

November 12, 2018

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

***Re: Docket No. FDA-2018-N-1794: FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices in Accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA)***

Dear Sir or Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, we are pleased to submit these comments in response to the Food and Drug Administration's (FDA's) invitation for comments on FDA's *Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices in Accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA)*.

The Advanced Medical Technology Association (AdvaMed) is the world's largest trade association representing medical device and diagnostics manufacturers. AdvaMed's member companies produce the innovations that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 400-member companies, ranging from the largest to the smallest medical technology innovators and manufacturers. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, rapid product approvals, appropriate reimbursement, and access to international markets.

AdvaMed commends FDA for submitting its report to Congress in a timely and efficient manner. FDA made a good faith effort to be responsive to the questions posed by Congress in FDARA. Nonetheless, there are a number of areas and recommendations in the report where we will outline our perspective which differs from the FDA's in key respects.

There are many concepts and ideas embedded in the report which makes it challenging to provide efficient and effective comments. AdvaMed will provide comments on a section-by-section basis.



## Comments on Executive Summary

FDA states on the one hand that “*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, ... that would justify imposing additional/different, burdensome regulatory requirements*” and then makes what appears to be a contradictory statement that “*the objective evidence indicates that many OEMS and third parties provide high quality, safe and effective servicing of medical devices.*” FDA would have objective evidence on which to make a determination about the safety and effectiveness of third-party servicing practices if FDA required third-party servicers to register and report MDRs.

We do not agree that it is burdensome for third-party servicing entities to register with FDA, report MDRs (Medical Device Reports) and comply with QSR (Quality System Regulation) requirements that are consistent with the level of servicing they conduct. FDA QSR<sup>1</sup> requirements are risk-based, flexible, scalable and feasible for any company to meet – regardless of size, from the very smallest to the largest device companies – to ensure the continued safety and effectiveness of devices. Small device companies – some with extremely limited numbers of staff – are not allowed to exempt themselves from QSR compliance. QSR compliance is understood to be a basic necessity of doing business in the device sector. FDA has stated “quality systems ... help ensure that ... products consistently meet applicable requirements and specifications.” For these reasons, we believe all companies, OEMs and third parties alike, should be held to the same quality standard.

## Comments on Section 1: Introduction

We agree with FDA’s comments that “*the availability of timely, cost-effective, quality maintenance, and repair of medical devices is critical both to the successful functioning of the United States (U.S.) healthcare system and to the continued quality, safety, and effectiveness of marketed medical devices in the U.S.*” Indeed, many OEMs (original equipment manufacturers) act as third-party servicers to other OEMs or rely on contracted third-party servicers to meet their own servicing needs. AdvaMed believes high quality third-party servicers – supported by training for appropriate product knowledge – are needed to ensure sufficient device servicing capacity and cost-effective servicing.

The report states that “*some have tied... alleged problems to third-party entities’ difficulty in obtaining necessary device servicing manuals, technical specifications, quality replacement parts, and access to training from original equipment manufacturers.*” Many OEMs provide training on servicing of their devices in order to ensure that the device remains safe and effective for patients (e.g., their own personnel, hospital customers, and affiliated servicers). Some OEMs train their service personnel to service specific product lines, and as an example, training on the product line may require three months or more with periodic recertification required (e.g., every two years).

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<sup>1</sup> AdvaMed recognizes that FDA is moving toward ISO 13485:2016 as a replacement for QSR.

It's also important to understand sharing manuals, specialized tools or software does not ensure the servicing is done correctly. Without basic quality systems in place (e.g., such as ensuring training of personnel, evaluating parts suppliers, calibrating tools and maintaining records of such, and maintaining device service and preventive maintenance records, etc.) there is no way for FDA to ensure that products serviced by third-parties continue to meet applicable requirements and specifications.

FDA indicated it used the same working definitions for recondition/refurbish/rebuild, service, repair, remanufacture, and remarket for the FDARA report as it used for its October 2016 public workshop. AdvaMed continues to support the changes to these key definitions that we outlined in our comments to the 2016 public workshop docket. Our recommended changes to the definitions are provided again below. We would also note that third-party servicers may use multiple terms to describe the types of activities they perform, not all of which may be captured by the below definitions. If FDA decides to take action in this area, it should make clear all like activities are intended to be covered whether specifically referenced and/or defined or not.<sup>2</sup>

**FDA definition of recondition as modified:** ~~Restores and/or refurbishes a medical device to the OEM's original specifications. Under limited circumstances the medical device may be restored and/or refurbished to current specifications.~~

And

**FDA definition of refurbish:** Restore device to a condition of safety and effectiveness that is comparable to when new. This includes reconditioning, repair, installation of certain software/hardware updates that do not change the intended use of the original device, and replacement of worn parts.

**AdvaMed comment:**

AdvaMed believes that given the similarities between the FDA proposed definitions of recondition and refurbish and the fact that both definitions are defined by the other term (i.e., the definition of recondition includes refurbish and the definition of refurbish includes reconditioning), only one term and corresponding definition is needed. We recommend retaining the term "refurbish." We would note, however, that there is ambiguity as to what "comparable to new" means, i.e., is it "new" at the time of manufacture or as updated by the OEM? Similarly, if FDA retains the definition of recondition, there is ambiguity around "under limited circumstances" i.e., when would devices be reconditioned to original specifications versus current specifications?

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<sup>2</sup> For example, FDA referenced the term "rebuild" in the title of the Federal Register Notice but it is not proposed to be defined. Third-party service providers could then argue that FDA does not intend to regulate rebuilding.

**FDA definition of repair:** Return the device or component to original specifications including replacing non-working components or parts outside of routine or periodic upkeep for the current owner of the device.

**FDA definition of service as modified:** Preventive maintenance or repair of a finished device after distribution for purposes of maintaining it within or returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing *cannot* change the intended use(s) of the device from its original purpose(s).

**FDA definition of remanufacture:** Process, condition, renovate, repackage, restore, or any other act done to a finished device that significantly changes the finished device's performance, safety specifications, or intended use.

**AdvaMed comment:** AdvaMed agrees with the FDA definitions of repair and remanufacture. We believe the definition of service should be modified to incorporate the concept of preventive maintenance i.e., preventive maintenance or repair of a finished device after distribution for purposes of maintaining it within or returning it to the safety and performance specifications established by the OEM and to meet its original intended use. Servicing *cannot* change the intended use(s) of the device from its original purpose(s).

**FDA definition of remarket as modified:** The act of ~~facilitating the~~ transferring of a previously owned medical device from one party to another by sale, donation, gift, or lease.

**AdvaMed comment:** AdvaMed recommends removal of the term “facilitate” because it implies the use of “brokers” or third-parties who refurbish or remanufacture medical devices. Under the FDA definitions of refurbish or remanufacture, these devices must meet certain safety and effectiveness requirements. However, not all remarketed devices meet safety and effectiveness requirements. For example, used medical devices may be sold on e-Bay without any entity ensuring the safety and effectiveness of the device. The essential issue is that remarketing results in the transfer of a used medical device. If FDA decides to take action in this area, it should ensure that minimum safety and effectiveness standards govern all device remarketing. Some third-parties are significantly modifying OEM devices and then reselling them – typically on the internet (e.g., via eBay) – with no guarantee of safety or performance. It is unclear whether these entities are remanufacturers who are failing to follow FDA regulations or remarketers. This is extremely concerning, and we believe FDA should address these remanufacturer and remarketer issues.

AdvaMed is concerned that the report only reflects information received through December 31, 2017. AdvaMed provided FDA with information in January 2018 from six manufacturers who recorded at least 281 adverse events (also referred to as Medical Device Reports or MDRs) from 2012 to 2017 associated with third-party servicing. For some devices (e.g., imaging devices), up to **38,500 patients and/or operators were exposed to the potential for harm**. These included the following adverse events representing *Actual or potential patient and/or operator impacts from these reports include:*

- Screwdriver tip lodged in patient,
- Operator injury, counterpoise support system arm (80-93 pounds) struck operator,
- Potential for repeat CT scans and contrast administration with concomitant risk of additional radiation exposure,
- Potential for burns including internal or oral third-degree burns which may not be apparent until burning tissue is sensed,
- Delayed surgery (potential for worsening patient condition),
- Prolonged surgery (may result in longer exposure to anesthesia, greater potential for infection, and more blood loss),
- Potential for concussions and/or fractures,
- Infusion therapy - Air in System – potential harms include death, neurological changes, stroke, seizures, cardiac and/or respiratory arrest, pain, decreased oxygenation, arrhythmia, pulmonary hypertension,
- Delays in infusion therapy with delay of pharmacological effects and/or worsening of patient condition including death,
- Insufficient or excessive infusion therapy or interruption of therapy and/or worsening of patient condition including death, and
- Temporary hearing loss; ringing in ears.

Unfortunately, it appears this information did not factor into the report.

### **Comments on Section 2: Existing Authorities and Regulations**

FDA states “*proper servicing is critical to the ongoing safety and effectiveness of many devices, particularly those used on numerous patients over long periods of time; **poor quality servicing may lead to poor device performance, malfunction, and adverse events.** Further, FDA believes it could interpret certain activities to which certain statutory requirements apply to include servicing. Given these, and that the requirements of the FD&C Act continue to apply after a device is sold, for example, to a hospital or other user facility, FDA believes it has statutory authority to regulate device servicing.*”

We concur that FDA has statutory authority to regulate device servicing. Indeed, during the May 2, 2017 Energy and Commerce Health Subcommittee hearing titled “Examining Improvements to the Regulation of Medical Technologies,” Dr. Jeff Shuren, Director, Center for Devices and Radiological Health, responded to Representative Gene Green’s (D-TX) question about the rules and requirements that currently apply to third-party service providers, stating “So, in our regulation on quality systems, we had made clear that third-party servicers are manufacturers, but they have been subject to *enforcement discretion* [emphasis added]. We have not enforced those requirements.”

In the October 1996 final rule establishing the Quality System Regulation (QSR) makes clear in numerous sections of the regulations that servicing falls within FDA’s statutory authority:

- FDA stated in the Preamble to the QSR that the rule applied to contract sterilizers, installers, specification developers, repackagers, relabelers, and initial distributors “primarily because all such persons may have a significant effect on the safety and effectiveness of a device and on the public health” and that “all persons who perform these functions meet the definition of manufacturer, and therefore should be inspected to ensure that they are complying with the applicable provisions.”
- In 820.1(a) Applicability, FDA states that “Current good manufacturing practice (CGMP) requirements are set forth in this quality system regulation. The requirements in this part govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing [emphasis added] of all finished devices intended for human use. The requirements in this part are intended to ensure that finished devices will be safe and effective and otherwise in compliance with the Federal Food, Drug, and Cosmetic Act (the act).”
- In Section 820.50 Purchasing Controls, FDA states “first as used in the regulation ‘service’ [emphasis added] means parts of the manufacturing or quality system that are contracted to others . . . . Second, FDA believes that all suppliers of such services must be assessed and evaluated, just like a supplier of a product. As always, the degree of control necessary is related to the product or service purchased.”
- In Section 820.100, FDA requires manufacturers to “establish and maintain procedures for implementing corrective and preventive action including analyzing processes, work operations, . . . service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.” FDA requires “appropriate statistical methodology shall be employed where necessary to detect recurring quality problems” including “identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems” among others.<sup>3</sup>
- Ultimately, FDA decided to exclude the terms “ ‘servicer’ and “ ‘refurbisher’ ”... in this final [quality system] regulation, even though it believes that persons who perform such functions meet the definition of manufacture.” Instead, FDA said “FDA has

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<sup>3</sup> If third-party servicers fail to report problems with the device, manufacturers will then, by definition, be unable to meet this section of the QSR (i.e., use appropriate statistical methodologies and correct and prevent issues associated with their device). Additionally, if the OEM does not have visibility to the servicing and refurbishment activities of third parties – some of whom may service devices incorrectly or utilize incorrect replacement parts – OEM efforts to perform product performance trending will be compromised and some corrective and preventive actions will not occur.

elected to address application of the CGMP requirements to persons who perform servicing and refurbishing functions outside the control of the original manufacturer in a separate rulemaking later this year, with another opportunity for public comment.”

- In December 1997, FDA issued an advance notice of proposed rulemaking indicating its intent “to revise and amend its compliance policy guides and regulatory requirements relating to . . . the persons who refurbish, recondition, rebuild, service or remarket” devices. Unfortunately, FDA never acted further to exercise the authority it has clearly stated it has to regulate servicers.

It is unclear why FDA never completed action on a regulation to establish regulatory requirements for third-party servicers and remarketers. Despite determining that “proper servicing is critical to the ongoing safety and effectiveness of many devices,” FDA appears to have established a higher bar for regulation of OEM servicing versus FDA choosing not to enforce regulation of third-party servicers unless a “widespread public health concern related to . . . third-party servicing”<sup>4</sup> exists. Unfortunately, while FDA acknowledges it has authority to regulate servicers and that poor-quality servicing may lead to poor device performance, malfunction and adverse events, FDA has not taken any steps to oversee third-party servicing outside of indicating it will issue guidance on remanufacturing (and hold a related public meeting). All parties servicing medical devices should be equally regulated.

### **Comments on Section 2.1.2: Medical Device Reporting (MDRs)**

This section of the report outlines adverse event reporting requirements that apply to OEMs and device user facilities. FDA states that “There is no obligation for User Facilities (UFs) or manufacturers to notify third-party entities about adverse events related to the servicing of the device. Manufacturers, UFs, device users, and others may choose to inform third-party servicers voluntarily.”

The report fails to note the fact that if third-party servicers are not required to register or mark the devices they service, it will be impossible, in the vast majority of cases, for the OEM to notify third parties about adverse events. More importantly, FDA fails to point out that third-party servicers are not required to report MDRS, *either* to FDA *or* the OEM.

FDA acknowledges there are limitations with the MDR system: “. . . this passive surveillance system has limitations . . . .” However, continuing to practice ‘enforcement discretion’ with respect to MDR reporting by third-party servicers will not enhance reliability of the surveillance system.

AdvaMed recommends that a new question should be added to FDA’s MDR reporting form 3500A to ask whether the device was serviced by a non-OEM service provider followed by a

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<sup>4</sup> FDA Report on the Quality, Safety, and Effectiveness of Servicing of Medical Devices; p. 23.  
Note: OEM servicing is already regulated by FDA.

check box for “Yes” and a checkbox for “No.” We also believe the name of the service entity and the address of the service entity should be requested to enable more granular analysis of MDR data by FDA.

### **Comments on Section 2.2: Centers for Medicare and Medicaid Services (CMS) and The Joint Commission (TJC)**

FDA notes that in 2013 CMS issued updated guidance that enables a “*hospital [to] adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment, based on a risk-based assessment by qualified personnel, unless other Federal or state law or hospital Conditions of Participation (CoPs) require adherence to manufacturer’s recommendations and/or set specific requirements, the equipment is a medical laser device, or new equipment without a sufficient maintenance history ....*” Such policies are referred to as Alternative Equipment Maintenance (AEM) policies. This CMS guidance essentially allows hospitals to establish AEM programs for the vast majority of devices without reference to the OEM’s servicing and preventive maintenance recommendations which are based on the device’s design control process (e.g., reliability, durability and usable life of device components) and validation and verification testing. Since hospitals do not have access to device design controls, it is unclear how they can reliably establish AEM schedules. FDA also referred to the Joint Commission’s standards in this area.

Importantly, the CMS and TJC policies on equipment maintenance focus only on the maintenance choices of the hospital, and do not govern the activities of the servicer which could include a hospital biomedical engineer. A hospital may be compliant with its AEM, which is problematic in and of itself, but if the entity performing the service does not have a quality system in place, the safety of patients and healthcare professionals may be at risk. CMS and TJC could follow the lead of the United Kingdom which requires hospitals and community-based organizations to use service providers or third-party organizations who comply with relevant quality systems such as European Standard BS EN ISO 13485:2012 [20] or BS EN ISO 9001:2008 [21] when possible.<sup>5</sup>

### **Comments on Section 2.3 U.S. Federal Trade Commission (FTC)**

FDA outlines the U.S. Federal Trade Commission’s mission and quotes from the FTC website: “*A vertical arrangement may violate the antitrust laws, however, if it reduces competition among firms at the same level (say among retailers or among wholesalers) or prevents new firms from entering the market. This is particularly a concern in markets with few sellers or those dominated by one seller.*”

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<sup>5</sup> See Medicine’s & Healthcare products Regulatory Agency Guidance for healthcare and social service organisations: Managing Medical Devices, April 2015, p. 34 at: [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/421028/Managing\\_medical\\_devices\\_-\\_Apr\\_2015.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf)

An agreement between an OEM manufacturer and a buyer regarding parts or services is a vertical agreement. The FTC statement cited by the FDA points to two potential problems raised by vertical agreements. The first is that, under some circumstances, they may promote horizontal collusion or coordination among manufacturers or among buyers. There is no evidence that provisions regarding repairs or service promote coordination at either level and, in fact, the critics of these restrictions have never argued that these provisions have that effect. The second problem suggested by the FTC statement is that vertical restrictions may exclude companies from entering into a market and create a dominant market position for the company imposing the restrictions, creating an uncompetitive market. For example, if a dominant manufacturer of a particular device type requires all its customers to purchase repairs services from the manufacturer, it could be attempting to acquire a dominant position in the repair market. Determining whether there is an anti-competitive effect depends on a variety of factors, including the market share of the manufacturer, the structure of the repair market, the specific policies of the manufacturer in sales of parts and information to customers and third parties, and the technical reasons for the restrictions.

There are several reasons why medical device OEM's restrictions on spare parts and repair services do not raise any competitive problems. First, as a general matter, any restrictions imposed by an OEM on a buyers' use of non-OEM spare parts and service manuals can only harm competition if the manufacturer has significant market share for the device, and medical device manufacturers rarely have significant market share in any relevant market. That is true even if the manufacturer has a patent because there are still competing manufacturers in the same market. Second, OEM manufacturers have a strong incentive to provide a favorable environment for their buyers when buyers need to repair or service their products. Sophisticated buyers, such as hospitals, consider any restrictions OEM manufacturers may require regarding parts and repairs when they make a decision to purchase the device. If the buyer places a high value on the ability to repair the device themselves or to access aftermarket parts instead of OEM parts, it can consider purchasing the device from another source.

Finally, the evidence is clear that OEM manufacturers are not attempting to gain a dominant position in the repair market for themselves. Instead, they have an incentive to sell replacement parts to buyers and third-party service providers as long as they can be assured that the repairs will meet minimum safety and quality standards. Manufacturers that require use of OEM parts are typically willing to sell those parts to buyers of the device as well as to third parties along with a license to use them if they are patented. Often, they allow third parties to manufacture replacement parts if they conform to certain standards. Thus, the overwhelming evidence is that manufacturer restrictions on sale of parts and service providers is to protect patients and maintain the high-quality functioning of a device rather than to gain a dominant position in the replacement parts and service markets.

Sometimes it is argued that if manufacturers require buyers to purchase replacement parts only from the manufacturer, this constitutes a "tying arrangement" that violates the antitrust laws. However, it is rare that an illegal tying arrangement exists. The leading Supreme Court case in this area, *Kodak Co. v. Image Technical Services, Inc.*, 504 U.S. 451 (1992), involved a restriction by Kodak which prohibited buyers from purchasing replacement parts unless they

agreed not to purchase repair services from independent service providers. Similarly, in *In re. Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322 (Fed. Cir. 2000), an independent service organization (ISO) claimed that a manufacturer's refusal to sell its patented parts and copyrighted manuals and to license copyrighted software violated antitrust laws. The United States Court of Appeals for the Federal Circuit held that (1) the manufacturer's refusal to sell or license its patented parts did not violate antitrust laws, and (2) the manufacturer's refusal to sell or license its copyrighted materials and software did not violate antitrust laws. In summary, most manufacturers do not prohibit their buyers from purchasing repair services from third parties. Further, a restriction on the buyer which requires buyers to use OEM parts can harm competition only if the manufacturer had significant market share in the repair market and charged anti-competitive prices in that market. That is rarely the case.

### **Comments on Section 2.4 State Regulations**

In this section, FDA discusses states where right to repair legislation has been introduced. Right to repair legislation was introduced in eighteen states in 2018. However, the legislation failed to pass in every state except for Vermont, where a bill to study and report on repair of consumer electronics prior to the next legislative session was enacted. Further, right to repair legislation has largely been focused on consumer electronics and a number of states amended their legislation to exempt medical devices due to patient safety concerns.

### **Comments on Section 4: Public Workshop**

The report makes the following statements:

*“The workshop participants expressed general agreement on the importance of quality medical device service. Quality servicing maintains and/or restores device conformance with specifications and performance standards; resolves unintended, inappropriate, or improper device function and does not contribute to a recurrence of problems; and produces sufficient information for the facility and those servicing the device in the future to know the service history and current device configuration. All stakeholders presenting and participating in the panel discussions emphasized the importance of and their commitment to patient safety, and agreed that quality medical device service is essential to ensuring patient safety. Participants also spoke of patients’ and healthcare providers’ shared interest in ensuring that a medical device continues to perform according to its original design and intended use.”*

*“The panel members representing hospital end users and engineers emphasized the importance of service engineers with appropriate qualifications, adequate training, appropriate and calibrated test equipment, and the availability of field service reports and maintenance records. They noted the apparent overlap between TJC oversight and FDA QS regulation requirements, in such areas as quality audits, personnel, document control, inspection, acceptance, and records.”*

*“The panel members from ISOs agreed that high quality servicing entities share the following core characteristics: a patient safety focus, strong quality management system, alignment within users of serviced equipment, commitment to scheduled preventative maintenance, and a local presence important to end users.”*

We concur that there was general agreement on the importance of quality medical device servicing, the key elements of the QSR as they apply to servicing, and that ISOs agree that high quality servicing includes a strong quality management system. We believe the public workshop provided FDA with support to apply scalable regulatory requirements to third-party servicing.

### **Comments on Section 5.3: ECRI Institute Analysis**

FDA briefly summarized an ECRI Institute Analysis without providing important commentary. In an attempt to better understand the outcomes of the ECRI Search, AdvaMed attempted to analyze the methods, results, and conclusions of the report. We found multiple issues that require further clarification along with other problems that raise questions regarding the validity of ECRI’s conclusion.

The hallmark of a valid search conducted on FDA’s MAUDE Database is the ability for the search to be repeatable. If the search cannot be conducted in the same manner (to as much of a degree as possible) then it will not be possible for outside parties to validate or confirm the results of such a search. The following details of the search method of the ECRI search were not outlined in ECRI’s comments to FDA’s original docket:

- It is unclear as to how the search was limited to only capital equipment. While the report indicates that records were excluded based upon being prostheses, implants, reagents, etc., it is not stated whether this was done by an individual review of each report or if a higher-level means was utilized to narrow the search to capital equipment (i.e., by product code).
- The search was stated to be limited to only capital equipment, but it is not indicated as to whether or not multiple use, non-serviceable devices were also excluded.
- ECRI stated that general search terms were utilized to search the database and that additional search phrases were linked to the search terms. It is unclear if the additional search phrases were utilized as a filter after the reports were narrowed down, creating a new subset of reports which were then deemed applicable. An updated number of applicable reports from the original denominator was not provided at this point (or the original denominator was not provided). Additionally, ECRI stated that “These search strategies were cross-referenced many ways...”. Further detail was not provided on the ways in which the strategies were cross-referenced.
- After the search strategies were conducted, ECRI stated that each report was individually analyzed and hits were then excluded based upon certain criteria. It was not stated how many reports were excluded due to the individual analysis. It remains

unclear as to whether the first identified denominator of 2,114,303 reports is the outcome of all of these search strategies, or if this number was further narrowed based upon the search strategies.

#### **Comments on Section 5.4: Medical Device Reports (MDRs)**

FDA conducted its own analysis of MDRs received and publicly posted in the Manufacturer and User Facility Device Experience (MAUDE) database between March 1992 and June 30, 2017. Per FDA, they found 4,301 MDRs including 40 deaths, 294 serious injuries, 3,791 malfunction reports, and 176 reports classified as “other.”

Although, the MAUDE database cannot be used to conclusively establish a definitive relationship between third-party servicing and a particular adverse event, 40 deaths is significant in any scenario. Additionally, nearly 3,800 malfunction reports potentially associated with third-party servicing is concerning as it speaks to the effectiveness of the devices. In addition, as described in more detail above, in January 2018, AdvaMed shared information with FDA from six manufacturers who recorded at least 281 adverse events (also referred to as Medical Device Reports or MDRs) from 2012 to 2017 associated with third-party servicing. For some devices (e.g., imaging devices), up to 38,500 patients and/or operators were exposed to the potential for harm. Importantly, if FDA had processes or controls in place to monitor third-party servicing (e.g., required reporting of MDRs), it would be in a significantly better position to conclusively link a specific MDR to third-party servicing problems.

#### **Comments on Section 6: Summary of Key Issues and Ongoing Activities**

FDA makes the statement that *“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’.... ”*

While we concur that remanufacturing of devices is a concern, the data outlined in the report does not substantiate this claim (i.e., 28 remanufacturing complaints plus 1 remanufacturing death were identified versus 334 MDRs of deaths or serious injury). Further, if remanufacturing is being undertaken by third-party servicers, it is unclear how FDA could communicate or inform these entities of regulatory requirements if they are not registered and are therefore unknown to FDA. The report clearly states that the number of third-party servicers is unknown and FDA relied on an estimate.

#### **Comments on Section 6.1: Promote the Adoption of Quality Management Principles by Medical Device Servicers**

We concur with FDA that *“[quality management principles] ...are flexible, scalable, and adaptable so organizations can tailor the application of these standardized processes to their individual circumstances and needs.”* Thus, we are concerned that FDA stopped short of applying these principles to all medical device servicers and instead indicates that FDA will

work with servicers to identify voluntary quality standards. This process is unnecessary as FDA has already identified proper QSR tenets that manufacturers must meet. The same scalable standards should apply to third-party entities.

FDA also appears to suggest that it supports provision of OEM service manuals to third-party servicers: *“Quality management principles provide a quality framework for companies and organizations to ensure that: . . . Technical and service manuals are accurate, understandable, and available to those providing service and maintenance.”*

This implies that simply providing manuals to third-party servicers will ensure appropriate servicing. However, sharing of OEM manuals and specialized tools does not ensure the servicing is done correctly. Some OEMs train their service personnel to service specific product lines and as an example, training on the product line may require three months or more with periodic recertification required (e.g., every two years). Without basic quality systems in place (e.g., such as ensuring training of personnel, evaluating parts suppliers, calibrating tools and maintaining records of such, and maintaining device service and preventive maintenance records, etc.), there is no way for FDA to ensure that products serviced by third parties continue to meet applicable requirements and specifications. Simply providing manuals will not ensure safe and effective servicing.

Based on input from AdvaMed’s membership, AdvaMed has found that OEMs limit distribution of OEM manuals and specialized tools to non-affiliated third-party servicing entities for the following reasons:

- Security concerns (e.g., cybersecurity concerns)
- HIPAA and patient privacy concerns
- Intellectual property concerns
- Safety and efficacy concerns
- Processes are not in place to notify third-party servicers when significant changes to the device have occurred
- Third-party servicer(s) do(es) not have acceptable device maintenance process in place

### **Comments on Section 6.2: Clarify the Difference Between Servicing and Remanufacturing**

FDA recently issued a white paper on this topic and is planning a public meeting on the topic in December 2018. AdvaMed is still reviewing the white paper and will provide comments on the paper and the workshop to the FDA docket. We will note though that since FDA does not know which third parties may be servicing (or in actuality, remanufacturing devices), it is not clear how the 16,000 to 20,000 third-party servicers will become aware of guidance on this topic.

### **Comments on Section 6.3: Strengthen Cybersecurity Practices Associated with Servicing of Medical Devices**

FDA made the following statement:

*The servicing of medical devices by entities other than the OEM raises specific cybersecurity challenges related to the servicer's need, in many cases, for privileged access to perform the necessary diagnostic, maintenance and repair functions. Servicers may also play an important role in reducing cybersecurity risks by ensuring that the latest security patches and software updates have been successfully installed.*

It is unclear what FDA is suggesting. If FDA is suggesting that OEM and OEM-affiliated third-party servicers can play an important role in reducing cybersecurity risks by ensuring the latest security patches and software updates have been installed, we agree. However, if FDA is suggesting, as some third-party servicers have suggested – that OEMs provide hard-coded passwords to the third-party servicers that are not affiliated with OEMs, then we disagree. It is hard to understand how unfettered distribution of passwords to thousands of third-party servicers enhances cybersecurity (per FDA's estimates, possibly 16,520 to 20,830 third-party servicers exist).

Again, it is unclear if FDA is suggesting this, but it would also be directly contrary to the advice FDA provides in its guidance entitled: ***Content of Premarket Submissions for Management of Cybersecurity in Medical Devices***. The guidance states: "Limit access to devices through the authentication of users (e.g., user ID and password, smartcard, biometric);" and "Strengthen password protection by avoiding "hardcoded" password or common words (i.e., passwords which are the same for each device, difficult to change, and vulnerable to public disclosure) and limit public access to passwords used for privileged device access...."

It is also contrary to the advice of the Department of Homeland Security's Industrial Control Systems Cyber Emergency Response Team (ICS-CERT) which cites FDA's advice: "Take steps to limit unauthorized device access to trusted users only, particularly for those devices that are life-sustaining or could be directly connected to hospital networks.

- Appropriate security controls may include: user authentication, for example, user ID and password, smartcard or biometric; strengthening password protection by avoiding hard-coded passwords and limiting public access to passwords used for technical device access; physical locks; card readers; and guards."

### **Comments on Section 6.4: Foster Evidence Development to Assess the Quality, Safety, and Effectiveness of Medical Device Servicing**

FDA made the following statements:

*"Entities engaged in servicing activities (including OEMs, healthcare establishments, and ISOs) have access to, or could collect comprehensive information on device types, number of devices serviced, frequency of servicing, frequency of service-related*

*complaints, frequency of service-related adverse events, and characteristics of the servicing entity. FDA believes that any concerted data collection and analysis effort should be a multi-stakeholder enterprise.”*

*“As noted previously, we have concluded that the 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 additional/different burdensome regulatory action. To evaluate the servicing ecosystem more fully would require more than limited, anecdotal adverse event reports, but robust, systematically-collected, quantitative data addressing the rates of servicing-related errors, malfunctions, and adverse events, across different device types and different servicers.”*

FDA has already acknowledged it has the regulatory authority to regulate servicing, including third-party servicing. As noted previously, OEM servicing is already regulated. FDA could require all the relevant stakeholders to submit MDRs on servicing which would begin to build the data FDA states is necessary to evaluate the device servicing ecosystem. FDA’s recommendation for multi-stakeholder efforts while at the same time not requiring third parties to report Adverse Events, is contrary to obtaining objective evidence to assess servicing.

In closing, thank you for the opportunity to provide AdvaMed’s comments on the FDA Report on the Quality, Safety and Effectiveness of Servicing of Medical Devices in Accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA). Please don’t hesitate to contact me if I can respond to any questions you may have.

Sincerely,

/s/

Tara Federici  
Vice President  
Technology and Regulatory Affairs