Witness:
Mr. George W. Conk
Fordham Law School
Adjunct Professor

Testimony

Introduction - Statement of George W. Conk, Fordham Law School

S. 975, the proposed "Project BioShield II Act of 2005", broadly addresses " biological and chemical agents, toxins, and nuclear and radiological materials that may be used as weapons of mass destruction or that are infectious diseases with respect to which the Secretary finds that research to develop new and improved countermeasures is in the national interest of the United States."

Biodefense as protection against terrorist attack is properly seen as but a part of a comprehensive plan to protect and improve the public health system. We cannot say if or when we will be attacked with biological weapons. But our experience with HIV and SARS, immigration, and international travel enable us to say with certainty that new pathogens will present major challenges to our public health system.

Naturally-occurring biological threats and criminal attacks (whether political or otherwise) using biological and other such weapons closely overlap in the pathologies inflicted and in the human and material resources needed to respond effectively. Biodefense against terrorists is but a subset of our overall public health preparedness. As the Institute of Medicine said after the recent smallpox vaccination campaign: "Readiness to respond to public health emergencies (including smallpox [and other] emergencies) should be part of overall continuous quality improvement of the public health system. "

Our approach to civil liability and victim compensation too should generally treat alike compensation issues arising from general public health measures and "biodefense" against criminal use of pathogenic biological agents. We need not overhaul our system of compensation and liability - but should adjust it to address specific shortcomings. But S. 975 unwisely federalizes a wide swath of our public health system. The United States would gratuitously insure a wide swath of industry, researchers, hospitals, and health care workers. S. 975 substitutes the United States in their stead as defendant in an unknowable number of cases, displacing state common law with federal limits on damages, and eliminating the common law right to trial by jury which is preserved in every state.

We rely on three main approaches: tort liability (including product liability), workers compensation, and statutory compensation schemes for special needs. Among the special needs cases are the childhood vaccine compensation program which addresses complications arising from mandatory vaccination, and the smallpox vaccination program in which we asked health workers to volunteer to subject themselves to a live virus which carried a risk of vaccine-related disease in the recipients. Thirty years ago we enacted a special measure for swine flu vaccinees.

We should adhere to the state law based common law tort system and workers compensation as the principal sources of compensation, offering out-of the ordinary

compensation only exceptionally, such as to those who volunteer to subject themselves to extraordinary risks.

The federal government should not gratuitously insure “biodefense” manufacturers, distributors and administrators for their negligence. S. 975's broad expansion of such undertakings is unwarranted.

Our priorities in public health defense must be to:

- maximize the health of the American people
- ensure public confidence that government is making its best efforts to protect the health of all who live in, work in, and visit America
- recognize that public trust requires both candor and acceptance of responsibility for error

The tort system and product liability law

One who through his fault causes harm to the person or property of another is liable in tort. One who employs a negligent person is responsible for the harm caused by the negligence of his/her employee. Product liability law has often been described otherwise - as strict or even absolute liability. But product liability law has grayed, as leading treatise author Prof. David Owen has observed. It is a mature body of law which yields generally predictable outcomes.

The basic propositions of our product liability law are these:

- when products depart from specification and cause injury to others the manufacturer of the product bears responsibility for the harm caused by its departure from the norm

- manufacturers must exercise stewardship over their products - studying them sufficiently that users and others are given sufficient information to use them safely, and to make a reasonable assessment of those risks which unavoidably accompany use of a worthwhile product

- manufacturers are responsible for the harm done by negligent design - the unreasonable omission of practical and feasible safer alternative designs.

These principles express deeply embedded normative expectations of our citizens. Federal, state and local government, individuals, and industry accept similar responsibility for their errors. A heavy burden of persuasion therefore should be imposed on those who favor immunity or limited liability for designers, manufacturers, researchers, and administrators of vaccines and other biological, pharmaceutical, and medical products.

The employer-funded workers compensation system plays a major role in protecting health and emergency workers. Injuries arising out of and in the course of employment

are compensable regardless of fault. Only a causal connection between the work and the illness need be shown.

The tort and workers compensation systems are capable of (and do) handling the needs of those injured They adequately limit the liability risks of those who undertake to do the research, develop, and deploy the technologies which the Congress seeks to encourage. And they do it without relieving actors of liability for their faulty conduct and without the federal government gratuitously assuming liability for harms it did not create.

Free insurance and limited liability

In the past 25 years I have represented those injured by asbestos products and machine sellers who did not exercise reasonable stewardship over their products. Tort liability was properly imposed. In my representation of hemophiliacs and their families I saw that an industry immunized by "blood shield laws" escaped liability despite its failure to pasteurize blood products which were given to hemophiliacs. Nearly every hemophiliac in America, Western Europe, and Japan was infected with HIV and/or hepatitis as a result.

Of the three epidemics the legal system dealt far more justly with asbestos and industrial accident than it did with hemophiliacs. I therefore view very skeptically those who would shift to the public the cost of compensating those who have been injured by a manufacturer's negligent (or more egregious) conduct.

Such a shift would be the result of S. 975. The bill relieves of responsibility for their errors manufacturers, distributors, and administrators of "biodefense" and other public health measures. It insures the negligent without charge and offers limited compensation to victims of medical and industrial error who can prove fault by the immunized in whose place the United States stands. S. 975 is a legislative massive expansion of Executive Order 10789 contractual indemnification by government coupled with a thin compensation program modeled on the 2003 Smallpox Emergency Personnel Protection Act of 2003, which amended the Public Health Service Act.

This expansion of aspects the Smallpox Emergency Personnel Act is undertaken without study of its cost. If the cost proves to be small and industry's fears are unwarranted, the expansion of federal responsibility is unneeded. If the cost is shown to be large then candor and fiscal responsibility require that we make provision for that budgetary burden. If we lack adequate information we should not act.

False alarms

Fears are expressed that incalculable, and impliedly huge, liability is faced by "biodefense" manufacturers. I believe these fears are unwarranted and do not justify the proposed broad expansion of the defense, indemnification, and compensation scheme adopted in the Smallpox Emergency Act. Nor is it necessary for the United States to assume the burden of defending, as it would public health officers in its employ, all who

“manufacture, distribute and administer” “biological and chemical agents, toxins, and nuclear and radiological materials that may be used as weapons of mass destruction or that are infectious diseases with respect to which the Secretary finds that research to develop new and improved countermeasures is in the national interest of the United States.”

Last October this Committee was warned that “a test kit for Anthrax exposure that may, perhaps, provide false positives would expose the manufacturer to tremendous and likely (un)insurable liability thereby preventing widespread deployment, even if the diagnostic is the current state of the art.” No such liability risk exists.

HIV tests have recognized rates of false positives. The test is therefore administered twice, since consecutive false positives are rare. No liability problems have ensued. If by “state of the art” one means current practice, liability is not categorically ruled out. But a legal presumption that FDA approval indicates reasonableness in design and warnings is common. Such a presumption must be rebutted by competent evidence that critical safety information was unreasonably omitted or not developed, or that a safer alternative design was practical, feasible, and unreasonably omitted.

Others have suggested that those who have obtained approval for emergency measures - such as distribution of a biologic that has been tested only on animals, and allowed to be distributed as an emergency measure, after findings of specific threats at the Secretarial level and FDA approval under 21 U.S.C. 360bbb-3 need special protection from liability claims. But the law of torts is founded on a determination of reasonable risk imposition - and an emergency is an appropriate circumstance for taking risks in rescue efforts that otherwise would not have been taken.

In almost every jurisdiction the Second Restatement of Torts § 402 A, comment K would be cited for the proposition that an unavoidably unsafe but useful product is not defective if it is administered with reasonable care, and the patient is given reasonable notice of the dangers presented by the product (either directly or by informing the prescribing physician), and the good done by the product exceeds the harm it causes. The factual determination of necessity by the Secretary of Defense and Secretary of Homeland Security of a specific threat and FDA approval of such a product are all powerful indicia of reasonableness and necessity. Administration of such emergency medications, with adequate advice to recipients, is certainly reasonable and therefore is not actionable - under common law tort principles.

It has also been suggested that vaccines which cannot ethically be deployed in clinical trials because of their hazards present grave liability risks for manufacturers who can test them only on animals and therefore may not be able to identify risks to humans. Such limitations of evidence are but a factor for the FDA and others to consider in determining safety and effectiveness. If such risk is unavoidable for ethical or other reasons, then use of such products is reasonable and non-actionable. In fact the archetypal example taught to every law student is the unavoidable risks of the Pasteur rabies vaccine which faced a patient with the choice of risking a horrible death from rabies if the animal was rabid, or

taking the risk of taking the unavoidably unsafe vaccine. Such products are not defective - every law student learns.

Who has potential claims? How are they treated? How should they be treated?

Under existing law potential claimants include:

1. Persons who while in the course of their employment work with infectious materials or persons, toxic materials, or devices and who suffer illness or injury (such as health workers exposed to HIV or tuberculosis). Such workers are entitled to workers compensation benefits. And in the case of injury by a defective product, or inadequate warning they have a right to bring a third party product liability suit. The present system is adequate.

2. Persons who volunteer to administer vaccines or render medical care to others who become ill or suffer injury because of their care for others. Such persons are not compensated, except if a fault-based tort action is available. Such persons should be compensated either by workers compensation or by a no-fault system of compensation such as Congress devised for those who administered or received smallpox vaccination.

3. Volunteers who offer to be vaccinated as part of preparation for service to others (e.g. medical personnel who volunteered to be vaccinated against smallpox). Such volunteers are not compensated unless they assumed the risk at the request of their employer and the risks arise from the employment. Pure volunteers should be compensated via a no fault system. Common law product liability actions should be retained.

4. Volunteer subjects in clinical trials. No provisions exist for compensating such volunteer subjects. Compensation - including medical care should be afforded for such persons.

5. Persons who are compelled to be vaccinated (such as children who cannot be admitted to school unless they are vaccinated). Children who suffered recognized complications (or provable complications) are entitled to be compensated under the National Childhood Vaccine Injury Compensation Act of 1986. Persons compelled to take such risks should be compensated.

6. Patients who, to protect their health, are vaccinated voluntarily and become sick thereby. Such persons do not receive compensation and should not be compensated unless the product was defective or the medical advice was unreasonable.

7. Household members or others who become sick through contact with dangerous materials, infected persons, or the like (such as intimate contacts of smallpox vaccinees). They are compensated only through tort actions - which are generally not available. Even if the physician who ordered the vaccination knew of the risk to the household member and failed to warn of it, an action is not viable absent a physician-patient relationship.

The extent of the duty of a physician is best left to developing common law tort law.

Compensation Choices

BioShield I immunized smallpox vaccine manufacturers by compelling all claims to be made against the United States under the Tort Claims Act - allowing recourse against the manufacturer only for gross misconduct or contract violation. S. 975 permits (limited only by unreviewable administrative fiat) broad expansion of that burden to an “initial list” of 75 agents of disease, and “(a)ny other new and emerging natural infectious disease threats.”

Why should the United States, if it chooses to assume such a burden as insurer, do so without fee? And why, in any event, should it limit its right to recover from its suppliers to instances of breach of contract or gross misconduct? Why should the United States - if it chooses to compensate citizens for the wrongful conduct of independent contractors - not retain the right of recovery from those whose negligence or defective products caused injury? In my view the United States should not gratuitously insure manufacturers, distributors and administrators of defective products and those who act negligently.