MedicalXpress

FDA's 'flawed' device pathway persists with industry backing

November 27 2018, by Matthew Perrone

Roughly 3,000 medical devices enter the U.S. market every year through a system that generally requires little or no patient testing to verify safety and effectiveness.

Unlike new pharmaceuticals, most medical devices reviewed by the Food and Drug Administration are cleared based on similarities to already-approved devices, not specific clinical trial testing.

The agency's streamlined review system has been blamed for a string of defective devices coming to market, including hip replacements that can leach metal debris into patients' joints and pelvic mesh that can puncture internal organs. Still, the 42-year-old system persists, in part because of the power of the medical device lobby, which floods Washington with hundreds of lobbyists and millions of dollars.

On Monday, the FDA proposed changes to the system that would push manufacturers to incorporate more up-to-date safety features into their devices. FDA Commissioner Dr. Scott Gottlieb described it as "the most significant modernization" of the agency's review pathway in a generation, though some of the reforms could take years to implement. The FDA's move came one day after the publication of a global investigation into medical device safety by more than 50 media organizations, including The Associated Press.

Nearly a decade ago, the FDA had responded to criticism of the system by asking the Institute of Medicine to study whether the process was

helping the FDA fulfill its dual goals of protecting patients and promoting medical innovation. The nonpartisan group—now part of the National Academies of Sciences, Engineering and Medicine—advises the federal government on medical matters.

Industry observers assumed the institute would seek to bolster safety standards by suggesting reforms to the streamlined process, which clears more than 95 percent of medical devices now on the market. But the group concluded the process offered little assurance that devices were actually safe and effective and said there was no evidence to support industry's claim that the system supported "innovation."

Instead of trying to improve a "fundamentally flawed" system, the experts recommended the FDA develop a new framework for medical device review.

Dr. David Challoner, a former university administrator who led the study, said his group came under fire from industry long before its findings were released.

He had assembled a 12-member panel of medical experts, including several device industry consultants. But the industry thought it should have more representation, said Challoner, who himself had previously served as a board director for a device manufacturer.

As the committee was finalizing its report, a University of Minnesota professor co-authored a paper in May 2011 arguing that the FDA could be "legally prohibited" from using any of the committee's recommendations because industry was not adequately represented. The paper did not disclose that the co-author, Ralph Hall, had previously been an executive for the device maker Guidant and had also worked for an industry lobbying group. Hall did not respond to multiple requests for comment.

In June, another industry ally weighed in. The conservative Washington Legal Foundation filed a petition to the FDA, saying the agency would be breaking the law if it took advice from a panel that was not "fairly balanced."

Richard Samp, the group's chief counsel, says his group intervenes when appropriate to urge agencies to follow the law.

By July 2011, the FDA rejected the findings of the report it had commissioned, saying its longstanding review process should stand.

The FDA said in a statement to the AP that it can—and sometimes does—require "exhaustive testing" for devices reviewed through the streamlined pathway, but that patient testing and clinical trials are not appropriate or needed for most lower-risk devices, such as syringes.

Lawmakers later introduced a flurry of industry-backed proposals that would have loosened FDA oversight. One failed measure would have even rewritten the FDA's mission to include "job creation."

Since then, the relationship between regulators and the regulated has grown closer.

Federal lobbying records analyzed by the nonprofit Center for Responsive Politics show that the 50 largest device manufacturers and trade groups have spent more than $140 million to deploy 450 lobbyists in Washington since 2013.

The industry's chief lobbyist—the Advanced Medical Technology Association, or AdvaMed—said there's no evidence that requiring additional patient studies would improve safety. Regarding Challoner, AdvaMed said the device industry "was nothing but supportive" and that his committee "failed to provide any meaningful recommendations" to

improve the FDA's review system.

In August 2015, AdvaMed lobbyists met with the FDA to discuss the group's "priorities for the year," according to an FDA memo of the meeting, first published by Inside Health Policy. At the meeting, AdvaMed and the FDA discussed how they had "worked together" on provisions of a bill then moving through Congress, the 21st Century Cures Act.

The measure, later signed into law, required the FDA to emphasize the "least burdensome means" for reviewing medical devices and to train staff in the concept. That effectively gave manufacturers a legally binding tool to challenge FDA requests for more information during the review process.

The FDA said in a statement that the "least burdensome" requirement is misunderstood and is intended to eliminate "outdated, unnecessary burdens." It does not change the agency's approval standards, the FDA said, adding that streamlined reviews are generally reserved for lower-risk devices that are not truly "new products." When appropriate, the FDA said, it requires patient testing.

In recent years, the FDA said, it has been "raising the bar" for certain devices, including insulin pumps used to treat diabetes. As a result, the average page count for a device application submitted for streamlined review has doubled since 2009 to more than 1,100 pages.

The closed-door meetings that helped produce the Cures bill, which included FDA and device lobbyists, were convened by staffers for Rep. Fred Upton, R-Michigan, who then chaired the House Energy and Commerce Committee. Upton has received more than $118,300 in campaign contributions from the device industry since 2013, federal records show.

Tom Wilbur, a spokesman for Upton, said the Cures bill was the result of "unprecedented" collaboration between various parties, adding, "We're proud of this bipartisan work, which is helping patients across the country."

AdvaMed said it does not write laws but is "routinely asked to comment on various concepts and policies that lawmakers and regulators are considering."

Meetings between the FDA's device division and industry are now routine.

The agency's public calendars show that since January 2017, the FDA's medical device chief has met with industry representatives more than 60 times, including at FDA headquarters and industry conferences. That's nearly six times the number of industry meetings attended by the FDA's drugs director in the same time frame.

Looking back, Challoner said he was "pretty naive" about the industry's influence.

Initially, he thought the device lobby was similar to the pharmaceutical industry, a handful of multibillion-dollar companies concentrated in a few states. But the device industry's geographic layout—and political clout—is much broader, including thousands of smaller firms in congressional districts across the country, he said.

"We really ran up against a political stonewall," Challoner said. "I don't think anything has changed since."

Reacting to Monday's announcement by the FDA, he said: "If the device industry comes back at this full bore with their lobbying efforts, this could all die a slow and painful death."