

**Time for a Tune Up in America’s Healthcare Market:
Securing the Right to Repair for Medical Devices**

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I. INTRODUCTION

“The concept behind this is as old as it is simple: if you own something, you own all of it, including the right to repair it.”¹ Thus remarked New York Representative Joe Morelle on June 30, 2021, upon introducing the Fair Repair Act—the first federal bill

1. 167 CONG. REC. 3315 (daily ed. June 30, 2021) (statement of Rep. Joe Morelle).

broadly advancing the consumer protection concept known as the “right to repair.”² This expansive bill followed closely on the heels of a substantially narrower proposal, although borne of the very same concept, made in the form of two identical bills entitled the Critical Medical Infrastructure Right-to-Repair Act.³ Lawmakers introduced these two bills in the House of Representatives and the Senate in August 2020, in the heat of a summer defined by the COVID-19 global pandemic’s destabilizing foray into American life.⁴ While none of these federal bills have advanced beyond committee consideration at the time of this writing, their proposal alone reflects the culmination of a major groundswell of consumer-driven demands for true ownership occurring in the American economy. This movement of broadly drawn constituents finds itself united under the banner of the “right to repair,” an idea now poised like a battering ram at the doors of several major economic sectors, including, notably, the medical device industry.

What, then, is the right to repair? In the abstract, the idea is that once a consumer purchases a product from its manufacturer, the consumer should thereupon be entitled to complete ownership and control over that product. That is, the consumer “should be able to open, hack, repair, upgrade, or tie bells on it.”⁵ This simple notion of unfettered ownership stands in stark contrast to the dismayingly complicated reality consumers face today. Manufacturers significantly restrict repairs on their products in a panoply of ways, from physical design barriers inhibiting reparability to more intangible barriers such as restrictive license and warranty agreements, exclusive repair networks, the withholding of technical information and repair materials, and assertions of the protective rights afforded by the current regime of American intellectual property law.⁶ Thus, advocates of the right to repair wish to see, mainly by way of legislative reform, the demolition of these restrictions to the extent necessary to enable consumers to repair their own products or have independent third-party repair businesses do so, which requires “access to the same

2. Fair Repair Act, H.R. 4006, 117th Cong. (2021). Notably, the Fair Repair Act specifically excludes medical devices from its scope.

3. Critical Medical Infrastructure Right-to-Repair Act of 2020, H.R. 7956, 116th Cong. (2020); Critical Medical Infrastructure Right-to-Repair Act of 2020, S. 4473, 116th Cong. (2020); *see also* Stephanie Condon, *Lawmakers Call for “Right to Repair” Medical Equipment During COVID-19 Pandemic*, ZDNET (Aug. 6, 2020), <https://www.zdnet.com/article/lawmakers-call-for-right-to-repair-medical-equipment-during-covid-19-pandemic/> [<https://perma.cc/ALK6-3BLX>] (reporting on the heightened need for a codified right to repair for medical devices during the COVID-19 pandemic).

4. *See* Derrick Bryson Taylor, *A Timeline of the Coronavirus Pandemic*, N.Y. TIMES (Mar. 17, 2021), <https://www.nytimes.com/article/coronavirus-timeline.html> [<https://perma.cc/8TLS-MUD4>] (recounting the unfolding of the COVID-19 pandemic one year after its arrival in the United States in January 2020).

5. *We Have the Right to Repair Everything We Own*, iFIXIT, <https://www.ifixit.com/Right-to-Repair/Intro> [<https://perma.cc/Y28N-SYXP>].

6. Leah Chan Grinvald & Ofer Tur-Sinai, *Intellectual Property Law and the Right to Repair*, 88 FORDHAM L. REV. 63, 66–67 (2019); DANIEL A. HANLEY, CLAIRE KELLOWAY & SANDEEP VAHEESAN, OPEN MKTS. INST., *FIXING AMERICA: BREAKING MANUFACTURERS’ AFTERMARKET MONOPOLY AND RESTORING CONSUMERS’ RIGHT TO REPAIR* 9–13; *A “Right to Repair” Movement Tools Up*, ECONOMIST (Sept. 30, 2017), <https://www.economist.com/business/2017/09/30/a-right-to-repair-movement-tools-up> [<https://perma.cc/MU54-M92E>].

diagnostics, information, and parts available to the dealer’s facilities.”⁷

This Note argues that the COVID-19 pandemic cast into sharp relief the pressing need for Congress to intervene and pass right-to-repair legislation, at least with respect to medical devices for hospitals. Part II of this Note introduces the relevant technical and legal concepts implicated by repair restrictions and examines the right-to-repair movement’s origins and recent developments. Part III analyzes the unique nature of today’s healthcare sector, finding this market to be in special need of the right to repair, and addresses the shortcomings of extant copyright and contract law insofar as the current law stands in the way of achieving such consumer protections. Part IV recommends that, regardless of a public health exigency such as the COVID-19 pandemic, Congress should move forward to adopt legislation guaranteeing a permanent right to repair medical devices—the enactment of which would serve not only as a preventative measure to protect Americans from future public health crises in an increasingly globalized world but would also function as a foothold for the advancement of broader repair legislation in years to come.

II. BACKGROUND

A. *The Modern Consumer’s Encounter with Repair Restrictions*

According to some estimates, the business of repairs constitutes up to three percent of the U.S. economy.⁸ After-market repair and maintenance services for products provide “a lucrative revenue stream that original equipment manufacturers [(OEMs)] are incentivized to capitalize on,” and indeed they do.⁹ Although the United States did not always have restrictive repair markets,¹⁰ technological advancements and the evolution of modern industry—most notably the “electrification and computerization of products,” including the ubiquitous proliferation of embedded software within everyday products—have made it much easier and more profitable for OEMs to deprive consumers of their ability to make after-market repairs.¹¹

Today, OEMs employ an overwhelming variety of tactics to secure control over repair and maintenance markets. Pursuant to a directive of Congress, the Federal Trade Commission (FTC) issued a report in May of 2021 examining consumer protection and antitrust issues relating to repair restrictions with a focus on the prevailing practices of

7. *It’s Time for a Common-Sense Perspective*, REPAIR.ORG, <https://www.repair.org/policy> [<https://perma.cc/Y74C-UK4U>].

8. Grinvald & Tur-Sinai, *supra* note 6, at 66; accord Jennifer J. Huseby, *Who Gets to Operate on Herbie? Right to Repair Legislation in the Context of Automated Vehicles*, 2020 J.L. & MOBILITY 41, 46 (2020).

9. Huseby, *supra* note 8, at 46; see also HANLEY, KELLOWAY & VAHEESAN, *supra* note 6, at 3 (“Repair and aftermarket sales are a fundamental part of manufacturers’ revenue streams, accounting for 10% to 40% of revenue for industrial companies.”).

10. Historically, “[t]he freedom to repair durable goods used to be an established norm in American society” throughout the nineteenth and early twentieth centuries. HANLEY, KELLOWAY & VAHEESAN, *supra* note 6, at 4; see also Daniel J. Kevles, *The U.S. Started as a Nation of Tinkerers*, SCI. AM. (Dec. 1, 2015), <https://www.scientificamerican.com/article/the-u-s-started-as-a-nation-of-tinkerers/> [<https://perma.cc/2A62-Q3NY>] (discussing the various American innovators in physics, medicine, and technology that *Scientific American* magazine has reported on since its very first issue in 1845).

11. HANLEY, KELLOWAY & VAHEESAN, *supra* note 6, at 4.

mobile phone and auto manufacturers.¹² In its report, the FTC identified eight primary methods by which OEMs restrict independent repair and repair by consumers:

- Product designs that complicate or prevent repair;
- Unavailability of parts and repair information;
- Designs that make independent repairs less safe;
- Policies or statements that steer consumers to manufacturer repair networks;
- Application of patent rights and enforcement of trademarks;
- Disparagement of non-OEM parts and independent repair;
- Software locks and firmware updates; and
- End User License Agreements.¹³

Software locks, often called digital rights management (DRM) tools or technological protection measures (TPMs), are access controls through which OEMs have throttled independent repairs on a wide range of software-enabled products.¹⁴ End-user license agreements (EULAs) are “contracts that users must agree to before using a product or service,” which are also known as “click-wrap,” “shrink-wrap,” or “terms of service” agreements, constituting another major way OEMs restrict repairs.¹⁵ In the style of adhesion contracts—inundating consumers with virtually every digital service and software-enabled product they utilize—EULAs often impose post-sale usage, repair, and modification restrictions, granting corporations “unprecedented access to monitor, manage, and restrict how consumers use their products, even going so far as to revoke ownership.”¹⁶

These restrictions indeed drive at the heart of ownership (or, perhaps more accurately, its erosion) in the modern economy. By some accounts, the American economic landscape

12. U.S. FED. TRADE COMM’N, NIXING THE FIX: AN FTC REPORT TO CONGRESS ON REPAIR RESTRICTIONS 3 (2021); *see also* Jon Porter, *FTC Report Blasts Manufacturers for Restricting Product Repairs*, VERGE (May 7, 2021), <https://www.theverge.com/2021/5/7/22424363/ftc-repair-restrictions-report-nixing-the-fix-smartphones-automakers> [<https://perma.cc/KQW8-BHMY>] (“With the findings submitted to Congress, the question now is how to make repairing devices easier. The FTC’s report makes several suggestions, including the introduction of new legislation to address repair restrictions and open repair markets.”).

13. U.S. FED. TRADE COMM’N, *supra* note 12, at 6.

14. Nicholas A. Mirr, *Defending the Right to Repair: An Argument for Federal Legislation Guaranteeing the Right to Repair*, 105 IOWA L. REV. 2393, 2398 (2020); *see also* Huseby, *supra* note 8, at 45 (“[DRM software] serves as a gatekeeper to enforce any restrictions or limitations demanded by manufacturers, and can do things like restrict your iTunes purchases to Apple products, or prevent you from using your DVR to record your favorite show if the copyright holder objects.”). In one controversial example of such restrictions, John Deere withheld diagnostic software necessary to identify issues and fixes in their computerized tractors, prompting U.S. farmers to use a bootlegged Ukrainian version of the software in lieu of the expensive trip to a John Deere dealership. *See* Jason Koebler, *Why American Farmers Are Hacking Their Tractors with Ukrainian Firmware*, VICE (Mar. 21, 2017), https://motherboard.vice.com/en_us/article/xykkkd/why-american-farmers-are-hacking-their-tractors-with-ukrainian-firmware [<https://perma.cc/72NT-KPSM>].

15. HANLEY, KELLOWAY & VAHEESAN, *supra* note 6, at 14.

16. *Id.*; *see also* Huseby, *supra* note 8, at 49 (“The insurgence of the right-to-repair movement can be traced to the development of end-user license agreements.”); Peter Eckersley, *Sony Steals Feature from Your PlayStation 3*, ELEC. FRONTIER FOUND. (Mar. 30, 2010), <https://www.eff.org/deeplinks/2010/03/sony-steals-feature-from-your-playstation-3> [<https://perma.cc/THV6-R52S>] (reporting that Sony utilized its “vast and sticky web of DRM restrictions” to downgrade the PlayStation 3 gaming system, after-market, pursuant to its EULA with users in order to remove users’ ability to use alternative operating systems).

appears to be transforming into a “sharing economy” of temporary access, wherein the individual’s control over goods is being transmuted into the mere provision of a service.¹⁷ In this way—with consumers tethered to OEMs via post-transaction repair restrictions—stakeholders contend that these major OEM corporations monopolize repair markets at a substantial societal cost.¹⁸ The character of the right-to-repair movement’s war against this broad economic transformation is described in Part II.B, and its particular battles with these specific repair restrictions, waged in the theaters of federal intellectual property law and state contract law, are briefly illustrated in Part II.C.

B. The Right-to-Repair Movement Today

Leading the charge for the right-to-repair movement today is the Repair Association, comprised of notable consumer-rights groups and industry organizations such as the U.S. Public Interest Research Group (PIRG),¹⁹ the Electronic Frontier Foundation,²⁰ and iFixit,²¹ along with a variety of other members whose interests align with advancing the right to repair.²² The right-to-repair movement consists of two main, interdependent branches.²³ The first is focused on amending the Digital Millennium Copyright Act (DMCA),²⁴ an important facet of the federal intellectual property law regime.²⁵ The second branch of the movement is focused on pushing bills through legislatures, mainly at the state level. These proposed bills seek to alleviate restrictions on repair—beyond the scope of the Copyright Act and the DMCA—and are grounded in state contract law, mainly with respect to EULAs.²⁶

17. Bernard Marr, *The Sharing Economy – What It Is, Examples, And How Big Data, Platforms and Algorithms Fuel It*, FORBES (Oct. 21, 2016), <https://www.forbes.com/sites/bernardmarr/2016/10/21/the-sharing-economy-what-it-is-examples-and-how-big-data-platforms-and-algorithms-fuel/?sh=29a0a187c5af> [<https://perma.cc/5XNS-CTLG>]; see also AARON PERZANOWSKI & JASON SCHULTZ, *THE END OF OWNERSHIP: PERSONAL PROPERTY IN THE DIGITAL ECONOMY* 169–70 (2016).

18. See generally Chris Jay Hoofnagle, Aniket Kesari & Aaron Perzanowski, *The Tethered Economy*, 87 GEO. WASH. L. REV. 783 (2019) (illustrating consumer and market-level harms caused by “tethered” products and exploring potential legal solutions); see also HANLEY, KELLOWAY & VAHEESAN, *supra* note 6, at 15–18 (outlining the major consequences of monopolized repair markets; to wit: increased costs to consumers, stifling of the repair economy and local resiliency, rising e-waste, and the loss of tinkering and innovation). The enforcement of antitrust law against repair monopolies is an ameliorative route this Note does not discourage but rather concludes to be insufficient for effectively enshrining a right to repair in the medical device context absent reform at the federal legislative level. See *infra* Part III.D.

19. *About Us*, PIRG, <https://uspirg.org/feature/usp/about-us> [<https://perma.cc/JD6U-NP3Z>].

20. *About EFF*, ELEC. FRONTIER FOUND., <https://www.eff.org/about> [<https://perma.cc/UV89-ZPAE>].

21. *Who We Are*, IFIXIT, <https://www.ifixit.com/Info/background> [<https://perma.cc/9TSB-A9TC>].

22. *We Are the Repair Industry*, REPAIR.ORG, <https://www.repair.org/members#> [<https://perma.cc/4HB2-WBRT>].

23. *Working Together to Make Repair-Friendly Public Policy*, REPAIR.ORG, <https://www.repair.org/legislation> [<https://perma.cc/8CRL-RNP2>]; Grinvald & Tur-Sinai, *supra* note 6, at 67–68.

24. Pub. L. No. 105-304, 112 Stat. 2860 (1998) (codified in scattered sections of 5, 17, 28, and 35 U.S.C.).

25. See *infra* Part II.C.1 (discussing repair restrictions leveraged by intellectual property law).

26. See *infra* Part II.C.2 (discussing EULA repair restrictions). This Note contends that such legislative reform at the state level is particularly inappropriate in the medical device context because of the market’s interstate nature, the staggering cost of hospital infrastructure, and the special concerns for patient safety requiring

The right-to-repair movement's lodestar for legislative progress, which has substantially shaped the national conversation surrounding the right to repair,²⁷ is the Massachusetts automotive repair bill enacted in 2012: The Act Protecting Motor Vehicle Owners and Small Businesses in Repairing Motor Vehicles.²⁸ Although limited to automobile repairs, this landmark state law mapped the core provisions of template legislation advanced by the Repair Association for enshrining the right to repair broadly across industries.²⁹ Pursuant to these provisions, the Massachusetts law gave car owners and independent repair shops access to the same manuals, diagnostic software, and diagnostic repair tools provided to licensed dealerships by their respective automobile manufacturers.³⁰ Specifically, the law required motor vehicle manufacturers to “make available for purchase by owners . . . and by independent repair facilities the same diagnostic and repair information” and “all diagnostic repair tools” provided to dealers by OEMs on “fair and reasonable terms.”³¹

This single state law soon had major national implications. In 2014, the Alliance of Automobile Manufacturers, the Association of Global Automakers, and two automobile aftermarket industry groups came together to sign a “Memorandum of Understanding” by which the automobile industry nationwide effectively agreed to voluntarily abide by substantively the same provisions of the Massachusetts right-to-repair law.³² Unsurprisingly, the law generated considerable momentum for the right-to-repair movement over the following years, which saw a greatly amplified nationwide effort by advocates pushing for legislation “that would recognize the right to repair consumer electronics—not only smartphones, laptops, and televisions, but also household appliances, wearable technology, farm equipment, and medical devices, to offer just a few

regulatory uniformity and Food and Drug Administration (FDA) oversight. All three of these concerns are best addressed by federal law alone. *See infra* Part III.D.

27. Aaron Perzanowski, *Consumer Perceptions of the Right to Repair*, 96 IND. L.J. 361, 375–77 (2021).

28. MASS. GEN. LAWS ANN. ch. 93K (West 2019).

29. *See generally* REPAIR.ORG, MODEL STATE RIGHT-TO-REPAIR LAW (updated Dec. 21, 2021), *available at* <https://docs.google.com/document/d/1NrMThgWR7DbqyImAx2M-ChS2EbAwTWoz> [<https://perma.cc/79C3-C36N>]; *see also* U.S. FED. TRADE COMM’N, *supra* note 12, at 47–48 (explaining the key provisions of the template legislation). The key provisions of current state right-to-repair bills will be analyzed *infra* Part III.D. and are incorporated in this Note’s proposed draft bill included in the Appendix.

30. Huseby, *supra* note 8, at 48.

31. MASS. GEN. LAWS ch. 93K, § 2 (West 2019).

32. Memorandum of Understanding Among Kathleen Schmatz, President & CEO, Auto. Aftermarket Indus. Ass’n, Ray Pohlman, President, Coal. for Auto Repair Equal., Mitch Bainwol, President & CEO, All. Auto. Mfrs., and Michael Stanton, President & CEO, Ass’n Glob. Automakers (Jan. 15, 2014), <https://wanada.org/wp-content/uploads/2021/01/R2R-MOU-and-Agreement-SIGNED.pdf> [<https://perma.cc/9TZV-SC5Q>]; *see also* Grinvald & Tur-Sinai, *supra* note 6, at 72 (“While this voluntary agreement has been successful in providing independent repair shops with the ability to repair cars, this agreement has been frustrated in recent years by tactics employed by car manufacturers that are enabled by the growing use of software, electronic components, and wireless technologies in the car industry.”). Continuing to lead the way, in 2020, Massachusetts citizens expanded their automobile repair law with a vote achieving 75 percent approval, requiring manufacturers to make real-time telematics data available to vehicle owners and independent repair shops. Adi Robertson, *Massachusetts Passes ‘Right to Repair’ Law to Open Up Car Data*, VERGE (Nov. 4, 2020), <https://www.theverge.com/2020/11/4/21549129/massachusetts-right-to-repair-question-1-wireless-car-data-passes> [<https://perma.cc/L2GY-R3ZY>].

examples.”³³

As of the time of this writing, 34 states have introduced bills proposing the right to repair for either medical equipment, agricultural equipment, home appliances, or, broadly, all consumer products.³⁴ None of these states, however, have enacted the legislation.³⁵ Major OEMs targeted by the right-to-repair movement are, predictably, staunchly opposed to the desired legislative reforms and have lobbied fiercely to prevent their enactment.³⁶

C. Right to Repair in the Courts: Conventional Restrictions and the Twin-Bulwarks of Intellectual Property Law and Contract Law

1. Intellectual Property Reforms Targeted by the Repair Movement

In large part, the major OEMs lobbying against right-to-repair legislation have relied on assertions of their intellectual property rights under federal copyright and patent law.³⁷ Those arguing against the right to repair in the medical device context are no exception.³⁸

33. Perzanowski, *supra* note 27, at 376. The current movement has garnered the notable support of Senators Bernie Sanders and Elizabeth Warren, the American Farm Bureau, the New York Times Editorial Board, and the Illinois Health and Hospital Association. *Id.* at 377; *see also* “Right to Repair” Movement, *supra* note 6 (“The hope is that once an important state passes such a law, the country will follow—as was the case in the car industry after Massachusetts in 2012 passed a right to repair law for cars that led to a national memorandum of understanding between carmakers and repair shops.”).

34. *Working Together to Make Repair-Friendly Public Policy*, *supra* note 23.

35. *See* Grinvald & Tur-Sinai, *supra* note 6, at 72–73, 80–81 (suggesting that lobbying efforts by major OEMs are throttling these bills).

36. *See* Perzanowski, *supra* note 27, at 377–78 (“The companies condemning right to repair proposals—occasionally publicly, but more often behind closed doors—include Apple, AT&T, Caterpillar, Dyson, GE Healthcare, John Deere, Lexmark, LG, Medtronic, Microsoft, Toyota, Verizon, and Wahl. This partial list excludes trade associations and industry groups like the Entertainment Software Association . . . and AdvaMed, among others, that lobby against repair bills on behalf of their members.”); *Mirr*, *supra* note 14, at 2403–06 (“Manufacturers . . . have a vested interest in preventing the right to repair legislation from becoming law because it could seriously decrease their profits.”); Grinvald & Tur-Sinai, *supra* note 6, at 80 (“Some larger manufacturers have been active in attempting to forestall the passage of any right to repair law.”); Anne Marie Green, *Who Doesn’t Want the Right to Repair? Companies Worth Over \$10 Trillion*, PIRG (May 3, 2021), <https://pirg.org/articles/who-doesnt-want-the-right-to-repair-companies-worth-over-10-trillion/> [<https://perma.cc/LF9R-3L9A>] (collecting evidence of major companies lobbying against the right to repair); *see also* Jason Koebler, *Appliance Companies Are Lobbying to Protect Their DRA-Fueled Repair Monopolies*, VICE (Apr. 25, 2018), <https://www.vice.com/en/article/vbvk3b/appliance-companies-are-lobbying-against-right-to-repair> [<https://perma.cc/9GY7-RHDQ>] (criticizing several arguments advanced by OEMs lobbying against right to repair bills). The key arguments advanced by lobbyist opposition to medical device right-to-repair reforms, in particular, revolve around concerns over patient safety, cybersecurity, and OEMs’ intellectual property rights and regulatory compliance obligations. This Note addresses those concerns *infra* Parts III.C–D.

37. Grinvald & Tur-Sinai, *supra* note 6, at 83.

38. *See, e.g., Top Three Issues of SB 605: Medical Device Right to Repair Act*, CAL. LIFE SCI., <https://www.califesciences.org/news/top-three-issues-of-the-sb-605-medical-device-right-to-repair-act/> [<https://perma.cc/RPT2-CX6Z>] (criticizing California’s proposed medical device right to repair bill on the ground that it would “eviscerate intellectual property protections”); *see also* Ofer Tur-Sinai & Leah Chan Grinvald, *Repairing Medical Equipment in Times of Pandemic*, 52 SETON HALL L. REV. 461, 481 (2021) (“To keep [medical] equipment working, some repair professionals sometimes resort to self-help measures, like printing

With respect to copyright law, Section 1201 of the DMCA prevents anyone from disabling a technological protection measure (TPM) that a copyright owner has placed on their copyrighted software (i.e., a “software lock”).³⁹ “Consumers cannot disable the digital lock without being liable under § 1201, even if the purpose for such a hack was to diagnose, maintain, or repair the product;”⁴⁰ and, if done willfully or for commercial gain, the circumventer may even face criminal liability.⁴¹ Moreover, Sections 1201(a)(2) and 1201(b) (the DMCA’s “anti-trafficking” provisions) prohibit the distribution of information describing the ways to disable a digital lock.⁴² It is standard practice for device makers to embed such TPMs in their software-enabled products.⁴³ Section 1201 has a built-in safety valve, however, which authorizes the U.S. Copyright Office to adopt exemptions to these prohibitions on TPM circumvention, although these exemptions expire after three years.⁴⁴

With this framework against which to wrestle, the right-to-repair movement began taking forward steps in 2018 upon persuading the Copyright Office to officially recognize repair as a valid reason for TPM circumvention.⁴⁵ On October 26, 2018, the Librarian of Congress adopted the recommendation of the Copyright Office,⁴⁶ which thereby codified an exemption to Section 1201 of the DMCA, allowing users to circumvent TPMs provided that it is done to diagnose, repair, or maintain certain software-enabled devices within which the TPM is embedded.⁴⁷ The types of devices covered were limited, however, to “motorized land vehicles,” smartphones, and “home appliance[s] or home system[s]” such as refrigerators or thermostats.⁴⁸

Three years later, hoping for at least a renewal from the U.S. Copyright Office when these limited exemptions were due to expire, the right-to-repair movement met resounding approval and redoubled its progress on the copyright front. On October 28, 2021, the

replacement parts or sharing repair manuals, but these efforts have triggered legal threats by OEMs, based primarily on intellectual property grounds.”); Kit Walsh, *Medical Device Repair Again Threatened with Copyright Claims*, ELEC. FRONTIER FOUND. (June 11, 2020), <https://www.eff.org/deeplinks/2020/06/medical-device-repair-again-threatened-copyright-claims> [<https://perma.cc/2MRC-P7KQ>] (posting letter from medical device manufacturer threatening copyright action against iFixit’s “Medical Device Repair Database”).

39. 17 U.S.C. § 1201(a) (1999).

40. Grinvald & Tur-Sinai, *supra* note 6, at 104.

41. 17 U.S.C. § 1204 (2010).

42. 17 U.S.C. § 1201(a)(2), (b) (1999).

43. HANLEY, KELLOWAY & VAHEESAN, *supra* note 6, at 12–13.

44. 17 U.S.C. § 1201(a)(1)(C)–(D).

45. Hamza Shaban, *‘Right-to-Repair’ Advocates Claim Major Victory in New Smartphone Copyright Exemption*, WASH. POST (Oct. 26, 2018), <https://www.washingtonpost.com/technology/2018/10/26/right-repair-advocates-claim-major-victory-new-smartphone-copyright-exemption/> [<https://perma.cc/KP3K-DK4E>].

46. Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 83 Fed. Reg. 54,010, 54,028–29 (Oct. 26, 2018) (to be codified at 37 C.F.R. pt. 1); *see also* U.S. COPYRIGHT OFFICE, SECTION 1201 RULEMAKING: SEVENTH TRIENNIAL PROCEEDING TO DETERMINE EXEMPTIONS TO THE PROHIBITION ON CIRCUMVENTION (2018) (recommending to the librarian exemptions to the prohibitions on Section 1201 circumvention).

47. Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 83 Fed. Reg. 54,010, 54,028–29 (Oct. 26, 2018).

48. *Id.* at 54,029–30.

Librarian of Congress adopted a greatly expanded recommendation of the Copyright Office,⁴⁹ now exempting from liability under Section 1201 all TPM circumvention done for the purposes of diagnosis, repair, or maintenance on any software-enabled device designed for consumer use.⁵⁰ Additionally, the Librarian of Congress adopted a new exemption specifically allowing TPM circumvention for access to firmware and related data files on medical devices and systems for diagnosis, maintenance, and repair purposes.⁵¹

Yet, these expanded exemptions ultimately remain only a partial victory for the right-to-repair movement, as the exemptions last only for three years at a time, and Section 1201's anti-trafficking provisions still apply, greatly limiting consumers' and repair servicers' ability to access circumvention information beyond what they themselves can generate.⁵² Moreover, mere exemptions from liability under copyright law remain all but meaningless when OEMs nevertheless withhold the necessary parts, tools, diagnostics, firmware, manuals, and training needed to actually make repairs.⁵³

Of similar concern on the intellectual property front is patent law. While recognizing the right to repair to a considerable extent,⁵⁴ particularly with respect to medical devices,⁵⁵ patent law nonetheless poses a problem for making repairs when OEMs obtain patents

49. U.S. COPYRIGHT OFFICE, SECTION 1201 RULEMAKING: EIGHTH TRIENNIAL PROCEEDING TO DETERMINE EXEMPTIONS TO THE PROHIBITION ON CIRCUMVENTION (2021).

50. Exemption to Prohibition on Circumvention of Copyright Protection Systems for Access Control Technologies, 86 Fed. Reg. 59,627, 59,640 (Oct. 28, 2021) (codified at 37 C.F.R. § 201.40(b)(14)) (emphasis added). This action aligns with developments in the federal executive branch under the Biden administration, reflecting a policy of increasing support for the right-to-repair movement. *See infra* Part II.D.

51. 86 Fed. Reg. 59,627, 59,640 (Oct. 28, 2021) (codified at 37 C.F.R. § 201.40(b)(15)); *see also* U.S. COPYRIGHT OFFICE, *supra* note 49, at 224–29 (weighing the arguments for and against allowing medical device TPM circumvention and concluding that “the prohibition on circumvention of TPMs is causing, or is likely to cause, an adverse impact on the noninfringing diagnosis, repair, and maintenance of medical devices and systems”).

52. *See* Grinvald & Tur-Sinai, *supra* note 6, at 106 (“[T]he ‘anti-trafficking’ provisions of § 1201 may be implicated once the broken machine is given to a repair shop, given that these shops are likely turning to instruction manuals provided by third parties online.”); *Mirr, supra* note 14, at 2409 (“Without an exemption for ‘trafficking,’ individuals would be forced to code or design their own TPM circumvention tools before they can repair their device.”).

53. *See* Whitney Kimball, *We Just Got the Right to Repair—in Theory*, GIZMODO (October 27, 2021), <https://gizmodo.com/we-just-got-the-right-to-repair-in-theory-1847948848> [<https://perma.cc/GT42-5PFU>] (“[C]opyright law still can’t do much to fix the fact that Google, Amazon, Apple, and Microsoft have deadbolted their devices, shot down right to repair bills, and hoarded parts, all forcing us to simply throw out an otherwise fixable device and purchase a new one. So the change [under the copyright exemption] doesn’t mean that manufacturers have to make it any easier on users to crack open the back panel or provide the parts, but it gives you the right to try.”).

54. *See* Grinvald & Tur-Sinai, *supra* note 6, at 100–01, 112 (explaining that under the patent exhaustion doctrine, the sale of a patented product generally exhausts the rights of the patentee to bring an infringement action).

55. *See* Huseby, *supra* note 8, at 49 (“Interestingly, broad constructions of the [patent exhaustion] principle of permissible repair are seen especially in the context of medical device maintenance cases, even though one would expect a higher consideration of the patent owner’s rights because of public interest in maintaining high quality repair standards for the sake of medical safety.”) (footnote omitted).

specifically for individual repair parts.⁵⁶ Even if one manages to independently manufacture a given part—“for instance, by reverse engineering an original part and creating [a computer-aided design] file” to 3D print a needed repair part—this can trigger patent liability when OEMs hold patents over the design of those parts.⁵⁷ Ultimately, just as with copyright law, the repair movement identifies the reform of patent law as necessary but insufficient to effectively reify the right to repair.⁵⁸

2. EULAs Ensnaring Consumers in State Contract Law

Even if federal intellectual property law were to be amended to accommodate for the right to repair, the path to enshrining the right to repair also requires the elimination of another major legal impediment to repair: the enforcement of restrictive end-user license agreements (EULAs) under state contract law.⁵⁹ Until 1996, courts that had analyzed EULAs as shrink-wrap licenses consistently declared them unenforceable.⁶⁰ Following the Seventh Circuit case *ProCD, Inc. v. Zeidenberg*⁶¹ in 1996, however, courts have routinely upheld EULA enforcement.⁶² Through these restrictive unilateral contracts, essentially

56. See Grinvald & Tur-Sinai, *supra* note 6, at 112–13 (illustrating how partial-product and fragment design patents override the exhaustion doctrine’s affordance of liability-free reparability and noting that this restrictive practice has prevailed in litigation and has increased over time, accelerating since 2005). Though beyond the scope of this Note, further legal issues arise on the intellectual property front with the prevalence of 3D-printing technology and its ability to facilitate repairs. See generally Deven R. Desai & Gerard N. Magliocca, *Patents, Meet Napster: 3D Printing and the Digitization of Things*, 102 GEO. L.J. 1691 (2014); Timothy R. Holbrook & Lucas S. Osborn, *Digital Patent Infringement in an Era of 3D Printing*, 48 U.C. DAVIS L. REV. 1319 (2015); Mark A. Lemley, *IP in a World Without Scarcity*, 90 N.Y.U. L. REV. 460 (2015); see also Amy Feldman, *Meet the Italian Engineers 3D-Printing Respirator Parts for Free to Help Keep Coronavirus Patients Alive*, FORBES (Mar. 19, 2020), <https://www.forbes.com/sites/amyfeldman/2020/03/19/talking-with-the-italian-engineers-who-3d-printed-respirator-parts-for-hospitals-with-coronavirus-patients-for-free/?sh=12ebca1c78f1> [<https://perma.cc/34PV-EKYC>] (noting that the uncertain threat of patent infringement liability stopped an engineer from widely distributing his digital design file to 3D-print repair valves for ventilator devices).

57. Tur-Sinai & Grinvald, *supra* note 38, at 478; see also Feldman, *supra* note 56.

58. *Working Together to Make Repair-Friendly Public Policy*, *supra* note 23.

59. See U.S. COPYRIGHT OFFICE, SOFTWARE-ENABLED CONSUMER PRODUCTS: A REPORT OF THE REGISTER OF COPYRIGHTS 63 (2016) (stating that “any concerns about EULAs for embedded software cannot be fully resolved through copyright”); Grinvald & Tur-Sinai, *supra* note 6, at 100–03 (2019) (explaining that even though the Supreme Court’s holding with respect to the patent exhaustion doctrine in *Impression Products v. Lexmark International, Inc.*, 137 S. Ct. 1523 (2017) rules out remedies in patent law for an alleged violation via after-market repair, the potential for EULA enforcement under state contract law remains a major obstacle to the right-to-repair movement); *Mirr*, *supra* note 14, at 2415 (“Under the courts’ current interpretation of § 301 of the Copyright Act [preempting state claims related to potential copyright infringement], even if there were no longer any copyright violation claims at issue, corporations could, through the use of EULAs, prosecute those who are attempting to facilitate repairs by developing and distributing software to circumvent TPMs during the repair process.”).

60. Mark A. Lemley, *Terms of Use*, 91 MINN. L. REV. 459, 468 (2006).

61. *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447 (7th Cir. 1996).

62. Rebecca K. Lively, *Microsoft Windows Vista: The Beginning or the End of End-User License Agreements as We Know Them?*, 39 ST. MARY’S L.J. 339, 350–51 (2007); see also *Mirr*, *supra* note 14, at 2411–15 (analyzing caselaw developments since *ProCD* and noting that courts are willing to allow contractual claims to be asserted in addition to, or in lieu of, copyright violation claims, including claims related to the distribution

creating “a parallel legal system,” OEMs have benefitted tremendously at the expense of consumer freedoms.⁶³ In the context of the COVID-19 pandemic, it appears that the experience of consumers in a strained economy wrought with such repair restrictions has led to frustrations sufficiently powerful that the right to repair has since gained considerable traction in the federal political sphere.

D. The Federal Executive Branch Broadly Supports the Right-to-Repair Movement

The FTC’s report in May of 2021⁶⁴ criticized OEMs’ restrictive repair practices and sided unanimously (i.e., signed on to by all its commissioners) in favor of the right to repair, concluding that “there is scant evidence to support manufacturers’ justifications for repair restrictions.”⁶⁵ Two months later, on July 9, 2021, President Joe Biden went on to commit the entirety of the executive branch to a policy broadly supporting the right to repair by signing an Executive Order entitled “Promoting Competition in the American Economy.”⁶⁶ The Executive Order included 72 initiatives calling upon more than a dozen federal agencies to implement its sweeping policy objectives.⁶⁷ The Order states that it is the policy of the Biden Administration “to enforce the antitrust laws to combat the excessive concentration of industry, the abuses of market power, and the harmful effects of monopoly and monopsony — especially as these issues arise in . . . healthcare markets (including insurance, hospital, and prescription drug markets), [and] repair markets [inter alia] . . .”⁶⁸ The Order also directs the Chair of the FTC to exercise its rulemaking authority to address “unfair anticompetitive restrictions on third-party repair or self-repair of items, such as the restrictions imposed by powerful manufacturers that prevent farmers from repairing their own equipment.”⁶⁹

The White House also released a fact sheet to accompany the Order, outlining its directives.⁷⁰ The fact sheet affirms that the Order generally supports the right to repair, including an introductory bullet point noting that the Order will “[m]ake it easier and cheaper to repair items you own by limiting manufacturers from barring self-repairs or third-party repairs of their products.”⁷¹ The fact sheet goes on to include certain sections

of TPM circumvention software). *But see* Nancy S. Kim, *Developments in Digital “Wrap” Contracts*, 77 BUS. LAW. 275, 282 (Winter 2021–2022) (noting the recent trend in the enforcement of digital wrap contracts that courts are willing to “consider and evaluate the context of the transaction, the interaction of the user and the company, and the contracting process” in digital EULA scenarios on a case-by-case basis).

63. Jason Koebler, *Corporations Use End User License Agreements to Create a Parallel Legal System*, VICE (Mar. 29, 2017), https://www.vice.com/en_us/article/wn949b/how-corporations-use-end-user-license-agreements-to-create-a-parallel-legal-system [<https://perma.cc/BA34-JAHJ>].

64. *See supra* note 12 and accompanying text.

65. U.S. FED. TRADE COMM’N, *supra* note 12, at 6.

66. Exec. Order No. 14,036, 86 Fed. Reg. 36,987 (July 9, 2021).

67. *Id.*

68. *Id.*

69. *Id.*

70. *Fact Sheet: Executive Order on Promoting Competition in the American Economy*, WHITE HOUSE (July 9, 2021), <https://www.whitehouse.gov/briefing-room/statements-releases/2021/07/09/fact-sheet-executive-order-on-promoting-competition-in-the-american-economy/> [<https://perma.cc/FN5U-D4LM>].

71. *Id.*

entitled “Agriculture” and “Technology,” which emphasize, respectively, that the Order encourages the FTC to guarantee the ability of owners to freely repair farm equipment and consumer technology such as cell phones.⁷² The fact sheet also carves out a specific “Healthcare” section explaining that the Order targets “four areas where lack of competition in healthcare increases prices and reduces access to quality care”—those are: prescription drugs, hearing aids, hospital consolidation, and health insurance.⁷³ Notably, unlike the “Agriculture” and “Technology” sections, there is no explicit mention of the anticompetitive repair restrictions specifically burdening the healthcare sector.⁷⁴

Twelve days after President Biden signed the Executive Order, the FTC unanimously adopted a policy statement aimed at securing the right to repair, declaring that the FTC would target repair restrictions that violate antitrust laws enforced by the FTC or the FTC Act’s prohibitions on unfair or deceptive acts or practices.⁷⁵ Commissioner Rohit Chopra issued a separate statement, remarking in relevant part:

The pandemic exposed serious weaknesses in our nation’s resilience and ability to recover from shocks. While we typically view improper repair restrictions through its effects on fair competition, consumers, and small businesses, the Right to Repair movement also showed us how these problems can be matters of life and death.

During the FTC’s review of this issue, we heard about hospitals worried that they would be unable to fix a ventilator because a manufacturer was seeking to deny access to repair it. Outages caused by repair restrictions like these can make the difference in times of emergencies.⁷⁶

Commissioner Chopra’s observations aptly bring to the fore the grave harms sustained within the American healthcare sector without the guarantee of a robust right to repair for medical devices.

72. *Id.*

73. *Id.*

74. See *Biden’s Executive Order Hits on Right to Repair*, ICE MAG. (July 14, 2021), <https://theicecommunity.com/bidens-executive-order-hits-on-right-to-repair/> [<https://perma.cc/XZ7T-D8ZR>] (noting the omission of medical device repair from the Order); Lars Thording, *Why the Right-to-Repair Conversation Needs to Extend Further*, MEDCITY NEWS (Oct. 5, 2021), <https://medcitynews.com/2021/10/why-the-right-to-repair-conversation-needs-to-extend-further/> [<https://perma.cc/3Y7U-K7CJ>] (criticizing the Order’s failure to address medical device repair and re-use, arguing that this issue should be “right in the center of any administrative initiative about competition, the environment, and the desperate need for cost savings in healthcare”).

75. U.S. FED. TRADE COMM’N, POLICY STATEMENT OF THE FEDERAL TRADE COMMISSION ON REPAIR RESTRICTIONS IMPOSED BY MANUFACTURERS AND SELLERS (2021), https://www.ftc.gov/system/files/documents/public_statements/1592330/p194400repairrestrictionspolicystatement.pdf [<https://perma.cc/SM6J-529Y>]; *FTC to Ramp Up Law Enforcement Against Illegal Repair Restrictions*, FED. TRADE COMM’N (July 21, 2021), <https://www.ftc.gov/news-events/press-releases/2021/07/ftc-ramp-law-enforcement-against-illegal-repair-restrictions> [<https://perma.cc/EG3F-SC8E>].

76. U.S. FED. TRADE COMM’N, PREPARED REMARKS OF COMMISSIONER ROHIT CHOPRA 1 (July 21, 2021), https://www.ftc.gov/system/files/documents/public_statements/1592354/final_chopra_prepared_remarks_on_right_to_repair.pdf [<https://perma.cc/39WC-CXYL>].

III. ANALYSIS

While the sprawling web of machinations inhibiting repair causes harm to American consumers universally, nowhere is the injurious effect more uniquely pronounced than in the medical field. In view of a legal landscape that affords OEMs an abundance of approaches in deploying repair restrictions,⁷⁷ one might optimistically expect a state of exception for the law in the context of life-sustaining healthcare infrastructure⁷⁸—one which eschews traditional corporate economic incentives in pursuit of that which is most optimal for the maintenance of human health.⁷⁹ This is not so.⁸⁰ While medical device repair differs from all other domains because the stakes are higher—often meaning the difference between life and death—the very same repair restrictions hamstring biomedical engineering technicians (BMETs) who repair medical devices.⁸¹ Although sound justification existed hitherto, the unfolding of the COVID-19 global pandemic effectively cast into sharp and striking relief the already-critical need for intervention at the federal level to safeguard the right to repair medical devices.

77. See generally *supra* Part II.

78. See NORMAN DANIELS, JUST HEALTH CARE 6 (1985) (“Someone who claims a right to health . . . should be understood to be claiming that certain individuals or groups (or society as a whole) are obliged to perform certain actions which promote or maintain his good health and are obliged to refrain from actions which interfere with it.”).

79. See Marcel Kahan & Edward B. Rock, *Systematic Stewardship with Tradeoffs*, 48 J. CORP. L. (forthcoming 2023) (emphasizing the “single firm focus” of extant corporate law, which demands that “the objective of a corporation is to promote the value of the corporation, within the boundaries of law, for the benefit of the corporation’s shareholders”) (internal quotations omitted). In refraining from any proposed change to the legal sense of corporate purpose, this Note accordingly advocates for amending the boundaries of law within which corporate entities must pursue their objective. See *infra* Part IV.

80. Notably, however, in 2013, the Centers for Medicare and Medicaid Services (CMS), which regulates medical devices through conditions of participation for health facilities receiving federal payments, updated its guidelines for hospital maintenance requirements. While hospitals generally must maintain equipment in accordance with the OEM’s recommendations, this update permitted hospitals to adopt an “Alternate Management Equipment” program to adjust their maintenance regimen by complying with a risk-based assessment by qualified personnel (such as a biomedical engineering technician) and so long as the program complies with certain reporting requirements. DEP’T HEALTH & HUM. SERVS., HOSPITAL EQUIPMENT MAINTENANCE REQUIREMENTS (2013), <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-14-07.pdf> [<https://perma.cc/9QHH-MASF>]. Yet, even if the OEM’s medical device affords the possibility of such repair by third parties, a major obstacle remains the unwillingness of OEMs to provide information to third parties sufficient to comply with these regulations. See *infra* Parts III.A.–C. (describing various reports of biomedical engineering technicians (BMETs) inhibited by repair restrictions).

81. Generally, hospitals achieve repairs to medical devices by contracting with a combination of BMETs either employed in-house, by third party services, or by OEMs themselves—an arrangement which may be governed, at least in part, by the degree of restrictiveness the OEM imposes, since dealing exclusively with OEMs typically costs significantly more. NATHAN PROCTOR & KEVIN O’REILLY, PIRG, HOSPITAL REPAIR RESTRICTIONS 5–6 (2020), https://publicinterestnetwork.org/wp-content/uploads/2022/07/Hospital_Repair_Restrictions_USPEF_7.8.20b.pdf [<https://perma.cc/8JNU-9XMC>].

A. Repair Restrictions are a Chronic Problem in American Healthcare

Repair restrictions have inhibited independent and in-house BMETs for years,⁸² particularly at smaller hospitals,⁸³ and debates over the medical device right to repair were well underway before the onset of the COVID-19 pandemic.⁸⁴ On July 16, 2019, the FTC held a workshop⁸⁵ pursuant to Congress' directive that the FTC issue a report regarding anticompetitive practices related to repair markets.⁸⁶ The Alliance for Quality Medical Device Servicing (Alliance), a coalition of seven of the nation's largest independent medical device service organizations,⁸⁷ attended the workshop. Upon the FTC's request for feedback and data regarding medical device repair, the Alliance expressed substantial concerns regarding the negative impacts on safety and efficiency caused by repair restrictions.⁸⁸ The Alliance provided a lengthy list enumerating the wide variety of repair restrictions inhibiting independent and in-house BMETs from making efficient repairs and driving up costs:

The exclusionary conduct of certain OEMs includes the following:

- tying agreements for ongoing service and maintenance to the purchase of original Equipment or replacement parts;
- refusing to provide manuals to purchasers and their agents;
- refusing to provide service training to ISOs [independent service organizations];
- requiring licensing agreements in order for purchasers to obtain service/repair manuals;
- refusing to provide purchasers with a preventative maintenance schedule;
- refusing to provide purchasers with key codes to access software needed to run necessary reports;
- bundling discounts for purchasing service contracts along with original

82. See Tur-Sinai & Grinvald, *supra* note 38, at 474 (“[H]ospital or third-party biomedical technicians often face significant problems that restrict their ability to service and repair medical equipment. For the most part, the restrictions are imposed deliberately by OEMs, as part of their efforts to maintain tight control over repair markets. This is not a new phenomenon, and in fact, appears to be a long-standing strategy.”).

83. See Agam Shah, *Who Has a Right to Repair Your Farm or Medical Tools?*, AM. SOC'Y MECH. ENG'RS (Apr. 16, 2019), <https://www.asme.org/topics-resources/content/has-right-repair-farm-medical-tools> [<https://perma.cc/CRF8-LSGV>] (“Many smaller hospitals, which are already financially strapped, have come out supporting the right to repair . . .”).

84. See, e.g., Bob Sanders, *Heavy Debate Ensues over 'Right to Repair' Bill*, NH BUS. REV. (Feb. 13, 2018), <https://www.nhbr.com/heavy-debate-ensues-over-right-to-repair-bill/> [<https://perma.cc/LEA3-FF2K>] (describing medical device companies debating over a proposed right-to-repair bill at a hearing of the New Hampshire House Commerce Committee in 2018).

85. See FED. TRADE COMM'N, *Nixing the Fix: A Workshop on Repair Restrictions*, REGULATIONS.GOV, <https://www.regulations.gov/docket/FTC-2019-0013> [<https://perma.cc/23KC-9CRL>] (collecting public comments and empirical research submissions).

86. See *supra* note 12 and accompanying text.

87. *About Us*, ALL. FOR QUALITY MED. DEVICE SERVICING, <https://deviceservicingalliance.com/> [<https://perma.cc/7GT7-LD7Y>].

88. *Comment to the FTC on "Nixing the Fix" Workshop*, ALL. FOR QUALITY MED. DEVICE SERVICING (Sept. 13, 2019), <https://deviceservicingalliance.com/wp-content/uploads/2020/06/The-Alliance-for-Quality-Medical-Device-Servicing-FTC-Response-on-Right-to-Repair-13Sep2019.pdf> [<https://perma.cc/R9SZ-X6DR>].

- Equipment or parts that can only be obtained from the OEM;
- requiring that only OEM service personnel, procedures, and parts can be used in servicing Equipment, or conversely, prohibiting the purchaser or its agent from performing maintenance, repair, service or installation of Equipment;
- pressuring purchasers to not use ISOs for maintenance or other servicing under unsubstantiated safety and outcome claims;
- taking advantage of a recall situation to sell unneeded replacement OEM parts, for commercial gain, as part of a safety recall increasing cost and delaying a safety fix; and
- restricting completion of recalls by preventing (inappropriately) qualified ISO from executing the corrective action associated with a recall, delaying a safety fix and increasing cost.⁸⁹

Consequently, the stage as it was set before the entrance of COVID-19 saw BMETs turning to decentralized online information-trading communities—on websites such as Reddit, Facebook, FranksHospitalWorkshop, Medwrench, and DotMed—to circumvent repair restrictions in order to repair essential medical devices.⁹⁰ One need not be a physician, a BMET, or a hospital patient to see that such an opportunistic and inefficacious struggle through a landscape of inhibitory repair restrictions clearly reflects a suboptimal arrangement for all stakeholders in the medical device market, save for OEMs.

The positions maintained on either side of the medical device right-to-repair debate were substantially the same preceding the pandemic. Supporters of the medical device right to repair have argued that increasing the capacity of in-house and third-party BMETs to maintain hospital equipment would cut costs and, most importantly, would support the timely delivery of care to patients when a device malfunctions without reducing patient safety, thus alleviating repair delays seen with OEM exclusivity.⁹¹ Through concerted lobbying efforts which downplayed or denied these benefits, OEMs have asserted concerns about such reforms jeopardizing patient safety, cybersecurity, and OEMs' intellectual property rights.⁹² The dire effects of the COVID-19 pandemic have now emphasized that in the context of medical device repair, where the maintenance of essential hospital equipment can mean the difference between life and death en masse, the arguments of right to repair proponents should win the day—and indeed they should have won yesterday.

B. COVID-19 Revealed the Untenable Fragility of Perpetuating Medical Device Repair Restrictions

Almost immediately after COVID-19 struck the United States, hospital systems

89. *Id.*

90. Paul Detrick, *Hospital Technicians Ignore Copyright Law to Fight COVID-19*, REASON (Apr. 13, 2020), <https://reason.com/video/2020/04/13/hospital-technicians-ignore-copyright-law-to-fight-covid-19/> [https://perma.cc/2FNC-XT8Y]; PROCTOR & O'REILLY, *supra* note 81, at 6–7.

91. Sanders, *supra* note 84; PROCTOR & O'REILLY, *supra* note 81, at 5; *see also* Perzanowski, *supra* note 27, at 364 (“Authorized repair, which often requires shipping devices back to the manufacturer, can leave hospitals without critical equipment for days or weeks.”).

92. Sanders, *supra* note 84. This Note contends against these specific arguments in greater detail in Part III.D. *See infra* text accompanying notes 116–22.

across the country strained to support a population beset by life-threatening illness, now more reliant on medical devices than ever.⁹³ Dependence skyrocketed, in particular, upon the ventilator device and its critical role in caring for those afflicted with respiratory illness—the nationwide short supply of which dramatically exacerbated the societal pandemonium.⁹⁴ Ventilators flew out of storage while OEMs ramped up their efforts to produce more—and yet, one of the most regrettably compounding components of the COVID-19 crisis quickly came to bear: the breaking down of existing ventilators from constant use and the inability of hospital systems to efficiently repair them.⁹⁵ The regrettable nature of this piece of the crisis is due to the fact that, although surely not entirely avoidable, the morbidly consequential inefficiencies borne of repair restrictions deliberately imposed by OEMs were to blame for a meaningful measure of such hindrances to delivering critical care—and indeed, quite understandably, supporters of the right-to-repair movement were outraged.⁹⁶

C. Data Reveals the Need for Medical Device Right to Repair Regardless of an Active Public Health Emergency

A 2020 report by the U.S. Public Interest Research Group (PIRG) surveyed 222

93. See Taylor, *supra* note 4 (recounting the unfurling of the COVID-19 pandemic one year after its arrival in the United States in March of 2020).

94. Peter Sullivan, *Severe Ventilator Shortage Sparks Desperate Scramble*, HILL (Mar. 26, 2020), <https://thehill.com/policy/healthcare/489734-severe-ventilator-shortage-sparks-desperate-scramble> [<https://perma.cc/KSK9-UEBY>].

95. See Markian Hawryluk, *As Ventilators Become Crucial in Saving Lives, Repair Roadblocks Remain*, KAISER HEALTH NEWS (Apr. 17, 2020), <https://khn.org/news/as-ventilators-become-crucial-in-saving-lives-repair-roadblocks-remain/> [<https://perma.cc/8Y3V-YP9S>] (“When any ventilator breaks down amid the surge of cases, waiting two weeks for a repair can mean patients die.”).

96. See, e.g., Jason Koebler, *Hospitals Need to Repair Ventilators. Manufacturers are Making That Impossible*, VICE: MOTHERBOARD (Mar. 18, 2020), <https://www.vice.com/en/article/wxekgx/hospitals-need-to-repair-ventilators-manufacturers-are-making-that-impossible> [<https://perma.cc/9EZN-Y5SX>]; Detrick, *supra* note 90; An-Li Herring, *‘Right-To-Repair’ Advocates Worry that Hospitals Can’t Fix Broken Ventilators*, 90.5 WESA (Apr. 20, 2020), <https://www.wesa.fm/economy-business/2020-04-20/right-to-repair-advocates-worry-that-hospitals-cant-fix-broken-ventilators> [<https://perma.cc/9THG-QA49>] (noting that repair restrictions “have forced hospitals to wait days for device makers to send their own repair people”); Leticia Reynolds & Kevin O’Reilly, Opinion, *Repairing Ventilators That Can Save Coronavirus Patients Shouldn’t Be a Business Decision*, MARKETWATCH (May 5, 2020), <https://www.marketwatch.com/story/repairing-ventilators-that-can-save-coronavirus-patients-shouldnt-be-a-business-decision-2020-05-04> [<https://perma.cc/27JU-CE4H>]; Susan Decker, *Broken Ventilators Spark Push to End Limits on Who Can Fix Them*, BLOOMBERG (May 16, 2020), <https://www.bloomberg.com/news/articles/2020-05-16/broken-ventilators-spark-push-to-end-limits-on-who-can-fix-them> [<https://perma.cc/6RUY-B47T>]; Lauren Goode, *Right-to-Repair Groups Fire Shots at Medical Device Manufacturers*, WIRED (May 19, 2020), <https://www.wired.com/story/right-to-repair-medical-equipment-ifixit/> [<https://perma.cc/SDC5-59AC>]; Laura Bliss, *Broken Ventilators Add Momentum to ‘Right to Repair’ Movement*, BLOOMBERG BUSINESSWEEK (May 6, 2021), <https://www.bloomberg.com/news/articles/2021-05-06/right-to-repair-movement-gains-momentum-as-states-consider-bills> [<https://perma.cc/76RJ-W37C>] (statement of Jodiane Tritt, executive vice president of the Arkansas Hospital Association) (“[Right to repair has] been an issue since before the pandemic, but the pandemic highlighted any hole we had in health-care infrastructure.”).

BMETs, many of whom were employed by hospitals, to gather data on how repair restrictions affect medical device maintenance.⁹⁷ Nearly half of those BMETs reported that they had been denied access to necessary repair parts and information during the pandemic.⁹⁸ Furthermore, nearly all of them reported that the removal of restrictions on repairs is an issue that is “critical” or “very important” to their work.⁹⁹

It should be noted that during the pandemic, some OEMs, such as Medtronic PLC and General Electric Co., voluntarily agreed to turn over manuals and information necessary to ensure that hospitals could manage repair during the time of crisis.¹⁰⁰ Such voluntary ad hoc agreements, however, are wholly inadequate to address a problem long-plaguing the medical field at the systemic level.¹⁰¹ Indeed, PIRG’s report found that outside the context of the COVID-19 pandemic, almost 92% of BMETs have been denied service information for “critical equipment” such as ventilators, defibrillators, anesthesia machines, and imaging equipment, with nearly 17% reporting this happens “most of the time” and half reporting it happens “somewhat frequently.”¹⁰²

The data gathered by PIRG reveals that the current state of the law permits the ongoing exploitation by OEMs of economic incentives to restrict repairs. And the law allows this to take precedence over the optimization of a more efficient system of hospital infrastructure maintenance, ultimately undermining the integrity of peoples’ health and wellbeing in America. With the medical equipment maintenance market projected to grow with a 9.4% compound annual growth rate through 2030,¹⁰³ OEMs can be expected to fight tooth and nail to maintain their tight control over repair markets and profits therefrom afforded by the law today. The COVID-19 pandemic resoundingly emphasized that the law must evolve to accommodate the right to repair in American healthcare. Thus, the only question is how to implement it most effectively.

D. The Need for Uniformity Requires Federal Legislative Intervention

OEMs have surely felt the pressure mounting as the prevailing discourse has trended increasingly toward decrying repair restrictions and the swelling of support for the right to repair. Just as we have seen the Biden Administration¹⁰⁴ and the FTC¹⁰⁵ take firm stances in support of the right to repair in the public sector, recent examples of shareholder pressure

97. PROCTOR & O’REILLY, *supra* note 81.

98. *Id.* at 10.

99. *Id.*

100. Decker, *supra* note 96.

101. See Kaisey Arena, *Medical Device Repair Act: The Right to Repair*, INTERMED (Oct. 15, 2020), <https://intermed1.com/medical-device-right-to-repair-act/> [<https://perma.cc/A9HQ-R5LU>] (“[C]ooperation [by OEMs] is often the exception rather than the norm During the pandemic, a few OEMs have lifted temporarily such restrictions when they realized the potential harm to public health and consequential negative publicity; however, they very well may revert to their restrictive policy once the pandemic subsides.”).

102. PROCTOR & O’REILLY, *supra* note 81, at 9.

103. *Medical Equipment Maintenance Market Worth \$45.1 Billion by 2030 Says P&S Intelligence*, MKTS. INSIDER (Feb. 24, 2021), <https://markets.businessinsider.com/news/stocks/medical-equipment-maintenance-market-worth-45-1-billion-by-2030-says-p-s-intelligence-1030120875> [<https://perma.cc/R9AL-5DSM>].

104. See *infra* Part II.D.

105. See *infra* notes 11–12, 63 and accompanying text.

have begun to reflect the same enthusiasm for steering corporate policy in the private sector.¹⁰⁶ But while there is broad consensus with respect to the policy ends—securing a right to repair in America—the same cannot necessarily be said as to the means, which includes the open question of how to properly secure the right to repair in the medical device context.

Ultimately, it seems, any attempt at achieving the right to repair for medical devices save for federal legislative intervention will inevitably fall short. In the same statement in which FTC Commissioner Rohit Chopra remarked on the harmful effects of improper repair restrictions on hospitals and patients,¹⁰⁷ the Commissioner also recognized the inability of the FTC to fully address the problem solely through antitrust enforcement:

[T]he scope of existing federal and state laws may be too limited in terms of coverage and in terms of remedies. For example, the Magnuson-Moss Warranty Act only covers goods for household use, and it is not simple for the FTC and state attorneys general to obtain civil penalties or other monetary relief from large firms that violate the law. The Commission should devote resources to assisting policymakers, including at the state level, as they craft Right to Repair laws, to ensure that any new laws are clear and enforceable.¹⁰⁸

Notably, Commissioner Chopra encourages the efforts of lawmakers at the state level to secure the right to repair—and indeed, a state could pass a right-to-repair law (as many have tried¹⁰⁹) which might, perhaps, produce a similar nationwide ripple effect as that of

106. See, e.g., Maddie Stone, *Bowing to Investors, Microsoft Will Make Its Devices Easier to Fix*, GRIST (Oct. 7, 2021), <https://grist.org/accountability/bowing-to-investors-microsoft-will-make-its-devices-easier-to-fix/> [<https://perma.cc/L85V-MWLG>] (discussing Microsoft meeting the demands of activist shareholders to make devices easier to repair); Nathan Ingraham, *Why Apple Changed Its Mind on Right to Repair*, ENGADGET (Nov. 19, 2021), <https://www.engadget.com/apple-user-iphone-repair-policy-change-173047862.html> [<https://perma.cc/CR9G-WPNH>] (discussing Apple’s similar concessions to shareholders demanding easier repair and suggesting that “Apple is giving people what they want, while also trying to avoid government regulation”). It is immediately clear, however, that public shareholder activism alone cannot bring about the desired right to repair reforms in the medical device context, given not only the existence of private OEM companies but the overarching single-firm value maximization imperative imposed by corporate law. See Rock & Kahan, *supra* note 79. These business objectives remain glaringly at odds with a hospital infrastructure maintenance system most optimal for delivering patient care.

107. *Supra* note 76.

108. U.S. FED. TRADE COMM’N, *supra* note 76, at 2.

109. See Proctor, *supra* note 34 (discussing proposed state legislation). California, Texas, Arkansas, and Hawaii have each introduced and failed to pass a medical device right-to-repair bill through their respective state legislatures. See S.B. 605, 2021–2022 Leg., Reg. Sess. (Cal. 2021); H.B. 2541, 87th Leg., Reg. Sess. (Tex. 2021); S.B. 332, 93d Gen. Assemb., Reg. Sess. (Ark. 2021); S.B. 760, 31st Leg., Reg. Sess. (Haw. 2021). As of this writing, none of these states have enacted these bills, which appears attributable—at least in part—to concerns expressed by opposing lobbyists regarding an absence of uniform safety compliance standards for independent repair providers. See Terry Wilcox, Opinion, *Lessons Learned from Failure of Medical ‘Right to Repair’ Bill*, CAPITOL WEEKLY (June 21, 2021), <https://capitolweekly.net/lessons-learned-from-failure-of-medical-right-to-repair-bill/> [<https://perma.cc/N994-LP9V>]; Sally Pipes, *New Medical ‘Right to Repair’ Legislation Endangers Patients*, FORBES (May 10, 2021), <https://www.forbes.com/sites/sallypipes/2021/05/10/new-right-to-repair-legislation-endangers-california-patients/?sh=a81d3ac180c8> [<https://perma.cc/T2RX-S6W3>]. But see *infra* notes 116–19 (contending that patient safety concerns are unfounded). Extinguishing these political concerns is thus a

the Massachusetts automobile repair law.¹¹⁰ This solution, however, is incomplete—severing but one head of the hydra, so to speak.

First, according to law professors Leah Chan Grinvald and Ofer Tur-Sinai, who together have written extensively on the subject of the right to repair,¹¹¹ including in the medical device context,¹¹² “it is impossible to implement an effective right to repair without addressing intellectual property law.”¹¹³ Because the intellectual property laws thwarting the right-to-repair movement are federal law,¹¹⁴ only Congress can foreclose such ever-present threats of infringement liability when BMETs access the information needed to undertake repairs. Second, even if a certain state were to mandate the right to repair for medical devices, such a law—unique to the rest of the country—would likely throttle the otherwise permissive interstate medical device market and, by forcing OEMs to undertake maneuvering in divergent markets, may thereby increase healthcare costs ultimately shouldered by the patient.¹¹⁵ That is to say, a state repair law for medical devices may inadvertently prove to be a regrettable misstep away from the goal of optimizing cost-effective and efficient healthcare delivery. Accordingly, comprehensive federal reform appears ultimately necessary to properly embrace medical device right to repair.

In view of proposed federal legislation, the prevailing argument levied against the right to repair in the context of medical devices is that of a concern for patient safety.¹¹⁶ Scant to no evidence exists, however, to suggest that BMETs employed in-house or via third parties are any less qualified or capable of providing medical device repairs as compared to those employed within OEMs’ repair networks.¹¹⁷ Indeed, in 2018, the Food and Drug Administration (FDA), pursuant to a directive of Congress, issued a “Report on the Quality, Safety, and Effectiveness of Servicing Medical Devices.”¹¹⁸ In its report, the FDA concluded that “many OEMs and third party entities provide high quality, safe, and effective servicing of medical devices” and that “[t]he continued availability of third party entities to service and repair medical devices is critical to the functioning of the U.S.

key objective of the draft bill proposed by this Note, which accordingly proposes to issue a directive to the FDA requiring an expansion of medical device maintenance recordkeeping and reporting requirements. *See infra* Part IV.C.

110. *See supra* notes 27–31 and accompanying text.

111. *See, e.g.*, Grinvald & Tur-Sinai, *supra* note 6.

112. Tur-Sinai & Grinvald, *supra* note 38.

113. *Id.* at 462.

114. *See supra* note 24.

115. This might be especially true if OEMs decided to forgo device sales in a state altogether due to a cost-benefit analysis against a perceived risk of increased liability exposure introduced by third-party repairs. *See* Mirr, *supra* note 14, at 2417 (“While the ‘states as laboratories’ approach to inspiring change at the federal level has functioned well in other cases . . . the size of the corporations opposed to securing a right to repair frustrates this system.”). To neutralize this perceived risk, this Note proposes increased recordkeeping and reporting requirements pursuant to an expansion of FDA regulations for purposes of adequately tracing a given party’s culpability for tort liability claims. *See infra* Part IV.C.

116. Tur-Sinai & Grinvald, *supra* note 38, at 499.

117. *Id.*

118. U.S. FOOD & DRUG ADMIN., FDA REPORT ON THE QUALITY, SAFETY, AND EFFECTIVENESS OF SERVICING OF MEDICAL DEVICES 7–8 (2018).

healthcare system.”¹¹⁹ Thus, it would appear that lobbyists’ concerns over patient safety are largely, if not entirely, unfounded.

A second major concern of lobbyists is the alleged cybersecurity risks posed by medical device repair legislation.¹²⁰ Once again, however, the FDA has squarely addressed this concern in favor of the right to repair. In June 2021, the FDA released a discussion paper considering cybersecurity issues unique to medical devices.¹²¹ Significantly, the report stated:

FDA expects manufacturers to appropriately secure their devices in order to continue to assure the devices’ safety and effectiveness, for example, by implementing adequate access controls to ensure only authorized privileged access to the device regardless of the entity performing servicing activities. Importantly, FDA is not suggesting that devices be secured to prevent non-OEM servicing when such servicing is technically feasible and appropriate. Some manufacturers design their devices with the anticipation of non-OEM servicing and permit secure servicing by such entities, as needed and appropriate. Similar to these manufacturers, we recognize that non-OEM servicing entities play an important role in maintaining the quality, safety, and efficacy of medical devices without compromising cybersecurity.¹²²

These remarks are indeed in accord with, and lend considerable credence to, the understanding that BMETs outside of OEM networks who perform medical device repairs not only do so safely and securely, but that such repairs are essential to a healthcare market optimized for delivering care to patients efficiently and effectively.

As this Note has endeavored to illustrate, the time is well past nigh for the American healthcare industry to secure the right to repair its medical devices. Furthermore—and of concomitant importance—the necessary means for implementing an effective right to repair for medical devices is through Congress with the passage of appropriately comprehensive legislation at the federal level.

IV. RECOMMENDATION

This Note urges Congress to enact legislation guaranteeing the right to repair for

119. *Id.* at i.

120. *See, e.g.*, Peter J. Pitts, *The Major Health Care and Cybersecurity Risk of ‘Right-to-Repair’ Laws*, HILL (June 29, 2021), <https://thehill.com/opinion/healthcare/560741-the-major-health-care-and-cybersecurity-risk-of-right-to-repair-laws> [<https://perma.cc/QX4S-UQUJ>] (“By allowing third parties without any FDA competence to repair regulated, complicated medical devices, Right-to-Repair also opens the door to breaches in cybersecurity.”); Surabhi Dangi-Garimella, *Right to Repair: A Catch-22 for Patient Health*, PATIENTS RISING NOW (Jan. 31, 2022), <https://patientsrisingnow.org/right-to-repair-a-catch-22-for-patient-health/> [<https://perma.cc/DNJ4-H4BC>] (“Medical equipment . . . [is] also highly prone to cybersecurity breaches, which can allow digital hackers to access highly confidential information or change equipment settings, thereby affecting device safety and putting patients at risk.”).

121. U.S. FOOD & DRUG ADMIN., STRENGTHENING CYBERSECURITY PRACTICES ASSOCIATED WITH SERVICING OF MEDICAL DEVICES: CHALLENGES AND OPPORTUNITIES 2 (2021).

122. *Id.* (emphasis added).

medical devices in a form consistent with the provisions of the draft bill included in this Note's Appendix. The proposed draft bill is comprised of several interlocking parts: basic provisions guaranteeing access to necessary medical device repair materials; amendments to the federal intellectual property regime to accommodate the medical device right to repair; a federal override of contracts inhibiting the medical device right to repair; and, lastly, provisions for increased FDA oversight to ensure both patient safety and servicer accountability through enhanced recordkeeping and reporting regulations.

A. Basic Provisions Guaranteeing Access to Necessary Medical Device Repair Materials

At the heart of the proposed draft bill are provisions requiring OEMs to provide, on fair and reasonable terms, documentation, parts, service access methods, and tools needed for purposes of inspection, diagnosis, maintenance, or repair of the medical device, along with training courses and materials on the operation, inspection, diagnosis, maintenance, and repair of their medical devices—all of which is required only to the extent consistent with that which is already provided to the OEM's authorized repair provider. These core provisions echo the template right-to-repair legislation advanced by the Repair Association,¹²³ tailored specifically for medical devices. These tailored provisions follow the course charted by the state medical device right-to-repair bill proposed in California¹²⁴ and the federal bill proposed for the Critical Medical Infrastructure Right-to-Repair Act of 2020,¹²⁵ the combination of which, and guiding rationale, is further described within the footnotes of the proposed draft bill.¹²⁶

B. Changes to Intellectual Property Law and Contract Law to Accommodate the Medical Device Right to Repair

Keeping at the fore the preeminent policy interest in optimizing the efficacy of patient care, which necessarily requires eliminating the looming threat of copyright or patent infringement liability, the draft bill proposes carving out an exception to federal copyright and patent law to accommodate right-to-repair reforms for hospital infrastructure nationwide. Doing so would eliminate the threats of copyright and patent infringement actions brought by OEMs.¹²⁷ Such threats jeopardize the arrangement envisioned by the draft bill, one which would allow hospitals to contract with repair servicers who are most competitive in terms of timeliness and quality, thereby optimizing the delivery of patient care.

Furthermore, to ensure that the foregoing basic repair access provisions and intellectual property provisions are not simply circumvented through private ordering—

123. See MODEL STATE RIGHT-TO-REPAIR LAW, *supra* note 29.

124. S.B. 605, 2021–2022 Leg., Reg. Sess. (Cal. 2021).

125. Critical Medical Infrastructure Right-to-Repair Act of 2020, H.R. 7956, 116th Cong. (2020); Critical Medical Infrastructure Right-to-Repair Act of 2020, S. 4473, 116th Cong. (2020).

126. See *infra* notes 131–38 and accompanying text.

127. See *supra* Part II.C.1. (discussing intellectual property liability in the absence of federal legislative repair accommodations).

particularly through the pervasive practice of unilateral EULAs¹²⁸—the proposed draft bill includes an essential provision declaring null and void a contract that prohibits or restricts the ability of a covered medical device user to repair or maintain the medical device in contravention of the right-to-repair law.

C. FDA Oversight of Medical Device Repair Necessary to Secure a Sound Repair Reform

Updated FDA recordkeeping and reporting requirements are essential to address lingering safety and liability concerns regarding medical device repairs. Accordingly, the draft bill proposed by this Note is unique in that it contains a directive tasking the FDA with updating and expanding its medical device reporting requirements. This enhanced documentation system would remedy the lack of servicing data identified in the FDA's 2018 report on the servicing of medical devices.¹²⁹ Such an update, enabling safely regulated and traceable third-party repairs, would be consistent with 2013 CMS guidelines allowing hospitals to adopt "Alternate Equipment Management" plans and, indeed, would appear to reify the improved arrangement envisioned by the CMS in permitting such repair and maintenance plans in the first place.¹³⁰

V. CONCLUSION

Hospitals and patients cannot afford the price of dealing with repair restrictions, whether that cost is computed in dollar figures or the direr measure of experiencing suboptimal patient care. The COVID-19 pandemic has cast into sharp relief the already pressing need for Congress to intervene and pass right-to-repair legislation, at the very least with respect to medical devices for hospitals. The right-to-repair movement has seen substantial progress over the past decade, including rapidly growing consumer sentiment favoring the right to repair, FTC dedication to antitrust enforcement against repair monopolies, corporate shareholder pressure demanding that companies loosen repair restrictions, and attempts at legislative action at the state and federal level. The unique concerns implicated by healthcare in America, however, make the fight for the right to repair especially urgent in this domain. In order to remedy the infirmity of American medical infrastructure absent the right to repair, the only practical approach is to do so at the federal level with a carefully crafted, comprehensive legislative reform that ensures the protections of the right to repair nationwide.

128. See *supra* Part II.A.

129. See U.S. FOOD & DRUG ADMIN., *supra* note 118, at 7–8 ("Although medical device reports (MDRs) are a valuable source of information, this passive surveillance system has limitations, including the potential submission of incomplete, inaccurate, untimely, unverified, or biased data. In addition, the incidence or prevalence of an event cannot be determined from this reporting system alone due to potential under-reporting of events and lack of information about frequency of device use."); see also Dangi-Garimella, *supra* note 120 (recommending expanded regulatory oversight to "[e]nsur[e] independent contractors comply with regulatory standards that are the same as OEMs"); *supra* note 115 (noting that enhanced recordkeeping also serves to facilitate tracing a given party's culpability for purposes of tort liability claims).

130. See *supra* Part II.

APPENDIX

Draft Medical Device Right to Repair Bill

Section 1: Definitions¹³¹

(a) “Authorized repair provider” means an individual or business who is unaffiliated with an original equipment manufacturer and who has an arrangement with the original equipment manufacturer, for a definite or indefinite period, under which the original equipment manufacturer grants to the individual or business a license to use a trade name, service mark, or other proprietary identifier for the purposes of offering the services of inspection, diagnosis, maintenance, or repair of medical devices under the name of the original equipment manufacturer, or other arrangement with the original equipment manufacturer to offer those services on behalf of the original equipment manufacturer. An original equipment manufacturer who offers the services of inspection, diagnosis, maintenance, or repair of its own medical devices, and who does not have an arrangement described in this subdivision with an unaffiliated individual or business, shall be considered an authorized repair provider with respect to that equipment.

(b) “Covered healthcare provider” means:

(1) a healthcare provider who is the owner, lessee, or licensee of medical devices; or

(2) the agent of a person described in clause (1).

(c) “Documentation” means any manual, diagram, reporting output, service code description, schematic, or other guidance or information used in effecting the services of inspection, diagnosis, maintenance, or repair of medical devices.

(d) “Embedded software” means any programmable instructions provided on firmware delivered with medical devices, or with a part for that equipment, for purposes of equipment operation, including all relevant patches and fixes made by the manufacturer of the equipment or part for these purposes.

(e) (1) “Fair and reasonable terms” for obtaining a part, tool, documentation, or training course and materials means at costs and terms that are equivalent to the most favorable costs and terms under which an original equipment manufacturer offers the part, tool, documentation, services access method, or training course and materials to an authorized repair provider, including all of the following requirements:

(A) Accounting for any discount, rebate, convenient means of delivery, means of enabling fully restored and updated functionality, rights of use, or other incentive or preference the original equipment manufacturer offers to an authorized repair provider, or any additional cost, burden, or impediment the original equipment manufacturer imposes on an independent repair provider.

(B) Not conditioned on, or imposing, a substantial obligation or restriction that is not reasonably necessary for enabling a covered healthcare provider or independent repair

131. This section is adapted from Section 111611.2 of California’s proposed right to repair bill, S.B. 605, 2021–2022 Leg., Reg. Sess. (Cal. 2021), with the alteration (indicated in italics) of the defined term “powered medical equipment” to “medical device” such that the draft bill’s term comports with the same term as defined by the FDA under 21 U.S.C. § 360c (2017).

provider to engage in the diagnosis, maintenance, or repair of medical devices made by, or on behalf of, the original equipment manufacturer.

(C) Not conditioned on an arrangement described in subdivision (a).

(2) For documentation, including any relevant updates, “fair and reasonable terms” also means at no charge, except that, when the documentation is requested in physical printed form, a charge may be included for the reasonable actual costs of preparing and sending the copy.

(3) For software tools, “fair and reasonable terms” also means all of the following:

(A) Provided at no charge and without requiring authorization or internet access.

(B) Without imposing impediments to access or use, in the course of effecting the diagnosis, maintenance, or repair and without impairing the efficient and cost-effective performance of the diagnosis, maintenance, or repair.

(C) Enables full functionality.

(4) If an original equipment manufacturer does not utilize an authorized repair provider, “fair and reasonable terms” means an equitable price in consideration of the actual cost to the original equipment manufacturer to prepare and distribute the part, tool, service access method, or documentation, exclusive of any research and development costs incurred.

(f) “Firmware” means a software program or set of instructions programmed on medical devices, or on a part for that equipment, to allow the equipment or part to communicate within itself or with other computer hardware.

(g) “Independent repair provider” means an individual or business, other than the manufacturer or covered healthcare provider, that is engaged in the services of inspection, diagnosis, maintenance, or repair of medical devices for purposes of returning it to the safety and performance specifications established by the manufacturer and to meet its original intended use.

(h) “Medical device” means any device classified and approved by the United States Food and Drug Administration under section 360c of title 21, United States Code, that is used in the treatment, monitoring, or diagnosis of a patient, and includes assistive, adaptive, and rehabilitative devices.

(i) “Medical device contract” means a contract relating to the purchase, licensing, repair, or maintenance (including periodic maintenance) of medical devices.

(j) “Original equipment manufacturer” means a business engaged in the business of selling, leasing, or otherwise supplying new medical devices manufactured by, or on behalf of, itself, to any individual or business.

(k) “Part” means any replacement part, either new or used, made available by an original equipment manufacturer for purposes of effecting the services of inspection, diagnosis, maintenance, or repair of medical devices manufactured by, or on behalf of, sold, or otherwise supplied by the original equipment manufacturer.

(l) “Repair,” when used with respect to medical devices, means to restore that medical device to a state that is in accordance with the original specifications of that medical device, including any changes to those original specifications that are issued by the manufacturer of the medical device.

(m) “Service access method” means any password, key, code, software, or token that

allows access to medical equipment diagnostics, error logs, or configuration settings that is necessary to facilitate installation or restoration of medical equipment to normal operation.

(n) “Tools” means any software program, hardware implement, or other apparatus used in inspection, diagnosis, maintenance, or repair of medical devices, including software or other mechanisms that provision, program, or pair a new part, calibrate functionality, or perform any other function required to bring the product back to fully functional condition.

(o) “Trade secret” has the meaning given the term in section 1839 of title 18, United States Code.

Section 2: Copyright Reform¹³²

(a) In General—Title 17, United States Code, is amended—

(1) in chapter 1, by adding at the end the following:

“§ 123. Limitation on exclusive rights: incidental copies of service materials made during maintenance or repair of medical devices

“(a) Definitions—In this section—

“(1) “Covered service provider” means—

“(A) the owner or licensee of a copy of service materials; or

“(B) the agent of a person described in subparagraph (A).

“(2) “Medical device” means any device classified and approved by the United States Food and Drug Administration under section 360c of title 21, United States Code, that is used in the treatment, monitoring, or diagnosis of a patient, and includes assistive, adaptive, and rehabilitative devices.

“(3) “Repair,” when used with respect to medical devices, means to restore that medical device to a state that is in accordance with the original specifications of that medical device, including any changes to those original specifications that are issued by the manufacturer of the medical device.

“(4) “Service material,” when used with respect to medical devices—

“(A) means any information or material that the manufacturer of that medical device provides directly, indirectly, or wirelessly to—

“(i) technicians of the manufacturer; or

“(ii) repair facilities that are authorized by the manufacturer; and

“(B) includes—

“(i) schematics, wiring diagrams, mechanical layouts, and other pertinent data with respect to that medical device;

“(ii) computer programs used in diagnosing problems with respect to that medical device or in calibrating, repairing, or maintaining that medical device;

132. This section is adapted from Section 3 of the Critical Medical Infrastructure Right-to-Repair Act of 2020, H.R. 7956, 116th Cong. (2020) but intentionally omits all references to a “covered emergency,” as this draft bill intends for its right to repair protections to apply at all times, i.e., regardless of a public health emergency. This section also alters (indicated in italics) the defined term “critical medical infrastructure” to “medical device” such that the draft bill comports with the same term as defined by the FDA as prescribed in Section 1 of the draft bill.

“(iii) service keys that are required to access diagnostic information, and otherwise authorize repairs, with respect to that medical device;

“(iv) access to error logs that are required to diagnose required repairs with respect to that medical device;

“(v) preventative and corrective maintenance, inspection, and repair procedures with respect to that medical device;

“(vi) information regarding safety alerts, recalls, service bulletins, specification updates, and the need for adjustments to maintain efficiency, safety, and convenience with respect to that medical device; and

“(vii) any other information provided to diagnose problems with respect to, or to service, maintain, repair, activate, certify, or install, that medical device, including—

“(I) with respect to any replacement part or equipment relating to that piece of the medical device; and

“(II) training materials with respect to that medical device.

“(b) Limitation—Notwithstanding the provisions of section 106, it is not an infringement of copyright for a covered service provider to make, or to authorize the making, of a separate copy of service materials with respect to the covered service provider, if making that separate copy is incidental to the repair or maintenance of medical devices; and

“(c) Rule Of Construction—(1) Nothing in this section may be construed to imply that the actions explicitly authorized under this section may not also be permitted under another provision of this title;” and

(2) in section 1201, by adding at the end the following:

“(l) Repair of Medical Devices—

“(1) Definitions—For purposes of this subsection—

“(A) the terms ‘medical device,’ ‘repair,’ and ‘covered service provider’ have the meanings given those terms in section 123(a) of this title.

“(2) Permissible Circumvention—Notwithstanding the provisions of subsection (a)(1)(A), it is not a violation of that subsection for a covered healthcare provider to circumvent a technological measure that effectively controls access to a work protected under this title, if the purpose of the act of circumvention is to repair or maintain medical devices with respect to that covered healthcare provider.

“(3) Enabling Circumvention—Notwithstanding the provisions of subsections (a)(2) and (b), it is not a violation of either such provision for a covered healthcare provider to manufacture, import, offer to the public, provide, or otherwise traffic in technological means to circumvent a technological measure that effectively controls access to a work protected under this title, or to circumvent protection afforded by a technological measure that effectively controls access to a work protected under this title, if that action by that covered healthcare provider enables a repair or maintenance permitted under paragraph (2).

“(4) Rules Of Construction—Nothing in this subsection may be construed to—

“(A) exempt a covered healthcare provider from compliance with any other applicable law or regulation relating to the repair or maintenance of medical devices, except as explicitly provided in this subsection; or

“(B) prevent the Librarian of Congress from determining, under the applicable

subparagraphs of subsection (a)(1), that subparagraph (A) of such subsection (a)(1) shall not apply to a covered healthcare provider relating to the circumvention of a technological measure that effectively controls access to a work protected under this title.”.

Section 3: Patent Reform¹³³

Section 271 of title 35, United States Code, is amended—

(a) by redesignating subsections (h) and (i) as subsections (i) and (j), respectively; and
(b) by inserting after subsection (g) the following:

“(1) Design Patents—

“(A) Definitions—In this subsection—

“(i) the terms ‘medical device,’ ‘repair,’ and ‘covered healthcare provider’ have the meanings given the terms in section 123(a) of title 17.

“(B) Non-Infringement—It shall not be an act of infringement with respect to a patent for design obtained under section 171 for a covered healthcare provider to fabricate a part on a non-commercial basis, and as needed, for the repair or maintenance of medical devices with respect to that covered healthcare provider.

“(C) Rule Of Construction—Nothing in this subsection may be construed to exempt a covered healthcare provider from compliance with any other applicable law or regulation relating to a part or medical device described in paragraph (B).”.

Section 4: Contracts¹³⁴

Notwithstanding any other provision of law or regulation, a provision of a medical device contract is null and void if that provision of the medical device contract prohibits or restricts the ability of a covered healthcare provider that is a party to the contract to repair or maintain the medical device with respect to the covered healthcare provider.

Section 5: Application to Medical Device Original Equipment Manufacturers¹³⁵

133. This section is adapted from Section 4 of the Critical Medical Infrastructure Right-to-Repair Act of 2020, H.R. 7956, 116th Cong. (2020), but intentionally omits all references to a “covered emergency” as this draft bill intends for its right to repair protections to apply at all times regardless of a public health emergency. This section also alters (indicated in italics) the defined term “critical medical infrastructure” to “medical devices” such that the draft bill comports with the same term as defined by the FDA as prescribed in Section 1 of the draft bill.

134. This section is adapted from Section 5 of the Critical Medical Infrastructure Right-to-Repair Act of 2020, H.R. 7956, 116th Cong. (2020), and alters the defined term “critical medical infrastructure” to “medical devices” such that the draft bill comports with the same term as defined by the FDA as prescribed in Section 1 of the draft bill.

135. This section is adapted from Section 111611.3 of California’s proposed right to repair bill, S.B. 605, 2021–2022 Leg., Reg. Sess. (Cal. 2021), and alters (indicated in italics) the defined term “powered medical equipment” to “medical device” such that the draft bill’s term comports with same term as defined by the FDA as prescribed in Section 1 of the draft bill. Also altered is the term “hospital” to “covered healthcare provider” such that the draft bill’s term is consistent with the term as defined by the Critical Medical Infrastructure Right-to-Repair Act of 2020, H.R. 7956, 116th Cong. (2020), as portions thereof are employed in the draft bill; also

(a) For medical devices, and parts for medical devices, sold, leased, or otherwise introduced into commerce in the United States, an original equipment manufacturer shall make available to a covered healthcare provider and an independent repair provider engaged by the covered healthcare provider for the purpose of providing medical equipment maintenance and repair, on fair and reasonable terms, any documentation, parts, service access methods, and tools, including any updates to information or embedded software, needed for purposes of inspection, diagnosis, maintenance, or repair of the equipment. This section does not require an original equipment manufacturer to make available a part if the part is no longer available to the original equipment manufacturer.

(b) For medical devices, and parts for medical devices, sold, leased, or otherwise introduced into commerce in the United States, an original equipment manufacturer shall make available to a covered healthcare provider and an independent repair provider engaged by the covered healthcare provider for the purpose of providing medical equipment maintenance and repair, on fair and reasonable terms, training courses and materials on the operation, inspection, diagnosis, maintenance, and repair of the equipment. This section does not require an original equipment manufacturer to make available a training course or material if the original equipment manufacturer does not provide a training course or material to an authorized repair provider.

Section 6: Protection of Trade Secrets¹³⁶

(a) Subject to paragraph (b), a manufacturer of medical devices may not be required to publicly disclose information that, if made public, would divulge methods or processes entitled to protection as trade secrets under chapter 90 of title 18, United States Code.

(b) A manufacturer of medical devices may not withhold information under paragraph (a) on the ground that disclosing the information would divulge methods or processes entitled to protection as trade secrets under chapter 90 of title 18, United States Code, if that information is provided directly or indirectly to authorized dealers or service providers.

Section 7: Medical Device Recordkeeping and Reporting by Covered Healthcare Providers and Independent Repair Providers¹³⁷

altered is the inclusion of the language “leased” to cover leased medical devices as well as the language “or otherwise introduced into commerce in the United States” for jurisdictional purposes. The substance of this Section 5 of the draft bill maps the core provisions of the template legislation advanced by the Repair Association. REPAIR.ORG, *supra* note 29.

136. This section is adapted from Section 6 of the Critical Medical Infrastructure Right-to-Repair Act of 2020, H.R. 7956, 116th Cong. (2020), and replaces the defined term “critical medical infrastructure” with “medical devices” such that the draft bill comports with the same term as defined by the FDA as prescribed in Section 1 of the draft bill.

137. This section is original to this Note’s proposed draft bill and is a key feature of the draft bill insofar as it uniquely aims to extinguish concerns of political opponents to the medical device right to repair regarding patient safety and unwarranted product liability exposure. *See supra* notes 109, 115, 129 and accompanying text (contending against these concerns).

(a) Not later than 100 days after the date of enactment of this section, the Secretary of Health and Human Services shall promulgate proposed regulations to amend Chapter 1, subchapter H, Code of Federal Regulations, to establish medical device reporting requirements—

(A) which require independent repair providers undertaking services on medical devices to register as such with FDA under Title 21, Code of Federal Regulations, Section 807 for purposes of adequate recordkeeping and transparency between device user facilities, original equipment manufacturers, and FDA; and

(B) which require device user facilities to maintain servicing records concerning the servicing history of the medical device, such as who serviced the device and what service was done, when the device was serviced, how often the device was serviced, what parts were replaced or repaired, and what testing was completed after the device was serviced; and

(C) which require independent repair providers, in a timely manner upon servicing a device, to provide reports:

(i) to the original equipment manufacturer sufficient to meet the quality system requirements imposed on original equipment manufacturers under Title 21, Code of Federal Regulations, Section 820.200; and

(ii) to the device user facility sufficient to meet the servicing records described in paragraph (B); and

(D) which require reports to FDA made by device user facilities under currently enforceable medical device reporting requirements under Title 21, Code of Federal Regulations, Section 803, to include the servicing records described in paragraph (B).

Section 8: Enforcement by the Federal Trade Commission¹³⁸

(a) A violation of this section, or a regulation promulgated under this section, shall be treated as a violation of a rule defining an unfair or deceptive act or practice prescribed under section 18(a)(1)(B) of the Federal Trade Commission Act (15 U.S.C. 57a(a)(1)(B)).

(b) The Federal Trade Commission (referred to in this subsection as the “Commission”) shall enforce this section and any regulation promulgated under this section in the same manner, by the same means, and with the same jurisdiction, powers, and duties as though all applicable terms and provisions of the Federal Trade Commission Act (15 U.S.C. 41 et seq.) were incorporated into and made a part of this section. Any person who violates this section or a regulation promulgated under this section shall be subject to the penalties and entitled to the privileges and immunities provided in the Federal Trade Commission Act. Enforcement by the Commission shall be the exclusive means of enforcing compliance with this section and any regulation promulgated under this section.

(c) Rulemaking Authority—The Commission shall have authority under section 553 of title 5, United States Code, to promulgate any regulations necessary to implement this section.

138. This section is adapted without alteration from Section 6 of the Critical Medical Infrastructure Right-to-Repair Act of 2020, H.R. 7956, 116th Cong. (2020) for purposes of enforcement.