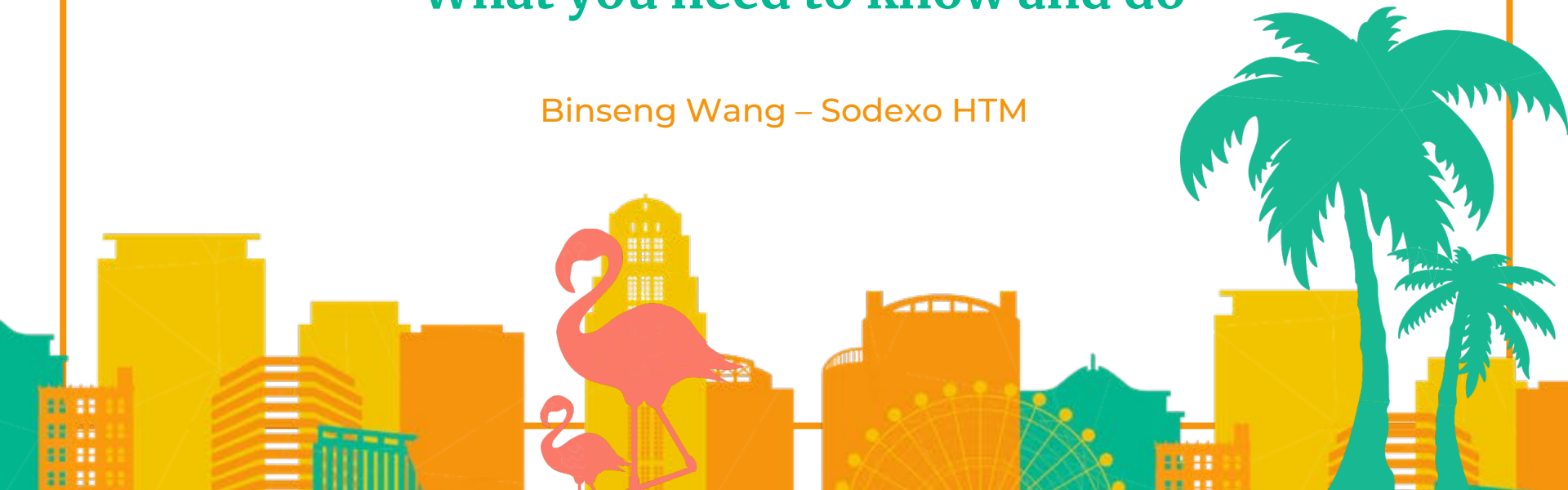
MDEXPO
Orlando, FL • October 29-31, 2023

Right to Repair

What you need to know and do

Binseng Wang – Sodexo HTM



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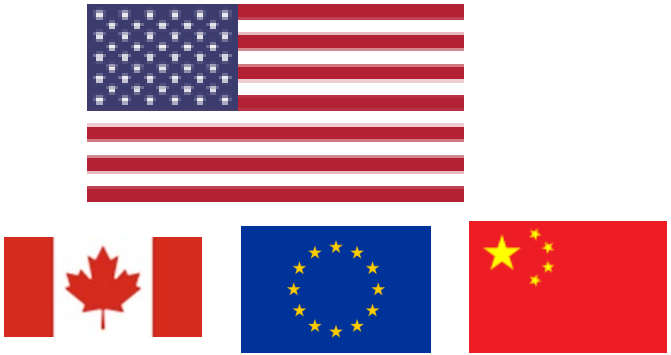

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About the Speakers: Binseng Wang

- 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).

Binseng Wang, ScD, CCE

INTRODUCTION

- What is the Right to Repair?

We Have the Right to Repair Everything We Own

- According to Repair.org: "If you bought it, you should have the right to use it, modify it and repair it wherever, whenever and however you want."
- Benefits
  - Freedom: owners can decide who, when, where and how the device should be maintain (if it is not against the law)
  - Environment: reduce waste (especially toxic electronic waste)
  - Economy: foster competition and, thus, reduce cost of ownership, as well as productivity (e.g., farming equipment)
  - Safety: downtime can negatively impact the users and in the case of medical devices, it can delay or even divert care of patients

The Right to Repair Medical Equipment - USA

- PAST
- PRESENT
- FUTURE

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	

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	

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

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

2018 FDA's 710 Report [my emphasis in color and **bold** fonts]

- FDA's Conclusions
  - *The currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing, including by third party servicers, of medical devices that would justify imposing additional/different, burdensome regulatory requirements at this time;*
  - *Rather, the objective evidence indicates that many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices;*
  - *A majority of comments, complaints, and adverse event reports alleging that inadequate "servicing" caused or contributed to clinical adverse events and deaths actually pertain to "remanufacturing" and not "servicing"; and*
  - *The continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S. healthcare system.*

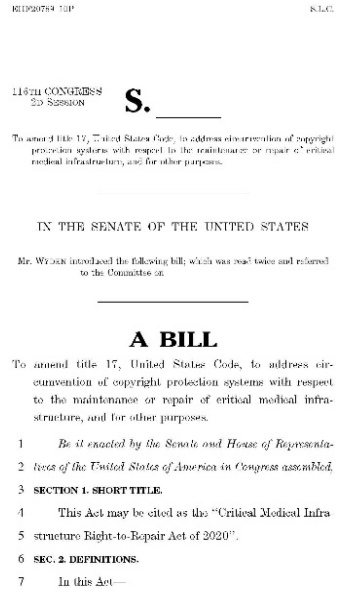
We believe the currently available objective evidence is not sufficient to conclude whether or not there is a widespread public health concern related to servicing of medical devices, including by third party servicers, that would justify imposing additional/different burdensome regulatory requirements at this time. *Although we do not believe that additional, formal regulatory action is warranted, based on the available information and findings, we intend to pursue the following actions:*

1. *Promote the Adoption of Quality Management Principles;*
2. *Clarify the Difference Between Servicing and Remanufacturing;*
3. *Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices; and*
4. *Foster Evidence Development to Assess the Quality, Safety and Effectiveness of Medical Device Servicing*

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
2020		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 Critical Medical Infrastructure Right-to-Repair

- Introduced by Senator Wyden (D-OR) & Rep. Clarke (D-NY)
- Provisions:
  - Protect equipment owners, lessees, and servicers from liability under federal copyı law for creating an incidental copy of service materials or for breaking a digital lock during the course of equipment repair in response to COVID-19;
  - Allow equipment owners or lessees to fabricate patented parts on a noncommercia basis and as needed for repair or maintenance in response to COVID-19;
  - Invalidate provisions in equipment contracts to the extent that they prohibit or restr the repair or maintenance of critical medical infrastructure in response to COVID-1
  - Require manufacturers to provide, on fair and reasonable terms, access to informa and tools used to diagnose problems and service, maintain, or repair equipment; a
  - Require the Federal Trade Commission to evaluate the bill's impact and effectiven on innovation and competition in the critical medical infrastructure market.
- Some OEMs objected to this bill and it was not voted



KID20789 7IP S.L.C.

116TH CONGRESS
2D SESSION

S. _____

To amend title 17, United States Code, to address circumvention of copyright protection systems with respect to the maintenance or repair of critical medical infrastructure, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. WYDEN introduced the following bill; which was read twice and referred to the Committee on

A BILL

To amend title 17, United States Code, to address circumvention of copyright protection systems with respect to the maintenance or repair of critical medical infrastructure, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

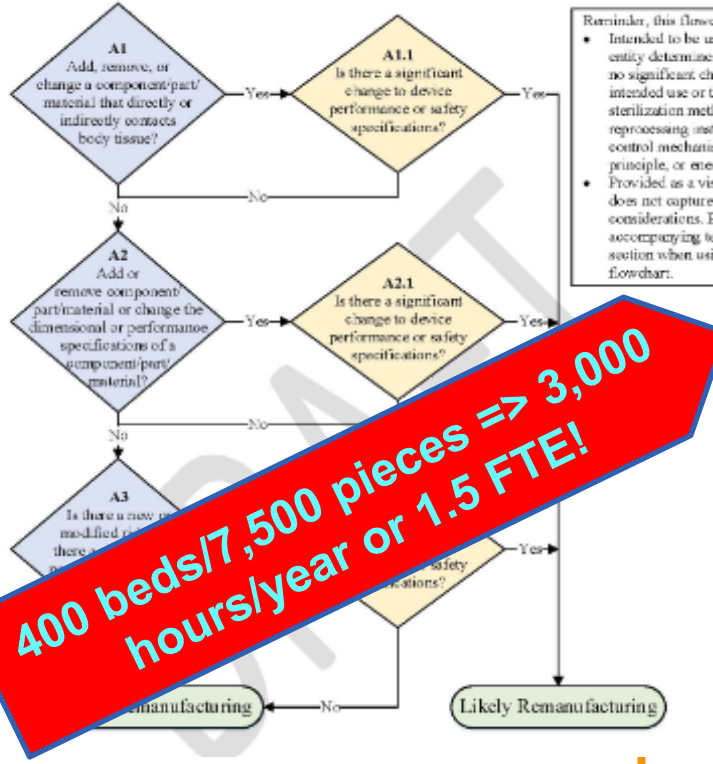
This Act may be cited as the "Critical Medical Infrastructure Right-to-Repair Act of 2020".

SEC. 2. DEFINITIONS.

In this Act—

FDA's draft guidance document on remanufacturing

- Guiding Principles
  1. Assess whether there is a change to the intended use
  2. Determine whether the activities, individually and cumulatively, significantly change the safety or performance specifications of a finished device
  3. Evaluate whether any changes to a device require a new marketing submission
  4. Assess component/part/material dimensional and performance specifications
  5. Employ a risk-based approach
  6. Adequately document decision-making
- Implementation
  - Except when following OEM instructions, use the flowchart **after each service** to determine likelihood of remanufacturing
  - Decision made by technician/engineer must be **reviewed by supervisor**



400 beds/7,500 pieces => 3,000 hours/year or 1.5 FTE!

Can you afford it? Can the patients wait?

FDA's discussion document on medical device cybersecurity

- **Purpose**: seek input from stakeholders on how to strengthen cybersecurity practices associated with the servicing of medical devices, recognizing that "[c]ybersecurity is a shared responsibility among stakeholders, including OEMs, healthcare establishments, healthcare providers, and independent service organizations (ISOs)."
- **Cybersecurity Challenges and Opportunities**

1. **Privileged Access**: access to operating systems and applications be limited, and that user authentication and appropriate controls be in place
2. Identification of Cybersecurity Vulnerabilities and Incidents: need help from servicers to identify cybersecurity vulnerabilities and exploits
3. Prevention and Mitigation of Cybersecurity Vulnerabilities: encourage all interested stakeholders to collaborate on methods or pathways that could be used to efficiently develop, validate, and implement software changes
4. Product Life Cycle Challenges and Opportunities: what to do with the "legacy devices"

Is "Privileged Access" the new "License to Kill?"

- Privileged access = limiting "access only to privileged device users" because it is "a key component of ensuring a secure medical device."
  - "devices that lack basic security may present significant safety concerns" but
  - without "privileged access, servicing activities may not be possible."
- Servicing is not the only challenge!
  - Increased downtime => additional backup equipment estimated at **$50 billion** for USA
  - Shortened lifecycle => additional capital expense estimated at $**12 billion/year** for USA
  - Legacy devices => need prompt replacement with estimated quantity of 2.4–5.6 million pieces, costing **$30-70 billion** to replace in the USA

Link to 24x7 webpage:
https://24x7mag.com/standards/privileged-access-new-license-kill/

US Copyright Office (Library of the Congress)

- Issued a final rule on 10/28/2021 entitled: Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, in which it states

> Computer programs that are contained in and control the functioning of a lawfully acquired medical device or system, and related data files, when circumvention is a necessary step to allow the diagnosis, maintenance, or repair of such a device or system.

- i.e., it is legal to access the diagnostic and maintenance software without the OEM permission.
- However, this is only legal for the equipment owner, not third-parties.
- Also, software vendors cannot sell software that allows such circumvention

The Right to Repair Medical Equipment - **USA**

- PAST
- PRESENT
- FUTURE

Cybersecurity [my notes in color]

- Senator Mark R. Warner (D-VA) issued a white paper “Cybersecurity is Patient Safety – Policy Options in the Health Care Sector” in Nov 2022 to offer his view on this subject and invite comments and recommendations that could result in a bill to be presented to the Congress.
  - Insecure Legacy Systems: how to address the 2.4 – 5.5 million devices with an estimated replacement cost of $30 - 70 billion? Suggest to replace the “cash for clunkers” style program with an incentive for OEMs to work with software companies and HDOs to manage and gradually replace these legacy systems.
  - Role of the RtR: third parties currently cannot extend the life of legacy systems without collaboration from OEMs due to FDA regulations, but RtR could help to service equipment more safely, faster and less onerously

Cybersecurity (cont.) [my emphases in color]

- The Consolidated Appropriations Act of 2023's section 3305 authorizes the FDA
  - "*…to implement and enforce new cybersecurity regulatory standards for premarket submissions of medical devices to ensure that devices are secure from the time they are introduced into the market. Under the new provisions, a party that submits a premarket medical device application must provide to the FDA Secretary a plan to monitor, identify, and address, as appropriate, in a reasonable time, post-market cybersecurity vulnerabilities and exploits. The plan must include coordinated vulnerability disclosure and related procedures.*"
  - OEMs are required to submit "*… to the FDA a software bill of materials ("SBOM"), includingcommercial, open-source, and off-the-shelf software components.*"
  - **Cyber devices** defined as "*devices that*
    - *Include software that is validated, installed, or authorized by the sponsor;*
    - *Has the ability to connect to the internet; and*
    - *Contains any technological characteristics that could be vulnerable to cybersecurity threats.*"

RtR for Motor Vehicles [my emphases in color]

- "Right to Equitable and Professional Auto Industry Repair Act" introduced by Rep Neal P. Dunn (R-FL) in Jan 2023
  - PROHIBITION ON MOTOR VEHICLE MANUFACTURERS WITHHOLDING OF DATA, CRITICAL REPAIR INFORMATION, AND TOOLS: i.e., "…*all necessary technical and compatibility information, tools, equipment, schematics, parts nomenclature and descriptions, parts catalogs, repair procedures, training materials, software, and technology, specifically including but not limited to information related to diagnostics, repair, service, calibration or recalibration of parts and systems to return a vehicle to operational specifications*."
  - REQUIREMENT TO PROVIDE MOTOR VEHICLE DATA TO OWNERS: give owners or their designees "… *without restrictions or limitations… access to vehicle-generated data*."
  - PROHIBITION ON CERTAIN MANDATES BY MOTOR VEHICLE MANUFACTURERS RELATED TO REPAIRS to use "… *any particular brand or manufacturer of parts, tools, or equipment*"
  - Creates a "Fair Competition After Vehicles are Sold Advisory Committee," with the duty of "… *provide recommendations to the Commission on implementation of this Act and competition issues after motor vehicles are sold, including those facing the vehicle repair industry to include an assessment of existing and emerging barriers related to vehicle repair, as well as ensuring motor vehicle owners' control over their vehicle-generated data."*

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Alliance Proposing Medical Device 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!!!

State-Level RtR Bills

- Approved
  - Medical Devices
    - Colorado – power wheelchairs
  - Non-medical devices
    - New York – consumer electronics
    - Minnesota – consumer electronics
    - Colorado – agricultural equipment
    - California – consumer electronics
- Work in Progress
  - Medical Devices
    - California – power wheelchairs

The Right to Repair Medical Equipment - USA

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- FUTURE

FUTURE – Multi-front War

- **State Level**
  - CE/HTM community will continue to support RtR bills in every state that is being considered
  - AdvaMed and 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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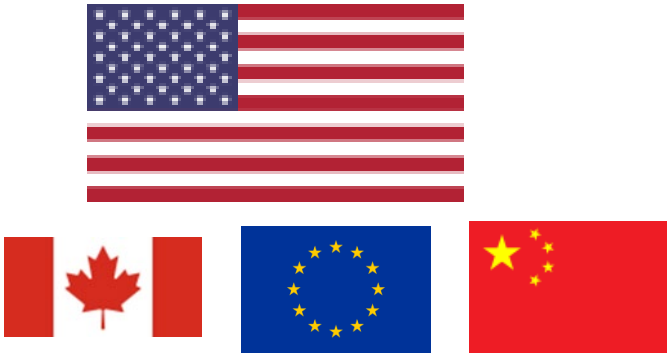

Canada [my emphases in color]

- Provincial Initiative
  - The Northwest Territories Health and Social Services Authority's (NTHSSA) Biomedical Engineering initiated a Right to Repair Policy at the territorial level by creating a Right to Repair Purchasing Guidelines requiring vendors to provide service information, parts and training in order to participate in territorial procurement process.
- National Initiative
  - A 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. It also allows the manufacture, importation, distribution, sale, renting and provision of technologies, devices or components used for the diagnosis, maintenance or repair of such products."

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.*

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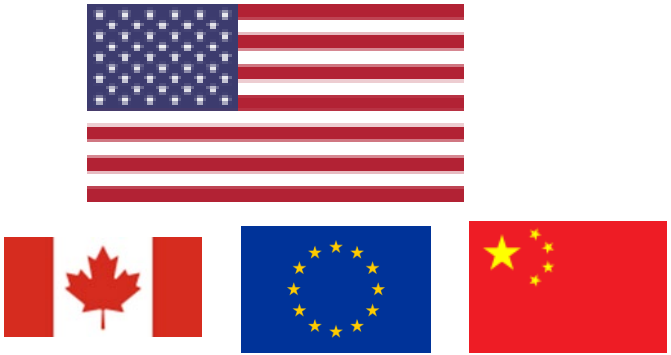

REBUTTALS TO CLAIMS

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).

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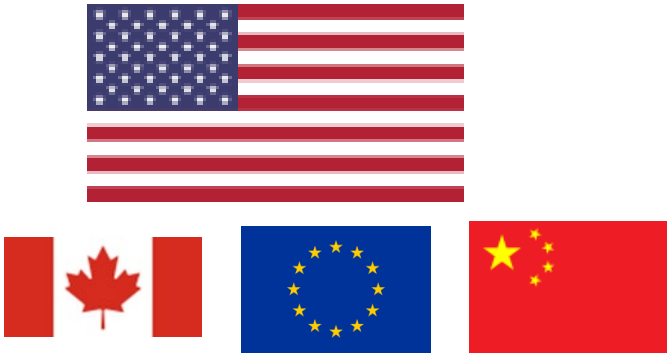

DISCUSSION & CONCLUSIONS

- 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!

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

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We value your feedback!

Please scan the QR code to submit a survey for this session.

Thank You!