MEDTECH INSIGHT
CITELINE COMMERCIAL

10 Jan 2022 | **Analysis**

Right To Repair Proponents Gearing Up To Fight In State Legislatures Again

by Ferdous Al-Faruque

Groups advocating to force medtech manufacturers to provide tools and manuals to service their products are renewing efforts in state legislatures despite recent losses.

Right to repair proponents are gearing up for another year of legislative battles to push through bills that would force medtech manufacturers to give third parties the ability to service their products.

Advocates admit it's an outsized fight, casting themselves as "David versus Goliath," but they aim to pass bills in states like Pennsylvania and California that they hope will have a domino effect.

Over the past few years, right to repair campaigners around the country have been lobbying to get bills passed in state legislatures to require manufacturers to provide access to parts, service manuals and tools required to repair products. While much of the focus has been on consumer electronics, cars and farm equipment, many of the bills also target medical devices.

Proponents argue that hospitals' and third-party servicers' inability to repair medical devices on their own inconveniences and delays patient care, while giving manufacturers carte blanche to charge whatever they choose even for minor repairs. The medical device industry contends that giving unfettered access to their products could hurt patients, weaken cybersecurity on connected devices and endanger their intellectual property.

Barbara Maguire, vice president for quality at ISS Solutions, a subsidiary of Geisinger Health Management, says the Pennsylvania hospital system her company services would save $15m a year if they could repair devices in-house.

"We're not asking to have unqualified people tinker with medical equipment," she told Medtech

Insight. “We have qualified technicians on site.”

“These are technicians who have associate’s and bachelor’s degrees in electronics and computer science and then they go through additional training for the specific type of medical equipment they are working on,” Maguire added. “We’re agreeable if manufacturers say, ‘You can only work on this equipment if you’ve taken our training class.’ And they make that training available to us at a reasonable cost.”

> *In Pennsylvania, Republican state Sen. Elder Vogel has already introduced a right to repair bill, and a hearing is expected in late January or early February, according to Kevin O’Reilly.*

The right to repair issue came to the fore in 2012 when Massachusetts passed a law that forced automobile manufacturers to provide manuals and tools to consumers and third-party servicers. Since then, the issue has grown to encompass other industries.

By 2015 four states introduced right to repair bills, and that number jumped to 27 last year, though only two of those measures passed through committee in New York and Arkansas, only to fail before getting a full vote. Another measure in California saw significant momentum but also eventually perished, according to Kevin O’Reilly, director for the right to repair campaign at the US Public Research Interest Group (US PIRG).

At the federal level, US Sen. Ron Wyden, D-OR, and Rep. Yvette Clarke, D-NY, floated right to repair bills in their respective chambers in 2020 but failed to make headway and eventually decided against reintroducing the bills.

O’Reilly says support for such bills has been steadily increasing nationally, despite opposition from big industry names with deep pockets, because lawmakers are hearing from a coalition of constituents about hurdles they face, including tinkerers, repair shops, environmental advocates, farmers and biomedical repair technicians. .

"There are really powerful interests that want to maintain complete control of the repair market because that allows them to charge whatever they want and it allows them to dictate consumer behavior with premature obsolescence," said O’Reilly.

Companies lobbying against right to repair legislation include multinational corporations, and in

total O'Reilly estimates they are worth more than $10.7 tn.

"That power, the amount of influence these companies garner is just difficult to overcome, which is the main reason you haven't seen a right to repair bill passed yet," O'Reilly said.

"This is a David versus Goliath story," he added. "Maybe a David versus five Goliaths when we're up against Apple and Amazon and Phillips. This is just people who want to fix things, and who want to make sure things can be fixed, up against some of the most powerful companies in the world."

Despite the formidable opposition, O'Reilly believes the right to repair side is winning in the court of public opinion. He says US PIRG's 2019 YouGov polling of more than 1,000 registered voters shows 71% of those surveyed supported right to repair legislation and 7% opposed. The remaining respondents didn't have an opinion either way. The same polling found 65% of democrats supported right to repair legislation, as did 73% of independents and 76% of Republicans.

With that in mind, O'Reilly and other right to repair advocates are feeling motivated to again start pushing for bills around the country.

"It's the beginning of the year so legislatures are preparing to present a new onslaught of bills across the country, and we are getting ready for that to happen," he said.

In Pennsylvania, Republican state Sen. Elder Vogel has already introduced a right to repair bill, and a hearing is expected in late January or early February, according to O'Reilly.

"That's going to be a big moment where advocates and opponents are going to come out and speak about the bill, and that could have a big impact on how that bill is going to go," he said.

O'Reilly says California Democratic state Sen. Susan Eggman plans to reintroduce a medtech right to repair bill that failed last year, but he's optimistic that it has a good chance of advancing in the current session.

"There are a lot of things in talks, but from Hawaii to Missouri to Florida to maybe even Minnesota, there are just states across the country where we've received interest from legislators," he added.

Industry Maintains 'Serious Concerns'

Peter Weems, director of policy and strategy at the Medical Imaging & Technology Alliance (MITA), says the issue is really about patient safety, cybersecurity and intellectual property.

"Essentially what these policies would require is that medical device manufacturers and innovators hand over their proprietary intellectual property to their unregulated competitors for free," he said. "This raises a number of serious concerns from our perspective."

Weems notes that currently the US Food and Drug Administration regulates and oversees servicing by manufacturers, but not third-party service providers, to ensure the safety and efficacy of their products. He says that's an issue that MITA has been working with the agency and Congress to rectify so that everyone is regulated on a level playing field. The right to repair policies being proposed would only make things worse, he says.

Weems argues that unlike with other products, if a medical device servicer makes a mistake during a repair, it could have life or death consequences. He also argues that as medical devices become increasingly connected, allowing greater access could mean more opportunities for hackers to break into a product to hijack patient data, harm patients and steal intellectual property.

"We are not opposed to third-party servicing," said Weems. "We are not trying to put anybody out of business or shut out the third-party servicing industry. Our primary concerns are protecting patient safety and making sure our devices are working properly."

> ***"When we're talking about an x-ray system where the radiation controls have been bypassed, that's not the kind of thing that would have been solved whether or not whoever did that had a service manual." – Peter Weems***

He also says a major consideration is that health care providers, manufacturers and servicers have innumerable contractual arrangements already in place across the country that would be negated by right to repair bills requiring manufacturers to share sensitive information and tools.

Weems says a lack of medtech right to repair bills hasn't hurt competition for the estimated 16,000 to 20,000 medical device servicers around the country. Many of them work with manufacturers to service their products, but at the end of the day they don't play by the same regulatory rules the manufacturers do.

"Where we want to get to is a place where third-party servicers are registered with the FDA so the FDA knows who they are, where they are and what they're doing," he said.

Ultimately, he says manufacturers want servicers to be required to report adverse events to the FDA so the agency has data on the quality and safety of the servicers, and have a quality management system in place.

"We've seen some very egregious instances of devices being mangled by unregulated third-party servicers," said Weems. "When we're talking about an x-ray system where the radiation controls have been bypassed, that's not the kind of thing that would have been solved whether or not whoever did that had a service manual. That's the kind of thing that comes back to having basic quality and safety control processes in place."

Already, right to repair advocates have been able to achieve a rule through the Federal Communications Commission that changes the Digital Millennium Copyright Act to allow hacking of devices in order to repair them. He says this essentially allows anyone to hack a device and gain access to the manufacturer's intellectual property.

"This raises a host of concerns about patient safety, cybersecurity, and IP," said Weems. "We're reviewing it and thinking through potential remedies."

Barbara Maguire at Geisinger doesn't buy the argument that requiring such access poses a real cybersecurity risk.

"You need other people at the hospital who understand how the equipment works to ensure cybersecurity," she said. "If anything having qualified people at the hospital improves cybersecurity and even the FDA has said [cybersecurity of medical devices] should be a partnership."

Maguire is still hopeful that industry will eventually sit down with right to repair advocates to find a workable compromise. She says not all manufacturers are against giving third-party vendors and hospitals access to their devices, but as devices have become more computerized companies increasingly are using passwords and access keys to limit ability to repair products, she said.

"There are still some manufacturers that freely provide training, they sell us parts, they see a value in having that partnership with the hospital," said Maguire. "And then there are manufacturers we think intentionally limit repair access in order to protect their revenue for service."

Maguire also doesn't agree that without added oversight manufacturers will take on greater liability when things go wrong.

"Any time a medical device fails there's shared liability between the clinician using it correctly,

the hospital servicing it correctly, and the manufacturer designing it and building it correctly," she said. "Of course, the manufacturer wouldn't be held liable for a repair that someone else did, and I think it reduces their liability if they partner with hospitals to properly prepare and equip the people on site to repair the equipment correctly... I think it reduces their liability because it reduces the likelihood that a repair could be done incorrectly."

There of course are questions of revenue and costs that manufacturers and servicers have to take into consideration as each side argues for or against access to medical devices.

Maguire says if hospitals are unable to service their equipment, they may need to cut costs by having fewer in-house servicers. While she estimates a typical repair done by the manufacturer costs between 15-20% of the value of the equipment, in-house repairs typically costs 6-8% with much shorter response time.

Maguire gave the example of an operating room light at one of Geisinger's hospitals, which broke down recently due to a minor issue that could easily have been fixed in-house; instead, the device was out of commission for three weeks until the manufacturer could send a servicer to fix it. In the meantime, the hospital had to find workarounds so they could continue to treat patients in the room.

Similarly, she said a piece of lab equipment recently went down, needing just a simple module replacement, but the manufacturer isn't willing to sell it, and the hospital is still waiting to hear from the company on the next step.

No MOU Without Legislation

If proponents are able to get a medical device right to repair bill passed in just one state, US PIRG's Kevin O'Reilly expects it to result in an industry-wide memorandum (MOU) of understanding similar to what the automobile industry adopted after the 2012 Massachusetts bill. That MOU essentially meant car manufacturers would voluntarily provide access to their products nationwide in order to avoid a patchwork of bills that may have differing requirements.

O'Reilly says the medtech industry in the past told right to repair proponents they were willing to discuss development of an MOU to avoid the issue being legislated.

"The important thing to note is that we've seen manufacturers across industries come forward and say they want to engage in negotiations about an MOU ahead of a bill passing but none of those efforts has been in good faith," he said. "They essentially amounted to stall tactics."

"What we've learned is yes, maybe an MOU is the way to get this problem solved, but it won't happen without legislation," he added.