TIMOTHY D. PROCTOR reads

on behalf of the

PHARMACEUTICAL MANUFACTURERS ASSOCIATION

before the

PENNSYLVANIA HOUSE LABOR RELATIONS AND JUDICIARY COMMITTEE

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My name is Timothy D. Proctor. I am Counsel, Merck Sharp & Dohme, Division of Merck & Co., Inc., headquartered in West Point, Pennsylvania. I am here on behalf of the Pharmaceutical Manufacturers Association of which Merck is a member.

The Pharmaceutical Manufacturers Association is a trade association representing more than 100 research-based pharmaceutical companies responsible for nearly all the new prescription medications discovered, developed and marketed in this country. Sixteen member companies have facilities in this state, among which Connaught Laboratories, Johnson & Johnson, the Rorer Group, SmithKline, Wyeth-Ayerst and Merck have major corporate offices in Pennsylvania. In total, PMA members companies employ over 27,000 Pennsylvania citizens.

Last year, PMA members spent $6.5 billion on the research and development of new medicines. Once marketed, many of these medications will bring significant therapeutic advances to Pennsylvanians and, indeed, to people throughout the country and around the world.

There are several bills being discussed today that PMA supports. I would like to focus my remarks on House Bill 916, which addresses product liability; and, in particular, on Section 8381 of that bill, which addresses punitive damages in cases involving products regulated by the Food and Drug Administration. Other witnesses are covering the other provisions of H.B. 916 and the other important bills.

Product liability is a subject of particular concern to research-based pharmaceutical manufacturers. To quote from a report of the Board of Trustees of the American Medical Association:

> "Product liability is having a profound negative impact on the development of new medical technologies. Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of

safety or efficacy, but because product liability suits have exposed manufacturers to unacceptable financial risks."

Among these risks, the threat of punitive damages can be particularly discouraging for manufacturers engaged in pharmaceutical research. Section 8381 of H.B. 916 would prohibit punitive damages in cases involving products regulated by the Food and Drug Administration, when there is no evidence of fraud or misrepresentation by the manufacturer.

Let me summarize the arguments in favor of this provision. Punitive damages are intended to deter and to punish knowing, willful, wrongful conduct. A pharmaceutical manufacturer who has complied in good faith with the rigors of the FDA regulatory process, including years of study, the submission and review of literally a truckload of data, and thoughtful approval of product labeling has, by definition, not engaged in the kind of wrongful conduct that should be subject to punitive damages.

Requiring such a manufacturer to face the threat of punitive damages is a completely unwarranted deterrent to pharmaceutical research and development, research which ultimately benefits patients in the Commonwealth, employees of pharmaceutical companies in the Commonwealth, and the Commonwealth's economy. Removing this

threat in the context of compliance with FDA regulations represents no compromise of the rights of injured parties.

Product liability concerns, and the threat of punitive damages in particular, inhibit the access of patients to useful pharmaceutical products.

Consider, for example, vaccines. The magnificent results they have achieved are beyond challenge. Smallpox has been eradicated worldwide. The number of measles cases has dropped from 525,000 per year before 1962 to 3,032 in 1981. Polio has dropped form 57,000 cases in 1952 to 4 in 1984. Whooping cough, still a dreaded killer disease in third world countries, is largely controlled here. And yet, there has been a sharp decline in the number of vaccine manufacturers, and liability exposure is an important cause of that decline. A number of our most important vaccines are now produced by only one manufacturer.

Merck, the company I am associated with, is currently the sole U.S. supplier of vaccines against mumps, measles and rubella. It is also the developer and marketer of a vaccine against hepatitis B, the first vaccine for human use produced using recombinant DNA technology. Much of the work leading to this scientific breakthrough was done in our laboratories here in Pennsylvania for sale worldwide.

Hepatitis B is a very serious, infectious disease. Chronic manifestations of the disease are associated with liver cancer. While vaccines comprise approximately seven percent of Merck's U.S. pharmaceutical sales, they are responsible for half the product liability lawsuits we have faced in recent years. At this time, the total of pending claims in industry-wide vaccine lawsuits is more than ten times the total annual sales of all vaccines in the U.S.

It is this kind of experience with vaccines that led to the enactment of the National Childhood Vaccine Injury Act, federal legislation which recognized the inability of the tort system to deal with the scientific and public policy issues raised by vaccine lawsuits. For those injured by pediatric vaccines, it provides for a no-fault compensation fund derived from an excise tax on the vaccines covered. A claimant unsatisfied with his award can still initiate a suit under modified rules, including a limitation on the availability of punitive damages similar to that being proposed here. Vaccines intended primarily for adults, such as our hepatitis B vaccine, are not covered by the Act at all and future pediatric vaccines are not automatically covered. An AIDS vaccine would not be covered by this Act.

H.B. 916 attempts to address some of the excesses that have come to exist in our tort system. H.B. 916 does not in any way exempt manufacturers from responsibility for defective products. Instead, the bill fairly limits inappropriate threats to those manufacturers who endeavor to provide quality products of significant benefit to society.