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## Introduction: Product Liability Aspects of Innovation

*Dirk Barrett\**

**P**fizer is a multinational pharmaceutical company. We have businesses in the medical device area including orthopedic implants and other surgical products. We have a food additive business, a small, hopefully soon to grow, consumer products business, and an animal health business. We also have, particularly in recent years, rich experience in the product liability area.

I am pleased to talk about that subject today. It has been one that has lately gotten a lot of press. Recently tort reform legislation has passed in the House of Representatives, and it is good, after having listened to speeches for two days, to finally get a chance to talk about something that is in the Contract for America.

I think it is quite clear and widely acknowledged that there is a product liability crisis. Although there are strong dissenters from that standpoint, there has been discussion about the increase in the number of lawsuits on product liability and the increase in the size of awards in those lawsuits including punitive damage awards.

The significance of that to our topic, I think, falls into several areas. One is the possible unavailability or increase in price of insurance for companies. Secondly, even if insurance is available, there is often a large increase in the ongoing operating cost, running cost as it were, attendant upon having product liability problems. It was reported in 1987 that the total cost of the tort system, taking into account all components, was \$117 million. I think that includes medical malpractice as well as product liability. That number is well over two percent of GDP at that time. That is a fixed built-in cost to the economy which itself arguably can have some effect on innovation. That is money that could be spent on R&D or other things. It is not being so spent.

Thirdly, from the perspective of our industry, the health care industry, I think you can look at a number of experiences arising out of product liability litigation that have had what I would call a "blackout effect" on research and development in certain areas. The best recent example is in the area of contraceptives. You had the example of the Dalcon shield, a very serious litigation, followed by the Copper Seven litigation. Together they, as well as litigation affecting oral contraceptives, have been in large part responsible for what has been reported to be a reduction of companies doing research on contraceptives in the

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United States, from thirteen to one in recent years.

Similarly, you have the example of the Vanvechten case where you had a drug that was used to treat morning sickness. It was at that time the only available drug for morning sickness, and was widely held by medical opinion to be safe for that purpose. But, it was the subject of a number of liability lawsuits against Merrill, its manufacturer, most of which were won. Nevertheless, because of the costs of those suits, Merrill withdrew the product from the market, and to my knowledge there are no morning sickness drugs available and there is probably little research in that area.

There has been a similar experience in the vaccine area, and I think it is safe to say that the breast implant business has been very effectively shut down or substantially reduced.

In a general sense, tort prices have led to criticisms to the effect that high awards lead to unpredictability, uncertainty for businesses, high risk, high expense, arbitrary experience, and have led to calls for tort reform.

So we have, as I mentioned, had this issue included in the Contract for America. Last March 15th, the reassuringly titled Common Sense Product Liability and Legal Reform Act, passed the House of Representatives, and included a number of very significant tort reforms or changes in the liability system, principally in the area of punitive damages and joint several liability and others. I think it is a significant piece of legislation.

I just want to let you know what is at stake here in addition to innovation and the availability of safe medical products and other products. In case there were any doubts that rhetorical excess was in danger with the Republicans taking over, I will just read finding number one from the text of the bill. The civil justice system which is designed to safeguard our most cherished rights to remedy injustices and to defend our liberty is increasingly being deployed to abridge our rights, create injustice, and destroy our liberty. This is what is at stake here, folks.

We have two very distinguished and qualified speakers to talk about this today. Our first will be from the Cleveland law firm of Squire, Sanders and Dempsey, Mr. Thomas Hermann.