Avoiding Liability for Injuries Suffered by Recipients of Vaccines and Drugs Administered in Response to Bioterrorism

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The Risks

In any large-scale administration of vaccines, antibiotics, or other drugs, it is inevitable that some recipients will suffer adverse reactions, including death and permanent injuries.

If manufacturers are left to defend tort claims under varying state laws, and with juries free to award judgments based in part on emotion and sympathy for innocent plaintiffs, the potential exposure to manufacturers could easily exceed the profits, if any, to be made in supplying the needed vaccines and drugs.

The risks are particularly high in any mass inoculation or administration because most states will not recognize the learned intermediary doctrine under such circumstances. Rather, the manufacturer may be held to have a nondelegable duty to ensure that each and every recipient receives a warning of all risks—known and knowable—that are, in the view of the jury, complete and adequate.¹

The Swine Flu Program

Confronted in the past with the need to “incentivize” manufacturers to supply essential vaccines and drugs, the federal government has taken various approaches, providing differing levels of protection. Faced with the threat of an epidemic of “Swine Flu,” and with manufacturers and private insurers reluctant to assume the liability risks inherent in a mass inoculation program, Congress precluded injured persons from seeking damages against the manufacturers. Instead, under the National Swine Flu Immunization Program of 1976 (Pub. L. No. 94-380), injured recipients of the vaccine were given a right of recovery against the United States, and Congress decreed that such “remedy . . . shall be exclusive of any other civil action or proceeding for . . . personal injury or death against . . . any program participant,” including suppliers of the vaccine and healthcare providers involved in its administration. Suits were allowed to be brought only against the United States; actions naming manufacturers or healthcare providers were “deemed” to be solely against the United States, and the Attorney General was required to defend those cases. To ensure that manufacturers or healthcare professionals did not have carte blanche to act carelessly, the government was given the right to sue for damages resulting from the negligence of private parties. Such suits, however, were rarely filed.²

The Swine Flu Program was the ultimate paradigm in the insulation of private entities against tort liability for adverse drug reactions. Unfortunately, the number and severity of injuries alleged to have resulted from the administration of the Swine Flu vaccine exceeded expectations, and the cost to the government of defending the cases and paying judgments or settlements quickly exceeded the amounts Congress had contemplated.³

The Childhood Vaccine Injury Program

Congress was more cautious the next time it faced the need to combat the threat of vaccine shortages by protecting manufacturers against liability. In the National Childhood
Vaccine Injury Act of 1986 (Pub. L. No. 99-660, 42 U.S.C. §§ 300aa et seq.), Congress required that those alleging injuries from specified vaccines typically given to infants and children initially seek compensation under a no-fault federal program within the claims court. Unlike the Swine Flu Program, however, a claimant not satisfied with the outcome under the Vaccine Injury Act is free to reject it and then initiate a civil action against the manufacturer or other culpable person, with certain limitations. Moreover, the funding for the vaccine injury program is not U.S. general revenues, but the proceeds of a special tax imposed on sales of the covered vaccines. As was the case in the Swine Flu Program, the government is free to pursue claims on a subrogation theory against suppliers of defective products or others whose negligence has caused the government to incur liabilities. Again, however, pursuit of such negligence claims has been almost nonexistent.

**Negotiated Indemnification**

After September 11, 2001, Congress began to consider the Swine Flu and Childhood Vaccine models, as well as other formulations, to provide protection for companies being asked to supply vaccines and drugs to combat the threat of bioterrorism. Thus far, Congress has declined to provide statutory protection against liability claims.

The Center for Law and the Public’s Health at Georgetown and Johns Hopkins Universities recently drafted, on behalf of the Centers for Disease Control and Prevention (CDC), a Model State Emergency Health Powers Act, which would empower state officials to declare a state of public health emergency and immunize private entities from liability except for “gross negligence or willful misconduct.” As of this date, no state has adopted the Model Act.

While there has been no legislatively-bestowed protection, by Executive Order 13,232 (Oct. 20, 2001), President Bush authorized the Department of Health and Human Services (DHHS) to provide governmental indemnity or other protection for suppliers through the process of contract negotiation. This was accomplished by adding DHHS to the list of departments and agencies previously authorized to “exercise certain contracting authority in connection with national defense functions” under Executive Order 10,789 (Nov. 15, 1958).

Under this approach, the extent to which manufacturers obtain protection from tort liability becomes just another item to negotiate, with the inevitable trading off of price and other contract terms for defense and indemnity protection. Negotiations for the previously-announced contract awards for smallpox vaccine remain pending.

**The Government Contractor Defense**

Even without statutory or negotiated protection, manufacturers who supply vaccines and drugs under contract with the federal government to protect against or treat the effects of bioterrorism should be able to invoke the protection of the Government Contractor Defense.

In *Boyle v. United Technologies Corp.* (487 U.S. 500 (1988)), the Supreme Court adopted the “Government Contractor Defense” as a branch of preemption under the Supremacy Clause and an extension of the government’s own tort immunity in the exercise of its discretionary functions. As formulated by the Court, a private company is immune from liability under state or federal law for injuries flowing from products supplied under contract to the United States where:

- the United States approved reasonably precise specifications;
- the [product] conformed to those specifications; and
- the suppliers warned the United States about dangers in the use of the equipment that were known to the supplier but not to the United States.

*Boyle, 487 U.S. at 512.*
The Boyle case involved an allegedly defective design in a helicopter supplied to the U.S. Marines—plaintiff’s decedent was a Marine pilot. Most of the cases applying the doctrine have involved products furnished to the military, and most of the plaintiffs in such cases have been members of the military or their survivors. Some courts have held that the “Government Contractor Defense” is really just a “Military Contractor Defense” and should be limited to military procurement. Moreover, in some non-military cases where the defense might have been applied, the parties and the court appear to have assumed it to be not applicable. The doctrine also has been applied where the injured party has not been a member of the military or a government employee.

Moreover, even prior to Boyle, the defense had been held to bar recovery by a veterinarian injured by a vaccine furnished under contract to the U.S. Department of Agriculture and by a recipient of a flu vaccine sold under contract with the U.S. Public Health Service.

While Boyle involved a claim of a defective design, the Government Contractor Defense also has been held to bar claims based on allegedly inadequate warnings, where the language and format of the warning also could be said to have been the subject of “reasonably precise specifications” approved by the government. With respect to the requirement that the supplier have warned the government of dangers, the doctrine requires only that the supplier have warned of those risks and dangers that “were known to it” and does not—as most state tort laws do—impose a duty to warn of dangers that were not actually known, but in the view of a jury were merely “knowable” or “should have been known.”

When the Government Contractor Defense applies, both the government and the private suppliers are entitled to summary judgment and the injured plaintiffs have no remedy. If Congress declines to enact the sort of statutory remedy provided under the Swine Flu and Childhood Vaccine Programs, and the application of the Government Contractor Defense would leave innocent victims without any remedy, there is likely to be resistance in state, and perhaps even federal, courts to proper application of the doctrine in particular cases. Indeed, there are very few cases in state courts in which the doctrine has been successfully invoked to shield suppliers from liability.

The supply of vaccines, antibiotics, and other drugs to any department or agency of the United States—particularly for purposes of the nation’s security against bioterrorism—unequivocally should be covered by the Government Contractor Defense, and suppliers should be immune from liability for injuries that may be suffered by those who receive the vaccines and drugs. Whether suits are filed in state or federal courts, the doctrine should be asserted in the defendant’s answer, and a record developed for prompt resolution by summary judgment.

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5. For discussion of the line between discretionary and nondiscretionary functions with respect to vaccines, see Berkowitz v. United States, 466 U.S. 531 (1988).
6. See, e.g., In re Hawaii Federal Asbestos Cases, 960 F.2d 806, 810-12 (9th Cir. 1992).
7. See, e.g., Mazur v. Merck & Co., 964 F.2d 1348 (3d Cir. 1992) (vaccine sold under contract to CDC but no discussion of government contractor defense).
12. See, e.g., Tate v. Boeing Helicopters, 140 F.3d 656 (6th Cir. 1998); Kerstetter v. Pacific Scientific Co., 210 F.3d 431 (5th Cir. 2000).
13. See, e.g., Kerstetter, 210 F.3d at 431.
14. See, e.g., Allison v. Merck, 110 Nev. 762 (1994) (state court refusing to apply doctrine in nonmilitary setting and, in any event, leaving for the jury the question of whether government had approved “reasonably precise specifications” for vaccine); Orthopedic Equip. Co. v. Pietz, 562 So.2d 152 (Ala. 1989), cert. denied, 498 U.S. 823 (1990) (state court leaving to the jury whether to apply the defense and limiting doctrine only to “military” contracts, narrowly construed).