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Product Liability: DPT Vaccine

COUPLE RECEIVES $4.5M UNDER VACCINE INJURY COMPENSATION PROGRAM

Special Master Bryan J. Bernstein of the U.S. Claims Court in Washington, DC, on April 12 approved an award of over $4.5 million to the parents of Andrew Nuzzo because DPT shots given to Andrew allegedly left him suffering from chronic seizures and in need of constant care. The Nuzzos' attorney, Kenneth Moll of Chicago, said he believes this to be the largest award ever given under the National Vaccine Injury Compensation Program.

The award stems from two DPT shots administered in 1986 to Andrew, who lives in Bradford, Pennsylvania. Andrew's mother, Colleen Nuzzo, said that the money will be used for rehabilitation and care of her son.

The Centers for Disease Control in Atlanta estimate that one in every 310,000 DPT vaccinations results in permanent brain damage. The government estimates that about 18 million DPT doses are administered yearly, including three shots the first year for 3.5 million newborns, plus two boosters, one at 18 months and one just before entering kindergarten.

President Reagan signed the no-fault National Vaccine Injury Compensation Program into law on Nov. 14, 1986. Under the program, children could obtain payments from the government without proving fault or wrongdoing by the vaccine manufacturer. About 50 to 75 children each year suffer neurological injuries from one of three vaccines: DPT (diphtheria-pertussis-tetanus), polio and MMR (Measles-mumps-rubella).

The Compensation Program was part of an omnibus health bill containing the texts of nine separate bills. When he signed it, Reagan expressed "serious reservations" about the Compensation Program portion of the bill, saying there were "substantial deficiencies" in the vaccine plan, including the fact that it would be "administered not by the executive branch, but by the Federal judiciary," an "unprecedented arrangement" inconsistent with the constitutional requirement for the separation of powers. At the time he signed the bill, he objected to suggestions that the program be funded through a new tax on pharmaceutical companies, and he added, "Any acceptable measure to implement a vaccine compensation program should structure the program so that no funding will be provided from the Treasury of the United States."

The program provides that people cannot sue a manufacturer for vaccine-related injuries without having first completed the compensation process. If they accept a compensation award, they would waive the right to sue separately, but could pursue legal action if they rejected compensation. Under the legislation, trials would be split into three parts, the first to determine liability, the second compensatory damages and the third punitive damages. The program

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provides that manufacturers would not be liable for injuries or deaths resulting from unavoidable side-effects if the vaccine were properly prepared and accompanied by proper warnings and directions for use.

According to the program's administrator, Dr. Tullio F. Albertini, so far 236 claims have been filed, resulting in 51 awards totaling $24.2 million. Claims are paid out of a trust fund financed by surcharges on DPT, polio and MMR vaccines. Claims for injuries that occurred before Oct. 1, 1988 must be filed by Oct. 1, 1990. Information on the program can be obtained by calling (301) 443-6593, or by writing Administrator, National Vaccine Injury Compensation Program, Parklawn Building, Room 7-90, 5600 Fishers Lane, Rockville, Maryland 20857.

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Patent Infringement: Genentech v. Wellcome Foundation

DE CT. SAYS WELLCOME FOUNDATION INFRINGED GENENTECH PATENTS

A jury in the U.S. District Court for the District of Delaware on April 6 held that The Wellcome Foundation Limited (Wellcome) and the Genetics Institute (GI) had infringed three patents held by Genentech, Inc. covering the glycoprotein tissue plasminogen activator (t-PA) and its production (Genentech, Inc. et al. v. The Wellcome Foundation Limited et al., D DE, Nos. 88-330-JJF and 89-407-JJF).

(See P. 5,297 for Genentech's opening brief in support of a motion in limine to exclude reference to an injunction upon finding of infringement, and the Special Interrogatories Verdict Form.)

Last year Genentech sold $196.4 million worth of t-PA, at $2,200 per treatment, under the trade name Activase. The anti-heart-attack drug accounts for half of Genentech's revenues.

This patent action consists of two consolidated cases that relate to alleged infringement of three patents describing t-PA and its production. Both cases were filed against Wellcome and others — the first filed by Genentech, Innovi N.V. and Leuven Research and Development VZW and involving U.S. Patent Nos. 4,766,075 (the '075 patent) and 4,752,603 (the '603 patent), and the second filed by Genentech only and involving U.S. Patent No. 4,853,330 (the '330 patent). Defendants had asserted a counterclaim alleging antitrust violations against Genentech.