2-27-2003

Assessing the Need to Enact Medical Liability Reform

Sara J. Rosenbaum
George Washington University

Taylor Burke
George Washington University

Testimony Before the United States Commerce Committee
Subcommittee on Health and the Environment Regarding
Assessing the Need to Enact Medical Liability Reform

February 27, 2003

Sara Rosenbaum, J.D.
Harold and Jane Hirsh Professor, Health Law and Policy
Interim Chair, Department of Health Policy
The George Washington University Medical Center
School of Public Health and Health Services

With the assistance of

Taylor Burke J.D., candidate for L.L.M.
The George Washington University School of Law

Mr. Chairman and Distinguished Members of this Subcommittee:

I am a professor of health law and policy at the George Washington University, specializing in health services law. I am the co-author of one of the nation's leading health law textbooks and have regularly appeared as a Congressional witness over the past 25 years.

Thank you for inviting me to present testimony on H.R. 5, The Help Efficient, Accessible, Low Cost, Timely Healthcare (HEALTH) Act of 2003. My testimony will focus on the scope of the legislation's proposed shield against non-economic damages with respect to the plaintiffs whose claims would be affected, the corporate defendants that would benefit from the shield, and the types of injuries that would be shielded.

H.R. 5 is drafted broadly and is ambiguous in its use of terms and definitions. However, reading the bill in a common sense fashion, I have concluded that this measure is so vast in scope that it reaches every conceivable health care claim against every health

care corporation or manufacturer of health care products, regardless of whether the violation of law in question bears any relationship to what would reasonably be considered the types of injury commonly associated with the concept of medical liability. In this sense the measure extends far beyond its popular billing as one related to the crisis facing physicians and other medical professionals in individual practice.

Key Elements of H.R. 5

H.R. 5 would establish federal standards for causes of action that fall within a new federal definition of "health care lawsuit." The term "health care lawsuit" is defined as

> "any health care liability claim concerning the provision of health care goods or services affecting interstate commerce, or any health care liability action concerning the provision of health care goods or services affecting interstate commerce, brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, or market, promoter or seller of a medical product, regardless of the theory of liability on which the claim is based * * *" §9(7)

A health care liability claim means

> A demand by any person, whether or not pursuant to ADR against a health care provider, health care organization, or the manufacturer, distributor, supplier, marketer or promoter or seller of a medical product * * * which are based on the provision of, use of, payment for (or the failure to provide, use or pay for) health care services or medical products, regardless of the theory of liability on which the claim is based * * * §9(9)

The term "health care goods or services" means

> Any goods or services provided by a health care organization, provider or by any individual working under the supervision of a health care provider that relates to the diagnosis, prevention or treatment of any human disease or impairment or the assessment of the health of human beings." §9(12)

The term "medical product" encompasses both drugs and devices as defined under the federal Food, Drug and Cosmetic Act. §9(14). Because it would be the Sense of Congress that a "health insurer should be liable for harm caused when it makes a decision as to what care is medically necessary and appropriate," §13, I interpret this provision to extend a shield to managed care organizations for both acts of medical negligence and negligent medical decision-making in the context of coverage of coverage determinations.

The Scope of the Shield Against Damages in H.R. 5

The popular understanding of this legislation, as reflected in press coverage, is that it is intended to shield individual clinical practitioners against punishing liability judgments. However, the bill's actual reach is breathtaking.

Plaintiffs

Because the definitions reach actions by "any" person, I interpret this to cover individual, private legal claimants as well as State Attorneys General and the U.S. Attorney General representing the public interest under public laws that permit financial recoveries of any kind (money damages, civil money penalties, fines, and other financial penalties).

I have reached this conclusion based on the fact that the bill specifically reaches both "action" and "claim," and that a customary use of the term "action" is to describe governmental enforcement actions that may carry criminal, injunctive or monetary penalties. The bill appears to contain no provision that exempts enforcement actions brought by federal or state public officials.

Defendants

The sweep of the above-cited definitions mean that any corporate defendant engaged in the "health care" business would be covered by the shield, regardless of the size of the corporation or the nature of the offense. The only exception to the shield would be if an individual plaintiff could prove either a deliberate failure on the defendant's part to avoid unnecessary injury or a malicious intent to injure, which is defined as "intentionally causing or attempting to cause physical injury other than providing health care goods or services." §9(13).

Claims

The measure appears to encompass within the scope of the claims to which the shield applies every conceivable health care liability claim under law, not simply claims involving professional medical negligence of a clinical nature. Thus, criminal laws, laws to prevent anticompetitive conduct, civil rights law, worker protection law, and environmental laws all appear to fall within the ambit of the protection. Every conceivable claim appears to be affected regardless of underlying theory (defenses would be preserved). Examples of State law claims theories are:

- common law or statutory medical negligence claims (either individual or against medical care corporations under vicarious or direct theories)
- common law and statutory law theories of product liability such as breach of express or implied warranty, failure to warn, general corporate negligence, defective design, defective manufacturing
- fraud and deceit
- unfair trade practices

- civil rights laws
- labor law (including worker protection statutes)
- criminal law
- consumer protection
- antitrust law
- environmental laws

Examples of Federal law claims apparently covered by the Act are:

- fraud and abuse (e.g., RICO, False Claims Act)
- antitrust (Sherman Act, Clayton Act, other laws)
- civil rights laws
- criminal statutes
- federal food and drug laws including standards for the production and sale of prescription and over-the-counter drugs and devices and dietary supplements
- federal environmental health laws
- federal labor laws
- federal contract enforcement laws that provide for liquidated damages
- restitution to the extent that restitution is not understood to be part of economic damages

The only federal law that appears to be saved is the federal Vaccine Injury program. Otherwise, only federal defenses are preserved. H.R. 5, §10.

Examples of Claims Affected by the Legislation

The following examples are meant to be illustrative of the types of claims that are filed (or could be filed) against providers of health care goods and services or manufacturers, suppliers, or promoters of medical products:

- A nationwide, publicly traded managed care corporation, with full access to the medical records of an exceedingly high risk pregnant woman, denies round-the clock inpatient preterm management care and orders part day home care instead. An hour after the nurse leaves for the day, the woman goes into preterm labor and loses her baby before they can be transported to the hospital. The corporation rebuffed both the overwhelming evidence in her case (including a similar previous labor) as well as all appeals by her physician.

- A renowned organ transplant medical center fails to institute the most basic "redundancy" safeguards within its organ transplant surgery program, such as deliberate and repetitive matching of donor and recipient blood types. As a result, the wrong organs are transplanted and the patient dies.

- A national health care corporation is sued by the United States Attorney for knowingly and deliberately overcharging ERISA subscribers hundreds of millions of dollars in premiums by deliberately concealing the actual cost of goods and services covered, even while promising to pay 80% of subscribers' claims. In some cases, subscribers actually paid nearly 80% of the claim as a result of fraud. The federal government seeks billions of dollars in restitution.

- A restraint of trade action is brought by generic drug manufacturers against large pharmaceutical companies for price-fixing, with the potential for recovery of treble damages under U.S. antitrust law.

- A False Claims Act case is instituted against a large for profit hospital chain for deliberately overcharging the federal government by manufacturing unnecessary surgeries through its cardiac care centers.

- A national nursing home chain is accused by HHS and the U.S. Attorney of deliberately incentivizing its members to engage in a series of unsafe practices, ranging from over-medication to the unlawful use of restraints. The same chain is accused by the Department of Labor of numerous violations of federal occupational safety violations.

- A manufacturer of medical devices develops a form of contraceptive that when used as directed causes death and injury including rare and oftentimes fatal septic abortions.

- A pharmaceutical company manufacturers a drug which, when used as directed, causes a rare form of malignant vaginal cancer.

- A device manufacturer develops a heart valve that when inserted as directed, actually results in valve failures caused by fractures at the point at which struts were welded to the valve rings.

- A large manufacturer of health care goods and services fails to exercise reasonable care when getting rid of toxic manufacturing materials and succeeds in poisoning the water supply of a community.

- A pharmaceutical manufacturer produces an appetite suppressant that when taken as directed causes heart valve abnormalities, disability and death.

Virtually none of these claims relates to specific acts of professional negligence by individual clinicians while furnishing health care to patients. They all involve acts by in many cases enormous corporations, and range from violations of health laws to violations of every conceivable form of state or federal law that relates to health care services or the manufacturing of health care products.

I am happy to answer questions.

Testimony Before the United States Commerce Committee
Subcommittee on Health and the Environment Regarding
Assessing the Need to Enact Medical Liability Reform

February 27, 2003

Sara Rosenbaum, J.D.
Harold and Jane Hirsh Professor, Health Law and Policy
Interim Chair, Department of Health Policy
The George Washington University Medical Center
School of Public Health and Health Services

With the assistance of

Taylor Burke J.D., candidate for L.L.M.
The George Washington University School of Law

Summary

. My testimony will focus on the scope of the legislation's proposed shield against non-economic damages with respect to the plaintiffs whose claims would be affected, the corporate defendants that would benefit from the shield, and the types of injuries that would be shielded. I have concluded that this measure is so vast in scope that it reaches every conceivable health care claim against every health care corporation or manufacturer of health care products, regardless of whether the violation of law in question bears any relationship to what would reasonably be considered the types of injury commonly associated with the concept of medical liability.

Because the definitions reach actions by "any" person, I interpret this to cover individual, private legal claimants as well as State Attorneys General and the U.S. Attorney General representing the public interest under public laws that permit financial recoveries of any kind (money damages, civil money penalties, fines, and other financial penalties).