

# Omnibus Health Bill: Vaccines, Drug Exports, Physician Peer Review

*Congress rolled nine separate health bills into a single package; the President signed it reluctantly*

As the 99th Congress moved toward a close, it looked as if a lot of health legislation would remain unfinished, left to languish in the desperate effort to complete the tax reform bill. But at the last minute, health leaders in both the House and Senate negotiated a deal that took most observers completely by surprise. The omnibus health bill contains something for nearly everyone: infants, the elderly, the mentally ill, children injured by vaccines, physicians who sit on medical peer review boards, and the pharmaceutical industry.

With a bill to guarantee mental health services (S. 1744) as the vehicle, eight other pieces of health legislation were tied together as a package that won easy congressional approval. Senators Orrin G. Hatch (R-UT) and Edward M. Kennedy (D-MA) and Representatives Henry A. Waxman (D-CA) and Edward R. Madigan (R-IL) were chief negotiators of this legislatively successful deal that ended up being supported by virtually every important health outfit and opposed by Attorney General Edwin Meese. Meese urged President Reagan to veto the bill because vaccine compensation would be paid for by a new tax on vaccine sales. Meese argued against legislating a new tax for a program for which "no legitimate national need has been demonstrated."

The Attorney General's view that the whole health bill should be vetoed because of the vaccine tax provision helped galvanize supporters who became vocal and public in calling for the President's signature. "Mr. President, Please Sign S. 1744" read the headline on a full page ad in the *New York Times*, that carried the names of Hatch, Kennedy, Waxman, and Madigan, as well as the endorsement of 56 groups that included several drug companies and more than a dozen professional medical associations.

Last month, President Reagan signed—with "mixed feelings" and "serious reservations."

The bill contains the following:

■ **Vaccine Compensation.** This bill establishes a no-fault system for compensating people who are injured as a result of getting

a mandatory vaccine. The Centers for Disease Control estimates, for instance, that 50 children suffer permanent brain damage every year from pertussis vaccine, which is required for admission to school, and that eight children may be paralyzed after receiving oral polio vaccine. Under the new law, families may choose to take their case to a special "master" or arbiter appointed by the U.S. District Court, who can authorize compensation without resorting to a costly and lengthy trial. Because a certain number of injuries are bound to occur even with the most carefully produced vaccines, the law provides compensation without requiring families to demonstrate that the manufacturer was negligent. In theory, this will make compensation easier to get in cases of legiti-

Administration sees an opportunity to block or modify it. Even with Congress in recess, proposals for handling the issue in a way that will win both congressional approval and White House endorsement are already circulating on Capitol Hill.

In addition to objecting to this bill because of the vaccine tax, Meese also dislikes its unprecedented system for using the federal judiciary system as a mechanism for satisfying claims without having to prove wrongdoing on anyone's part.

■ **Drug Exports.** The pharmaceutical industry has lobbied for years for a bill that would permit companies to export drugs to countries that have approved them even though the U.S. Food and Drug Administration has not completed the approval pro-

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*The vaccine compensation, drug export, and peer review immunity measures each generated considerable controversy when they came before Congress as separate bills.*

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mate injury, while also protecting vaccine manufacturers from many lawsuits.

Compensation for pain, suffering, and death is capped at \$250,000; no punitive damages are allowed. Anyone who takes a claim to the court-appointed master and is dissatisfied with the outcome is free to move into the regular court system instead. In that case, however, injured parties will have to demonstrate negligence on the part of the manufacturer in order to win at trial.

Money for the compensation will come from taxes on vaccines covered in the bill, including polio, diphtheria, pertussis, whooping cough, tetanus, measles, mumps, and rubella. Although the basic legislation is now in place, Congress has yet to actually enact the controversial tax provision. So, in effect, the vaccine act is only half passed. Waxman says he expects Congress to establish the tax as soon as it reconvenes. The

process for sale in this country. The new law permits just that, within certain limits. It is regarded as a boon both to large U.S. drug houses and to new biotechnology companies on grounds that it will enhance their position in international competition. "Under the old law, when a country such as France approved a U.S.-made drug earlier than FDA, the manufacturer had to locate his plant abroad to supply France with the product," says Gerald Mossinghoff, president of the Pharmaceutical Manufacturers Association. "Now our companies have the option of supplying that product from a plant in the United States. The legislation will create thousands of new jobs . . . , and will stimulate capital investment here and spur exports."

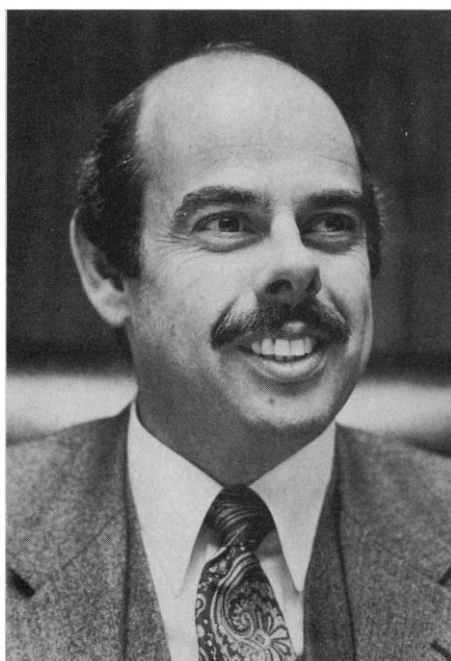
Richard D. Godown, president of the Industrial Biotechnology Association, also lauded the bill. "This change in the law will

do more to maintain U.S. leadership in biotechnology than any other action I can think of, and it is not a trade restriction," he said. "At a time when the Japanese government has made it a number one priority to take over the leadership in biotechnology, there should be no hesitancy on our part in engaging in self help."

■ **Peer Review.** According to Representative Ron Wyden (D-OR), the "Health Care Quality Improvement Act" is "the first step in the development of a national strategy to reduce malpractice" through two measures. One requires the Secretary of Health and Human Services to set up a national databank to keep track of settled malpractice claims and disciplinary action against physicians. It mandates that insurance companies,

unqualified is stripped of hospital privileges, for example.

In today's litigious climate, it is common for doctors to have a couple of malpractice cases brought against them during years of practice. According to a Wyden aide, these are not the people the bill is aimed at. Rather, "It's the people who have had 20, 30, or 40 suits filed against them." It is estimated that 3% to 5% of physicians are not competent to practice (that is about 18,000 doctors). Under the new law, the appropriate medical authorities are required not only to report information to the databank, they are also required to use the databank to gather information about people practicing on their staffs or applying for privileges.



**Henry Waxman (left) and Orrin Hatch negotiated the omnibus health bill.**

state licensing boards, and hospital review committees report actions against physicians to help protect the public from physicians who, in Wyden's words, "move from state to state to escape their malpractice record."

A second measure provides immunity from lawsuits for physicians who judge a colleague to be incompetent. "Each year several hundred doctors who have received poor peer review evaluations sue the members of the peer review panel," says Wyden, observing that "This trend has discouraged good, honest doctors from bringing cases of incompetence to the attention of the authorities." Under the bill, if peer review is carried out according to established procedures, panel members cannot be sued for "restraint of trade" if someone they judge

■ **Infant Mortality.** A 1-year commission is created to hold hearings and conduct a study of causes of infant mortality. It will include two members each from the House and Senate, the Secretary of Health and Human Services, six experts in child and maternal health, and the Comptroller General of the United States.

■ **Mental Health Services.** This bill authorizes up to \$10 million a year to give grants to state governments to support programs to provide comprehensive care to the chronically mentally ill—many of them homeless. Rehabilitation, employment, housing, and medical care are to be included. Although the bill "authorizes" or allows Congress to spend the \$10 million in fiscal years 1988 and 1989, separate legislative

action is required before the money can be appropriated or spent.

■ **Health Planning.** Existing health planning legislation created a mechanism, which included the state and local authorities, that was intended to reduce medical costs by regulating hospital construction and the purchase of hugely expensive equipment, for instance, or the creation of expensive new programs. A "certificate-of-need" could be required before several institutions in one area started heart transplant units, or bone marrow transplant services. President Reagan has wanted to undo the planning law since 1981, and there is no new appropriation for this fiscal year. As part of the omnibus health package, the federal health planning authority is repealed.

■ **Health Maintenance Organizations.** (HMO's), which have become a popular source of health care for many people, have been fostered by various forms of federal support. On the assumption that they no longer need special treatment, the HMO act is amended to eliminate certain grants. The Secretary of Health and Human Services is also directed to conduct a study of HMO's and to report to Congress within 18 months.

■ **Geriatric Training.** With the aging of the American population, there are estimates that by 1990 the country will need 10,000 physicians trained to take care of the elderly. This bill, sponsored by Kennedy, adds \$6 million over 3 years to existing funds for grants to train physicians in geriatrics, with an emphasis not in creating specialists but in adding geriatrics education to the training of primary care doctors and dentists.

■ **Alzheimer's Disease.** Beginning in fiscal year 1988, the bill authorizes spending \$14.4 million a year for 4 years for Alzheimer's research and education. One of its sponsors, Senator Howard M. Metzenbaum (D-OH), says the legislation is meant to bring a "coordinated, comprehensive, and compassionate" approach to this devastating disease which is expected to increase as more and more people live beyond the age of 65.

President Reagan waited until the last minute before signing the omnibus health bill that for a while seemed sure to be vetoed. Powerful lobbying on behalf of the drug export part of the measure weighed heavily in the ultimate decision to sign it into law. That measure is seen as creating more than 8000 new jobs and could, theoretically, increase drug exports by more than \$400 million a year. The President himself said it would "aid other nations" as well. It will be interesting to see whether any of these predictions turn out to be right. ■

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