Testimony of Philip J. Phillips before the Subcommittee on Health

Hearing - Medical Devices: Are Current Regulations Doing Enough for Patients?

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Mr. Chairman, Mr. Ranking Member, thank you for the opportunity to share my testimony with the Committee. It has been a little over 34 years since the 94th Congress drafted the Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act thereby creating the framework for device regulation that still exists today. Before this time, the medical device industry was largely unregulated. Therefore, Congress had little experience in dealing with the industry and, understandably, an uncertainty about the breadth and complexity of their undertaking. Despite this handicap, Congress drafted an enormously successful statutory framework that protects the American public from unsafe and ineffective medical devices.

The 1976 amendments created a "classification system" for devices that applies a level of FDA regulation commensurate with the risks associated with devices. While the law has been amended a half dozen times since 1976, the original framework exists and continues to accommodate not only the diverse nature of medical devices, but also rapidly evolving device technology.

Under the US regulatory system, general controls; controls including good manufacturing practices, labeling, and registration and listing, assure the safety and effectiveness of class I devices that pose the least amount of risk. Class I includes devices such as bandages, manual surgical instruments, and eyeglasses. For more complex and riskier class II devices, "special controls", in addition to the general controls, may apply. For class II devices such as powered wheel chairs, infusion pumps and many orthopedic implants, special controls provide FDA tremendous flexibility and include, but are not limited to, performance standards, agency guidelines and clinical testing. For class III devices; the most complex and riskiest devices including implantable defibrillators, artificial organs, and sophisticated lasers for vision correction, general controls, any applicable special controls, and "premarket approval" all apply. Perhaps most important, but too often neglected, our system of device regulation allows for adjustments in classification over time based on increasing knowledge and experience. Thus, through "reclassification" FDA can titrate the level of regulation that is needed to meet evolving public health priorities.

In accordance with the statutory framework, FDA designed and implemented a premarket review program responsible for the regulation of all medical devices. Serving as the foundation of this program was the premise that the lowest level of regulatory control sufficient to provide a reasonable assurance of safety and effectiveness should be applied.

This was the mandate of the 16 expert advisory panels that made recommendations to FDA on the proper classification of all devices in existence at the time. It also led to the premarket notification (510(k)) process becoming the predominant path for new devices to enter the domestic market.

What is 510(k); other than perhaps the most misunderstood premarket review program in FDA? It is the means by which FDA classifies new devices. When FDA reaches a determination that a new device is "substantially equivalent" to a legally marketed device, the new device can go to market only after satisfying the requirements associated with its assigned class.

When I entered FDA in 1981 as a review scientist, "substantial equivalence" had not yet been defined. For most 510(k) submissions this was not a problem, but as devices changed and their use and technology evolved, it became apparent that guidance was needed if consistency and the goals of the program were to continue to be achieved. From an internal agency task force convened to look at the 510(k) program, came the needed guidance, elements of which just 4 years later became codified in law through the Safe Medical Devices Act of 1990. The definition of substantial equivalence and the basic process by which it is determined still exists today, but continuous improvements have occurred along the way to strengthen the program to ensure that it focuses on the important issues of device intended use and technology to maximize the program's contribution to public health.

At one time, most 510(k)s involved side-by-side comparisons between a new device and an old one. Since the earliest days of the program, there has been a shift away from clearances based on simple comparisons to requirements for performance data on new devices. Today's 510(k)s are replete with performance data on new devices. Testing routinely involves biocompatibility, sterilization, electrical safety, software validation and engineering analyses, but also includes clinical data when warranted. To get a sense of FDA's expectations one need only review one of the many device specific guidance documents that exist. To see how intent FDA is on ensuring that all of the necessary data is available for decision-making, examine the number of 510(k)s that are placed on hold to get the data that review scientists demand.

To see how a more progressive risk-based approach to 510(k) clearance works, I urge you to examine any of the class II special controls guidance documents. With the risk-based approach, the agency identifies the risks associated with devices and the measures capable of mitigating the risks. Rather than simply showing similarities to other devices, special controls place a greater emphasis on documenting device safety.

Turning to class III devices, the premarket approval (PMA) process remains the most rigorous and demanding path to market and is rightfully reserved for the riskiest and least understood devices. Large clinical trials, exhaustive preclinical testing, preapproval inspections and voluminous submissions over the entire life of the device translate into a process that should be applied only to those devices demanding this degree of regulation.

Quite simply, most of the creativity in the device industry originates from small entrepreneurial companies that are the least prepared to satisfy these demanding requirements. Please do not misunderstand me; PMAs are often warranted and should be required. My point is that "new" or "different" should not automatically translate into class III status and any misunderstanding over the capability of the 510(k) program should not result in a shift toward requiring more PMAs.

Independent of the actual paths to market, we must preserve the ability to change regulatory requirements based on the knowledge and experience that is gained with any technology over its lifetime. The existing regulatory system is designed to permit these changes in classification, but the "reclassification" program has been less than successful. Risk-based classification, or *de novo* classification, has enjoyed some success in preventing new or different devices from automatically being placed in class III, but by and large, FDA has not established a viable means to change the classification of a device based on new information. Perhaps changing the thought "once a PMA, always a PMA" would reduce the fear associated with being determined to be class III.

In summary, the flexibility of FDA's approach to device regulation has served the US healthcare community and consumers well through the years. It has permitted numerous devices to enter the marketplace in an efficient manner, thus keeping down the costs to consumers and the healthcare community. In this way, it has facilitated technological innovation, while permitting FDA to responsibly regulate the rapidly progressing medical device industry.

Perceptions that the 510k program is inadequate to ensure the safety and effectiveness of today's medical technology foster the opinion that more devices currently found substantially equivalent should be subject to PMA requirements. Before drawing such a conclusion, I urge the Committee to examine the facts, as such an action will have a significant impact on FDA resources, as well as the future investment in new medical technology. Any changes that would result in more devices being subject to PMA requirements should be supported by both a sound public health and scientific rationale.

Finally, the 510(k) program should not be judged on dissatisfaction expressed over a relatively small number of agency decisions. There have been over ¼ million devices cleared through section 510(k) since 1976 while the examples cited by the critics in support of changing the program are extremely few.

Before introducing new legislation, I recommend that FDA be given the time required to deal with the preamendment class III devices that were the subject of the recent GAO report. Furthermore, I believe that it is important that the agency development special controls in a priority manner for all class II devices. These efforts will require Congressional support and additional FDA resources, but in the end the effort expended will result in great public health impact. Whatever the future holds, I urge you to do your part to ensure that FDA has the necessary resources to meet expectations.