primary care to patient management. But managed care has also produced frustrations and even tragic cases where care was delayed or denied. A public consensus has emerged for policymakers to address what is wrong with managed care while protecting what is right: care that is more accessible and affordable.

To begin addressing these concerns, in March 1997 President Clinton established the Advisory Commission on Consumer Protection and Quality in the Health Care Industry. He asked Secretary of Labor Alexis Herman, and me, as Secretary of Health and Human Services, to co-chair the committee. The 34-member panel brought together health care providers and patients, business and labor leaders, state and local government representatives, and health care quality experts. The Commission was charged with recommending steps to ensure health care quality and to protect consumers and providers in the health care system.

In its final report, published in March 1998, the Commission outlined specific steps to guarantee health care quality. It included measures that would prevent overuse and underuse of services, as well as reduce injuries and errors. The Commission also proposed a Patients’ Bill of Rights.

The Patients’ Bill of Rights empowers doctors to communicate freely about treatment options, alternatives, risks, benefits, and consequences without “gag rules” in their contractual agreements.

It also insists on mutual respect and nondiscrimination in the health care industry and in insurance enrollment regardless of race, sex, age, sexual orientation, or genetic makeup.

Consumers have the right to accurate, easily understood information to make knowledgeable choices about their health care: what care is covered and what is excluded, which doctors are in a plan’s network, and how consumers can appeal a decision when coverage is denied. Consumers also have the right to be seen by a specialist when needed, and the right to emergency care when and where the need arises.

Soon after receiving the Commission’s interim report, the President signed an executive memorandum (W. J. Clinton, written communication, February 1998) applying the Patients’ Bill of Rights to all those enrolled in a federal health insurance plan. That guarantee covered 80 million people, one third of all Americans, including federal employees, veterans, military personnel, and Medicare and Medicaid enrollees. The administration believes that step alone will begin to transform the health insurance industry. Now the nation’s challenge is to find a way to guarantee basic patients’ rights to every American.

The President and I have both called on Congress to pass federal legislation to extend the Patients’ Bill of Rights to all private health plans. There is a bipartisan consensus in Congress on the need for action to guarantee patients’ rights, but there are differences about what rights to guarantee. The Clinton Administration believes that to be effective in addressing the needs of patients and providers, patients’ rights legislation should include a number of basic criteria (TABLE).

No matter what the outcome in Congress, clearly the process of guaranteeing patients’ rights is at the beginning, not the end. Making these rights a reality for every consumer across the United States will require the commitment of the nation’s current, and future, health care leaders. Moreover, it will require that students continue to remain informed, concerned, and engaged in this debate because nobody will have more of a challenge and opportunity to infuse patients’ rights into the health care system.

A public consensus has emerged for policymakers to address what is wrong with managed care while protecting what is right: care that is more accessible and affordable.

Table. The Clinton Administration’s Essential Rights for Patients

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<th>Right</th>
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<td>Universal coverage</td>
<td>Removal of “gag clauses”</td>
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<td>Access to specialists</td>
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<td>Continuity of care</td>
<td>Allow recourse if a health plan delays or denies care and a patient is maimed or killed as a result</td>
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<td>End to financial incentives to limit care</td>
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PERSPECTIVE

A Patients’ Bill of Rights: The Medical Student’s Role

Donna E. Shalala, PhD, US Secretary of Health and Human Services

REFERENCES


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Patients’ Rights Proposals: The Insurers’ Perspective

Charles N. Kahn III, President, Health Insurance Association of America

Today, in both state and federal arenas, much attention is focusing on “patients’ rights” legislation. If the interests of health care consumers are to be served, however, legislators need to ask themselves 3 key questions: First, do the bills best address, or even match, consumers’ concerns? Second, are those concerns all of equal weight and validity? Third, what are the costs of this legislation, and what impact would such proposals have on beneficiaries?

While “patients’ rights” bills contain many provisions, the most significant are health plan and employer liability, access to services and to grievances and appeals, and “quality,” often in the form of mandated benefits. These proposals have financial implications for providers, insurers, employers, and patients that would effectively increase the cost of health insurance.1 Placing new tort liability on health plans and employers, for example, would promote defensive medicine and lawsuits. Other provisions would require administrative outlays and expensive implementation systems. Mandating benefits such as mental health, chemical dependency treatment, and dental services would increase premiums by 9% to 15%.2

When health plans and insurers face increased costs, premiums rise. Certain legislative provisions could result in premium increases in excess of 30.2%. Higher premiums translate to fewer employers offering health benefits, more employee cost-sharing, and more people without insurance—possibly as many as 1.5 million.3 This risk is substantial, given that “patients’ rights” bills focus on “problems” that are illusory, exaggerated, or being addressed by the marketplace.

Prepaid health plans that integrate financing and delivery were a response to the escalating health care prices that began in the 1960s. Employers (who contribute the largest percentage toward insurance coverage)4 were seeking to provide health benefits at a reasonable cost, while maintaining quality care. In the early days of their development, managed care plans, primarily health maintenance organizations (HMOs), benefited both employers who saved on operating costs and employees who appreciated the convenience. Not only did such plans gain popularity, but indemnity insurers also adopted managed care techniques.

Employers, employees, and ultimately patients continue to influence plan structures and benefits. In the past few years, as health care inflation slowed and premium increases leveled off, patients began to demand more than what conventional HMOs offered: choice of physicians, direct access to specialists, and the ability to go “out of network”—elements found in patients’ rights proposals. The market responded, creating systems that cost little more than standard HMOs. Today, three quarters of health plans offer a point-of-service option5; preferred provider organizations (PPOs) are the dominant form of employer-based coverage; and almost 92% of employees in employer-sponsored plans are offered an option for selecting nonnetwork physicians.6

The majority of Americans rate the quality of their health plans favorably and are happy with the care they receive.7 Studies show that people in employer-sponsored health plans—HMOs, PPOs, and fee-for-service—are not constantly switching insurers, and that they do not plan to switch.8 Thus, the question arises, is this legislation necessary?

A second important question is whether patients are without protection. In every state, an insurance commissioner administers laws and regulations. Private accreditation initiatives guard consumers’ interests. Also, most plans have grievance processes that work well, despite the sometimes unfavorable and unreliable media accounts. Plans have committed themselves to quality for employers and patients.

More government intervention will not be better for consumers. The health insurance marketplace is dynamic and customer-driven. Insurers continue to adapt, tailoring new offerings that show sensitivity to costs and coverage. Thus, they serve the changing needs of the vast majority of the US population. Unnecessary regulation could limit that adaptability. Worse, the savings that characterize managed care could be lost. It would be a tragedy if patients’ rights bills curtailed innovation and forced more people out of the system. Perhaps, then, as legislators look at these issues anew, they should forgo tinkering with insurance policies, stop undermining the marketplace, and begin to face the big issue: the uninsured.

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American Independence and the Right to Emergency Care

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Asserting a “right” is a powerful statement in American political rhetoric. In this country, medicine has recognized patients’ rights for over 150 years. As early as 1886 there was a proposal to “draw up . . . a Bill of Rights which shall secure patients from any injustice from the votaries of science.” But it was not until almost a century later, in 1972, that the House of Delegates of the American Hospital Association (AHA) first formulated an official “Patients’ Bill of Rights.”

If US patients are so well endowed with rights, why has a Patients’ Bill of Rights been promoted by the President and debated in Congress? Observers from nations that provide universal health insurance for their citizens might reasonably presume that the additional “right” sought was the right to health care. But it was not a general right to health care that was created in the Patients’ Bill of Rights by an executive order of the President in February 1998, nor is it a general right to health care that is being endorsed by several prominent advocacy groups. The right being established is the right of access to emergency health care.

This country’s frontier heritage is one of independence rather than interdependence. Communal assistance is acceptable in the United States during emergencies so as to assist individuals to reassert their independence. It is this extraordinary value that US citizens place on independence that leads individuals to reassert their independence. It is this extraordinary value that US citizens place on independence that leads them to insist on a right to emergency health care: a form of communal assistance is acceptable in the United States during emergencies so as to assist those in “distress,” or in “time of necessity,” irrespective of a patient’s ability to pay.

The Right to Emergency Care

The 1716 New York Midwives Oath, the earliest formulation of medical ethics in the United States, unequivocally states a midwife’s obligation “to help any woman in labor, whether she be poor or rich . . . in time of necessity.” A similar sentiment was expressed a half century later in the constitution of the first permanent US medical society, which stipulated that physicians must “always most readily and cheerfully assist gratis . . . the distressed poor.” Medical professionals in colonial American society considered themselves obligated to provide care to those in “distress,” or in “time of necessity,” irrespective of a patient’s ability to pay.

The foundational document of US medical ethics, the Code of Ethics adopted by the American Medical Association at its founding meeting in 1847, reinforces this obligation. It stipulates that the first and preeminent duty of a physician is to “come when called,” that is, to attend to patients during an acute illness or an emergency. In the prologue to the Code duties and rights are held to be correlative. This implies that patients have a correlative right to be attended to in emergencies—even “when pestilence prevails,” for physicians also have a “duty to face the danger, and to continue their labors for the alleviation of suffering, even at the jeopardy of their own lives.”

The moral tradition formalized in these earlier codes of medical ethics continues to this day: like their 18th-century counterparts, emergency department nurses and physicians still see everyone “in time of need,” regardless of the patient’s ability to pay. A patient’s right to emergency care is thus the most enduring right in US medical ethics.

The Challenge by Managed Care

Managed care practices challenge the fundamental right to be seen by a doctor or nurse “in time of need.” Evidence of this was apparent in the cases cited in Congress to support the Patients’ Bill of Rights. For example, a father, 45 years of age, has a myocardial infarction requiring emergency surgery unavailable in his local hospital. Yet his health maintenance organization (HMO) declines to approve out-of-town treatment. Eventually they relent, but the man dies while waiting surgery. A mother, 55 years of age, discovers large bruises on her body while vacationing in Hawaii. Hawaiian emergency department doctors diagnose aplastic anemia and recommend immediate treatment. Her HMO insists that she return home for assessment. They decline payment for a “medi-vac.” Nine days later she dies, succumbing, in her weakened condition, to a fungal infection transmitted by the air recirculated on a commercial jet. In both cases managed care organizations refused to treat emergencies as emergencies, attempting instead to substitute ordinary care for emergency care; that is, they refused to recognize the patient’s right to emergency care.

These tales of death and delay were paraded before Congress to assert the need to protect patients’ rights to acute and emergency care, to appropriate care, and to continuity of care. The Patients’ Bill of Rights reasserts patients’ legal right to emergency treatment without prior authorization and defines “emergency” as “a medical condition manifesting itself by acute symptoms of sufficient severity . . . that a prudent layperson, who possesses an average knowledge of health and medicine,” would believe it needs immediate treatment.

The Position Taken by Managed Care

How did managed care organizations place themselves in the unenviable position of challenging patients’ rights? The answer involves ethics and law. Legally, the Federal Insurance Retirement Income Security Act of 1972 exempts managed care organizations from lawsuits under state malpractice laws.
Therefore, unlike doctors and nurses, managed care administrators cannot easily be sued for denying patients’ care, not even in cases as outrageous as those presented to Congress. Ethically, the issue is more complex. Medical ethics in the United States has traditionally been conceptualized in terms of physicians’ duties and patients’ rights. Managed care administrators, however, tend to conceptualize their obligations in terms of either stakeholder analysis or the utilitarian ethic that predominates in public health medicine.

Stakeholder analysis is a common form of business ethics that was developed as a theoretical framework to extend the concept of managerial responsibility beyond the boardroom, so that it encompassed communities, employees, and customers, as well as shareholders. When applied in the context of managing medical care, stakeholder analysis inadvertently, but inescapably, demotes patients from the position of primacy they enjoy in traditional medical ethics. In a stakeholder analysis patients’ interests become just one among many that must be balanced against those of (1) the managed care organization, which must retain its competitiveness in the market, (2) employers and other third-party payers, who have an interest in containing their costs, and (3) society at large, which seeks to minimize the number of uninsured by containing the cost of employer-financed health insurance. Additionally, in for-profit managed care organizations, (4) shareholders are stakeholders with a right to a reasonable return on their investment.

**Traditional Medical Ethics Subverted**

By 1990, when managed care emerged as the dominant form of employer-financed health care in the United States, employees found themselves unknowingly subject to ethical norms that had not been customary in the clinical practice of medicine. The examples paraded by the Democrats are cases in point. From the perspective of traditional medical ethics, these “horror stories” demonstrate the moral callousness of managed care. From the perspective of a stakeholder or by a utilitarian analysis, however, these cases, although unfortunate, are neither unfair nor unethical. Managers who accept the ethos of managed care will feel morally bound (either to multiple stakeholders and/or to maximize the greatest good) to manage health resources efficiently. Efficient resource utilization requires enforcement rules that may have unfortunate consequences for some individuals—such as those cited in Congress.

If the above analysis is correct, then what is at issue in the debate over patients’ rights is the very core of US medical ethics in the 21st century. From the Hippocratic oath to the bioethics revolution, the patient has traditionally been the central focus of medical ethics. Managed care organizations, however, operate from within ethical frameworks that counterenance practices that erode the centrality of patients’ needs.

The historic shift to managed care has thus generated a parallel moral paradigm shift that fundamentally challenges medical ethics and the patient-physician relationship, as they have traditionally been understood.

The question before us is whether we should sustain traditional medical ethics or adopt the new ethic of medicine implicitly embraced by managed care organizations. Those who believe that the individual patient and the patient-physician relationship is properly the focus of medicine and of medical ethics will need to find a mechanism that can successfully embed the values of traditional medical ethics within the ethos of managed care medicine. The idea of patients’ rights provides a well-tested mechanism for accomplishing this. Rights act as a “side constraint” on political and economic calculation as well as moral reasoning. Rights can stay the calculations of the utilitarian and stakeholder calculus, reasserting the centrality of the patient-physician relationship even within the larger framework of stakeholder and utilitarian ethics.

If one believes in the centrality of the patient-physician relationship, one ought to favor the creation of a framework of patients’ rights for individuals enrolled in managed care. Thus, health care professionals should champion the idea of patients’ rights in their professional organizations and in political fora as well. For almost 2½ millennia, patients and physicians have been well served by an ethic that focused on the needs of the individual. It would be tragic if this ethic were inadvertently jettisoned in the shift from fee-for-service medicine to managed care.

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THE BACKLASH AGAINST MANAGED CARE HAS ENTERED HOLLYWOOD. In the movie As Good As It Gets, audiences applaud when actress Helen Hunt uses obscenities to describe the health maintenance organization that treated her son. Moviegoers also cheer actor Warren Beatty, the suddenly truthful Senator in Bullworth, who accuses the health insurance industry of profiteering, deliberately excluding the poor, and corrupting politicians. When Hollywood distributes celluloid attacks on an entire industry, it relies on widespread public sympathy with the sentiments expressed.

The backlash against managed care has also reached Congress and state legislatures. Hundreds of bills to regulate managed care practices have been considered.1 Many of these are called a “patient bill of rights”; however, the label may prove to be as fictional as a Hollywood movie plot. Most bills focus on consumer protection and not patient rights—the differences between which are important.2 Consumer rights focus on purchasing decisions before a provider relationship is formed. They are necessary to help people choose a health plan, but they are not sufficient to protect patients when they need medical care. Patient rights focus on the relationship between patients and physicians (and other providers) and the type and quality of care provided.3 If patient rights are conflated with consumer rights, consumer protection legislation may unwittingly undermine important patient rights that remain necessary in or out of managed care.

Managed care engages in activities that require attention to both consumer and patient rights.2 As a business that sells health insurance and finances care, managed care should be subject to reasonable consumer protection laws. As an entity that manages and delivers health care, managed care should also be subject to laws that protect patient rights.

Arguably, consumer rights end, and patient rights begin, when the insurance contract is signed. The reality is somewhat more complex. In an ongoing relationship, contractual provisions agreed to by consumers can affect the type and quality of care provided to patients. Moreover, consumer and patient rights can conflict. For example, suppose that a patient refuses a recommended amputation to stop a gangrenous infection, as all patients have the right to do, and therefore requires a lengthy hospitalization, not covered by the health plan contract. Contractual limits on benefits should not override a patient’s existing common law right to refuse treatment. However, benefits are typically viewed as consumer contract issues, and consumers do not have contractual rights to treatment that the contract excludes. Thus, contractual limits may force individuals to forfeit their rights as patients in order to obtain consumer benefits.

Consumers become patients when they use health services, and they may be at risk of physical disability or death—not merely financial loss—if managed care plans fail to provide adequate services. Thus, it is reasonable to expect that minimum standards of quality be imposed on managed care plans or “products” in the same way that minimum product safety standards are imposed on other consumer products like automobiles. Most fundamentally, health plans must be directly accountable to patients for their actions.

State licensure laws prescribe standards for some of these matters: financial solvency, management capabilities, the format of contracts, methods of disclosing information, reporting requirements, marketing methods, and grievance procedures. However, many state requirements cannot be enforced against self-funded employee group benefit plans governed by the federal Employee Retirement Income Security Act (ERISA).4 Proposals for protecting consumers have largely avoided regulating the substance of health plans and have allowed health plans the autonomy to determine product offerings. They only require that information be disclosed to allow consumers to choose among the various options.5 But individual consumers cannot negotiate all of the provisions in a standard contract with insurers; in fact, individuals rarely see the contract before they have enrolled and paid the first premium. While standard form contracts are efficient, their use means that individual consumer choice—even where it does exist—cannot function as an effective mechanism to ensure that health plans offer what consumers need as patients.

It is precisely in these circumstances that regulation is appropriate to protect the rights of patients. Regulation limited to consumer protection is not sufficient to protect patient rights.2 Just as patients are not entitled to whatever they may want, regardless of need or effectiveness, so too health plans should not be permitted to create obstacles to the exercise of legitimate patient rights.

The patients’ rights legislation introduced in 1998 is a step in the right direction for consumers, but it fails to include all the rights of patients. Patient rights must be protected in any new consumer protection law. Otherwise, like the happy endings of Hollywood movies, a consumer bill of rights may give people the false impression that their rights as patients are protected when they are not.

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ALTHOUGH SOME MAY CONSIDER PHYSICIANS OUT OF PLACE IN the halls of Congress, our nation has a long history of physicians as “citizen legislators.” Four of the 56 colonists who signed the Declaration of Independence were physicians, 2 physicians signed the Constitution, and several physicians were members of the First Continental Congress.1 Currently 8 physicians serve in the US Congress: Sen William Frist (R, Tenn); Rep Tom Coburn (R, Okla); Rep John Cooksey (R, La); Rep Greg Ganske (R, Iowa); Rep Jim McDermott (D, Wash); Rep Ron Paul (R, Tex); Rep Vic Snyder (D, Ark); and Rep David Weldon (R, Fla).

Dr Frist, a cardiothoracic surgeon, advocates strong physician involvement in health policy. He explains that “if we are to preserve all that is good and sacred about the practice of medicine, we physicians no longer can operate solely within the operating theater of our individual clinical practice.... We must bring all our values, ethics, and skills out of the operating and examination rooms and into the theater of public policy.”

Dr McDermott, a psychiatrist, became politically active during the time of the Vietnam war. His first experience with public office was serving in Washington’s state legislature, where he developed the Washington Basic Health Plan, designed to provide insurance to the unemployed and working poor (J. A. McDermott, oral communication, May 1998).2

Dr Coburn, a family physician, ran for office because he grew disgusted with the House of Representatives being a “house of career politicians” that made decisions based on what motivated their own personal interests (T. A. Coburn, oral communication, May 1998). Dr Ganske, a plastic and reconstructive surgeon, sought congressional office when he lost confidence in the current welfare system. “I am here for a cause,” Dr Ganske said in an interview after being elected in 1994. “I am here for a revolution. I believe that the welfare system needs to be replaced.”

Physician-legislators were featured quite prominently in many of the health care debates of the 105th Congress. Dr Ganske sponsored the Patient Right to Know Act, which would prohibit “gag clauses” that contractually restrict what information physicians can give their patients.4 Dr Coburn authored legislation to amend the Social Security Act to include specific protections to Medicare beneficiaries who enroll in Medicare managed care plans, including guaranteed access to out-of-network services.5,6 Dr McDermott, for the sixth consecutive year, introduced a bill to provide universal access to health care.7

However, congressional physicians are sometimes not involved in health policy initiatives. This can be attributed to physicians-legislators often not being in Washington long enough to gain the seniority needed for an appointment to those committees from which health policy bills originate.

Interestingly, these physician-legislators have different opinions as to how patient protection might best be achieved. Dr McDermott believes that Rep Charlie Norwood “put a finger on a real problem” with the “factory-like nature” of some health maintenance organizations. He argued that this should not be a “partisan issue” and joined Dr Ganske in co-sponsoring both early Republican9 and Democratic10 proposals (J. A. McDermott, oral communication, May 1998). Dr Weldon explained that his main goal was to “restore the doctor-patient relationship.” He was therefore wary of supporting the Republican proposal11 because of language he felt would broaden allied health professionals’ scope of practice beyond what is appropriate. He was also opposed to the Democratic proposal12 because of provisions that would lead to increased litigation, representing what he called a “field day for trial lawyers” (D. J. Weldon, oral communication, July 1998). In the end, Dr Weldon chose to support the Patient Protection Act, which provided an appeals process but did not extend the right to seek legal redress.

As legislators, physicians will continue to play key roles in the formation of health policy. In the words of Dr Royal Copeland, an ophthalmologist and US Senator from 1923 to 1938, who crafted the legislation creating the Food and Drug Administration: “we [physicians] have something of value to contribute and we dare not... shirk our obligation to render service to the Nation as a whole, so that the good we attempt to do to individuals may be magnified and multiplied.”13 These physicians in Congress have certainly taken that sentiment to heart.

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counseling and testing data system was begun, and 1 (Florida) began HIV reporting very recently and not enough time has elapsed to have adequate data for analysis. The year-to-year median percentage changes in total number of HIV tests during 1992 through 1996 for areas with and without HIV reporting were similar in magnitude and trend.2 Although we showed no large declines in testing among MSM and other risk groups after HIV reporting, we agree with Aragon and Myers and Dr Woods and colleagues that trends in some subgroups—for example, in a small number of MSM concerned with reporting issues—could be hidden within the larger community of MSM. Because there will always be individuals concerned about these issues, we emphasized the importance of making anonymous testing available to promote knowledge of HIV status among at-risk people. The approval by the US Food and Drug Administration of home sample collection tests for HIV expands the availability of anonymous testing in all areas.3

Woods et al also state that, except for New Jersey, we included only low-prevalence states. This is incorrect. Louisiana (acquired immunodeficiency syndrome [AIDS] rate of 33.7 per 100 000 in 1997) and Tennessee (23.1 per 100 000) have high AIDS incidence, comparable with their own state of California (29.8 per 100 000)1 and are considered moderate-prevalence states.

Dr Solomon and colleagues are concerned that the study design was ecological and subject to the fallacy inherent in such studies, ie, that ecological correlations cannot be validly substituted for individual correlations. However, to demonstrate the impact of a policy change on a large population, ecological methods may be the most practical design. In an individual-level study, each individual’s awareness of the change in policy would be determined. On a population basis, this would be a difficult study to conduct, especially if attitudes of high-risk persons were to be assessed. Although our study cannot distinguish between people who were aware (“exposed”) and unaware (“not exposed”) of the change in reporting policy, the important fact remains that no large changes in testing behavior were observed in the population. Our results are supported by a recent study of more than 2500 people in high-risk groups (MSM, IDUs, and attendees of sexually transmitted disease clinics) in 9 states.4 In this study, more than 60% of participants were unaware of their state’s HIV reporting policy and, of those avoiding testing, only 2% stated that reporting was a main factor for not being tested.4 Furthermore, as Dr Paul and colleagues demonstrated in New Jersey, large numbers of people did not go to nearby states to be tested after HIV reporting was implemented.

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