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My name is Christine Ruther, and I am a medical device engineer. I am appearing today to speak in support of legislation to ensure that all medical devices are subject to market forces, including the possibility of lawsuits by injured patients, which I think is critical to help ensure the safety and effectiveness of medical devices. As a medical device engineer, I believe that it is important to keep the possibility of liability in front of those of us who create and maintain medical devices.

My testimony will focus on 3 points:

1. Lawsuits create a market force that puts pressure on those of us who design or market engineers to achieve and maintain safe and effective medical devices.
2. As good as FDA reviewers are, they will never be in a position to know for certain that any particular device is as safe and effective as the manufacturer's data seems to show.
3. Pre-emption of patients' lawsuits has had and may continue to have unintended consequences.

First (regarding market forces): As a medical device engineer, I believe that it is important to keep the possibility of liability in front of those of us who create and maintain medical devices. When hearing a possibly suspect approach, a colleague of mine is fond of asking, "If you precede that explanation with 'ladies and gentlemen of the jury', are you still satisfied with your position?" He's not really asking if the position is defensible from a legal standpoint. Rather, he wants his fellow engineers to consider if they would be comfortable defending their position should the specific decision become public.

There are a variety of routine pressures that designers and manufacturers face each day. Typical pressures include: wanting to be the first to market for a novel device or a new feature, fulfilling all demands for product, and wanting to contain costs. These pressures sometimes conflict with our goals of ensuring that we release only the absolutely highest quality, most reliable products. As we try to balance these pressures, the words that draw our attention are not "what would the FDA think," but "ladies and gentlemen of the jury." If we are comfortable that a design is adequate from a safety and effectiveness perspective when considered in light of "ladies and gentlemen of the jury," we proceed. Whether or not losing the threat of liability would lower the overall safety and effectiveness of devices, it will remove an important weapon in the battle to ensure a reasonable degree of safety and effectiveness.

Second (regarding limitations of FDA's review): FDA has talented reviewers who undoubtedly work tirelessly to ensure safe and effective medical devices reach the market. However, they are not (and can never be) as familiar with the nuanced issues associated with any one particular device as the designers and manufacturer are. The fullest understanding is (and will always be) limited to those of us who are intimately involved with the particular product.

The FDA has a prescribed list of information that device manufactrurers must provide. In very

general terms, manufacturers seeking marketing approval provide a description of the device and what it is intended to do. So that the FDA can evaluate the details of the design, we provide our top level engineering specifications, risk analyses, and similar information. We also provide laboratory and clinical test data so that the FDA can determine if we have met our design goals and if the overall device is safe and effective for its intended use. The FDA reviewers perform diligent reviews and ask many relevant questions which we respond to, providing additional information and test data. But throughout the process, we the manufacturers are the ones providing the information, and we always have more information than is submitted to the FDA. We don't lie, but we may omit information that we don't believe to be relevant to FDA's concerns. Such information might include features that were dropped from the project due to time or cost constraints, patent application information, or additional engineering level tests performed outside of the formal test plans. All are reasonable data to omit, but might provide insight that, if known, would sway FDA's opinion or result in additional questions. Or, for example, sometimes additional engineering testing is in progress to address issues that the FDA might raise. If the FDA asks, the manufacture will have (or soon will have) the data to address the concern. If the FDA doesn't ask, the data will not necessarily be shared with the agency.

On any given day with any given manufacturer and any given FDA reviewer, an important issue may be missed. Pre-emption, inappropriately limits a manufacturer's focus to satisfying the FDA, whereas lawsuits expand a manufacturer's focus to broader concerns about whether a device is really as safe and effective as it can be. Stated differently, as designers, we do not generally fear that the FDA will find fault with our designs, risk analyses, or other work. Irrespective of the FDA, we respect the prospect of liability, where a fellow engineer who is perhaps either highly competent in our type of product or very knowledgeable in the details of the design control techniques we use could find fault in our approaches or results

Third (regarding unintended consequences of pre-emption): Pre-emption of claims based on injuries from premarket approved medical devices may skew market forces or encourage companies to seek more rigorous review than needed, thereby unnecessarily using valuable FDA resources. Pre-emption also eliminates and possibly even discourages an important incentive for companies to make changes to improve products as real-world use demonstrates that such changes are needed. The reality is that, despite the best efforts of designers, manufacturers, and the FDA, not all device problems are identified in premarket testing. The potential for being held liable is a key force to ensure the most conscientious testing and to prompt correction of hazards as soon as they are identified.

And finally, would the pre-emption line tend to expand over time? Could one make the argument that what really makes the PMA process unique is the need to provide clinical data? If so, then it would be a reason to expand pre-emption to devices reviewed under FDA's 510(k) process where clinical data was, as an exception, required. And, if these devices make that hurdle, how far behind would be all medical devices reviewed under FDA's 510(k) process? If this happens, do we then have the unintended consequence of the majority of medical devices not being subject to market forces? It seems this could be a slippery slope.

Summary: It is my opinion that:

1. Allowing market forces to maintain pressure to achieve and maintain safe and effective

medical devices is desirable,
2. FDA reviewers cannot know for certain that any particular device is safe and effective based on the data presented to it by the manufacturer before the device is on the market, and
3. Pre-emption has had and may continue to have unintended consequences.

If no approved device had ever been recalled and if no approved device had ever injured a patient due to design or manufacturing failures, then pre-emption would be appropriate. But some devices have been recalled, and these and other devices have injured patients. As long as injuries and defective devices remain a reality, the possibility of liability will help ensure that designers, manufacturers, and others involved with medical devices remain vigilant.

I hope the information I've provided allows you to better weigh the advantages and disadvantages of any proposed legislation on the matter. Thank you.

My Background: I received my BS in Physics at Xavier University and MS in Biomedical Engineering at The Ohio State University. I have over 15 years experience in the medical device industry. I have worked in a variety of companies and with a wide range of medical devices, from relatively simple suction pumps to high tech implants. I currently assist medical device manufacturers in compliance & safety engineering, and in quality & regulatory affairs on a consulting basis.