TESTIMONY

FORMER COMMISSIONER

UNITED STATES FOOD AND DRUG ADMINISTRATION

BEFORE THE HOUSE COMMITTEE ON

OVERSIGHT AND GOVERNMENT REFORM

HEARING ON:

SHOULD FDA DRUG AND MEDICAL DEVICE REGULATION BAR STATE LIABILITY CLAIMS?

MAY 14, 2008

Mr. Chairman and Members of the Committee, thank you for inviting me to be here today to set forth my views on the question of whether FDA regulation of drugs and medical devices should preempt state liability cases.

My colleague Professor David Vladeck of the Georgetown Law School and I have recently coauthored a law review article titled, "*A Critical Examination of the FDA Efforts to Preempt Failure-To-Warn Cases.*" I request that article be included in the Committee's record.

Let me speak today from my personal experience having had the privilege to serve two Presidents in the role of Commissioner of Food and Drugs.

In 1996, Margret Jane Porter, a career public servant, who served as the agency's chief counsel while I was Commissioner, summed up the Agency's position at a Food and Drug Law Institute conference.

She was talking about medical devices, but the position was equally applicable to prescription drugs. Let me quote:

> "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant yet distinct layer of consumer protection. FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Preemption of all such claims would result in the loss of a significant layer of consumer protection leaving consumers without a remedy caused by defective medical devices."

So, in general, I believe, as did my general counsel, that the two systems should operate in a complementary but independent manner.

FDA, under the current Administration, has a different point of view.

I would like to discuss why the FDA system of drug and medical device regulation is not entirely adequate for assuring the protection of the public health.

But first let me discuss federal preemption more generally. I am not opposed to federal preemption in certain cases, but I think there should be specific criteria governing when it is deemed appropriate.

There are three elements that I believe should be met if FDA regulation is going to preempt state law in a given case.

First, the Agency took substantive and definitive action.

Second, there is a direct conflict between state action and agency action which would thwart the ability of the agency to achieve its statutory goals.

And third, there is a public health reason to favor preemption.

Let me give you two examples in an area outside of drug and medical device regulation -- the area of food regulation.

In the 1980's, food companies were making a lot of outlandish health claims on the food label. FDA could have acted and concluded that the claims were false and misleading, but it did not, for whatever reason -- bureaucratic intransigence, other regulatory priorities, concern about being able to sustain its enforcement actions in court, regulatory philosophy, or simply being asleep at the switch.

The state attorneys general stepped in under state food and drug laws and took action.

Applying the criteria I listed, in this food example there was no substantive and definitive agency action, no direct conflict, no public health reason to stop the AGs.

Let me give you a second example -- the food label.

In 1992, FDA promulgated final rules for the Nutrition Facts panel, implementing the Nutrition Labeling and Education Act of 1990—a statute that you, Mr. Chairman, were a key architect. Based on decades of study, including that by the National Academy of Sciences, and after hundreds of thousands of public comments, the Agency, along with its sister agency in the Department of Agriculture, promulgated with great specificity the requirements for what should be included on all packaged food labels.

What should happen if a state issued a different rule requiring a nutrition facts panel but specifying that the information be disclosed in a different way than mandated by federal law? I believe that preemption would be in order, and Congress expressly instructed that be the case. Going through the above criteria, FDA acted in a substantive and definitive way, there is a conflict between state and federal action, and the public health would be served with greater consistency and public familiarity.

Now let me shift to prescription drugs.

There are two very different aspects to drug review and it is important to understand each in the debate on preemption.

First is the period leading through approval. Manufacturers are supposed to

submit all preclinical and clinical data. FDA has to review all that data. FDA makes an affirmative decision that the drug can go on to the market if the drug meets the statutory standards for safety and efficacy. FDA must approve the drug's label, which is the equivalent of the physicians' package insert.

Let me move on to the second phase of a drug's life. The drug is on the market. If a drug is studied in a few thousand patients and a serious life threatening drug reaction occurs at an incidence of one in ten thousand, it is likely that this serious and life threatening risk will not have been seen in the clinical trials and will only emerge after the drug is on the market.

In fact, it has been noted that only a fraction of adverse reactions that appear on the label occur in the first seven years. Adverse reactions continue to occur during the postmarketing period. Companies have to file adverse reaction reports. Thousands of adverse drug and device reports come in to the Agency each year.

Those who favor preemption focus on the first part of a drug's life, the approval process. They suggest that the FDA's approval of a drug's labeling reflects the Agency's definitive judgment, regarding risks that must be shielded from the possible second-guessing that might take place in a failure-to-warn case. Otherwise, court rulings adverse to drug companies might force companies to add warnings not approved, or even rejected, by the FDA, thereby upsetting the balance of risks and benefits set by the FDA when it approves a drug label.

Of course, the moment the FDA approves a new drug is the one moment the Agency is in the best position to be the exclusive arbiter of a drug's safety and effectiveness. On that day, assuming the drug sponsor has fully and accurately provided all the data and appropriate analyses to the Agency, the FDA has had access to and has devoted considerable resources to reviewing carefully the health and safety data relating to the drug.

But I believe it is wrong to focus on the moment of approval as determinative of the preemption question. The relevant timeframe is *post*-approval, and the question is: What did the FDA and the drug company know about a drug's risks at the time the patient-plaintiff sustained the injury. As I just discussed, the FDA's knowledge-base of the risks posed by a new drug is far from static. At the time of approval, the FDA's knowledge-base may be close to perfect for that moment in time, but it is also highly limited because, at that point, the drug has been tested on a relatively small population of patients. Once the drug enters the marketplace, risks that are not overly common, that manifest themselves only after an extended period of time, or that affect vulnerable subpopulations begin to emerge. These are often risks not foreseen by the drug's manufacturer or the FDA and, for that reason, are not addressed on the label. The FDA's statutory and regulatory tools for gathering post-approval information are relatively crude and often ineffective, especially when contrasted with its tools for information gathering prior to approval. The expectation that even an enhanced FDA post-market surveillance program will detect all emerging safety problems with drugs or devices is not realistic.

The fact is that companies will always have better, and more timely information about their own products than FDA will ever have at its disposal. Moreover, there are real limits on FDA: There are limits on FDA authority that prevent it from acting quickly in some settings, *e.g.*, lack of drug recall authority and, as implemented by FDA, very slow device recall authority. In the drug advertising arena, FDA is never able to monitor what the thousands of drug representatives are saying to doctors that may be encouraging unsafe uses. Moreover, FDA usually gets the raw adverse reaction data, and does not have the benefit of all the analyses, review, thinking, and back and forth communication that occurred within the companies.

And, most importantly, there are real limits imposed by the limited resources the

Agency has available. The case for preemption must be examined in light of a clear-eyed appraisal of the FDA's ability to assure the safety of the drugs being marketed in the United States. As we all know, the reality departs from what we would all wish could be the resources allocated to the Agency. The Institute of Medicine (IOM) reported in 2006 that the FDA "lacks the resources needed to accomplish its large and complex mission today, let alone position itself for an increasingly challenging future." FDA doctors and scientists share this view -- many believe that the FDA lacks sufficient resources to protect the public health, and many worry that the FDA is not adequately monitoring the safety of drugs once they are on the market. The FDA has long been hamstrung by resource limitations. Even if FDA's funding were doubled or tripled, its resources and ability to detect emerging risks on the thousands of marketed drugs and devices would still be dwarfed by those of the drug and device companies who manufacture those products

For that reason, the tort system has historically provided a critical incentive to drug and device companies to disclose important information to physicians, patients, and the FDA about newly emerging risks.

My greatest concern with preemption is that it would, I believe, dramatically reduce the incentives for manufacturers to act quickly and responsibly to detect, analyze, investigate, and take action on potentially serious and life threatening adverse reactions once a drug is on the market.

While there are adverse reaction reporting requirements for the manufacturers to give the data on adverse reactions to the Agency, that does not mean that the Agency knows as much as the companies and in as timely a fashion as the companies. We limit the incentives for a company to uncover potentially serious and life threatening reactions if there is no liability for harm the drug or device causes. We limit the incentives to do anything more than be a passive transfer of adverse product reports that come within the company's knowledge. We limit the

incentives to do, in a timely and expeditious manner, the type of epidemiological studies to discover patterns and links between a drug, or a device, and the potential harm it causes. The tort system has always provided those incentives. Congress has recently given the Agency new tools to require more post marketing studies, but the Agency still needs to know what the potential risks are so that it is in a position to require such studies. And if the companies have little incentive on their own to undertake such post marketing studies, much harm can occur until the agency is in a position to act.

Mr. Chairman, I need to stress that it is the manufacturers, not the Agency, that are in a far better position to know when a new risk emerges from a drug or device. And it is the manufacturer that has the ability to make swift changes to a drug or device's warning or product features.

Doing away with the incentives to act responsibly and expeditiously to correct potential risks, incentives that are the result of state liability cases, would, I believe, jeopardize the public's health.