

## Registration is not Informed Consent: the Swine Flu Program Revisited

A negligently drafted registration form fails to provide adequate warning of swine flu vaccine risks in light of the congressional directive that the Government obtain the written, informed consent of vaccinees. *Petty v. United States*, No. C-78-4083 (N.D. Iowa, Dec. 31, 1980).

A suit was brought under the Federal Tort Claims Act, 28 U.S.C. §§ 2671, *et seq.*, and the National Swine Flu Immunization Act of 1976, 42 U.S.C. §§ 247b(j) to (l), for injuries suffered following plaintiff's receipt of a swine flu inoculation in October 1976. The United States District Court for the Northern District of Iowa found that a "registration form" signed by the plaintiff immediately before he received the shot was negligently drafted and did not comply with the requirements of 42 U.S.C. § 247b(j)(1)(F) that the Government inform all vaccine recipients of their rights and remedies arising out of the administration of the vaccine. As such, the registration form failed to shield the United States from claims for injuries that were proximately caused by the swine flu vaccine. Based upon the evidence presented at trial, the District Court found that the swine flu inoculation had caused the plaintiff's severe serum sickness and related disability and that the plaintiff was, therefore, entitled to recover from the United States \$212,807.22 in damages.

### RIGHT TO SUE

The Swine Flu Act of 1976, which authorized the largest immunization

program in this country's history, created a cause of action against the United States for any personal injury or death based upon any theory of liability including negligence, strict liability, or breach of warranty associated with the vaccination program. 42 U.S.C. § 247b(k)(2)(A). The act also made suit against the Government the exclusive remedy for such injuries and abolished any legal recourse against vaccine manufacturers participating in the program. 42 U.S.C. § 247b(k)(3). The legislative history of the act indicates that these statutory provisions were prompted in large part by the unavailability of commercial liability insurance for vaccine manufacturers and other program participants at the time the swine flu campaign was proposed. The source of this insurance problem appears to have been two Federal court decisions which found a manufacturer to be strictly liable for injuries associated with poliomyelitis vaccine it had produced. See *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir. 1968), and *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974).

The plaintiff, Robert L. Petty, received a swine flu inoculation on October 31, 1976, during a vaccina-

tion clinic conducted by the Sloux City Health Department as part of the national program. The evidence indicated that Petty had been persuaded to take the flu shot by an intensive media campaign conducted by the Federal Government that fall. The plaintiff stated that at the time of the inoculation, he had not heard or read anything derogatory about the vaccine and believed that the Government would not sponsor a harmful health program. Upon arriving at the clinic, Petty was told that he would have to sign a document identified as a "registration form" before receiving the vaccination. While waiting in line, he "skimmed" the form and signed and surrendered it before being inoculated.

### SERUM SICKNESS DIAGNOSED

The plaintiff's previous good health continued for 8 days after he received the swine flu shot. On November 8, 1976, while at work as an electrician, Petty began experiencing numbness in his legs and aching in his joints and muscles. His symptoms progressed to include a sore throat, fever, chest pains, and difficulty with breathing. He was admitted to a hospital, where his personal physician diagnosed his chest pains as "congestive heart failure." Petty remained in the hospital, showing little improvement until his physician began the administration of steroids on November 26, 1976. The

plaintiff was released from the hospital on December 8 and returned to his former employment in the spring of 1977.

At trial, Petty's physician testified that the swine flu vaccination was the cause of his patient's sickness, which was diagnosed as a "serum sickness-like reaction to a foreign protein." Although a physical examination just before trial revealed no permanent physical disability, Petty testified that he continued to experience aches in his joints and muscles which limited his physical ability to work and engage in personal activities. The United States did not present any expert testimony that rebutted Petty's evidence regarding the diagnosis of serum sickness or the alleged injuries. The Court, therefore, held that it was compelled to conclude that the plaintiff's condition was proximately caused by the swine flu vaccination in question. Accordingly, Petty was awarded \$25,607.22 in special damages (including medical expenses and lost income), \$87,200 in general damages for residual injuries, and \$100,000 for pain and suffering from the onset of his illness to the time of trial.

#### NO INFORMED CONSENT

The District Court's decision is significant, not because the Court found a causal relationship between the swine flu inoculation and the particular injuries experienced by the plaintiff, but because it based the liability of the United States on the Government's negligence in failing to adequately warn vaccine recipients of the dangers associated with the vaccination. The Court found that pursuant to the Swine Flu Act and the Federal Tort Claims Act, the Government had a duty to warn and fully inform potential vaccinees of the "risks and benefits" of receiving the swine flu vaccine. In the Court's opinion, the standard registration form used in the program was misleading in that it did not ask the registrant to assume the risks associated with the vaccination or to waive any legal remedies. The registration form merely listed in summary fashion "important information" about influenza, the nature of the vaccine, possible side effects, and special precautions for certain groups of people (for example, young children, people with known allergy to eggs). The requested response to this information was a

signed statement that the registrant had read the form and understood the benefits and risks of the flu vaccination. In light of the statutory requirement, the Court held that the act of signing this form was not sufficient to waive a vaccinee's right to sue and did not, therefore, constitute informed consent.

A multidistrict court, which had coordinated all pretrial proceedings in the numerous swine flu claims against the United States (including this one), held that nothing in the Swine Flu Act bars a plaintiff from demonstrating that the Government had an obligation to warn vaccinees of potential hazards. Indeed, the legislation created a clear duty on the part of the United States to prepare and implement a "written consent form" as well as procedures for assuring that vaccinees were given information sufficient to make an informed decision. Thus, the Court found that the Government could not avoid liability by hiding behind the four corners of a complicated registration form. Although conceding the difficulty of drafting a consent form that meets the statutory standard of 42 U.S.C. § 247b(j)(1)(F), the Court reasoned that the Government's "hard sell campaign" to encourage program participation, together with the prior knowledge by Federal officials of certain neurological complications that might arise from the vaccination and the widespread disagreement among medical experts as to the actual need for the swine flu program, made a "full, adequate and understandable warning of the risks and benefits, and

rights and remedies" imperative. Under these circumstances, failure to give such warning constituted statutory negligence.

The Court also suggested that evidence showing that Petty was "a hard-working, healthy taxpayer" who "responded to the call of his country" created a moral obligation on the part of the Government as well as a legal one. The Court stated:

It may well be argued (and probably will be) that the Government should not nurse the American public from cradle to grave. . . . However, the plaintiff herein asked for nothing prior to his vaccination. . . . The Government should not now look lightly on plaintiff and his illness.

The *Petty* decision contrasts with two other recent cases in which the legal sufficiency of the registration form used in the swine flu program was considered. In both *Bean v. United States*, Civil Action No. 79-F-571 (D.C. Colo., Aug. 19, 1980) and *Gundy v. United States*, Civil Action No. 79-F-587 (D.C. Colo., Sept. 9, 1980), the registration form was found to provide plaintiffs with adequate information to make an informed decision about the inoculation and thereby assume the inherent risks. The inconsistency of these rulings is likely to give rise to an appeal in the *Petty* case. At the time of publication, a motion for a new trial was pending before the District Court in Iowa, and a final judgment had not been entered.

—PETER A. PAVARINI, Attorney-Advisor, Office of the General Counsel, Department of Health and Human Services.

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## education notes

**Industrial hygiene ventilation systems.** The Rocky Mountain Center for Occupational and Environmental Health at the University of Utah is offering a course entitled "Design and Evaluation of Industrial Hygiene Ventilation Systems" (National Institute of Occupa-

tional Safety and Health No. 588) at Salt Lake City, Utah, October 5-9, 1981. The tuition will be \$500. For further information, contact Ms. K. Blosch, University of Utah, Bldg. 112, Salt Lake City, Utah 84112, (801) 581-5710.