Recent Controversies in Consumer Lawsuits: When Medical Devices Fail

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INTRODUCTION

When a medical device is approved by the Food and Drug Administration (FDA) for the health of the public, one would assume that many checks and balances have been applied to demonstrate the clinical worthiness and safety of the device. Lately, however, an increasing number of these devices, such as Boston Scientific’s Taxus drug-coated stents, have been recalled for further investigation after doctors reported injuries and deaths from their use. This article briefly discusses the roles of the FDA; the possible causes behind the need for recalls; the relationship between federal and state laws; the lawsuits that have, understandably, come into play; and the political forces that have sought to limit these lawsuits.

MEDICAL DEVICES: A DEFINITION

The FDA defines a medical device, in part, as any health care product that does not achieve its primary intended purpose by chemical action or by being metabolized.1 In the U.S., some states established regulations for medical devices before 1976. When Congress proposed the Medical Device Amendments (MDA), device manufacturers complained that they could not operate efficiently if they were subject to differing state regulations. Therefore, Congress included a provision in the MDA to prevent states from regulating medical devices and used its power to prohibit state regulations that interfered with interstate commerce.

Thus, in 1976, the landmark MDA, aligned with the Food, Drug, and Cosmetic Act, was signed into law. This Act required manufacturers of most medical devices, particularly moderate-risk or high-risk ones, to provide the FDA with safety and efficacy data before placing the devices on the market.2 Under Section 360(c) of the MDA, medical devices were categorized into three classes according to the degree of risk they posed to the patient:3

- Class I devices (e.g., tongue depressors) were subject to minimal controls because of their generally accepted safety standards.
- Class II devices (e.g., tampons) were subject to more specialized controls, such as performance standards or specific guidelines.
- Class III devices, such as pacemakers, had to undergo the stringent pre-marketing approval (PMA) process because of their central role in saving lives.

Before a medical device is approved by the FDA, companies must prove that (1) the device has been manufactured soundly and (2) the device is safe and effective, has caused no harm to patients, and can deliver its anticipated benefits.

SAFETY ISSUES AND LITIGATION

Occasionally, Class III devices fail and cause serious problems for patients. People file lawsuits and seek compensation from manufacturers for harm allegedly caused by such devices. Because such lawsuits are conducted in state courts, the federal pre-emption says that the federal government regulates interstate commerce.

If the state law and the federal law coincide, there is no conflict. If the state and federal laws have different requirements, the courts must decide which to enforce. In the cases involving powers reserved to the federal government (e.g., the regulation of interstate commerce), the federal law prevails.4 In cases involving the right of the state to protect the public health and safety (called police powers), the courts must balance the federal interests against those of the state and must determine which is more important.4

THE 1996 RULING

In a critical product-liability case that occurred in 1996, the Supreme Court ruled that patients who were injured by defective medical devices (e.g., by cardiac pacemakers), could seek damages under state law against the manufacturers even though the devices complied with federal regulations.4 The Court turned down a broad argument, forwarded by the medical-device industry, that a 1976 law, for the first time, brought medical devices under federal regulation and thus effectively prevented any private lawsuits for collecting damages. Under this argument, the federal law—the MDA of 1976—pre-empted all state-court damage actions.

The stakes for consumers and the industry were high in the 1996 decision because the federal law provided only for regulatory action against manufacturers of medical devices; it provided no damage remedies for individual consumers. Consequently, a victory for the manufacturers would have had the effect of barring all private, damage lawsuits in all courts.

As an example, the Supreme Court decision reinstated elements of a lawsuit against Medtronic of Minneapolis. Medtronic was the manufacturer of a pacemaker wire that suddenly failed while it was implanted in the heart of a 27-year-old woman; consequently, an emergency operation was necessary to save her life.5 In 1995, the 11th Circuit U.S. Court of Appeals in Atlanta ruled that although the patient could sue the manufacturer for damages based on allegations of negligent design, the claims on negligent manufacturing and failure to warn the patient were pre-empted by the federal law under which Medtronic had received the FDA’s approval to market the device. The Supreme Court decision of 1996 thus changed the earlier perceptions.

The Court’s decision addressed a particular category of medical devices that had been exempted under the 1976 law
from having to undergo the FDA’s full regulatory review because they were considered to be equivalent to devices that were on the market when the law took effect. Today, 80% to 90% of all medical devices now on the market, including most of the new ones, fall within this category. As a result, although the decision applies to most medical devices, it does not apply to all of them.

**LITIGATION “REVELATIONS” IN 2004**

A federal appeals court in Philadelphia threw out the lawsuit of a Pennsylvania widow who sought damages from a company for alleged design and manufacturing flaws in a heart pump used by her late husband. The plaintiff was appealing a U.S. District Court ruling that provisions in the 1976 MDA to the Food, Drug, and Cosmetic Act pre-empted her liability claim.

Recent disclosures suggest that the current White House administration, under President George W. Bush, has been intruding in court lawsuits to obstruct suits filed by individuals looking for compensation from manufacturers for serious injury allegedly induced by medical devices. The administration is opposed to what it calls “frivolous” lawsuits and would like Congress to pass legislation to do away with them. Quite unexpectedly, the administration has argued, in several cases, that individual consumers have no right to sue for any injury if the devices have been FDA-approved. If the courts continue to eliminate cases of this ilk, individuals would have no further legal recourse regardless of how just their complaints might be. Some members of Congress are worried that the administration has taken the FDA in a radical new direction, looking to protect manufacturers instead of the public.

In court papers, the Justice Department acknowledged that this position reflects a change in governmental policy, and it persuaded some judges to accept its arguments. Most recently, the department gained a victory in the federal appeals court in Philadelphia.

Lawyers from the Bush administration have conceded that their argument represented a change in government policy from the 1997 Supreme Court argument that state common laws could provide additional protection to consumers. In agreeing with the company in the Philadelphia case, the government argued that allowing individuals to sue manufacturers would weaken public health by allowing lay judges and juries to second-guess FDA experts and that this would probably result in the removal of beneficial products from the market. The majority ruling concluded that a lower court had correctly dismissed the case, because any judgment in the plaintiff’s favor would be an obstacle to, and would conflict with, the federal requirements imposed by the FDA’s pre-market approval process.

**LITIGATION RULING DENIED**

In the previously mentioned Pennsylvania lawsuit, filed by a woman whose husband died as a result of defects in the design and manufacture of a heart pump, the Bush administration argued that a claim such as this one should be barred because the device conformed to FDA-approved specifications.

The device in question had been manufactured and distributed by the Thoratec Corporation. It was a left ventricular-assist device, known as the HeartMate®, a pump that assists the blood flow between the heart’s ventricle and the aorta in patients with cardiac conditions. The inlet side tube is surgically attached to the heart via the ventricle and carries blood from the heart into the pump. The outlet side tube brings blood from the pump to the aorta, where it is dispersed to the body. A tube attached to the pump exits the body and connects to an external console. The console contains an air compressor that powers the device.

The facts underlying this case pertain to the outlet side tube, which connects the pump to the aorta. The connection between the pump and the tube, called the “elbow,” is inserted into an adapter conduit, which is screwed into the open port of the pump. A screw ring is secured over the elbow to ensure that it remains connected to the adapter conduit and the pump. A suture is tied over the screw ring and secured to the adapter conduit to ensure it will not rotate.

The patient had been waiting to receive a heart transplant. During the interim, the HeartMate® was implanted to provide circulatory support. However, the patient began to bleed from the spot where the HeartMate® tube exited his body. He then underwent exploratory surgery at Hershey Medical Center. During the procedure, the surgeon discovered that the suture on the device had worn off and that the screw ring linking the pump to the output side elbow was disconnected. The disconnection had allowed an air embolus to travel to the patient’s brain.

Although the surgeon reconnected the screw ring and once again linked the pump to the elbow, it was too late. The patient suffered a brain hemorrhage, and he was rendered brain-dead. The suture apparently broke because it rubbed against the breastbone, allowing the joint to separate and an air bubble to travel to the brain. Since this event, the manufacturer has designed a self-locking screw ring that requires no sutures; such a design probably would have avoided this accident.

**IS THE FDA DOING TOO MUCH?**

Perhaps in part because of its increased responsibilities, the FDA has had to recall a number of devices that it previously approved, leading some to wonder whether the organization has taken on too much of a workload. The FDA’s duties have been growing exponentially since the turn of the 21st century. Perhaps in part because of its increased responsibilities, the FDA has had to recall a number of devices that it previously approved, leading some to wonder whether the organization has taken on too much of a workload. The FDA’s duties have been growing exponentially since the turn of the 21st century. The magnitude of the FDA’s responsibility to public health is formidable. The goods whose standards are set by the FDA’s scientists and enforced by the agency’s regulators include:

- all foods except for meat and poultry
- all prescription and non-prescription drugs
- all blood products, vaccines, and tissues for transplantation
- all medical equipment and all devices that emit radiation, including microwave ovens
- all animal drugs and animal feed
- all cosmetics

Under the user-fee program, the number of new drugs approved in a year has increased by almost 40% and their total development time has been shortened by almost 20%. Biotechnology is generating novel drugs and gene therapies, genetic probes, and modified foods.

Other urgent priorities of the agency involve:
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• improving diagnostic tests for the nation’s blood supply to make it even safer than it is.
• enhancing the quality and accuracy of clinical trial designs so that firms can bring new drugs to patients faster and more cost-effectively.
• developing new methods to detect food contaminants to counter the emergence of previously unknown, virulent food-borne pathogens.

With all that the FDA has to do, then, and given the number of devices that have been recalled, some wonder whether the agency is scrutinizing medical devices appropriately before it approves them. If the FDA were approving potentially dangerous products, some would argue that this is all the more reason why consumers’ lawsuits against device manufacturers should be encouraged, not thwarted.

CONCLUSION

The current administration appears to be blocking lawsuits by consumers who have been injured by medical devices (as well as by prescription drugs) because these products have been FDA-approved and are therefore theoretically “safe.” The administration contends that lawsuits against the manufacturers would undermine public health and interfere with the regulation of devices and drugs.

This view differs from that of the earlier Supreme Court pronouncement. At that time, the government stated that the FDA approval established the minimum standard and that states could provide supplementary protection to consumers. Now the administration is saying, in effect, that the FDA’s approval of a device is the final word. However, some members of Congress are questioning the infallibility of the FDA and may establish a new compensation fund to help victims of failed medical devices.

REFERENCES

4. Richards EP. The Supreme Court rules on medical device liability—or does it? Available at: http://biotech.law.lsu.edu.