Discovering the Possibilities

RIGHT TO REPAIR

What you need to know and do

Nathan Proctor – US PIRG
Binseng Wang – Sodexo HTM

MDEXPO
Las Vegas • April 7-9, 2024

SESSION ORGANIZATION

Part 1: Right to Repair Overview
Nathan Proctor – US PIRG

Part 2: Right to Repair for Medical Devices
Binseng Wang – Sodexo HTM

Right to Repair Overview

BY : Nathan Proctor, U.S. PIRG

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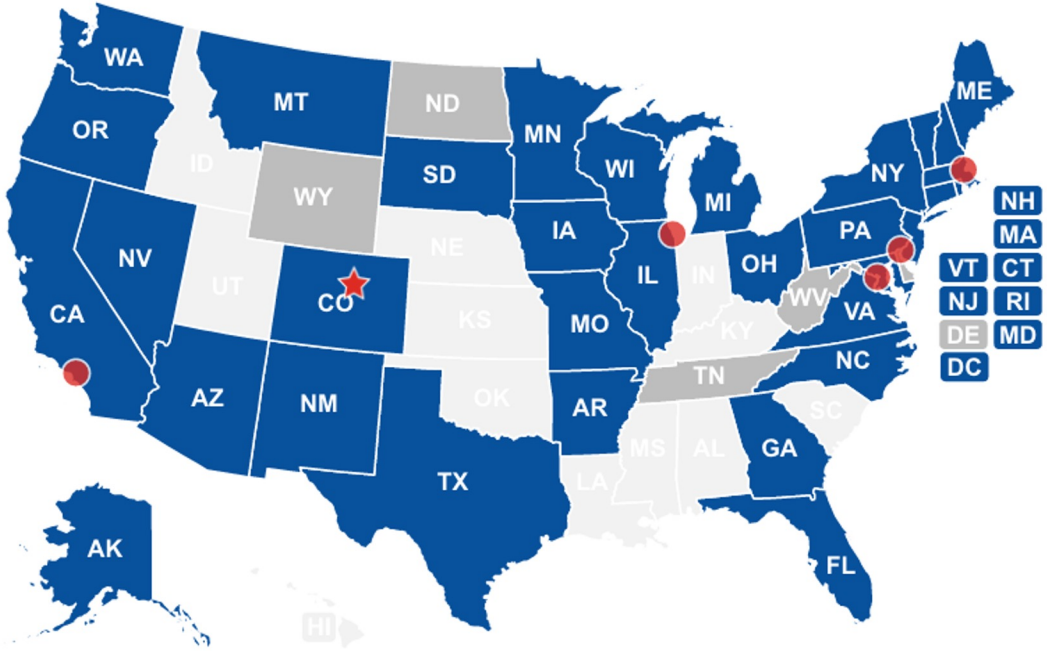
ABOUT THE SPEAKER: NATHAN PROCTOR

- Nathan Proctor is the Senior Director of U.S. PIRG's Right to Repair Campaign, where he has more than 18 years of experience in non-profit advocacy.
- Mr. Proctor has written or co-written some 14 reports on Right to Repair, including "Hospital Repair Restrictions," "Warranties in the Void," "Repair Saves Families Big" and more.
- His work has been featured in the New York Times, Wall Street Journal, National Public Radio, and even The Daily Show.
- A graduate of Tufts University, he lives in Arlington, Massachusetts with his wife and two children.

That's me, testifying in front of Congress on Right to Repair in 2022.

PIRG

PIRG is an advocate for the public interest. We speak out for a healthier, safer world in which we're freer to pursue our own individual well-being and the common good.

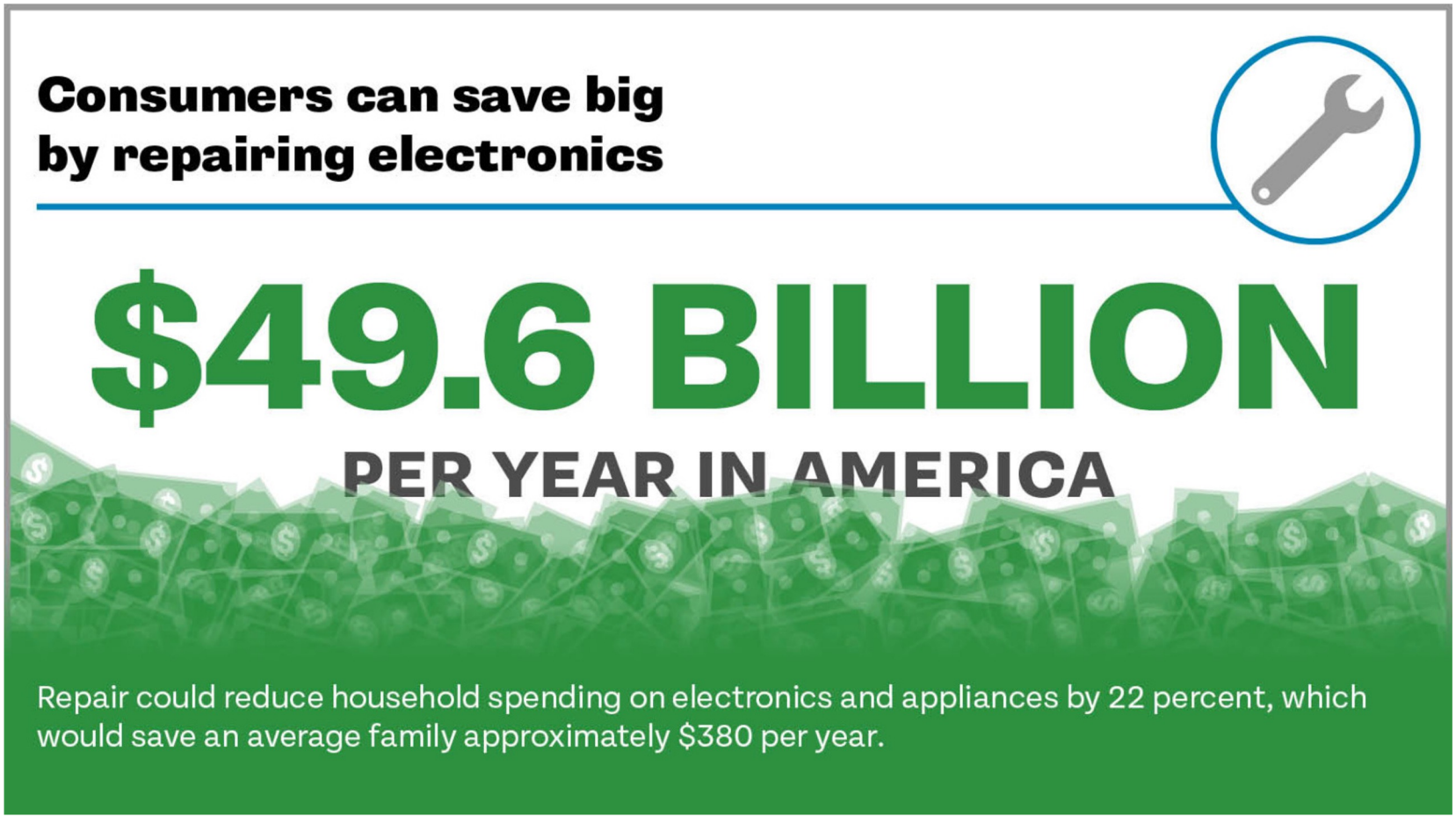


On average, Americans dispose of


Parking
Pharmacies
ATMs
DALAHAISHANG VILLAGE
DALAHAIXIA GUN
Weikuang Dam
JIAYI KILN
Baotou Huake Rare Earths Weijing Company

WASTING THE PLANET, AS WELL AS MONEY AND TIME

- When you can’t repair things, and toss them, that causes damaging **electronic waste.**
- When you can’t repair things, and have to buy new things, that **wastes money**.
- When you can’t repair things, and have to pay for “manufacturer-approved” servicing, they can **charge whatever they want**.
- When you can’t repair things, and have to wait for those few “manufacturer-approved” servicers to get all the way down the list to you, that **wastes time.**


Consumers can save big
by repairing electronics
$49.6 BILLION
PER YEAR IN AMERICA
Repair could reduce household spending on electronics and appliances by 22 percent, which would save an average family approximately $380 per year.

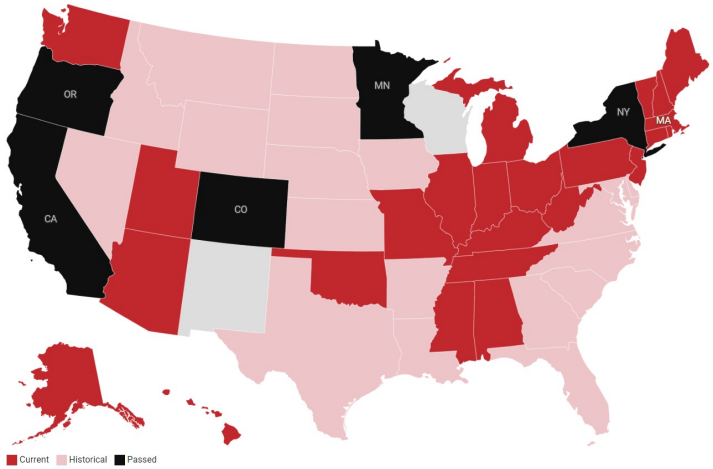
Right to Repair laws would save U.S. farmers

$4.2 BILLION PER YEAR

Farmers have to go to the dealership for many tractor fixes, leading to inflated repair costs and downtime that can cause crop losses. Right to Repair, which would provide farmers with access to necessary repair materials, would save U.S. farmers $4.2 billion a year.

WHAT BILLS HAVE PASSED?

- Cars:
  - 2012 Massachusetts law and ballot question
  - 2020 Massachusetts telematic access ballot question
  - 2023 Maine telematic access
- Wheelchairs:
  - Colorado in 2022
- Consumer devices:
  - New York in 2022
  - Minnesota in 2023 (which also includes many kinds of industrial equipment)
  - California in 2023
  - Oregon in 2024 (waiting for governor's signature)



COVID PUSHED US TO DO A LOT MORE ON MEDICAL

- Biomeds raised the alarm to us about conditions regarding devices
  - OEM servicers had travel restrictions
  - Additional equipment pressed into service, couldn't get PM kits or other materials
  - Conditions in the hospital were dire
- We surveyed 222 biomeds and HTMs about conditions as part of our report on these issues "Hospital Repair Restrictions"

BIOMED SURVEY RESULTS

of respondents reported to have equipment in their facilities which could not be used due to restrictions on spare parts and service information

claimed they had been denied service information for "critical equipment (defibrillators, ventilators, anesthesia machines, imaging equipment, etc.),"

FINDINGS FROM "HOSPITAL REPAIR RESTRICTIONS"

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%

DELAYED CARE

Nearly 70 percent of more than 200 medical repair professionals surveyed say that their hospital has had to “delay a patient procedure because [they] were waiting on a manufacturer service representative to fix a device.”

70%

CALLING FOR COOPERATION FROM OEMS

engadget

Public interest group tells medical equipment makers to release their repair manuals

The PIRG says that open-sourcing repair documentation could be the difference between life and death.

Daniel Cooper, @danielwcooper
March 19, 2020

SIGNED COVID PETITION

We write to you today in our capacity as top fiscal officers in each of our respective states. As you know, there is a nationwide shortage of ventilators in rotation to serve the estimates of patients that are anticipated to need them as a result of COVID-19 complications. For that

As you know, the U.S. Public Interest Research Group recently delivered a petition with 43,000 signatures to ventilator manufacturers, asking them to release repair information.

In these unprecedented circumstances, every American has been asked to make a sacrifice by not leaving their homes, shuttering businesses, and limiting travel to essential needs only. We are asking manufacturers to take these circumstances into consideration and release all repair information needed for hospitals to put these life-saving ventilators into their supply.

Joseph M. Torsella
Pennsylvania State Treasurer

Colleen C. Davis
Delaware State Treasurer

John B. McCuskey
West Virginia State Auditor

Eugene A. DePasquale
Pennsylvania Auditor General

David Young
Colorado State Treasurer

Seth Magaziner
Rhode Island State Treasurer

Michael Frerichs
Illinois State Treasurer

Deborah B. Goldberg
Massachusetts State Treasurer

Nancy K. Kopp
Maryland State Treasurer

Fiona Ma
California State Treasurer

VENTILATOR OEMs' REACTION

engadget

Ventilator companies are opening up critical repair documents to the public

After being called out by the US Public Interest Research Group.

Christine Fisher, @cfisherwrites
April 23, 2020

The PIRG says it delivered 43,000 petitions calling for the release of ventilator repair information, and iFixit partnered with the PIRG to catalog ventilator service manuals. While manufactures didn't say whether they modified their policies in response to those petitions, they have made changes. GE is sharing technical reference manuals and service applications without requiring the usual four-day in-person training. Fisher & Paykal are responding to PDF requests, and other companies, like Medtronic, are sharing similar documents in new web portals.

SEN WYDEN'S ADDRESS

"This is urgent business. It's common sense... Let's get the message out from sea to shining sea: that everyone should have the right to repair what they own in the middle of a pandemic." -- Sen. Ron Wyden

WHAT PROGRESS HAVE WE MADE?

- Won a copyright exemption under section 1201 of the DMCA for medical device repair.
- Manufacturers eased repair restictions during COVID … and the sky didn't fall.
- Introduced legislation in Congress, roughly a dozen states.
- Protected device servicing as part of the "remanufacturing" debate.

LEADING GROUPS AND NETWORKS TOTALING 254 HOSPITALS SIGNED THIS LETTER:

U.S. PIRG IAMERS

May 9, 2022

Chairman Frank Pallone
House Energy & Commerce Committee
2107 Rayburn HOB

Chairwoman Anna G. Eshoo
Subcommittee on Health
272 Cannon HOB

Ranking Member Cathy McMorris
House Energy & Commerce Committee
1035 Longworth HOB

Ranking Member Brett Guthrie
Subcommittee on Health
2434 Rayburn HOB

Re: Public interest and healthcare organizations oppose H.R.7253 and changes to definition of medical device remanufacturing

HOW CAN YOU HELP?

- Check out the MDSC: https://mdsc.online/
  - aims to be a collaborative approach recognizing that we need to come together.
- Get involved. Sign our letter:
- Reach out to us:
  - Nproctor@pirg.org

RtR for Medical Devices

BY : Binseng Wang – Sodexo HTM

MDEXPO
Las Vegas • April 7-9, 2024

Binseng Wang, ScD, CCE

Discovering the Possibilities

ABOUT THE SPEAKER: BINSENG WANG

- Binseng Wang is a vice-president with Sodexo HTM, an independent medical equipment service organization located in the USA.
- Previously, Dr. Wang was Director, Quality & Regulatory Affairs for Greenwood Marketing LLC, Vice President, Quality & Regulatory Affairs, for Sundance Enterprises, Aramark Healthcare Technologies, and MEDIQ/PRN. He also worked as a Visiting Scientist at NIH, Adjunct Professor at the Milwaukee School of Engineering, and Associate Professor at Univ. of Campinas, Brazil.
- He is a fellow of ACCE and AIMBE. He received the 2010 AAMI CE Achievement Award, the 2015 ACCE Lifetime Achievement Award and the 2019 AAMI-TRIMEDX Iconoclast award. He was inducted into the Clinical Engineering Hall of Fame by ACCE in 2017 and granted the title of Honorary Life Member by the Int'l Federation of Medical & Biological Eng. (IFMBE) in 2022. He was chair of ACCE International Committee 2018-2023.
- He earned a Doctor of Science (ScD) degree from MIT and is a Certified Clinical Engineer (CCE).

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- Medical Device RtR History in USA
  - Past
  - Present
  - Future
- RtR in Other Countries
- Rebuttals to OEM Claims
- Discussion and Conclusions

THE RIGHT TO REPAIR MEDICAL EQUIPMENT - USA

- PAST
- PRESENT
- FUTURE

PAST – HISTORY OF RIGHT TO REPAIR

YEAR	GENERAL RtR	MEDICAL DEVICES
<1996		Most OEMs would collaborate with ISOs to support HDOs in equipment service. Almost anyone could service medical devices
1996		FDA issued the Quality System regulation (21 CFR 820) without requirements on servicers despite OEM objections
1997		FDA issued a Request for Comments on medical device servicing but took no action
2012	Massachusetts passed Automotive Right to Repair Act initiated by the Aftermarket Automobile Industry Association (AAIA)	National Fire Protection Agency (NFPA) revised its NFPA 99 - Health Care Facilities Code to include requirement for manufacturers to provide service manuals
>2012	Other states considered or passed similar automotive RtR legislations	

PAST – HISTORY OF RIGHT TO REPAIR

YEAR	GENERAL RtR	MEDICAL DEVICES
2013	Digital Right to Repair Coalition was created, later renamed The Repair Association	
2014	AAIA and other auto repair organizations signed a Memorandum of Understanding (MOU) with the Alliance of Automobile Manufacturers and Association of Global Automakers: manufacturers will provide to owners and independent repair facilities: (1) diagnostic & repair info, (2) repair technical updates and (3) diagnostic repair tools => diagnostic car code reader	
2014	Unlocking Consumer Choice and Wireless Competition Act allowed cellphone owners to unlock it and transfer to another carrier.	
2014	First Digital Right to Repair Bill filed in SD	

PAST – HISTORY OF RIGHT TO REPAIR

YEAR	GENERAL RtR	MEDICAL DEVICES
2016		FDA issued another Request for Comments on medical device servicing but again took no action
2015	Bills filed in New York, Massachusetts and Minnesota	
2016	Bills filed in Nebraska, Iowa, Kansas, Tennessee and Missouri	
2017	Bills filed in Hawaii, New Jersey, New Hampshire	HR 2118 - Medical Device Servicing Safety and Accountability Act introduced in the Congress but did not pass.
2017	US Supreme Court ruled "a patentee's authority to limit licensees does not mean that patentees can use licenses to impose post-sale restrictions on purchasers that are enforceable through the patent laws." (Case: ink-jet cartridges remanufacturing)	HR 2430 (MDUFA IV) section 710 required FDA to investigate and report on the safety of medical device servicing

PAST – HISTORY OF RIGHT TO REPAIR

YEAR	GENERAL RtR	MEDICAL DEVICES
2018	Bills filed in Vermont, Illinois, Washington, Virginia and California	FDA issued the Section 710 (FDARA) report after investigating the safety of medical device servicing
2018	US Copyright Office/LoC issued rule exempting provision of the Digital Millennium Copyright Act (DMCA) that prohibits circumvention of technological measures that control access to copyrighted works… exemption for computer programs that control motorized land vehicles, including farm equipment, for purposes of diagnosis, repair, and modification of the vehicle.	**Alliance for Quality Medical Device Servicing** formed by TriMedx, Sodexo, Crothall, Agiliti, ABM (since acquired by Crothall) and The InterMed Group.
2018		FDA Issued a White Paper on servicing versus remanufacturing for public comment and convened a workshop in Dec to discuss it.
2018		FDA issued a Discussion Paper on cybersecurity

PAST – HISTORY OF RIGHT TO REPAIR

YEAR	GENERAL RtR	MEDICAL DEVICES
2019	Bills filed in West Virginia, Oregon, Indiana, North Dakota and Georgia (total 20 states)	HR 7956 - Critical Medical Infrastructure Right-to-Repair Act of 2020 introduced but was not voted
2021		FDA issued a Draft Guidance on Remanufacturing of Medical Devices and invited comments
2021	US Copyright Office (Library of the Congress) issued the final rule "Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies"	
2022	NY State passed the Fair Repair Act for consumer electronics	California's RtR bill for medical devices was approved unanimously by the Health Committee, it "disappeared" in the Finance Committee
2022		Colorado passed the Consumer Right To Repair bill but only for powered wheelchairs (HB22-1031)
2022		HR 7253 - Clarifying Remanufacturing to Protect Patient Safety Act introduced but was not incorporated into MDUFA V

THE RIGHT TO REPAIR MEDICAL EQUIPMENT - USA

- PAST
- PRESENT
- FUTURE

WHITE HOUSE & FTC

- The White House convened a discussion the RtR on Oct 24, 2023, with participation of administration officials and state legislative leaders. Participants included: White House staff, FTC chair, EPA, Apple, state legislators from CA, CO, MN, etc.
- US PIRG and iFixit petitioned the FTC to initiate a rulemaking “to protect consumers' right to repair products they have purchased.” Comments were due Feb 02, 2024, and 1685 comments were received from individuals and companies. Most company comments were not posted online due to “sensitive information.”

ALLIANCE PROPOSING MD RTR IN CONGRESS

- Alliance for Quality Medical Device Servicing is formed by TriMedx, Sodexo, Crothall, Agiliti, and The InterMed Group.
  - Affiliate members: Elite Biomedical, Avante Health Solutions
- A Medical Device RtR bill was drafted and presented to several congressional representatives and their staff
- Several House Representatives showed interest in supporting it
- However, we have not yet found bi-partisan sponsors to formally introduce it

Help needed!!!

THE RIGHT TO REPAIR MEDICAL EQUIPMENT - USA

- PAST
- PRESENT
- FUTURE

FUTURE – MULTI-FRONT WAR

- **State Level**
  - CE/HTM community will continue to support RtR bills in every state that is being considered
  - AdvaMed (including former MITA) will continue to oppose such bills using FUD (fear, uncertainty and doubt)
  - A few Big Tech's and farm equipment OEMs will lobby hard against all RtR (due to possible precedents for other technologies)
- **Federal Level**
  - **Congress**: Encourage elected officials to introduce RtR bills that would grant permanent access to service materials (manuals, proprietary parts, test & calibration tools and equipment, and software keys)
  - **Food and Drug Administration (FDA)**
    - Resist calls for servicing regulation or overly burdensome "guidance" on remanufacturing
    - Prevent cybersecurity be used as an excuse for refusing software access (privileged access)
    - Advocate for access to service information, material & software (similar to lasers)
  - **Federal Trade Commission (FTC)**: Present anti-competitive, restraint to trade evidence and arguments

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Canada [my emphases in color]

- Provincial Initiative
  - The Northwest Territories Health and Social Services Authority's (NTHSSA) created a Right to Repair Policy at the Territorial level and through that has created Right to Repair Purchasing clauses requiring vendors to provide service information, parts and training in order to meet the requirements of Government of the Northwest Territories health technology procurement initiatives.
- National Initiatives
  - Canadian Federal Bill (C-244) entitled "An Act to amend the Copyright Act (diagnosis, maintenance and repair)" was introduced in the House of Commons in the 2021-2022 session to "… allow the circumvention of a technological protection measure in a computer program if the circumvention is solely for the purpose of the diagnosis, maintenance or repair of a product in which the program is embedded." (https://www.parl.ca/legisinfo/en/bill/44-1/c-244). The bill is now in second reading of the Canadian Senate.
  - The Canadian Medical and Biological Engineering Society (CMBES) has formed a national working group to advance various Right to Repair initiatives in Canada and has written letters of support of Bill C-244 to the Canadian Parliament and Senate. CMBES is also encouraging Biomedical Engineering programs across Canada to submit Sentinel Events to Health Canada as well as ECRI Device Problem Reports, when they encounter situations where Right to Repair is obstructed and has resulted in delays or impacts on delivery of patient care.

EUROPEAN UNION [my emphases in color]

- **1993** MDD states in Annex I
  - 13. Information supplied by the manufacturer
    - 13.6 Where appropriate, the instructions for use must contain the following particulars:
      - (d) all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times;
- 2017 MDR states in Annex I
  - 23. Label and instructions for use
    - 23.4. Information in the instructions for use
      - (k) the information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant
        - details of the nature, and frequency, of preventive and regular maintenance, and of any preparatory cleaning or disinfection,

HOWEVER

MDD and MDR do not include keys to software locks (access to service and calibration software or configuration software required for parts replacement)! => OEMs have the *License to Kill*

PEOPLE'S REPUBLIC OF CHINA [my emphases in color]

- 2016 Decree "Measures for the Supervision and Administration of quality of the use of medical devices" issued by the State Food and Drug Administration
  - *Article 17 The unit using medical devices may, in accordance with the provisions of the contract, require the medical device production and trading enterprises to provide medical device maintenance and repair services, and may also entrust a maintenance service institution with conditions and capabilities to carry out medical device maintenance and repair, or carry out maintenance and repair of the medical devices in use on their own.*
  - *If the medical device user entrusts the maintenance service agency or carries out maintenance and repair of the medical device in use on its own, the medical device production and operation enterprise shall provide the preventive maintenance manual, corrective maintenance manual, software backup, fault code table, spare parts list, parts, maintenance password and other materials and information necessary for maintenance and repair in accordance with the contract.*

REBUTTALS TO CLAIMS

Some OEMs and their trade associations have made sweeping claims against 3rd-party servicers. Here are some examples of such claims and rebuttals prepared by the Alliance for Quality Medical Device Servicing (my emphasis in **color**).

CLAIM #1 - SAFETY: services provided by third parties are unsafe for patients.

a) In its 2018 report to Congress, FDA stated "… the objective evidence indicates that many OEMs and third party entities provide **high quality, safe, and effective** servicing of medical devices." Further, The FDA Report highlighted an ECRI Institute analysis indicating a statistically insignificant number of issues related to service and repair of medical devices.

b) Onsite staff provided by third parties can respond swiftly, while waiting for offsite service technicians may impede timely patient care, as clearly evidenced during the COVID-19 pandemic.

REBUTTALS TO CLAIMS

CLAIM #2 - REGULATORY OVERSIGHT: 3rd parties are not regulated by the FDA and, thus, pose risks to public health.

a) Third parties are contracted by hospitals, which are licensed by respective states and required to comply with the Conditions of Participation (CoPs) enforced by CMS through state agencies and accrediting organizations. Those requirements are typically transferred by the hospitals to the third parties, so effectively the third parties are indirectly regulated by FDA's sister agency, CMS.

b) The 2018 FDA Report emphasized that "…**the currently available objective evidence is not sufficient … that would justify imposing additional/different burdensome regulatory requirements at this time.**"

c) Several OEMs also provide services on equipment manufactured by other OEMs(aka multivendor service – MVS) thereby blurring the differentiation between OEMs and third party service providers.

REBUTTALS TO CLAIMS

CLAIM #3 - INTELLECTUAL PROPERTY (IP): providing service materials (technical specifications, service manuals, diagnostic and calibration software access, proprietary parts and test tools, etc.) would require OEMs to reveal trade secrets and IP.

a) We are not aware of any third party service providers interested in securing IP to produce competitive products. Servicers are focused on safely and effectively servicing devices, not manufacturing.

CLAIM #4 - CYBERSECURITY: providing access to equipment diagnostic and calibration software would allow servicers to introduce malware and, thus, pose cyber risks.

a) Most cyber-attacks are perpetrated by hackers or persons seeking monetary gains. Servicers have nothing to gain from ransomware attacks. Furthermore, third party servicers are required by hospitals to monitor and address promptly cyber vulnerabilities and attacks being onsite and in close contact with the equipment.

REBUTTALS TO CLAIMS

CLAIM #5 - REMANUFACTURING: servicers often exceed the limits of servicing and ended up remanufacturing devices, thus violating FDA regulations.

a) The 2018 FDA Report found a small number of cases involving complaints related to device remanufacturing and FDA has committed to issue a guidance to clarify the distinction between servicing and remanufacturing, with input from many stakeholders including the Alliance. It is possible that some of those remanufacturing activities were committed due to the lack of access to device specifications and service materials.

b) Since **1993**, OEMs are required by the European Union to release "… **all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed** to ensure that the devices operate properly and safely at all times." In contrast, such requirements only exist in the US for medical lasers (21 CFR 1040.10) and for assembly, installation, adjustment and testing of diagnostic X-ray systems (21 CFR 1020.30).

CLARIFICATION ON AIAT [my emphases in color]

- Some OEMs claim “we already provide IFUs and the AIAT information” per 21CFR820.170 and 21CFR1020.30(g)+(h)
  - 21CFR820.170(a) *Each manufacturer of a device requiring installation shall establish and maintain adequate installation and inspection instructions, and where appropriate test procedures…*
  - 21CFR1020.30(g) *Manufacturers … shall provide to assemblers … instructions for assembly, installation, adjustment, and testing…*
  - 21CFR1020.30*(h)* *Manufacturers of x-ray equipment shall provide to purchasers… manuals or instruction sheets which shall include the following technical and safety information:*
  - *…*
    - *(ii) A schedule of the maintenance necessary to keep the equipment in compliance with this section…*

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DISCUSSION & CONCLUSIONS

- Nothing to do with patient safety or wellbeing.
  IT'S ALL ABOUT MONEY!
- So this will be a long and arduous war, not a battle
- Best (or perhaps the only) hope: imitate the automobile repair groups, i.e., get enough state bills passed and some bills introduced in the Congress to convince OEMs to come to the table for a Memorandum of Understanding (MOU) on access to service material (manuals, parts, softkey, remote diagnostics, etc.)
- In essence, paraphrasing former American congressman John Lewis:
  Get in good trouble, necessary trouble, and help everyone around the world to get the Right to Repair!

TAKE AWAYS

- Right to Repair (RtR) for medical devices is not for saving money but for improving patient safety and care quality and timeliness
- RtR is also essential for reducing toxic wastes and climate change
- RtR has been mandated in other countries (EU, China, etc.) for years with little, if any, negative impact on OEM revenue or profit margin
- RtR is not a “free for all” but responsible maintenance and management of healthcare technology
- Everyone in the healthcare industry must work together to achieve a safe, balanced, equitable solution for all, **particularly the patients** (ALL OF US!).

THANK YOU!

- Acknowledgement: many of my past and present colleagues and friends contributed to the work presented here but I am solely responsible for the mistakes.
- Questions, comments and suggestions are welcome!
  - Binseng Wang, ScD, CCE
    - Email: binseng.wang@sodexo.com