

Via Electronic Submission

February 2, 2024

Federal Trade Commission
600 Pennsylvania Avenue NW
Washington, DC 20580

Re: Docket Number FTC-2023-0077 Petition for Rulemaking of PIRG and iFixit

Dear Sir/Madam:

These comments are submitted on behalf of the Advance Medical Technology Association (“AdvaMed”). AdvaMed is a trade association representing the world’s leading innovators and manufacturers of medical devices, diagnostic products, digital health technologies, and health information systems. Together, our members manufacture much of the life-enhancing and life-saving health care technology purchased annually in the United States and globally. AdvaMed members range from the largest to the smallest medical technology producers and include hundreds of small companies with fewer than 20 employees.

The comments are in response to a notice issued by the Federal Trade Commission (FTC) on January 3, 2024, requesting public comment regarding a petition by the Public Interest Research Group (“PIRG”). PIRG petitioned the FTC to initiate a broad rulemaking proceeding with the goal of promulgating a rule that would impose requirements on manufacturers of many types of products to allow users a “right to repair” those devices. As envisioned by PIRG, the rule would include not only consumer devices such as television and home appliances, but also complex medical devices regulated by the Food and Drug Administration (FDA). For the reasons discussed below, AdvaMed urges the Commission not to initiate a rulemaking proceeding that includes provisions creating a right to repair FDA-regulated medical devices.¹ Our comments do not address a possible rule regarding other products.

¹ The term “medical devices” is a broad one. It conceivably includes many products that are not regulated by the FDA. Throughout our comments we refer to FDA-regulated medical devices as simply “medical devices.”

AdvaMed has previously made submissions to the FTC staff regarding many of the issues raised by the repair and maintenance of medical devices, which we have attached.² These include a “Submission to the FTC Regarding Servicing Restrictions” (Attachment 1) and a “Supplementary Submission to the FTC Regarding the Repair of Medical Devices” (Attachment 2). In connection with these submissions, AdvaMed representatives met with FTC staff virtually to discuss these issues and respond to their questions. Because the analysis and information in these submissions remain current, we include them as part of our comments. Our Imaging Section, which includes the largest U.S. manufacturers of medical imaging equipment, such as X-ray machines and MRIs, has also prepared an analysis of right to repair issues, which will be filed separately. We believe this analysis can be helpful to the FTC as a useful, detailed analysis of why such a rule would not be helpful to consumers or competition.

II. Lack of Evidence of Unfairness or Deception

The FTC has asked for comment on a possible rulemaking proceeding based on 15 U.S.C. 57a(1)(B) of the FTC Act. That section provides authority to the FTC to promulgate rules regarding “unfair or deceptive practices.” The FTC notice does not propose rulemaking based on Section 6(g) of the FTC Act, 15 U.S.C. 46. Thus, we assume that the FTC is not contemplating a rule based on a finding of unfair methods of competition.

The FTC only has authority to promulgate a rule under § 57(a)(1)(B) if the practice “causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or to competition.”³ Although the terms “unfairness” and “deception” are not defined in the Act itself, the FTC has issued policy statements summarizing the relevant case law and the FTC’s own interpretation of them. Ultimately, the courts determine the meaning of these terms, but the FTC will no doubt rely upon its own interpretation in any rulemaking proceeding. The meaning of these terms, therefore, are of central importance in deciding whether to initiate a rulemaking proceeding. In order to promulgate a rule, the FTC must have substantial evidence that practices regulated by the rule are “unfair” or “deceptive” or both.

There is no serious allegation that manufacturers of medical devices engage in deceptive practices regarding repair policies. The PIRG petition includes no evidence of deception and no serious allegations have been made by others. Therefore, we do not address the possibility that the FTC

² The idea of “right to repair” typically includes maintenance as well as repair. Below we refer to “repair” to include maintenance.

³ 15 U.S.C. 45(n). We assume that “consumers” in this context means patients who receive medical services.



might base a rule on a finding of deceptive practices. Thus, any rule issued by the FTC would have to be based on a finding of unfair practices.

The Commission Statement of Policy on the Scope of the Unfairness Authority (Policy Statement) remains the most authoritative statement of what constitute “unfair practices” within the meaning of Section 5 of the FTC Act.⁴ The Policy Statement identifies three factors that should be applied in determining whether unfair practices are taking place: 1) whether the practice injures consumers; 2) whether it violates established public policy; and 3) whether it is unethical or unscrupulous. As discussed below, none of these factors exist.

Manufacturers of medical devices employ a wide variety of policies regarding their customers’ repair of their products. In many cases, the manufacturer imposes no restrictions on repairs. In other cases, they do. The types of repair restrictions imposed by medical devices manufacturers are described in Attachment 1.⁵ Repair restrictions are related to the complexity of the device and the classification of the device by the FDA.

Medical devices regulated by the FDA fall into three categories – Class I, Class II and Class III.⁶ Class I devices, which can be sold to consumers, are comparatively simpler devices, such as hospital beds and crutches, which may not require repairs or maintenance. Class II and Class III devices are subject to general pre-market and post-market regulatory controls. Some Class II devices are also subject to special pre-market and/or post-market controls. Additionally, some Class II devices are sold directly to consumers, but these are rarely subject to restrictions on repair and maintenance. In general, the only medical devices that are subject to restrictions on repair and maintenance are either Class II or Class III devices, which are sold to medical providers, such as hospitals and clinics. We presume that, if the FTC initiates a rulemaking proceeding that includes medical devices, the scope of the rule would be limited to these types of devices.

When repair restrictions are applied to Class II or Class III devices, their primary purpose is to ensure that unqualified repair personnel do not create a risk to patients or health care personnel through repairing devices improperly. Any FTC blanket “right to repair” rule would need to take into account FDA’s pre-market and post-market general controls that apply to all devices as well as any pre-market and post-market special controls that may apply to certain Class II devices. This would

⁴ The Commission’s notice does not refer to a rule based on a finding of “unfair methods of competition.” As we have shown in a previous submission, there is no credible claim that restrictions imposed on repairs by medical device manufacturers harm competition. See Attachment 1, pp. 2-4.

⁵ See p. 6.

⁶ The FDA’s classification system is described in *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1004-05 (7th Cir. 2020). See also [Classify Your Medical Device | FDA](#).



create significant complexity and any such rule could conflict with FDA regulatory requirements since some of these post-market controls apply to repair and servicing.

There is no evidence that repair restrictions harm consumers.

Repair restrictions by medical devices manufactures do not harm consumers. The reality is exactly the opposite. Repair restrictions benefit consumers by preventing repairs by unqualified persons that can cause these devices to become dangerous or to function improperly. There is considerable evidence that repairs by unqualified persons have harmed consumers. See Attachment 1, p. 6.

Claims that repair restrictions harm consumers generally fall into two categories. The first is that restrictions designed to prevent unqualified persons from repairing devices increase the costs of repairs through reducing competition. That is a claim often made by Independent Service Operators (ISOs), which offer repair services. This industry has many participants, which are typically small businesses. See Attachment 1, p. 4.

The claim that repair restrictions raise the costs of repairs essentially amounts to a claim of unfair methods of competition, which we do not understand to be the FTC's focus. In any event, we have shown that these restrictions do not harm competition.⁷ The other claim is based on isolated examples where there is an allegation that repairs were delayed or prevented because the owner of the device could not comply with a manufacturer's repair policies. For example, one allegation is that, during the COVID pandemic, restrictions on repairs caused a delay in the repair of ventilators. We have investigated this claim and have found no evidence to support it. In fact, medical device manufacturers made substantial efforts during COVID to ensure that ventilators and other devices used to diagnose and treat patients were repaired and serviced promptly and properly.

Restrictions on repairs and maintenance do not violate established public policy.

There is no established public policy that manufacturers should allow unqualified persons to repair medical devices. The principal policymaker regarding the quality of medical devices is the FDA. We discuss the role of the FDA in Attachment 1.⁸ The FDA has thoroughly reviewed the market for repairing medical devices because of its responsibility to ensure that regulated devices are safe and effective. Medical device original equipment manufacturers ("OEMs") are subject to the FDA's Quality System Regulations ("QSR").⁹ The QSR requires that OEMs ensure the quality

⁷ See Attachment 1, pp. 1-2, 7 and Attachment 2, Appendix.

⁸ See p. 7.

⁹ See 21 CFR Part 820.



and safety of their products even after an initial sale to a medical provider. In other words, the public policy of the FDA is that manufacturers ensure that these devices are repaired and serviced properly. It does not mandate a “hands off” approach that would give buyers of these devices unfettered discretion in deciding how devices are repaired. AdvaMed’s position is that the FDA should extend these policy standards to Independent Service Organizations (ISOs), but the FDA has not chosen to do so.

Restrictions on repairs and maintenance of medical devices are not unethical or unscrupulous.

There are no serious allegations that these kinds of restrictions, which are intended primarily to protect patients, are unethical or unscrupulous as those terms have been used in prior FTC cases.

In summary, there is no evidence that restrictions on repairs implemented by medical devices manufacturers are unfair within the meaning of the FTC Act. Therefore, the FTC has no legal basis for promulgating a rule covering repairs of medical devices.

III. Purchasers of Medical Devices are Highly Sophisticated and Competent

The FTC’s traditional concern about unfairness is that consumers, because of a lack of information or a breakdown in competition, are vulnerable to harmful practices. That concern does not apply with respect to medical devices. Repair restrictions, where they exist, are typically applied to devices purchased by large, sophisticated purchasers, such as hospitals and clinics. If the FTC initiates a rulemaking proceeding that covers medical devices, the rule would have to address purchases by medical providers since consumers do not directly purchase complex medical devices. Medical provider entities that purchase these devices include large hospital networks with revenues exceeding one billion dollars. They typically have knowledgeable purchasing departments and legal counsel, which are extensively involved in drafting and negotiating contracts. Most hospitals rely on Group Purchasing Organizations (GPOs) to negotiate a large portion of their contracts. GPOs are also highly sophisticated in negotiating contracts, which include among their terms the way products will be repaired. In short, the purchasers of medical devices that would be the focus of any rule are quite capable of negotiating with sellers regarding how repairs will be done.¹⁰ Thus, the traditional rationale for the use of the FTC’s unfairness authority, that it is needed to protect vulnerable consumers from unfair practices, does not apply to repairs of medical devices.

¹⁰ See Attachment 1, p. 3.



V. The Importance of Intellectual Property

Many medical devices operate based on complex software programs. These programs are included in computer chips or drives that are stored within the device or they are executed by computers that are linked to the device. Most of these software programs are subject to protection by copyright laws. An FTC rule that attempts to bar restrictions on the use of these programs would have the practical result of preventing copyright owners from enforcing the rights associated with their copyrights. For example, a bar on enforcing a copyright would allow an ISO to copy computer programs and modify them.¹¹ Thus, not only would an FTC rule undercut restrictions intended to protect patients, it would undermine the rights of copyright holders.

IV. The Role of the FDA

The FDA is entrusted by Congress with the principal authority to ensure the quality and safety of medical devices. The FDA has exercised this authority by issuing its Quality System Regulations, which include a number of provisions related to repair and servicing.¹² In AdvaMed's view, any additional federal regulation in this area would be more effective and consistent with current law if done by the FDA. As we noted above, AdvaMed has urged the FDA to take a more active role in regulating the activities of ISO.

V. The Risks and Complexity of an FDA Rule

In its *Nix the Fix* report, the FTC staff described the options for the FTC in dealing with repair and servicing issues. These include rulemaking under the Magnuson-Moss Act and case-by-case enforcement.

In our view, applying the FTC Act to the repair of medical devices, if warranted, should proceed by case-by-case enforcement rather than a broad rule. Any rule that applies to medical devices would have to take into account the wide variety of medical devices and their classification by the FDA. In order to justify a rule applicable to these situations, the FTC would need to find that there is a widespread pattern of unfair practices by medical device manufacturers in restricting repairs of medical devices. As we explained above, there is no evidence of unfair practices.

If the FTC, despite this lack of evidence, proposes a rule that covers medical devices, the rule would have to take into account the wide variety of situations when medical devices are repaired.

¹¹ Some of these issues are addressed in pending litigation involving the implementation of the Digital Millennium Copyright Act (DMCA) by the Library of Congress. See *Medical Imaging & Technology Alliance, et al v. Library of Congress, et al*, Docket No. 23-05067 (D.C. Cir. Mar 31, 2023) .

¹² See Attachment 2, Appendix.



Unlike a comparatively simple situation when products are sold directly to consumers, an FTC rule would have to consider the clinical risks involved in improper repairs of such varied and highly complex devices including automated extended defibrillators, magnetic imaging devices, computerized tomography devices, and other diagnostic laboratory equipment. Untrained persons cannot repair these devices without creating risks for patients. It would be highly irresponsible of the FTC to promulgate a rule that allowed untrained and unqualified persons to repair these devices on the basis of some generalized “right to repair.” Thus, a rule would have to be based on a finding that particular training or qualification requirements imposed by manufacturers are “unfair.” We believe it is highly unlikely that courts would uphold a rule that is based on such a finding and that substitutes the FTC’s judgment about these requirements for manufacturers’ judgments.

In addition to the complexities involved in devising such a rule, the FTC would also have to include special provisions to avoid conflicts with the FDA’s QSR regulations. We presume that the FTC does not wish to promulgate a rule that undermines existing FDA regulations. Finally, the rule would have to take into account the intellectual property rights of copyright holders. To the extent that an FTC rule could undermine existing intellectual property rights, the FTC would have to craft a rule that protected these rights or explain how it has the authority to limit them.

In short, there are a number of complexities in trying to address repair restrictions applicable to medical devices in a broad FTC rule, which we feel would be better addressed in case-by-case enforcement. We believe it would be extremely difficult for the FTC to develop a rule that does not create far more harm to consumers than benefits and that does not disrupt the efficient functioning of the market for medical devices.

VI. Conclusion

We do not believe there is any legal basis for the FTC to promulgate a rule regarding repairs of medical devices. Any such rule is likely to do far more harm than good. Thus, AdvaMed recommends that the FTC deny the petition to the extent it proposes a right to repair rule that includes medical devices. AdvaMed takes no position regarding a rule that applies to other products.

Respectfully submitted by:

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SUBMISSION TO THE FTC REGARDING SERVICING RESTRICTIONS

I. INTRODUCTION

This paper discusses the policies of original equipment manufacturers (OEMs) regarding the maintenance and repair of FDA-regulated medical devices.¹ The primary buyers of these devices are hospital networks, individual hospitals and other health care providers. OEMs take various approaches to how their products will be serviced, including: 1) servicing the products themselves; 2) relying on OEM-authorized Independent Service Organizations (ISOs)²; or 3) leaving it up to buyers to arrange for servicing even though the repair entities are not authorized by the OEMs and may be unqualified.³ The primary dispute regarding “right to repair” is whether unauthorized servicing entities in this last category should be able to service devices and have access to information and manuals prepared by the OEMs.

Unauthorized servicing entities have argued that OEM policies on how buyers obtain servicing harm competition and patients.⁴ As we demonstrate in this paper, however, the general approach of OEMs toward the servicing of medical devices complies with FDA regulatory requirements and furthers competition by ensuring that patients are protected and that products are serviced properly. As we discuss below, the medical device manufacturing industry is highly competitive, and manufacturers do not make excess profits servicing products. Instead, limitations on how buyers can service products is intended to ensure that OEMs’ products are serviced properly.

If a device is repaired or serviced improperly, at best, the device is ineffective, and the patient receives no benefit. At worst, improper servicing or repairs can cause serious injury or even death to patients. Thus, OEM limitations on repairs in the medical device industry are good for competition and for patients.

¹ After they are put in use, medical devices require both regular maintenance and repairs. This paper uses the term “servicing” to refer to both types of activities.

² Independent Servicing organizations are comprised of individuals, small and medium sized businesses, and very large businesses. FDA has estimated that there are between 16,520 and 20,830 entities performing device servicing.

³ When health care entities decline OEM servicing and repair, the servicing is not subject to FDA regulation or oversight.

⁴ These policies typically include ensuring that those who service devices are properly trained, are using qualified replacement parts, and limiting distribution of repair manuals and specialized tools to appropriately trained individuals to assure safe and effective medical devices. These policies are also required by FDA Quality System Regulations.



This paper also discusses the FDA's regulatory approach for servicing. OEMs are subject to extensive regulation by the FDA, not only for manufacturing activities, but for their repair and service activities as well.⁵ FDA has the authority to regulate unauthorized servicing entities but has chosen to use its enforcement discretion not to do so.⁶ AdvaMed has recommended to the FDA that it impose the same servicing standards on unauthorized servicing entities that it imposes on OEMs. FDA recently issued draft guidance to help unauthorized servicing entities distinguish between servicing and remanufacturing of medical devices because "FDA concluded that a majority of the comments, complaints, and adverse event reports received by the Agency that referred to inadequate 'servicing' causing or contributing to adverse events and deaths actually pertained to remanufacturing".⁷ Many unauthorized servicing entities fail to understand that the servicing they are performing is actually remanufacturing which FDA actively regulates. However, it did not take the additional step of directly regulating the servicing activities of unauthorized servicing entities. In our view, the most productive step the federal government can take in regard to servicing and repairs of medical devices is for the FDA to impose quality and reporting requirements on these entities.

II. THE APPLICABLE ANTITRUST STANDARDS

The principal issues raised in the debate over OEM policies has been the effect on the costs and quality of repairs. Possible antitrust violations by the OEMs in connection with repair policies are typically analyzed as either monopolization or tying claims. In practice, the analysis for both violations is very similar. The question is whether a manufacturer is driving up repair

⁵ See 21 CFR § 820.1. ("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* of all finished devices intended for human use.") (emphasis added).

⁶ The FDA has acknowledged that it has the authority to regulate third-party repair entities but has decided to defer enforcement with respect to these entities. 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 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."

⁷ FDA has exercised enforcement discretion for servicing and repair but has consistently maintained regulatory authority over remanufacturing activities (i.e., remanufacturers). FDA defines remanufacturer at 21 CFR 820.3(w). FDA's website states "The FDA enforces requirements under the FD&C Act and its implementing regulations on entities engaged in remanufacturing, including but not limited to registration and listing, adverse event reporting, the Quality System (QS) regulation, and marketing submissions." See: <https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/remanufacturing-and-servicing-medical-devices>

costs over competitive levels by unfairly excluding rivals from selling repair services to the manufacturer's buyer or whether the manufacturer's repair policies benefit competition and patients.

The Kodak Decision

Tying cases involve situations when the seller conditions the purchase of one product (the “tied” product) to the purchase of another product (the “tying” product). Despite some early cases suggesting that harmful ties might occur frequently, more recent court opinions have found harm to competition only in a narrow set of circumstances.⁸ The Supreme Court's 1992 *Kodak* decision dealt with an OEM's repair policies that at least indirectly tied repairs to the purchase of original equipment.⁹ In that case, Kodak initially allowed independent repair entities to purchase replacement parts. These entities could then service Kodak products. However, after selling many of its products, it changed its policies and refused to sell parts directly to third party repair entities. Consequently, some of Kodak's buyers were forced to purchase the parts from Kodak. The Court expressed concern that buyers were “locked into” their Kodak device after the original purchase and, therefore, Kodak had the equivalent of a monopoly in the “installed base” of its products and its policies harmed competition in repairing them.

Later opinions and commentary on *Kodak* have been skeptical of the idea that repairs of a single manufacturer's products can constitute a relevant market. They argue that sophisticated buyers will take into account any excessive costs of repairs in their original purchasing decision as long as the repair policy is disclosed to buyers.¹⁰

Medical Device Purchase Contracts

The primary purchasers of FDA-regulated medical devices are hospitals or other health care providers, which typically rely on a procurement system staffed by experts. Sophisticated buyers, such as hospital networks or Group Purchasing Organizations (GPOs), are able to make an assessment of short-term and long-term costs at the time of purchase. As we discuss further below, customers are given a range of options when they purchase medical devices, including taking full responsibility for repairs. Limitations on repairs are frequently the subject of negotiation between OEMs and their buyers. Negotiations can include cost of repairs, and servicing response times by the OEM or OEM-authorized servicers. Thus, OEMs in the medical device industry have little to gain by unnecessarily restricting repairs of their products. Forcing

⁸ Recent opinions are discussed in the FTC's Staff Report, *Nix the Fix* (July 2021), pp. 9-16.

⁹ *Eastman Kodak Co. v. Image Technical Services, Inc.* 504 U.S. 451 (1992).

¹⁰ See, e.g., *Alcatel USA, Inc. v. DGI Technologies*, 166 F.3d 772 (5th Cir. 1999) (affirmed summary judgment for defendant where defendant had not changed its policies after the purchase).

buyers to incur extraordinary repair costs discourages hospitals and other health care providers from making the initial medical device purchase.

Effect of Repair Policies on Competition

The consensus view today is that there is unlikely to be harm to competition if the OEM market is competitive.¹¹ The FTC staff report concludes: “If a purchaser signed a contract containing aftermarket obligations for parts at the servicing at the initial sale, courts likely will not find liability if the purchaser had other options.... On the other hand, if aftermarket costs were unavailable up front, the courts may find that the purchaser is locked-in and liability is possible. Also, if there has been no change in policy by the manufacturer, the courts are unlikely to find the policy exclusionary.”¹²

It is impossible to characterize every product market in the medical device industry since there are hundreds, perhaps thousands, of product markets for devices where repair policies are conceivably an issue. However, the general characteristics of medical device markets make it highly unlikely that OEM repair policies constitute unlawful ties or monopolization. The product markets are generally competitive, and buyers are informed about repair policies and costs when they purchase products.

Medical device product manufacturing markets are highly competitive. Prices for medical devices have grown far more slowly than the Medical Consumer Price Index and even the overall Consumer Price Index. Over the period from 2009 to 2019, medical device prices have increased at an average annual rate of 0.4 percent, compared to 2.9 percent for the MC-CPI and 1.8 percent for the CPI. Consistent with these differences in price trends, medical device spending increased at an annual rate of only 3.1 percent from 2009 to 2019 in nominal dollars, considerably lower than the increase of 4.3 percent in aggregate national health accounts.¹³ There is also strong evidence of price competitiveness in product markets where servicing restrictions are most frequently used, such as diagnostic equipment and complex treatment devices such as ventilators. A J.P. Morgan market assessment for 2019 found that the medical diagnostic industry faced “headwinds” of “increasing competition” and “overlaps among platforms [that] pressures prices.”¹⁴

There is also significant competition for the repair of medical devices. The FDA has estimated that there are between 16,520 and 20,830 firms performing device servicing. Only modest capital investment is required to perform servicing and repairs and other barriers to entry

¹¹ The FTC staff report concurs with this view. See p. 14.

¹² Id.

¹³ Gerald F. Donahoe, Estimates of Medical Device Spending in the United States (June 2021) (analysis supported by AdvaMed).

¹⁴ Diagnostics Market Overview & Key Themes, J.P. Morgan, North American Equity Research (June 2019).

are low as well. Competition in product sales and repair services mean that the conditions for unlawful tying or monopolization are unlikely to exist.

III. OEM REPAIR POLICIES

Proper maintenance and repair of FDA-regulated medical devices are often essential to proper functioning. They are especially important in the case of complex Class III medical devices such as automated extended defibrillators (AED's) and Class II medical devices such as: 1) diagnostic devices, e.g., magnetic resonance imaging devices (MRIs), computerized tomography devices (CTs), and other diagnostic laboratory equipment; 2) complex equipment used in the surgical suite; and 3) other complex devices used in treatment, such as ventilators. These devices often utilize their own embedded software as well as highly precise components. Repairs require considerable training in the complexities of the function and design of the devices. None of these devices are "normally used for personal, family, or household purposes." Thus, they are not "consumer products" within the meaning of the Magnuson-Moss Warranty Act.

Support Strategies and Buyer Options

OEMs are required by the FDA to develop a "support strategy" for their buyers, which sets out how a device is maintained and serviced. Customers typically are given a number of options. First, the customer may choose to purchase services provided by OEM employees or by third parties authorized by the OEM. Second, if the OEM and the customer believe the customer's in-house staff is able to repair the product, the OEM can authorize the customer's employees to take responsibility for repairs. For example, a hospital network may have its own large, sophisticated repair and servicing department. Third, the customer can rely on its own unauthorized employees or unauthorized third parties to do repairs. The buyer may choose any of these options.

If the buyer takes the first or second approach described above and relies on authorized training personnel, the FDA requires the OEM to ensure that all persons who conduct repairs are qualified to repair the products. The FDA also requires the OEM to monitor the parts that are used. If the buyer chooses the third approach, which relies on unauthorized servicing entities, the OEM is not involved in the repair process and takes no responsibility for the quality of the repairs. In those cases, the OEM's warranty is typically void.

OEM warranties are not valid in the case of servicing performed by unauthorized servicing entities for two reasons. The most important reason by far is that an improperly repaired product can create serious risk of injury or death for patients. In addition to the very serious human costs, an OEM can be subject to liability if its employees or authorized repair personnel are responsible for the product failure. Second, even if a patient is not harmed, a

product failure can create serious reputational damage for the OEM because buyers and patients are uncertain about the primary responsibility for the problem. Since the most prominent and obvious entity associated with the product is the OEM, patients and buyers often associate a malfunction with the OEM even if the real cause is an improper repair.

Risks to Patients

The concern about risks to patients is not just theoretical. According to FDA's report to Congress on the *Quality, Safety, and Effectiveness of Servicing of Medical Devices*, required by Section 710 of the Food and Drug Reauthorization Act of 2017, the FDA found 4,301 adverse events associated with inadequate third-party device repairs and replacement parts, including 40 deaths and 294 serious injuries. These numbers were found despite the fact that unauthorized servicing entities are not required to submit Medical Device Reports (MDRs). Thus, the actual number of adverse events is probably much higher. Additionally, AdvaMed has shared information with FDA from six manufacturers who recorded at least 281 adverse events 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.¹⁵ This report represented a tiny fraction of all such adverse events.

Controlling Quality of Repairs

An OEM that wishes to ensure the quality of repairs of its products has a limited number of options. First, it can embed software in its product to make sure that only authorized repair entities can service a device. Second, as described above, it can limit the effectiveness of its warranty to cases where the buyer uses authorized personnel and parts. Third, an OEM can also restrict distribution of repair manuals and service information.

Much of the dispute between OEMs and unauthorized servicing entities involves the distribution of repair manuals. There are a number of reasons that OEMs frequently limit the distribution of these manuals. First, repair manuals may contain proprietary information regarding the way products are designed and manufactured including design schematics. Distribution of these materials undercuts the confidentiality of this information and can encourage counterfeiting. Second, and most importantly, widely distributing repair manuals encourages companies to attempt repairs even if they are not authorized by the OEM and their repair personnel are unqualified. Unauthorized servicing entities often claim that these restrictions unfairly prevent them from repairing an OEM's products. However, controlling the quality of repairs is helpful to both competition and patients. They benefit patients by reducing

¹⁵ This report was based on a very small fraction of ISOs. As noted above, the FDA has estimated that there are between 16,520 and 20,830 firms performing device servicing.

the risk of serious injury or death and they benefit competition by enabling competing manufacturers to offer higher quality, safer products.

IV. FDA REGULATION

Medical device manufacturers are subject to the FDA's Quality System Regulations (QSR). The QSR covers the entire device lifecycle of medical devices from device design, manufacturing and installation to servicing.¹⁶ The QSR is risk-based and scalable. It applies to all device manufacturers regardless of size. QSR compliance is understood to be a fundamental requirement of doing business in the device sector. The FDA has stated that "quality systems ... help ensure that ... products consistently meet applicable requirements and specifications."

Because OEMs are required by the FDA to ensure that repairs of their products comply with the QSR, OEMs cannot give buyers unlimited discretion in determining how products are repaired. If OEMs perform repairs, they must comply with the QSR. If OEMs rely on OEM-authorized third parties to perform repairs, they require that these third parties meet the same servicing standards that OEMs are required to meet. Widely distributing repair manuals and repair information to any unauthorized servicing entities that wishes to repair products is not only dangerous for patients, doing so would likely violate an OEM's obligations under the QSR.

The FDA has not yet chosen to directly subject unauthorized servicing entities to the QSR. Consequently, unauthorized servicing entities are not required to register with FDA, to submit adverse events associated with devices they repair to FDA or the OEM, or to comply with other FDA quality system regulations such as training of employees, maintenance of device repair records, and assuring that suppliers providing replacement parts are qualified and appropriate. It is not clear whether the FDA's position is based on the burden of regulating such a large industry or some other consideration. AdvaMed has urged the FDA to apply the same QSR standards that are applicable to OEMs directly to unauthorized servicing entities. In our view, direct regulation of unauthorized servicing entities by the FDA would significantly advance the goal of patient safety.

V. THE EFFECT OF THE PANDEMIC

The pandemic imposed serious stresses on the health care system in many ways, including increasing the need for the repair of certain devices, such as ventilators. Some have suggested that OEM repair policies contributed to the delays in repairs. We are not aware of reliable evidence to support this claim. Our members report that they were able to conduct all necessary repairs within contracted timelines except where hospitals prohibited entry of non-

¹⁶ See 21 CFR 820.1.

hospital personnel. During the pandemic, many OEMs made special efforts to assist hospitals in making repairs themselves or arranging for them.

The U.S. PIRG organization prepared a report claiming that there were delays in servicing medical devices, particularly ventilators, during the pandemic because of the refusal of OEMs to provide repair manuals to unauthorized servicing entities. We do not believe the data used by U.S. PIRG is reliable. Their conclusions depended heavily on a survey of independent service entities, which had an obvious bias in furnishing their responses.

VI. CONCLUSION

The FTC's recent policy statement regarding repair restrictions suggested three possible courses of action for the Commission: 1) increasing enforcement of the Magnuson-Moss Warranty Act; 2) challenging OEM repair policies as antitrust violations; and 3) challenging OEM repair policies as unfair or deceptive acts or practices.

With respect to the first item, as noted above, the Magnuson-Moss Warranty Act does not apply to FDA-regulated medical devices.

With respect to the second item, although, in theory, there could be unlawful tying or monopolization leading to harm to competition in a medical device servicing market, the characteristics of both medical device servicing markets and the compelling reasons for existing OEM servicing policies mean that, if violations exist, they are exceedingly rare. Thus, there is no justification to prioritize antitrust enforcement in this industry.

Finally, with respect to the third item, there is no evidence of deception in OEM repair restrictions in this industry, and unauthorized servicing entities have not pointed to any.

While unauthorized servicing entities may lose some business opportunities, the overall effect of OEM servicing policies is to benefit competition, comply with FDA QSR requirements, and most important, safeguard patients.

We are pleased to furnish any additional information¹⁷ that the FTC would like that is relevant to these issues and we hope to meet with FTC staff in the near future.

¹⁷ Please feel free to contact Edward Correia, Correia & Osolinik at ecorreia@advamed.org, 301-943-8647, or Tara Federici, Vice President, Technology and Regulatory Affairs, Advamed at tfederici@advamed.org or 202-434-7208.



SUPPLEMENTARY SUBMISSION TO THE FTC REGARDING THE REPAIR OF MEDICAL DEVICES

We are grateful for the opportunity to meet recently with FTC staff to discuss the repair and servicing of medical devices. During the meeting, the staff asked about the process to become qualified to repair complex medical devices, including the cost and length of training. In addition, we discussed the extensive role played by the FDA in regulating the repair process. As we noted, the FDA imposes substantial burdens on manufacturers to make sure repairs are performed properly, and, importantly, it has chosen not to regulate third party servicing entities¹ that engage in repairs and servicing. This paper addresses these two issues.

I. REPAIRS BY CUSTOMERS AND THIRD PARTIES

As we noted in our submission of December 2022 to the FTC staff, the FDA requires manufacturers of medical devices to develop for their customers a repair strategy for the devices they sell as part of their overall obligation to provide safe and effective products. Repair strategy is discussed by manufacturers and customers during contract negotiations. The strategy that is adopted by the customer – for example, a hospital network – depends, among other things, on the preferences of the customer, the complexity of the device, and the skill of the customer's in-house personnel.

Customers have several options in repairing and servicing products – contracting with the seller to service products, taking responsibility for repairing its own products through use of its own staff, adopting a hybrid approach where the customer's staff works with the manufacturer's staff, and relying on independent repair entities, multi-vendor organizations, or managed service organizations. There is significant variation in customers' reliance on manufacturer, customer and independent service organization (ISO) repair personnel.

If the manufacturer and customer cannot agree on a service model, the customer typically can still purchase the product and take complete responsibility for servicing, or it may choose to purchase similar equipment from a different manufacturer. Because customers have repair and servicing options, manufacturers cannot make excessive returns in repairing their products.

¹ There are two general categories of servicing entities: 1) those authorized by the OEM and 2) unauthorized servicing entities. Authorized servicing entities include the OEM's servicing employees, their customers' biomedical engineers and independent servicing organization (ISOs), both large and small. The latter two will have been trained by the OEM and may also receive access to special tools. Unauthorized servicing entities may include large and small ISOs and customer biomedical engineers and will not have received training.



Instead, manufacturer policies regarding repairs are intended to ensure that devices are repaired properly in order to avoid harm to patients and to the reputation of the manufacturer.

II. COSTS AND LENGTH OF TRAINING PROGRAMS

The FTC staff asked about the costs and length of training for service personnel. In general, the training offered by manufacturers is the same for in-house personnel, customer personnel, and independent entities. Based on the data provided by our members, training lasted from a few days to less than a year, depending on the risk of the device and its complexity and the number of devices involved. The cost of training ranged from \$4,000 to \$24,000 depending on the products involved. Costs are at the higher end of the range if the trainee is provided customer service tools (generally the manufacturer's intellectual property) to use after the training. Training costs and length are commensurate with the sophistication of the device (for example, devices range from simple blood pressure cuffs to complex computerized tomography (CT) scan machines) and typically comprises a small percentage of the total cost of ownership.

Manufacturers typically develop training programs for their own employees and make these training programs available to customers as part of a coordinated repair strategy. Medical device manufacturers are not regularly engaged in the business of occupational training and, therefore, do not make their programs available to the general public. In addition, making training available directly to the public, including ISOs who are not affiliated with a particular customer, would raise significant issues regarding the unlicensed use of intellectual property and actions that undermine cybersecurity.

Typically, training is designed to include access to higher level tools and diagnostics, both of which are part of the manufacturer's intellectual property. Consequently, most training is accompanied by an intellectual property license and secured privileged access. Ensuring cybersecurity is essential because failing to properly protect medical equipment can lead to serious adverse consequences for patients and for patients' confidential healthcare information.

III. THE FDA QSR REQUIREMENTS

The FDA imposes substantial requirements on manufacturers of medical devices regulated by the agency. The Quality System Regulation (QSR) applies to manufacturers' involvement in repair and servicing medical devices, just as it does to manufacturing.² A manufacturer can violate the QSR if its own employees fail to meet regulatory standards when they repair devices or if the manufacturer authorizes or enables others to engage in repair practices that do not meet these standards. For example, if manufacturers enable unqualified

² See the attached Appendix with the complete list of QSR servicing-related requirements.

ISOs to repair products by making repair information available to unqualified repair entities, the manufacturer might violate one or more of the QSR requirements.

There is no FDA or other regulatory requirement that ISOs receive any particular training or certification or comply with any of the other QSR requirements. Manufacturers that repair products are required to report product failures to the agency, but ISOs are not. Until September 2020, we have had no way of knowing how many product failures are the result of inadequate ISO servicing.³ The limited data that are available show that there are frequent problems caused by unqualified ISOs.⁴

The FDA has authority to apply these standards to independent repair entities, but it has chosen not to do so. As a result, the large, fragmented industry of independent service organizations (ISOs) is unregulated.⁵ AdvaMed has consistently advocated that the FDA use its authority to regulate the ISO industry in order to avoid the risks that unregulated ISOs pose to patients. If ISOs are permitted to service complex medical devices, they should be subject to the same regulatory standards applied to manufacturers.

³ FDA has modified its adverse event form to include a check box if the device was serviced by a third party. However, third parties are not required to submit adverse events and OEMs may not be able to forensically and conclusively identify adverse events related to third party servicing.

⁴ See our earlier submission, p. 6.

⁵ As we noted in our first submission, the FDA estimates there are between 16,520 and 20,830 firms performing device servicing.

Appendix

QSR Servicing Related Requirements

OEMs are subject to all aspects of FDA's Quality System Regulation (QSR) (21 CFR 820) no matter their size or number of personnel. FDA is using its enforcement discretion and does not apply *any* elements of the QSR to third party servicing entities.

Key requirements of the QSR that relate to servicing include good manufacturing practices and design controls.

Good Manufacturing Practices Include Servicing

- Under the QSR, good manufacturing practices requirements apply to servicing.

See *Subpart A - General Provisions*

Sec. 820.1 Scope.

Applicability. (1) 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.

- Under the QSR, device manufacturers are required to have sufficient personnel that are appropriately trained to perform servicing.

See *Subpart B - Quality System Requirements,*

Sec. 820.25 Personnel.

(a) General. ***Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed*** [*emphasis added*].

(b) ***Training. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented*** [*emphasis added*].

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.

- Under the QSR, device manufacturers must determine whether serviced devices meet conformance and acceptance requirements.

See *Subpart H - Acceptance Activities*

Sec. 820.86 Acceptance status.

Each manufacturer shall identify by suitable means the acceptance status of product, to indicate the conformance or nonconformance of product with acceptance criteria. The identification of acceptance status shall be maintained throughout manufacturing, packaging, labeling, installation, and ***servicing of the product*** [*emphasis*

added] to ensure that only product which has passed the required acceptance activities is distributed, used, or installed.

- **Under the QSR, device manufacturers must establish and maintain servicing instructions and procedures.**

See *Subpart N - Servicing*

Sec. 820.200 Servicing.

(a) Where servicing is a specified requirement, each manufacturer shall establish and maintain instructions and procedures for performing and verifying that the servicing meets the specified requirements.

(b) Each manufacturer shall analyze service reports with appropriate statistical methodology in accordance with § 820.100.

(c) ***Each manufacturer who receives a service report that represents an event which must be reported to FDA under part 803 of this chapter shall automatically consider the report a complaint and shall process it in accordance with the requirements of § 820.198. [emphasis added]***

(d) Service reports shall be documented and shall include:

- (1) The name of the device serviced;
- (2) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;
- (3) The date of service;
- (4) The individual(s) servicing the device;
- (5) The service performed; and
- (6) The test and inspection data.

QSR Design Control Requirements Apply to Servicing

The QSR and related guidance make clear that maintenance and servicing is integral to the safety and performance of the device and must be considered as part of the design process. This includes acceptance criteria related to servicing.

- See *Subpart A - General Provisions*

Sec. 820.3 Definitions.

(s) Quality means the totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance.

(y) Specification means any requirement with which a product, process, ***service*** *[emphasis added]*, or other activity must conform.

- See ***DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS*** (p. 8)

“The essential quality aspects and the regulatory requirements, such as ***safety, performance, and dependability*** *[emphasis added]* of a product (whether hardware, software, services, or processed materials) are established during the design and development phase. Deficient design can be a major cause of quality problems.”

- See *Subpart C - Design Controls*
Sec. 820.30 Design controls.

(d) Design output. Each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. ***Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified [emphasis added].*** Design output shall be documented, reviewed, and approved before release. The approval, including the date and signature of the individual(s) approving the output, shall be documented.

- See ***DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS*** (p. 2)

“Design controls are a component of a comprehensive quality system that covers the life of a device. The assurance process is a total systems approach that extends from the development of device requirements through design, production, distribution, use, ***maintenance [emphasis added]***, and eventually, obsolescence. Design control begins with development and approval of design inputs, and includes the design of a device and the associated manufacturing processes. Design control does not end with the transfer of a design to production. Design control applies to all changes to the device or manufacturing process design, including those occurring long after a device has been introduced to the market.”

- See ***DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS*** (p. 6)

“THE QUALITY SYSTEM AND DESIGN CONTROLS. In addition to procedures and work instructions necessary for the implementation of design controls, policies and procedures may also be needed for other determinants of device quality that should be considered during the design process. The need for policies and procedures for these factors is dependent upon the types of devices manufactured by a company and the risks associated with their use. Management with executive responsibility has the responsibility for determining what is needed. Example of topics for which policies and procedures may be appropriate are:

- risk management
- ***device reliability [emphasis added]***
- ***device durability [emphasis added]***
- ***device maintainability [emphasis added]***
- ***device serviceability [emphasis added]***
- human factors engineering
- software engineering
- use of standards
- configuration management

- compliance with regulatory requirements
 - device evaluation (which may include third party product certification or approval)
 - clinical evaluations
 - document controls
 - use of consultants
 - use of subcontractors
 - use of company historical data”
- See ***DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS*** (p. 14-15)

“RESPONSIBILITY FOR DESIGN INPUT DEVELOPMENT. Regardless of who developed the initial product concept, product developers play a key role in developing the design input requirements. When presented with a set of important characteristics, it is the product developers who understand the auxiliary issues that must be addressed, as well as the level of detail necessary to design a product. Therefore, a second key principle is that the product developer(s) ultimately bear responsibility for translating user and/or patient needs into a set of requirements which can be validated prior to implementation. While this is primarily an engineering function, the support or full participation of production and ***service personnel*** [*emphasis added*], key suppliers, etc., may be required to assure that the design input requirements are complete.”

- See ***DESIGN CONTROL GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS*** (p. 20)

“Design output includes production specifications as well as descriptive materials which define and characterize the design.

PRODUCTION SPECIFICATIONS. Production specifications include drawings and documents used to procure components, fabricate, test, inspect, install, **maintain, and service the device** [*emphasis added*], such as the following:

- assembly drawings
- component and material specifications
- production and process specifications
- software machine code (e.g., diskette or master EPROM)
- work instructions
- quality assurance specifications and procedures
- ***installation and servicing procedures*** [*emphasis added*]
- packaging and labeling specifications, including methods and processes used”