



Buyers Up • Congress Watch • Critical Mass • Global Trade Watch • Health Research Group • Litigation Group
Joan Claybrook, President

S. 1873: The National Biodefense Act That Leaves Consumers Defenseless

The National Biodefense Act of 2005, introduced by Senators Burr and Enzi, is being fast tracked through the Senate HELP Committee and onto the floor. But the only sure-fire “biodefense” in the bill is defense of the pharmaceutical industry against injury claims. The far-reaching scope of the legal immunity conferred by this legislation magnifies the public’s susceptibility to the dangerous side-effects of purportedly good intentions: heightened risk of injury, no forum in which to seek justice, and no compensation for damages. The unprecedented breadth of the liability shield goes far beyond what could arguably be considered a reasonable incentive to produce emergency drugs and vaccines. Indeed, the drug industry protection in the bill grossly exceeds in potential public jeopardy what it can hope to achieve in public benefit.

The primary flaws in the bill are as follows:

The liability shield is not restricted to countermeasures or epidemic/pandemic products.

Section 6 of the bill would preempt state laws pursuant to which a manufacturer, distributor, or health care provider could be held liable to an individual or a state for loss of property, physical injury or death. This preemption is triggered whenever a product is 1) in the Strategic National Stockpile, 2) deemed a security countermeasure, or 3) an epidemic or pandemic product. But the bill does not explicitly limit application of the liability shield *solely* to these circumstances. For example, suppose a commercially-available drug approved to treat strep throat were also approved as a qualified countermeasure to treat smallpox. Under this provision, the manufacturer or health care provider would be immune from lawsuit by a patient who was prescribed the medication for a strep infection and suffered injury—e.g., as a result of product contamination, improper administration of the drug, or perhaps an adverse reaction foreseen by the manufacturer but against which the manufacturer failed to warn.

Additionally, under 42 U.S.C. § 247d-6b, a product is considered part of the Stockpile so long as it is under the proprietary control of the Secretary of HHS—even though it is in the physical possession of a private vendor contracted to store the material. This arrangement raises security and quality assurance problems that are further exacerbated by allowing private contractors to escape responsibility for injuries caused by drugs that were spoiled or contaminated while in their custody. Without the deterrent of tort liability for negligent or reckless handling and storage, a contractor would have less of an incentive to maintain rigorous control over the safety and efficacy of the vital material in its charge.

Overly-broad language effectively immunizes manufacturers, distributors and medical providers against lawsuits brought by injured individuals or states.

The bill as currently drafted would preempt *all* claims for loss of property, personal injury or death involving epidemic drugs or countermeasures, even where the cause of action is medical malpractice, negligent or intentional failure-to-warn, design defect, negligent or willful disregard in manufacturing, breach of warranty. Even state unfair trade practice claims would be preempted where the injury is alleged to result from deceptive marketing. Antitrust statutes are expressly waived under certain circumstances.

Consider the implications of such a policy in the case of medical malpractice alone. In 1999, the Institute of Medicine warned that up to 98,000 people die needlessly each year due to medical negligence.¹ Recent studies indicate that the problem has reached still greater magnitude. One revealed that adults seeking preventive, chronic or acute treatment had only a 50 percent chance of receiving care that met the recommended standard.² A review of patient discharge abstracts in 28 states found that medical injuries during hospitalization may add some 2.4 million days to hospital stays, and kill over 32,000 patients a year.³ Another study concluded that 1 in 20 hospital patients is given the wrong medication, 3.5 million patients a year are given infections from unhygienic or improper procedures, and 195,000 die as a result of avoidable mistakes.⁴

Medical malpractice itself has reached epidemic proportions in the U.S., and this under ordinary conditions of medical practice. One could reasonably expect recklessness and negligence to increase during a bioterror threat or an infectious disease outbreak; at the same time, preventive and curative treatments themselves will be more hazardous because of the relaxed standard of review for qualified countermeasures under the expedited approval process. Nevertheless, under this bill there would be no remedy whatsoever for those whose injuries involve a countermeasure that was prescribed, distributed, donated sold or purchased during a declared public health emergency, “regardless of the date of alleged injury.” Thus, the victim of a negligently-administered emergency drug that was contraindicated for his underlying condition would be forced to suffer uncompensated loss; a patient infected with a life-threatening disease by a health worker who negligently failed to use a clean syringe for a vaccination would be left without recourse. Innocent individuals, families and communities would be saddled with the full measure of socio-economic consequences caused by the reckless conduct of others. Such an outcome is offensive to fundamental American principles of justice, fairness, and personal responsibility—and it is bad public policy.

Even when manufacturers, distributors or health care providers willfully or intentionally disregard patient safety, they cannot be sued by their victims under the proposed legislation unless the conduct violated either the Federal Food Drug and Cosmetics Act (FDCA) or the provisions of this bill. That lets malicious health care providers off the hook entirely because the

¹ Institute of Medicine, *To Err is Human*, 1999.

² Elizabeth A. McGlynn, et al., *The Quality of Health Care Delivered to Adults in the United States*, New England Journal of Medicine, 348:36, 6/26/03.

³ Chunliu Zhan, et al., *Excess length of stay, charges, and mortality attributable to medical injuries during hospitalization*, JAMA, 290:1868, 2003.

⁴ David Maxfield, et al., *Silence Kills: The Seven Crucial Conversations for Healthcare*, VitalSmarts, 2005

FDCA does not regulate the practice of medicine. In theory, manufacturers could face liability for FDCA violations, but the chances of a victim being able to sue a manufacturer on this basis is very slim, as explained below.

The incentives offered to pharmaceutical companies, distributors, health administrators and others in this bill go far beyond the bill's stated purpose of safeguarding the nation's health—in fact, they arguably jeopardize public health by rendering individuals increasingly vulnerable to medical injury while depriving them of recovery for damages. Moreover, it is not at all clear that the bill's liability shield will have an appreciable impact on new drug development and production. Vaccine shortages persist despite the 20-year existence of a no-fault compensation program for victims of vaccine injuries which, unlike the instant bill, at least provides a remedy for those who are harmed. Moreover, Harvard researchers recently noted that market factors, rather than fear of liability, were responsible for the drug industry's lack of interest in vaccine production, indicating that the exemptions gifted to pharmaceutical companies in this bill would do little to solve the vaccine shortage.⁵ In 1996, Michigan enacted the nation's most sweeping liability shield statute for pharmaceutical companies, which prohibits them from being sued for tortious injuries even where they have allegedly committed fraud. Proponents of the statute contended that it would lead to cheaper drug prices and save pharmaceutical jobs in Michigan. Ten years later, there is a bipartisan movement to repeal the law, whose promise remains unfilled while hundreds of Michigan residents have been deprived of legal recourse for harms inflicted by such drugs as Fenfen, Vioxx and Rezulin.

Consumers are burdened with impossibly onerous pre-conditions for filing suit that are rife with procedural pitfalls. Manufacturers, on the other hand, get the benefit of numerous loopholes.

Although the bill purports to allow suits against private parties for injuries caused by willful or intentional conduct, the bill establishes pre-conditions that are stacked so heavily against the victim as to effectively preempt even this avenue of redress. Specifically, the bill requires the injured claimant first to petition the Secretary of the HHS to conduct an investigation. For a lawsuit to go forward, the Secretary must find clear and convincing evidence that a violation of the FDCA occurred, that the violation made the product a significant health risk, and that the violation was the proximate cause of the victim's injury.

The bill gives the Secretary *sole discretion* over whether or not to investigate a claim, and if the Secretary declines to do so, that decision is *unreviewable*. Unlike a petition to the EEOC claiming employment discrimination, where the agency issues a “right to sue” letter if it elects not to investigate—thereby entitling the claimant to proceed with a private lawsuit—here the Secretary's refusal is an absolute dead end. The injured claimant has no right to appeal, no alternative administrative or judicial venue in which to be heard, no possibility of compensation. On the other hand, if the Secretary makes a determination in favor of the claimant and allows a lawsuit to proceed, the bill entitles the defendant to seek review of the Secretary's decision in the U.S. court of appeals. Moreover, the claimant is prohibited from intervening in that proceeding. This scheme makes it unlikely that victims will be able to hold manufacturers accountable, even

⁵ Mello MM, Brennan TA, *Legal Concerns and the Influenza Vaccine Shortage*, JAMA 294: 1820, 10/12/05.

where the Secretary has found by clear and convincing evidence that a company has intentionally violated a federal statute and as a result harmed a patient.

In any event, the Secretary cannot make a determination of culpability without first examining internal company documents as well as a victim's medical records. The bill, however, fails to give the Secretary the discovery tools needed to demand access to this material. As a result, the government would rarely, if ever, be able to find in favor of an injured claimant.

The bill unfairly places the burden of loss on innocent victims and their families.

This bill would force individuals to pay the price of misconduct by drug makers, distributors, administrators, and medical providers. Middle income families would be hit the hardest because they would not qualify for public assistance to help pay for injury-related medical expenses; those with health insurance may be denied coverage for treatment administered during an emergency, or involving a drug that did not meet regular FDA approval criteria. This is manifestly unfair. If Congress believes that a liability exemption for manufacturers, distributors and health providers is needed to ensure sufficient emergency drug supplies—something we nevertheless dispute—then the government should assume liability for injuries in their place. Spreading the risk among all taxpayers would significantly reduce the severity of the impact for those already harmed. Moreover, we all have an interest in ensuring the nation's ability to effectively confront the rapid spread of infectious diseases, whether caused by malice, accident, or a nature. It seems only fair that when innocent people are injured as a consequence of our collective effort to prepare and strengthen national biodefenses, the damage should be shared by everyone.