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Study of Medical Device Rules Is Attacked, Unseen

By **BARRY MEIER**

Allies of the medical device industry are waging an extraordinary campaign in Washington to discredit a coming report by one of the country's pre-eminent scientific groups that examines possible new regulations on the industry.

The scientific group, the [Institute of Medicine](#), is scheduled to release a report on Friday that could propose a tougher approval process for a wide range of devices like hip implants, hospital pumps and external heart [defibrillators](#). The report, commissioned by the Food and Drug Administration, comes after several well-publicized recalls in recent years of devices that have failed in thousands of patients, causing numerous injuries.

But a business group and others have taken the highly unusual step of making a pre-emptive strike, arguing that the report is biased. That attack began even before the study panel finished its review, and has intensified in recent weeks.

Device producers have also released a series of their own reports that say more regulation would slow innovation, harm patients and cost jobs. An official of a group that represents surgeons who implant hips and other artificial joints has also voiced support for a recent filing by a pro-business organization that challenged the scientific report's credibility and argued that the F.D.A. was statutorily required to ignore it.

Christine Stencel, a spokeswoman for the Institute of Medicine, which is part of the National Academy of Sciences, said the group was unaware of a previous instance in which one of its reports, sight unseen, was the target of a similar effort to invalidate it.

Dr. Sheldon Greenfield of the University of California, Irvine, who has served on several Institute of Medicine panels, said he was surprised by the campaign's intensity. "It is pretty audacious," he said.

The challenge to the panel has been led by Ralph F. Hall, a professor of law at the University of Minnesota and a device industry lawyer, who said the criticism was not an attempt to front-run

the report's conclusions but rather to air legitimate concerns about how the review had been conducted.

"I could have waited until the report came out," Mr. Hall said in an interview. "That seems intellectually less than satisfactory with me."

Medical experts said the institute's study, regardless of how it falls, was likely to have a significant impact on patient safety, device effectiveness and the speed at which new products reached the market.

With millions of dollars of product sales at stake, the experts said, it is not surprising that the device industry and others would want to avert what they see as potentially restrictive new rules. Still, the lobbying has taken on a tone akin to Washington infighting over an issue like bank regulation, rather than patient health, they said.

"We are trying to get to good policies, and the spin game doesn't help us," said Dr. Harlan M. Krumholz, a professor of medicine at Yale who has served on a different Institute of Medicine panel.

The Institute of Medicine is a widely respected organization that assembles experts to study a range of health-related issues, often at the request of government agencies. In 2009, the F.D.A. contracted with the group to review the adequacy of one of the two regulatory pathways through which it approves medical devices, a process known as 510K.

Some devices, like implanted heart defibrillators, undergo clinical trials in patients before they can be sold. But most medical devices, including implanted hips, go through the 510K route. Under that pathway, a producer need show only that a new product is "substantially equivalent" to one already sold to gain approval.

For example, so-called metal-on-metal artificial hips, which are currently the subject of scrutiny and lawsuits, appeared to work well when tested only on mechanical simulators but then failed disastrously when implanted in patients.

The 12-member review panel assembled by the Institute of Medicine included physicians, academics and two lawyers who had worked for device makers on regulatory issues. Another lawyer on the panel, Brian Wolfman, who once worked for Public Citizen, a consumer advocacy group, has come under particular attack by business-affiliated groups.

Mr. Wolfman and several other panel members declined to be interviewed for this article or did not respond to telephone calls or e-mails.

Last month, the Washington Legal Foundation, a pro-business group, filed a petition with the F.D.A. arguing that the agency was statutorily barred from adopting any of the report's recommendations because of what it claimed was the panel's bias. The legal foundation argued that the Institute of Medicine had failed to balance the panel by including officials from industry, the investment community or patients who had benefited from devices.

"We wanted to let F.D.A. know that there are significant concerns with the composition of the committee," said Richard A. Samp, a lawyer for the legal foundation.

Mr. Samp said his organization took action after the issue was brought to its attention by a lawyer who works at a firm that represents device makers. Shortly after filing its petition, the legal foundation was contacted by an official of the American Academy of Orthopaedic Surgeons, which represents doctors who perform joint replacements, who congratulated it for "taking the bull by the horns," Mr. Samp said.

A spokeswoman for the doctors' group confirmed that one of its officials had called Mr. Samp, adding that it was concerned that the Institute of Medicine panel did not include a practicing surgeon.

William Skane, a spokesman for the National Academy of Sciences, said the group worked hard to balance its committees and barred people from serving on a panel if they had a financial conflict of interest or a clear bias on an issue.

Dr. William Maisel, the chief scientist of the F.D.A. division that oversees medical devices, said the agency was satisfied with the panel's makeup.

"I think it would be difficult to find a more reputable scientific organization than the Institute of Medicine," Dr. Maisel said. He added that the F.D.A. was not bound to accept the report's recommendations.

Over the last year, the panel charged with reviewing device approvals has also held hearings to gather feedback and data from all interested parties, including device producers and investors.

Earlier this year, Mr. Hall, the lawyer and Minnesota professor, wrote an article with a colleague, arguing that the Institute of Medicine, in selecting its panel, had violated a little-known rule, the Federal Advisory Committee Act, which requires balance on such committees.

In the interview, Mr. Hall acknowledged that he had worked either directly or in the same law firm with the two lawyers on the panel who had advised device makers on F.D.A matters.

At a Congressional hearing this month, the editors of two medical journals — The Journal of the

American Medical Association, The New England Journal of Medicine and the Archives of Internal Medicine — questioned the value of two industry-backed studies that claimed that new regulations would create hardships for patients and producers, describing them as methodologically flawed.