HOSPITAL REPAIR RESTRICTIONS

Manufacturer-imposed barriers to fixing medical equipment cause inefficiencies and delays

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EXECUTIVE SUMMARY

COVID-19 is putting incredible stress on the U.S. medical system, including the work of hospital biomedical repair technicians, known as biomeds or BMETs. These technicians are essential; hospitals need working equipment to diagnose and treat patients. But in some cases, manufacturers restrict access to what biomeds need.[1]

As ventilators are pressed into around-the-clock use, repair and maintenance issues will increase.[2] While some ventilator manufacturers provide service information, other manufacturers make it hard to access manuals, read error logs or run diagnostic tests.[3]

We should remove each and every unnecessary barrier to repairing essential medical equipment, especially ventilators. If manufacturers won't remove these restrictions, public officials should require them to do so. Restrictions to fixing medical equipment are similar to tactics used by Apple and John Deere[4] to control repair marketplaces, and include:

- Requiring a password or service key to read diagnostic information
- Refusing to provide access to service manuals (some manuals are also password protected, others require an updated service contract to access)
- Designing machines to require calibration software to activate new spare parts, and then not making that software available
- Restricted access to specialty training

In order to determine how widespread repair restrictions are, and the extent to which restrictions impacted work under the stress of COVID-19, U.S. PIRG Education Fund surveyed 222 biomedical professionals. Nearly half reported they had been denied access to "critical repair information, parts or service keys" since March.

Manufacturers claim that these restrictions are in place to ensure patient safety.[5] However, manufacturers also benefit financially by limiting repair, giving them the incentive to cite safety concerns even without data to back up such claims.[6] In addition to higher costs, fewer options can lead to bottlenecks, especially in a time of crisis.[7] Federal regulators should make their own determinations for safe operation of equipment, separate from industry pressure to protect service profit.

FINDINGS

Medical equipment, and the technicians that service it, are already regulated

Repair of equipment used in hospitals and care facilities is highly regulated. Medical devices or equipment must be approved according to stringent standards[8] set by the Food and Drug Administration (FDA), and also are subject to rules under the National Fire Protection Agency (NFPA).[9] In addition, there are rules under the Code of Federal Regulations (CFR) 21,[10] Occupational Safety and Health Administration (OSHA), The Joint Commission (TJC), and hospital or Accreditation Association for Ambulatory Health Care (AAAHC) standards.

In 2018, the FDA investigated whether additional regulation of independent repair was appropriate, but instead found that "the continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system." Instead of finding safety issues, such as has been suggested by manufacturer lobbyists, the FDA's report found that third party repair carries no additional risk and that both they and manufacturers "provide high quality, safe, and effective servicing of medical devices."[11]

The FDA investigation cites a comprehensive study from ECRI Institute, which reviewed 2.1 million device failure reports submitted to the FDA over the ten years. According to ECRI's research, only 0.005 percent of failures could be attributed to service or maintenance issues.[12] The report concludes:

> *Based on the results of ECRI Institute's detailed database searches spanning the past 10 years, and on its monitoring of medical device problems and hazards for more than 40 years, we do not believe that a safety problem exists with the servicing, maintenance, and repair of medical devices by either third-party organizations or OEMs.*[13]

Manufacturers claim safety is the main reason they don't want to provide access to service information, training, software, or sell parts on fair and reasonable terms.[14] But the FDA study shows that existing regulatory standards appear sufficient to guard patient safety.

In addition, the 2012 NFPA 99 Health Care Facilities Code, which is required by the Centers for Medicare and Medicaid Services, states that medical equipment manufacturers should provide, "schematics, wiring diagrams, mechanical layouts, and other pertinent data for the appliance," as well as, "preventative and corrective maintenance, inspection, and repair procedures."[15] [16] These rules are not being adhered to by manufacturers.

The Joint Commission, which provides hospital accreditations,[17] added new requirements, effective 2018, including that "The hospital has a library of information regarding inspection, testing, and maintenance of its equipment and systems. Note: This library includes manuals, procedures provided by manufacturers, technical bulletins, and other information."[18]

Given the standards which point to ready access to service information, it seems obvious that hospitals should not have to fight to get information such as a service manual or calibration instructions. So why does this problem persist?

INTERVIEW WITH BARBARA MAGUIRE

Maguire oversees the maintenance for all clinical devices at Geisinger's nine hospitals and other clinics, which total more than 80,000 devices. She has been outspoken about her support of Right to Repair. "Getting access to the tools necessary to maintain equipment—such as test equipment, test materials, service manuals, parts and training -- has always been an issue for us. We want to make sure we have people on-site at the hospital who are well trained and have all they need to provide the best support for our caregivers and patients. Some manufacturers are very cooperative with this ... but some manufacturers—and over the last three years, I would say an increasing number of them—have tried to restrict our access to the tools that we need."

Maguire points out that on-site technicians save precious time. In some cases, "we don't have manuals or we will contact the manufacturer for technical support or to order spare parts, and they refuse to provide that to us. Either they will have no technical support, or the only way to get spare parts is for the manufacturer to dispatch their own service person, and there can be a long wait for that. Obviously, these solutions are not ideal if you have critical equipment in use in the ICU or OR that needs immediate service." On-site repair has also aided their COVID-19 response. "We had ventilators which were in storage, and since we already had three technicians trained, they were able to get 50 ventilators back into service over a weekend. "

In addition to saving time and having "much lower costs," onsite repair improves overall safety. "We believe that having well-trained people on-site not only lowers costs and [allows for] quicker repair, but it allows the clinicians, the doctors and nurses, to have a local technical resource who sees the medical equipment in use in the hospital environment and can ensure it is used in a way that is safe and effective for patients. Just having that resource locally provides a better level of care."

Interviewed May 7, 2020 by Emma Horst-Martz. Image courtesy of ISS Solutions

How Repair is Restricted

Before our supply of ventilators was put under such stress, ventilator service—which would have included a regular maintenance schedule, in addition to fixing broken devices—happened

like other repairs done in a hospital. Some of that maintenance and repair was done by in-house technicians, some was done by third-party vendors, and some was done by manufacturers. Manufacturers have an incentive to limit options to benefit their own services, which typically cost significantly more.[19]

However, that system was forced to adjust to the COVID-19 pandemic, which has exposed the ways in which these restrictions on repair have made the system more fragile as a whole.

Technicians (biomeds) or HTMs (health technology managers) often go to decentralized online forums to get access to necessary service information, including repair manuals.[20] That wastes precious time.

- Justin Barbour, a Houston-area biomed, told Reason, "I can honestly tell you that we don't have service manuals for a lot of stuff … we rely on forums."[21]
- "In many cases the in-house HTM professional doesn't always have the manufacturer's support in terms of documentation, technical support and/or parts to name a few," David Francoeur, senior vice president of marketing and sales at Tech Knowledge Associates LLC told 1TechNation.[22]
- On online forums, technicians ask each other for necessary documents and information.[23]
- Barbara Maguire, who manages repair and maintenance for more than 80,000 devices across multiple Pennsylvania hospitals told PennPIRG, "Getting access to tools that we need to do repairs—such as test equipment, test materials, service manuals, parts and training—has always been an issue for us … Some manufacturers … restrict our access to the tools that we need."[24]
- James Linton, who runs a college training program for biomedical engineering, reported to U.S. PIRG Education Fund that the inability to access manuals is so common, it's part of his training process. Linton instructs students to fix devices for which he knows there are no available manuals, forcing students to attempt to pry the necessary service information from the manufacturer through repeated, pleading phone call to the OEM. He reports that students are often shocked at the lengths they have to go through to get the information they need, noting "I get a lot of angry students."[25]

Prior to COVID-19, medical equipment manufacturers were known to use copyright claims to curtail organized central resources of medical service manuals.

- A popular website for service manuals is FranksHospitalWorkshop.com—Frank is a biomed in Tanzania who has found that most of the hospitals he works for have a large percentage of broken equipment and little or no access to training or service information.[26]

- Frank's site contains many disclaimers that indicate where manufacturers have sent him notices demanding that he take down the manuals, including Drager and Tecme ventilators.[27]
- Most recently, Steris, a company that manufacturers medical sterilizers, sent a request to iFixit, asking them to take down repair manuals on their website.[28]

Manufacturers might have previously required that their technicians perform all repairs, but these technicians are no longer allowed in the hospitals to prevent spreading the virus.

- David Francoeur also noted, "In many situations, health care facilities are not allowing service representatives into their facilities to perform maintenance …"[29] which highlights the need for manufacturers to work more cooperatively and share information with those already in the hospitals with the skills to repair devices.
- In a letter from Boston Scientific, the company tells customers they will limit in-person technician service, but instead will offer to help interpret error codes and other service questions via telephone support.[30]
- A director of clinical engineering at a Dallas-Fort Worth area hospital reported to U.S. PIRG Education Fund that early during the pandemic, "We started calling out for service on some of our devices and vendors were saying that they were not coming in … we were really hurting at that point, because here we are at the whim of a vendor who says they're not coming in because of COVID-19. And we have equipment down and we have patients that still keep coming." For this expert, these situations underscored the need for more repair options outside of the OEM.[31]

Repair software tools are hard to come by.

- Hannes Rudolph, who has been working to refurbish broken ventilators for New York and New Jersey hospitals, told U.S. PIRG that when he replaced parts in Drager Evita ventilators, completing the repair required some kind of software tool that he didn't have access to. [32]
- Requiring calibration software to complete repairs is not unique to ventilators but is common across the medical equipment industry—especially for imaging equipment, according to Robert Kerwin of IAMERs.[33]
- One biomed, who asked to remain anonymous, described an issue with a software locking mechanism on ultrasound imaging machines. The technician reported: "If you took the screws out of the case to troubleshoot the equipment, there was a little booby trap switch that would activate the software and you would be locked out of the machine. You couldn't use that machine at all until someone from the manufacturer came to reset the equipment."[34]

Device-specific trainings are artificially limited

- GE requires completion of a four-day, in person training program to receive access to service information for its ventilators, a requirement it is now waiving for the pandemic (after significant public pressure).[35] [36]
- Dr. John Sandham, Chairman of EBME (Electronic and BioMedical Engineering) in the UK, reported on a webinar that GE also requires re-trainings, and Siemens forbids trained technicians from training other colleagues—only the manufacturer is allowed to train.[37]
- If hospitals and their subcontractors can't control which technicians are allowed to be trained, the result is a training monopoly. Hospitals report they would like to expand training for their biomed staff, but price and availability cause them to ration training (as was explained by CABMET President Leticia Reynolds on a CoPIRG webinar).[38]
- Training costs can be prohibitive. One biomed, in an interview with U.S. PIRG Education Fund, said that the maintenance training for one device was $28,000—approximately 80% of the cost of the whole device (around $35,000). [39]
- For some equipment, no training is yet available. According to another biomed, one dialysis manufacturer has yet to even create training programs for their newest machine, which limits repair to the manufacturer's own technicians.[40]
- Another clinical engineering manager, who gave this example on the condition of anonymity, described how restricted trainings during the pandemic nearly prevented their staff from maintaining ventilators. "The [ventilator] manufacturer requires our technicians to recertify every two years. If we miss our recertification, they require us to go back through the trainings again. Obviously in the midst of a coronavirus, I'm not going to send somebody to train because a) they've cancelled all the trainings but b) they have been working on ventilators nonstop. There is no reason to put a hurdle in for recertification and bar us from doing work. We're qualified to service them. Obviously, in the midst of a crisis, they won't send technicians out to repair them, so I would have been down ventilators in the midst of a crisis. That's just crazy."[41]

Lack of repair options can cause delays and patient safety issues.

- Sometimes when critical equipment goes out of service on-site service is the only option quick enough to serve patients' needs. Nader Hammoud, who is with the California Medical Instrumentation Association and manages a biomedical engineering team at a California hospital, recalled multiple times in his career when he had to go into the hospital in the middle of the night to fix a device. He reported that the doctors were waiting to use these devices, and if "you don't get that device up and running in an hour or two hours, that patient will die." He said there is no time to discuss with the manufacturer whether you have the right kind of contract.[42]

- The Dallas-Fort Worth area clinical engineering director echoed concerns around delaying patient care while waiting on manufacturer-service after being told that the hospital "biomeds are not allowed to work on the equipment." When the hospital's CT scanner went down, and OEM technicians were delayed in their response, this was especially concerning for the diagnosis of trauma patients—such as those in a car accident. She noted that in the case of trauma patients, "delay in patient care could cause more damage." "I feel personally that biomed is the first line of patient safety," said the expert, adding "Why don't you work with us? Why aren't you partnering with us better, so that we can help support one another? It is very stressful."[43]

These restrictions have painful consequences today related to servicing ventilators and to other key items in the Intensive Care Unit (ICU). Equipment from various manufacturers is being loaned, shipped and traded between facilities.[44] Ventilators are being retrieved from stockpiles and sent to hospitals for urgent use.[45] Biomeds in those hospitals need access to service information and training materials on fair and reasonable terms in order to keep devices working. [46]

Survey of 222 medical repair professionals shows restrictions are pervasive

U.S. PIRG and the U.S. PIRG Education Fund created a survey for medical device repair professionals and shared it with several biomed associations. Our survey sought to determine how common issues around repair restrictions are, whether or not these issues persisted under COVID-19, and how important Right to Repair reforms are to medical repair professionals.

Our survey highlighted a number of concerning issues. 30.4% claimed to have equipment in their facilities which could not be used due to restrictions on spare parts and service information. Meanwhile, 91.8% claimed they had been denied service information for "critical equipment (defibrillators, ventilators, anesthesia machines, imaging equipment, etc.)," with 16.9% reporting this happens "Most of the time," and another 47.5% reporting this happens "Somewhat frequently." Restricted access to spare parts is another issue, though less common than restricted information: 88.7% of respondents reported that manufacturers had refused to sell spare parts, with 4.5% reporting this happens "Most of the time," 36.2% reporting this happens "Somewhat frequently," and 48.0% reporting this happens, "Sometimes, but infrequently."

In addition, we asked questions specific to the last 3 months, under the COVID-19 pandemic, and the repair on ventilators. 69.5% of survey respondents handle ventilator repair within their departments. Of those that work with ventilators, 29.2% report that they currently have

ventilators that they cannot use because they lack access to parts and service information. 24.2% of technicians reported that they had been denied access to ventilator repair information since March, and 51.9% report that they have ventilators they could not service on-site if they broke.

It appears that ventilator repair is in better condition than medical equipment repair on the whole: 48.8% report they have been denied access to "critical repair information, parts or service keys" since March.

When asked how important Right to Repair is to their industry, 67% of respondents answered "Critical: Right to Repair a top issue facing field," and another 25.3% answered "Very important," for a total of 92.3%. No respondents said Right to Repair was "Not important."

DEBUNKING CYBERSECURITY CLAIMS

In addition to citing safety as a reason for denying access to repair for third parties, manufacturers have also claimed that independent repair poses a cybersecurity risk. Billy Rios, a recognized expert on medical device security, disagrees. He is the CEO of WhiteScope, a cybersecurity company that conducts research on medical devices and critical infrastructure. WhiteScope consultants were involved in the first FDA cybersecurity advisory and one of the first FDA 510(k) cybersecurity submissions.

Rios agrees that the need to address software vulnerabilities in medical devices is urgent. However, he notes that there are already accepted industry best practices for addressing these issues that in no way impact independent maintenance or repair of medical equipment.

Rather, equipment makers misrepresent repair as a cybersecurity concern to limit competition in the repair market, not because access to diagnostic software, device schematics, or replacement parts poses any cybersecurity risk. "The manufacturers' concerns are not the most important," Rios says. "Concern is shared between patients, doctors and manufacturers." When it comes to life sustaining and saving equipment, the priorities of OEMs are not exclusive. "This is about safety and saving lives. The doctors and the patients need to have a say in that calculation as well," Rios said.

And, as other concerns are taken into account, it becomes clear that it's not in hospitals' or patients' best interest to lose repair options. Rios spoke to U.S. PIRG Education Fund by phone in May, 2020.

Case law underscores need for industry wide change

A recent case in Texas highlights the issue: Red Lion Medical Safety Inc. et al v. General Electric (Red Lion Medical is a member of The Repair Association).[47] [48] In the case, the jury found that GE had been in violation of antitrust laws by refusing to allow independent technicians

employed by Red Lion and others to attend training required by GE as a precondition for accessing essential service materials.

We believe that anti-trust law could also be applied to cases where manufacturers refuse to sell service parts, diagnostics and tools to any potential competitor in the market for repair services—as forms of illegal tying agreements. According to Repair.org, these are the same tactics used widely in the consumer electronics, agricultural equipment and home appliance industries.[49]

CONCLUSION

It's time to give hospitals the Right to Repair ventilators and other equipment.

The coalition supporting Right to Repair, Repair.org, led by Gay Gordon-Byrne, includes third-party medical device repairers.[50] In some states, hospitals have supported pro-Right to Repair legislation.[51] But medical device manufacturers have lobbied extensively against the Right to Repair,[52] and in many cases they have successfully convinced lawmakers to exempt medical equipment from pending state reforms.[53]

Manufacturers claim safety is the main reason they don't want to provide access to service information and software, or sell parts on fair and reasonable terms.[54] The FDA has found that there do not appear to be safety concerns under the current regulatory environment—that additional, manufacturer imposed regulations are, apparently, not necessary. [55]

Even when available, the service manuals for many newer model products exclude schematics necessary for certain repairs.[56] Biomeds told iFixit that GE has two levels of service documentation—one "dumbed-down" version to share with the hospital, and a full service manual for GE's internal use.[57]

Meanwhile, throughout the coronavirus pandemic, public support for manufacturers granting the Right to Repair for ventilators has been growing. U.S. PIRG has collected and delivered 43,915 petition signatures to manufacturers calling for them to release service information for ventilators,[58] and that call was echoed later by a group of state treasurers.[59]

Right to Repair reforms are common sense, and deeply rooted in American antitrust laws.[60] The problems facing hospitals trying to fix medical equipment only underscore the fragility and senselessness of creating a network of critical equipment—from our computers and cell phones,

to tractors and networking equipment—and then allowing manufacturers to monopolize repair of that equipment.

Recommendations:

Manufacturers should immediately publicly share all resources required to fix medical equipment, and no longer prevent sites such as frankshospitalworkshop.com or iFixit from acting as organized repositories. And if manufacturers won't, regulators or legislators could take the following actions to require them to:

- During these extraordinary times, governors should use emergency powers to compel cooperation when presented with local instances of manufacturers not providing access to service information.
- The FDA should clearly require manufacturers to provide service information needed to safely repair devices to in-house and independent servicers whom the hospitals engage.
- The FTC should assign a permanent liaison to the FDA to monitor the medical device industry for unfair market restrictions.
- As states possess authority on public health matters, and given the extraordinary importance to patients, hospitals, and independent businesses, state legislators should pass model Right to Repair reforms for medical equipment.

METHODOLOGY

This survey was taken by 222 biomedical repair professionals and was conducted online beginning in May 2020. A link to the survey form was sent by biomedical associations and hospital networks to their members across the country, as well as with biomedical repair professionals who had previously engaged with U.S. PIRG. Participation was voluntary, and all data was self-reported by respondents. Additional interviews were conducted with participants to gather the anecdotes published in this report. The survey collected additional information about the respondents beyond what is covered in this report.

APPENDIX

Additional questions and responses to our survey:

What best describes your employer?	# of responses	% of responses
Hospital-based HTM or Hospital-based HTM / CE	164	73.9%
Multi-site or offsite Independent Service Organization / Independent Repair Provider	50	22.5%
Original Equipment Manufacturer	3	1.4%
Other	5	2.3%

How often do manufacturers deny access to service information for critical equipment (defibrillators, ventilators, anesthesia machines, imaging equipment, etc.) you or your client had purchased?		
Most of the time	37	16.9%
Somewhat frequently	104	47.5%
Sometimes, but infrequently	60	27.4%
I have never had this happen	9	4.1%
Not sure	9	4.1%

How often do manufacturers refuse to sell you spare parts?		
Most of the time	10	4.5%
Somewhat frequently	80	36.2%
Sometimes, but infrequently	106	48.0%
I have never had this happen	17	7.7%
Not sure	8	3.6%

Do you fix ventilators in your department? (If yes, answer questions below)		
Yes	153	69.5%
No	67	30.5%

(If "Yes" To Ventilators) Do you have ventilators that you cannot put into use because you lack access to parts and service information?		
Yes	45	29.2%
No	65	42.2%
Not sure or N/A	44	28.6%

(If "Yes" To Ventilators) Have you been denied access to repair information, training, parts or service keys for ventilators since March?		
Yes	37	24.2%

No	65	42.5%
Not sure or N/A	51	33.3%

(If "Yes" To Ventilators) Do you have ventilators in your HDO that you could not service on-site if they broke?

Yes	80	51.9%
No	41	26.6%
Not sure or N/A	33	21.4%

Do you have any critical equipment (defibrillators, ventilators, anesthesia machines, imaging equipment, etc.) that you cannot put into use because your HDO lacks access to parts and service information?

Yes	66	30.4%
No	95	43.8%
Not sure or N/A	56	25.8%

Have you been denied access to critical repair information, parts or service keys for medical equipment since March?

Yes	106	48.8%
No	50	23.0%
Not sure or N/A	58	27.1%
Other	3	1.4%

How important is Right to Repair to repair to your work?

Critical: Right to Repair a top issue facing field	148	67.0%
Very important: Issues around repair restrictions are a persistent problem	56	25.3%
Somewhat important: Right to Repair would improve efficiency and/or provide other benefits	16	7.3%
Somewhat unimportant: Right to Repair provides only slight benefits	1	0.5%
Not important	0	0.0%

END NOTES

[1] Jason Koebler, "Hospitals Need to Repair Ventilators. Manufacturers Are Making That Impossible," Vice, March 18, 2020.

[2] M. Chatwin, S. Heather, A. Hanak, M. I. Polkey, A. K. Simonds; "Analysis of home support and ventilator malfunction in 1,211 ventilator-dependent patients," European Respiratory Journal, January 2010.

[3] Markian Hawryluk, "As Ventilators Become Crucial In Saving Lives, Repair Roadblocks Remain" Kaiser Health News, April 17, 2020.

[4] Jeff John Roberts, "One Controversial Thing Tractors and iPhones Have in Common" Fortune, June 29, 2017.

[5] Ibid 3, Hawryluk

[6] Susan Decker, "Broken Ventilators Spark Push to End Limits on Who Can Fix Them," Bloomberg, May 2020.
[7] Testimony of Nader Hammoud, May 18, 2020, recorded here: https://drive.google.com/file/d/1Z5FrI-cdFl8UHJZeHY51--81x3F_NOyS/view
[8] "Biomedical Engineering: FDA Regulations," Case Western University. Accessed May, 2020.
[9] Health Care Facilities Code, National Fire Protection Association, Accessed May 2020.
[10] Code of Federal Regulations Title 21, U.S. FDA, Accessed May 2020.
[11] "FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices," U.S. FDA, May 2018.
[12] "ECRI Institute's Comments on FDA–2016–N–0436," ECRI, March 4, 2016.
[13] Ibid 12
[14] Ibid 1 (Koebler)
[15] Ibid 9, Section 10.5.3, page 96
[16] "Life Safety Code & Health Care Facilities Code Requirements," Centers for Medicare and Medicaid Services, Accessed May 2020.
[17] Joint Commission Website, accessed May 2020.
[18] Joint Commission EC 01/01.01 EP 3 (2018), Accessed from https://medimizer.com/can-device-manufacturers-withhold-documentation/ May 2020.
[19] Nathan Proctor, "Right to Repair is a simple way to cut health care costs," Medium, September, 2018.
[20] *Author's NOTE: we have been told by some hospitals that they have channels to OEM information, and that they always get the service info to keep on file.*
[21] Paul Detrick, "Hospital Technicians Ignore Copyright Law to Fight COVID-19," Reason, April 13, 2020.
[22] John Wallace, "COVID-19 Spotlights Right to Repair Issue," TechNation, March 23, 2020.
[23] For example: Comment by Sai Akhil on the iFixit Ventilator forum, accessed May 2020.
[24] Personal conversation with Emma Horst-Martz of PennPIRG, May 2020.
[25] Personal conversation with Kevin O'Reilly, May 2020.
[26] FranksHospitalWorkshop.com, accessed May 2020.
[27] http://www.frankshospitalworkshop.com/equipment/ventilators_service_manuals.html, accessed May 2020.
[28] Kit Walsh, "Medical Device Repair Again Threatened With Copyright Claims," Electronic Frontier Foundation, June 11, 2020.
[29] Ibid 22 (Wallace)
[30] Letter from Boston Scientific to customers, April 2020.
[31] Personal conversation with Kevin O'Reilly, May 2020.
[32] Personal phone conversation with Nathan Proctor, April 2020.
[33] Personal phone conversation with Nathan Proctor, March 2020.
[34] Interview with Kevin O'Reilly, May 2020.
[35] "COVID-19 Ventilator Support," GE, Accessed April 2020.
[36] Matthew Gault, "Ventilator Companies Finally Make the Life Saving Devices Easier to Repair," Vice, April 23, 2020.
[37] "Repairing ventilators and COVID19 medical equipment – the big challenge ahead," Restart Project, April 3, 2020.
[38] COPIRG event, April 23, 2020.
[39] Personal conversation with Nathan Proctor, May 2020. The interviewee was not given permission to use his name publicly.
[40] Email communication, June 2020. The biomed was not given permission to speak publicly.
[41] Personal conversation with Kevin O'Reilly, April 2020.

[42] Nathan Proctor, "'Life and death' -- Medical equipment repairers push for Right to Repair during COVID-19 pandemic," U.S. PIRG, May 19, 2020.
[43] Ibid 31 (O'Reilly)
[44] Conversation with Nathan Proctor and a biomedical professional who was not given permission to speak publicly, May 2020.
[45] Ibid 3 (Hawryluk)
[46] Testimony of Ilir Kulloli, May 18, 2020, recorded here: https://drive.google.com/file/d/1Z5FrI-cdFl8UHJZeHY51--81x3F_NOyS/view
[47] "Red Lion Medical Safety, Inc. et al vs. General Electric Company et al" Law 360, March 2015. Author's Note: Additional legal filings indicate that the parties entered into a settlement agreement after the jury awarded damages.
[48] Jared Paben, "Legal case with 'right to repair' implications rolls forward," E-Scrap News, July 2018.
[49] Personal conversation with Gay Gordon-Byrne, April 2020.
[50] Repair.org member list, https://repair.org/members-1, accessed April 2020.
[51] Agam Shah, "Who Has a Right to Repair Your Farm or Medical Tools?" The American Society of Mechanical Engineers, April 2019.
[52] Ibid 1 (Koebler)
[53] Conversation with Gay Gordon-Byrne, April 2020. Sample: House Bill 218, Rep. Claire Cronin, accessed April 2020, which exempts all FDA regulated devices.
[54] An-Li Herring, "'Right-to-repair' advocates worry that hospitals can't fix broken ventilators," WESA, April 20, 2020.
[55] Ibid 11 (FDA)
[56] Conversation with biomedical technician, who was not given permission to speak publicly, May 2020.
[57] Conversation with Kyle Wiens of iFixit.com, April 2020.
[58] "43,000 CALL ON VENTILATOR MANUFACTURERS TO RELEASE REPAIR INFORMATION," U.S. PIRG, April 3, 2020.
[59] Ashley Matthews, "Five State Treasurers Call On Manufacturers To Release Ventilator Repair Manuals," PA Treasurer's Office, April 14, 2020.
[60] Daniel Hanley, Claire, Kelloway, Sandeep Vaheesan, "Fixing America: Breaking Manufacturers' Aftermarket Monopoly and Restoring Consumers' Right to Repair," Open Markets Institute, April 2020.