Medical device makers spend millions lobbying to loosen regulations in D.C.
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After Teresa Hershey nearly died from complications of a hysterectomy, she wanted future patients to know about the potential dangers of choosing robotic surgery for the operation. In 2013, the California woman added a detailed account of how the robot that operated on her had burned a hole in her bowels to a database maintained by the Food and Drug Administration.

The database is meant to warn the medical community about the risks associated with medical devices. Hershey’s was one of hundreds of similar accounts about the same robotic device.

But earlier this year, the FDA made a rule change that could curtail that database, which was already considered to be of limited scope by medical researchers and the FDA itself.

The new rule, which had been sought by medical device manufacturers, opens the door for a decrease in reported information for nearly nine out of 10 device categories, an NBC News analysis found. It could allow manufacturers to submit quarterly summarized reports for similar incidents, rather than individual reports every time malfunctions occur, meaning there will be much less detail about individual cases.

“They’re taking away the detailed reports,” said Hershey, who is now an advocate, working with other victims harmed by devices. She sued the maker of the robot, and the suit was settled in May. She was among those who voiced their opposition to the rule change to the FDA, writing to the agency that she believed it would lessen what the public could learn.

While her own report would not have been affected, she is concerned about the level of detail in reports from device makers, which form the vast majority of the database. “If they take that out, we’re not going to know what’s going on. Why
do we even have the reports in the first place?"

The new rule is one of several regulatory changes favoring the medical device industry that have been proposed and enacted since the beginning of the Trump administration. They are part of a decades-long campaign to decrease U.S. regulation of the industry — a massive global business that has existed for years with minimal international scrutiny.

An NBC News analysis of the 10 largest publicly traded medical device companies in the U.S. found that since the start of the Trump administration, the companies have spent more than $36.5 million on efforts to influence rules and legislation. Some of these companies manufacture a variety of medical products, including pharmaceuticals and lab equipment, but four of the 10 exclusively manufacture devices and lobbying disclosures for all 10 emphasize efforts to influence policy around devices.

BUILDING A PRESENCE IN WASHINGTON

The medical device industry was worth $405 billion worldwide in 2017, according to an Accenture market analysis. Despite its size, the medical device industry has only a patchwork of international oversight, even though when things go wrong with a device, the consequences can be serious.

But the single largest medical device market in the world is the U.S., worth an estimated $156 billion in 2017, according to the U.S. Department of Commerce. As the medical device market has boomed over the past several decades, the industry has built a sizable presence in Washington, D.C.

Many medical device companies have built sophisticated lobbying arms, often employing their own team of lobbyists in addition to hiring outside firms for specific issues. Several of the largest companies used between 15 and 50 lobbyists in 2017 alone, an analysis by the Center for Responsive Politics (CRP) found.

There are also two main trade groups for the industry to which device makers contribute membership fees to, both of which pack a hefty lobbying punch on their own. Since the start of 2017, the Advanced Medical Technology Association
(AdvaMed), the older and larger group, has spent more than $6 million and the Medical Device Manufacturers Association (MDMA) has spent nearly $2.6 million. The groups’ policy goals echo those that individual companies list on their lobbying disclosures, among them: decreasing taxes on devices, increasing insurance coverage and reimbursement and the FDA’s approval process for bringing a device to market.

The medical device lobbying effort is vast, with lobbyists seeking to be heard on Medicare and Medicaid reimbursement codes, device purchasing policies at the Veterans Administration, even cybersecurity and trade issues. Companies regularly lobby Congress, but also target agencies and offices across the executive branch, from the FDA to the Center for Medicare and Medicaid and the National Security Council.

Altogether, the industry has spent more than $20 million per year for the past five years lobbying the federal government, according to an analysis of campaign finance and lobbying data from CRP.

With the change in administration in 2017, that spending increased to more than $26 million, $2.2 million more than its highest level in any of the previous four years. Based on disclosures from the first three quarters of the year, medical device lobbying in 2018 is on pace to exceed 2017 levels.

An industry spokesperson noted that the U.S. pharmaceutical industry spends more heavily on lobbying than the device industry. Big Pharma, which was worth more than $453 billion in the U.S. in 2017, spent more than $171 million the same year — more than six times as much as the device industry, according to a Statista market analysis.

The lobbying resources of the device industry far outweigh those of consumer and patient advocates, which are often on the other side of regulatory debates on Capitol Hill. Very few advocacy groups spend time lobbying on devices, said Dr. Diana Zuckerman, a former HHS official under Obama and president of the National Center for Health Research, a nonprofit advocacy organization based in Washington.

“When we’ve talked to congressional staff about this,” she
said, “they say things like, ‘Well, we’re getting calls every day, all day long from various device companies or their lawyers,’ and the nonprofits are basically going to the Hill for visits a few hours a year.”

Zuckerman’s group is one of about a half dozen to lobby on devices over the past few years. Each of the largest spends no more than a few-hundred-thousand dollars annually to lobby on devices and all other consumer issues, according to their federal lobbying disclosures.

Trial lawyer groups, which the device industry spokesperson noted often sue device makers, also spent less than one third of what the device industry did in 2017, a CRP analysis found.

NBC News contacted the three companies that have spent the most on lobbying in the past five years to ask about their lobbying efforts. Baxter International and Abbott Laboratories did not comment. Medtronic said, “Despite the company nearly doubling in size, our lobbying-related efforts over the last 10 years have remained relatively stable.”

Previously, Abbott, Medtronic and a half-dozen other international device makers told the International Consortium of Investigative Journalists that they conduct business with the highest ethical standards, adhere to all laws and have rigorous programs to prevent employee misconduct.

In a statement to NBC News, Mark Leahey, president of MDMA, said, “As millions of Americans benefit daily from the more than 190,000 different medical devices available and in use in the United States, our members continue to work with patient groups and policy makers to advance policies that promote improved access for patients and providers. This dynamic innovation ecosystem remains committed to developing the cures and therapies of tomorrow, while reducing adverse events and learning from ongoing research and each patient’s experience.”

**OBAMA VERSUS TRUMP**

During its eight-year tenure, the Obama administration permitted some deregulation but also instituted the first FDA product ban since the 1980s.
Beginning in 2014, warning letters to industry began to drop steeply and approval of new devices to rise. By 2017, the number of FDA warning letters to device manufacturers about product safety had dropped to nearly 80 percent less than those issued in 2010, while approval numbers for new devices were more than three times as high as at the beginning of the decade. The FDA says the decrease in warning letters is due to a more interactive approach to working with violative companies, and the uptick in approvals is due to an increase in staffing and efficiency.

Under Obama, some FDA regulators responsible for overseeing the device industry pushed for deregulation. Administrators largely kept it in check, said Peter Lurie, an FDA associate commissioner during the Obama administration.

“It was accompanied by very heavy lobbying on Capitol Hill as well,” said Lurie. Priorities included faster device approval times and decreasing taxes.

During Obama’s final year in office, the FDA banned its first device in more than 30 years — a type of surgical glove — and proposed a ban on a home shock collar for behavior modification. That ban is still pending.

The industry successfully pushed for changes in a proposed regulation on unique device identifiers — identification codes for individual devices, similar to automotive vehicle identification numbers, and won the suspension of a tax on medical devices created to help fund the Affordable Care Act.

“Now with the advent of the Trump administration,” said Lurie, “the deregulatory gloves are off and we’re seeing a number of the device industry’s most desired objectives come to fruition.”

President Trump vowed to cut regulations across the government by 75 percent when he came into office.

Since he took office, the industry has successfully pushed for making device alternatives to opioids easier to pay for. It also negotiated a decrease in approval times for certain devices.
In 2002, Congress instituted a program in which the device industry pays “user fees” to fund the FDA office that oversees it, amounts which are agreed upon in negotiations between industry and the regulator every five years. Its first year, the fees provided 10 percent of funding for the device center, but by 2018, the fees brought in more than $153 million, providing more than 35 percent of the center’s budget.

“It’s carefully negotiated for weeks and months at a time,” said Jack Mitchell, former director of Special Investigations for the FDA. “And there’s a laundry list of things that industry gets FDA to agree to and that they’re paying for.”

If the most recent agreement, negotiated in 2017, had not gone through by the deadline, the agency would have legally been required to temporarily layoff at least one third of its device center staff. The final agreement included a decrease in approval time for certain devices.

“We do not believe user fee funding has influenced our decision making,” the FDA said in a statement, noting that other parts of the FDA are also funded by user fees.

The agency also noted that it held meetings with patient stakeholders in addition to industry when negotiating the user fee agreement, saying, “Patients are a critical part of the user fee process.”

The FDA emphasized that it does not always agree with the industry, citing as examples its support of legislation that makers of reusable devices provide instruction on how to prevent bacterial contamination with devices and of including device identifier codes in insurance claims forms.

‘IT MAKES THINGS EASIER FOR INDUSTRY’

The changes to how adverse events are reported was also an industry success.
The FDA database in which Hershey entered a report of her near fatal surgery complication back in 2013, called the Manufacturer and User Facility Device Experience Database, includes more than 750,000 incidents per year. The adverse events range from minor malfunctions to patient deaths linked to products being used around the world.

Despite its size, it’s widely accepted that the database is only a partial picture of the full scale of device complications.

The rule went into effect in August. The FDA said in a statement in November that though the reports are valuable, they were never meant to be sole source for determining if a device is causing harm.

“This type of reporting system has notable limitations,” said the FDA, “including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data.”

Patients like Hershey can report adverse events to the database themselves, but few know to do so. Companies are required to report the events. They don’t always do so.

The FDA said a third of all warning letters to device makers were to companies that failed to meet rules for reporting complications with devices.

The more companies that fail to file properly, the less the database accurately reflects what is happening to patients with devices.

Under the rule change, companies could be allowed to submit quarterly summarized reports for similar incidents, rather than individual reports each time malfunctions occur. Previously, qualified manufacturers could submit summarized reports if they filed a request with the agency. Now they can do so without making a request.

“[The database] is the way we’ve learned about some very serious health issues,” said Rita Redberg, a cardiologist at the University of San Francisco who studies adverse events like Hershey’s. “It’s the most widespread and publicly available database for adverse events, which is extremely important for patient safety.”
In a public comment in support of the rule change, AdvaMed called the change a “commonsense approach” that will reduce the volume of reports manufacturers need to submit to the FDA and streamline the information the FDA receives about malfunctions.

“This process will actually make it easier for third parties to assess the malfunction data in [the database],” said Greg Crist, a spokesperson for AdvaMed. “Comparing the old alternative summary reporting program to this new initiative is comparing apples to oranges.”

In response to public comments that critical report information would be lost with the change in reporting, the FDA wrote in the published rule that, “We do not believe there will be an adverse impact on the content of information provided to FDA.”

In a statement, the agency said the new program “streamlines the process for reporting of device malfunctions and allows us to more efficiently detect potential safety issues and identify trends. It also frees up resources to better focus on addressing the highest risks.”

But Redberg, the cardiologist, is worried that the new rule change will make searching an already unwieldy database more difficult, decreasing the ability of researchers and the public to search for misfiled reports or see accurate numbers of adverse events.

“It makes things easier for industry, it makes things worse for patients,” she said. “I really think it’s a public health crisis. We have more and more devices in use, and for many of them we really have no idea how safe they are because we don’t have accurate reporting.”

Incorrect. There are numerous data sources on device performance including FDA, manufacturers, patient and physician societies, etc.

The number of reported malfunctions will not change, some will just be in summary form. New types of malfunctions will still require individual reports.