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Cover Page Footnote

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The Future of Healthcare is Generic: Expanding Hatch-Waxman to Equitably Regulate the Healthcare Products Industry

George Encarnacion Jr.

I. Introduction

In the years leading up to 1984, the fight to preserve free-market power over the pharmaceutical drug industry was in full swing. There was a growing realization that the mechanisms in place to create generic drugs were becoming more impactful and as a result, more detrimental to private pharmaceutical profits.[1] The use of Abbreviated New Drug Applications (ANDAs) to create generic versions of branded drugs in a more expedited fashion would mean, in the eyes of the pharmaceutical industry, the end of their perpetual drug monopolies.[2] With this realization and after much lobbying from both the pharmaceutical industry and the generic drug manufacturers, Congress reacted with the Hatch-Waxman Act.[3]

This Act, a series of amendments to the Federal Food, Drug, and Cosmetic Act (FDCA), would allow for generic drug manufacturers to begin the approval process with the Food & Drug Administration (FDA) for their generic drug, under a "safe harbor" provision so as to avoid lawsuits for patent violations.[4] The catch was that brand-name drugs would be protected with longer patent monopolies for newly created drugs.[5] This plan had success in its beginning years, as there was a flood in generic drugs that entered the market. By 1990, about 40% of prescriptions were being supplied with generic drugs versus their brand-name counterparts, and by 2012, about 84% of prescription drugs were being filled with generic drugs versus brand-name drugs.[6] This method of compromise between private corporate profits and public health interests proved so

[1] Alfred Engelberg, *Unaffordable Prescription Drugs: The Real Legacy of the Hatch-Waxman Act*, STAT (Dec. 16, 2020), https://www.statnews.com/2020/12/16/unaffordable-prescription-drugs-real-legacy-hatch-waxman-act/.
[2] *Id.*
[3] *Id.*
[4] WENDY SCHACHT & JOHN R. THOMAS, THE HATCH-WAXMAN ACT: LEGISLATIVE CHANGES IN THE 108TH CONGRESS AFFECTING PHARMACEUTICAL PATENTS 3 (2004); Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. §§ 301, 355, 360.
[5] SCHACHT & THOMAS, *supra* note 4, at 3.
[6] Engelberg, *supra* note 1.

popular that in 2010, Congress followed up with the Biologics Price Competition and Innovation Act (BPCIA), which created a similar system for generics of biologic drugs, or "biosimilars".[7]

Given all this information, it would be safe to assume the overall cost of consumer and government spending has decreased as a result of patent expirations and generic prescriptions increasing. Yet, as data shows, the opposite has occurred. While the percentage of prescribed generics versus branded drugs has increased to 90% by 2018, spending for the top 20 branded drugs was higher than spending of all generics on the market.[8] Multiple branded drugs are also enjoying decades of monopoly patent protection through exploitations of the Hatch-Waxman Act, and the reality is that where patent-expired branded drugs can no longer provide a profit for pharmaceutical companies, price-gouging in newer drugs is implemented to offset that loss.[9]

This introduction serves to give a brief glimpse of just one of many sectors of the healthcare industry that is increasingly burdening consumers because of inefficient or nonexistent generic product markets. It also bolsters the argument that a new, more expansive generics system is necessary to replace the current healthcare regulatory system. The drug market is one part of a larger healthcare system that overall is lacking in generic products that could offset the over consumer and governmental costs of healthcare. Part II of this article will highlight the historical and current generics landscape of the healthcare industry's largest sectors, the pharmaceutical drug industry, and the medical device industry. Part III will focus on the obstacles faced in any attempts to implement regulatory and legal reform in the medical devices field. Part IV will highlight potential policy proposals that could be implemented for generic medical devices that can allow for generic devices and generic drugs to coexist under one coherent regulatory system.

[7] *Id.*
[8] *Id.*
[9] *Id.*

II. Generics Market Timeline: Then and Now

a. On Drug Regulation

The healthcare industry as we know it, and the regulating power that we understand today, did not come to formally exist until 1938, with the passage of the FDCA.[10] This Act was the response to decades of lax legislation on drug and food-specific regulation in the United States governed by the Pure Food & Drugs Act of 1906.[11] The FDCA brought a clean slate to the regulation of drugs and gave the FDA a larger set of powers to enforce their regulations.[12] These powers included requiring new drugs to be shown safe before marketing, being able to prosecute misbranding of drugs, authorizing the inspection of manufacturing factories, and launching the requirement for certain prescription-only drugs.[13]

From 1938 onward, there were many major amendments to the original legislation, aimed at answering many of the discrepancies in the language of the original Act and filling in holes in the healthcare landscape exacerbated by the Act.[14] One of these discrepancies came in the form of generic drugs, which from the onset of the original FDCA, were able to be approved and marketed under what is known as a New Drug Application (NDA).[15] This process, the same process that branded drugs have to go through, allows for manufacturers to prove the safety and effectiveness of their drug.[16] The predominant issue in the later decades after the FDCA enactment was the

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[10] U.S. FOOD & DRUG ADMIN., MILESTONES OF DRUG REGULATION IN THE UNITED STATES 2 (2018); Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.
[11] U.S. FOOD & DRUG ADMIN., *supra* note 10, at 1.
[12] Geert Van Kempen, *Everything You Need to Know About the Food, Drug, and Cosmetic Act*, VEEVA (Nov. 11, 2021), https://www.industries.veeva.com/blog/the-food-drug-and-cosmetic-act.
[13] *Id.*
[14] *Id.*; *see generally* Durham–Humphrey Amendment, Pub. L. No. 82-215, 65 Stat. 648 (1951) (specifically defining two categories of medication, prescription and over-the-counter); *see generally* Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (requiring drug manufacturers to provide proof of the effectiveness and safety of their drugs before approval and required the disclosure of accurate information regarding drug side effects).
[15] Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 Acta Pharmaceutica Sinica B 297, 298 (Sept. 2013), https://www.sciencedirect.com/science/article/pii/S2211383513000762?via%3Dihub.
[16] *Id.*

overwhelming cost of replicating all required clinical tests for generic drugs.[17] Generic manufacturers did not have the financial resources to compete with branded drug manufacturers and as a result, near-monopolies for many branded drugs became commonplace.[18]

As a result, Congress studied the issue and began work on the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the aforementioned Hatch-Waxman Act.[19] The idea behind the Act was relatively straightforward; it would allow for an expedited way for generic manufacturers to file their drug with the FDA and avoid costly clinical trials, while simultaneously giving branded drug manufacturers a longer patent life for their innovator drugs.[20] Looking specifically to generics manufacturers, the Act provides for the filing of abbreviated NDAs (ANDAs) to the FDA, which only requires:

1. Manufacturing process
2. Quality assurance
3. Bioequivalence.[21]

Further, The Act provides for a safe harbor provision for generics manufacturers during the time that the company is preparing for its ANDA application, which allows for the manufacturer to research the manufacturing process of the branded drug, test the quality of their created batches, and ensure that their generic is bioequivalent.[22] This provision, known as the research exemption, makes it possible for generic manufacturers to avoid patent infringement litigation for otherwise illegal patent conduct.[23] On the opposite side, innovator companies gain some protections from this Act. The Act provides a new form of market exclusivity, through a

[17] Boehm, *supra* note 15, at 298.
[18] Engelberg, *supra* note 1.
[19] *Id.*
[20] *Id.*; Boehm, *supra* note 15, at 298.
[21] 21 U.S.C. § 355
[22] SCHACHT & THOMAS, *supra* note 4, at 1.
[23] *Id.*

five-year period of data exclusivity awarded when the FDA approves a new "chemical entity", which prevents any generics from being formed off that chemical entity.[24] The Act also allows patents for new drugs to be extended by the time the drug is under regulatory review by the FDA, as an incentive for regulatory review consuming potential patent life.[25]

Since the passing of the Hatch-Waxman Act, there have been multiple amendments to the overall FDCA effecting the drug industry, but nothing that has comprehensively affected the generics manufacturing process since 1984.[26] As a result of the initial success of the Hatch-Waxman Act, Congress moved to create a similar system for the governance of generics in the biosimilars realm.[27] Biosimilars are described as products that are "biosimilar", that is, interchangeable, with some other FDA-licensed reference biological product separate from medical devices.[28] These products include more complex chemical compounds, such as vaccines and recombinant medical treatments.[29] The passage of the Biologics Price Competition and Innovation Act of 2009 allowed for generic versions of these products to be approved through a faster and more affordable process, with a recognition that the consumer and government burden on medical products can be lessened with the introduction of generic products.

b. On Medical Device Regulation

The FDCA was a monumental step in consumer protection and government assistance in the healthcare industry. However, from its' inception in 1938 and for the next four decades, there

[24] Boehm, *supra* note 15, at 300.
[25] Boehm, *supra* note 15, at 298.
[26] Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, 108 Stat. 4325 (1994) (defines and regulates dietary supplements); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 11 Stat. 2296 (1997) (reauthorized drug user fees and allowed more freedom to drug manufacturers in marketing drugs); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) (reauthorized drug user fees and amended post-marketing activities by drug manufacturers).
[27] Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as 42 U.S.C. § 262).
[28] *Id.*
[29] U.S. FOOD & DRUG ADMIN., BIOLOGICAL PRODUCT DEFINITIONS 1 (2018).

was no comprehensive regulation for medical devices. Medical devices were, prior to 1976, labeled as "drugs" for regulation purposes.[30] Starting in the 1960's and leading into the 1970's, there were growing concerns regarding the safety of newly created medical devices as technology and innovation in the medical industry began ramping up.[31] This ultimately led to the creation and passage of the Medical Device Regulation Act (MDRA), also known as the Medical Device Amendments of 1976.[32]

Notably different from the regulation of drugs, which are classified and grouped through the application of NDAs (branded drugs) and ANDAs (generic drugs), Congress elected to classify medical devices according to their risks and the regulatory controls necessary to provide a reasonable assurance of safety and effectiveness.[33] Class I devices are generally considered low risk for human use, and include such items like dental floss, bandages, and mechanical wheelchairs.[34] Class II devices have moderate risk for human use, and includes items like syringes, pregnancy tests, and electric wheelchairs.[35] Class III devices are the highest risk devices for human use, and include pacemakers, defibrillators, and ventilators.[36] Where drugs are approved through the "newness" of the drug, medical devices are organized and approved on the level of risk they pose in human use, regardless of whether the device is "new" to the market or not.

Since 1976, there have been multiple amendments to the original legislation regarding medical devices.[37] The Safe Medical Device Amendments of 1990 focused on enhancing the safety

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[30] Brian P. Wallenfelt, *Hatch-Waxman and Medical Devices*, 40 WM. MITCHELL L. REV. 1407, 1409 (2014), from ORACLINICAL.COM.
[31] Aron Shapiro, *Medical Device Regulation: A Review*, ORA, https://www.oraclinical.com/resource/medical-device-regulation-a-review/.
[32] Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified as 21 U.S.C. § 360).
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] *Id.*
[37] Safe Medical Device Amendments of 1990, Pub. L No. 101-629, 104 Stat. 4511 (1990) (codified as 21 U.S.C. § 360).

of Class III devices that were approved using the new-abbreviated method of FDA approval, the 510K premarket approval process.[38] The amendments required medical device manufacturers to report any adverse events involving their medical devices and show the effectiveness of their products under the expedited 510K approval process.[39] The FDA Modernization Act of 1997 moved to require the FDA to focus more on higher-risk devices in their approval process, due to the growing technological advances in medical device innovation.[40] In all these amendments, however, no changes for allowing generic medical devices have ever been introduced.

The FDA, with its distinguishable approval process for drugs versus devices, has never specifically recognized generic medical devices as it has for drugs. Medical devices, since the original 1976 Act, are approved in the same method regardless of whether the device is the generic equivalent of another device. The result is similar to the result in the drug industry prior to the Hatch-Waxman Act. With medical devices, larger medical device manufacturers have the purchasing power to create medical devices and effectively form a monopoly of that product, utilizing the high costs of FDA approval to gatekeep potential generics products from even getting a footing in their device's market.[41] As amendments have been added in the years after 1976, they have made FDA approval easier for already-existing medical devices.

The utilization of the 510(k) clearance process can now allow one medical device manufacturer to continuously patent new, but just slightly different enough, iterations of their original medical device in order to extend the longevity of their market monopoly on a specific medical device.[42] Potential generics manufacturers are effectively shut out of entire device

[38] *Id.*
[39] *Id.*
[40] U.S. FOOD & DRUG ADMIN., THE FDA MODERNIZATION ACT OF 1997 (2018).
[41] *What Are the Benefits of Generic Medical Devices*, KEMPER MEDICAL, https://kempermedical.com/blogs/high-pressure-syringes/the-benefits-of-generic-medical-devices (Jun. 12, 2020).
[42] Zachary E. Shapiro et al., *Nothing Generic About It: Promoting Therapeutic Access by Overcoming Regulatory and Legal Barriers to a Robust Generic Medical Device Market*, 98 N.C. L. REV. 595, 613-14 (2020).

markets, with the inflated costs of risk assessment and clinical trials too high for generics to be financially plausible.

III. Obstacles Generic Devices Face

While the idea of an entire field of generic medical devices sounds great, it would also face a multitude of obstacles due to the nature of the policy proposals, the existing structure of the medical device regulatory system, and other issues as mentioned in the prior section. This section will highlight the most pressing issues; the existence of the 510(k) clearance, and the lack of product liability protection for potential generic device manufacturers under the current regulatory scheme.

a. The 510(k) Clearance Process as a Liability

The classification of medical devices based on their risk to health and human safety, as explained in the previous sections, comes with its' own set of issues. Among them is the addition of the 510(k) clearance process, which allows for manufacturers to bypass the rigorous FDA process when creating devices that are similar enough to an already existing medical device that has already gone through one of the rigorous approval processes.[43] This approval process requires that manufacturers show a "substantial equivalence" to an already-existing device rated as Class I or II.[44] Class III devices, devices that are the highest risk, seldom get expedited through the 510(k) process. This is because the 510(k) process does not just focus on equivalence to prior devices, but the risk associated with that device.[45]

While the intention of Congress was to create a system that would incentivize manufacturers to continue innovating new devices at a lower overall cost, the end result of this new tool was on

[43] U.S. FOOD & DRUG ADMIN., PREMARKET NOTIFICATION 510(K) (2022).
[44] *Id.*
[45] *PMA Approvals,* U.S. FOOD & DRUG ADMIN., (2019).

the contrary. Since its' inception, this process has been used by large, established device manufacturers to simply create different variations of their already-existing low-to-moderate risk devices, effectively stiffing out any potential generics from the market. For Class III devices, established manufacturers that are capable of investing large amounts of capital into riskier devices close the opportunities for generic manufacturers in any attempts to break the market due to their financial power.

The issue of the 510K approval process does not stop there. As noted above, the 510(k) process does not require therapeutic equivalence in new devices. It only requires that new devices be substantially equivalent, making only small improvements to differentiate the product from its' prior in the marketplace. The result is that products have flooded the market in which there have been many small changes over time, to the point where the current device is drastically different from the original devices in terms of material composition, power structure, and usage for different parts of the body. This highlights the downfall of the 510(k) process, where small changes over time can result in large-scale changes with no sound, scientific data showing the safety and effectiveness of the new device.[46]

b. Product Liability Protection, or a Lack Thereof

Aside from the issue of current medical device regulation allowing for the bypass of safety and regulatory standards for 510K approved devices, there comes the issue of liability when devices may potentially fail. When observing the current landscape for generic drugs regarding product liability, the Supreme Court has shown a positive attitude towards protecting generic drug manufacturers from state tort product liability when it comes to product design defects and

[46] Shapiro et al., *supra* note 42.

labelling issues.[47] Since generic drugs must be equivalent to their original innovator drug in terms of its composition, design, and final labeling, federal law only allows for potential state action and liability in regard to the actual manufacturing of the drug, and any defects or inconsistencies that may occur in the drug manufacturing process.[48] Since the innovator drug manufacturer goes through the rigorous federal approval process for a new drug, from composition to labeling and marketing, it would be counterproductive to expose generics to state liability for complying with federal requirements through the innovator drug's approval process. Simply put, generic drugs must "copy" the innovator drug for approval and allowing liability against generic drugs on the state level when the innovator drug was approved as compliant would deter generic drug manufacturers from even entering the market.

The importance of this immunity from liability for generic manufacturers cannot be overstated, as the potential for high-cost litigation over design defects and improper labeling on the state level would severely deter, if not eliminate, any feasibility in having a generic drug market at all.

The same cannot be said for the medical device market when it comes to potential product liability. To start, when the Medical Device Amendments of 1976 were passed, there was an explicit preemption clause in the statute that would protect innovator devices from state liability claims when those devices were validated through the federal FDA process.[49] The breadth of this preemption was eventually brought before the Supreme Court in *Riegel v. Medtronic, Inc.*[50] This case questioned whether all or certain devices were protected from state liability claims.[51] The

[47] *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 624 (2011) (holding that generic drug manufacturers could not be held liable for under state tort law for failing to provide adequate warning labels pursuant to state law); *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472, 493 (2013) (holding that impossibility preemption applied to generic drug design defects).
[48] Shapiro et al., *supra* note 42, at 615.
[49] 21 U.S.C. § 360k(a).
[50] 552 U.S. 312 (2008).
[51] *Id.* at 321.

Court determined that this clause was not to cover all medical devices and would only cover Class III devices.[52]

Another recurring theme highlighted within this decision, is that on the federal level medical devices continue to be analyzed on not the equivalence of device to device, but on the risk that each device may or may not pose. The Court reasoned that because of how rigorous the approval process is for Class III devices in terms of determining the safety and effectiveness of the device, they can suffice not being exposed to potential state tort action for product liability.[53] Devices that are Class I or II, and devices that are approved through the 510(k) process, however, do not escape potential product liability for not following specific state product requirements.

The result of this is the further disincentive for generic device manufacturers to enter their products to the market. This is a stark, and important, distinction as compared to the drug industry. Innovator device manufacturers are protected against state tort liability for their Class III devices and are also able to afford potential litigation for liability in their Class I or II devices. Generic device manufacturers, even when they show substantial equivalence under the current regulatory scheme, will be subject to not only manufacturing liability, but also design defect liability and labelling liability for purely generic products based off of already-approved innovator devices. What has formed is a system where well-established manufacturers can create a multitude of variations of one product without any of the intensive and capital-consuming requirements of the Class III premarket approval process, effectively closing out any opportunity for entry of more affordable generic versions, and where if there are generic devices that can survive the premarket approval process, those devices run a significantly higher risk of losing capital on litigation and

[52] *Id.* at 322-23.
[53] *Id.* at 330.

liability costs if their generic device, created specifically in replication of an original innovator device, is found to be defective in any way.

This structure of the current risk-based device approval system provides no true incentives for generic device manufacturers unless devices are low-risk, and even then, those manufacturers need to have sufficient funds for potential future litigation for liability since there is no protection against generic low-risk devices.

IV. A Potential Full-Scale Statutory Proposal

Since its' inception in 1984, the framework for generic drug manufacturing has exploded and created a net positive benefit for consumer in terms of how much less the average consumer is paying for generic drugs.[54] While there are many downfalls of the current structure of the Hatch-Waxman Act regarding where the price of non-generic drugs is heading, something that for sake of this article will not be fully addressed, that cannot discourage or dissuade regulatory authorities from seeking a similar structure for medical devices. One such structure could be a full-sweeping statute that would swallow the medical devices and biosimilars industry into the same statutory scheme of the Hatch-Waxman Act, creating a uniform regulatory system managed by the FDA in which all regulated fields; medical devices, pharmaceutical drugs, and extensive biosimilars, can be created generically following the same guidelines for therapeutic equivalence and an "abbreviated" application process resembling the current ANDA process for potential generic drugs. Additionally, the risk-based approach for medical devices should be abandoned altogether, in favor of evaluating potential devices based on their safety and effectiveness. This would allow for the product liability protection of generic devices shown to be therapeutically equivalent to

[54] Engelberg, *supra* note 1.

innovator devices if the language of this proposed statutory change doesn't already include extended liability protection for devices.

a. An Across the Board "Accelerated" Application Process

To start this proposition for an all-encompassing regulatory system, there must be a change to the current accelerated application process for medical devices. Namely, this would require the elimination of the 510(k) clearance process. The current system allows for an accelerated application for devices that do not have a new use but have slight changes that do not affect the safety and effectiveness of the device and are within the lower-risk categories.[55] As explained previously, this has led to established manufacturers to simply make slight changes to their existing devices, closing out the opportunity for generic devices to enter the market.[56] The statutory proposal would change this process and instead require devices to be technologically equivalent to its innovator device. This would align medical device requirements with pharmaceutical drugs and the requirement for generic drugs to be bioequivalent to its innovator drug.

The next issue that would arise in following the generic drug process would be access to technical and scientific data that would be required in order for a generic device to be technologically equivalent. Under the current regulatory structure, any manufacturer that is seeking 510(k) approval or premarket approval has to provide their own manufacturing and design data in order to prove that their device is safe and effective.[57] The FDA currently allows for manufacturers to reference the data of prior device manufacturers through a Letter of

[55] *See generally* INST. OF MED. OF THE NAT'L ACADS., PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS (Theresa Wizemann ed., 2010) (providing a comprehensive report requested by the FDA on the effectiveness of the 510(k) clearance process); Medtronic, Inc. v. Lohr, 518 U.S. 470, 494 (1996) (the Court reasoned that the 510(k) process was not intended to do anything other than maintain the status quo with respect to existing medical devices and their substantial equivalents).
[56] Shapiro et al., *supra* note 42.
[57] *PMA Approvals*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals#pma (Dec. 16 2021).

Authorization.[58] This authorization must be approved or rejected by the innovator manufacturer, and the Letter must then be submitted to the FDA for validation.[59]

The obvious issue with this system is that innovator manufacturers have near-zero incentive to provide permission for potential generic device manufacturers to enter their market against their own devices. When looking to the drug industry, this issue was equally present at the time of the enactment of the Hatch-Waxman Act.[60] The solution offered by Congress to innovator drug manufacturers was to incentivize the providing of innovator drug data, through longer patent protection for the innovator drugs.[61] Similarly, innovator device manufacturers can be incentivized with longer patent protection for their original devices, and in return provide permission for the FDA to release innovator device data to future generic device manufacturers. Another potential incentive that can be offered are financial incentives for the innovator manufacturer, through royalties or fees assessed to the future generic manufacturer when they in turn apply for approval.[62]

One area of concern that this proposal considers is the possibility of therapeutically equivalent devices being different in regard to their material, composition, or design. To address this, we look to the system currently in place for biosimilars, established in the Biologics Price Competition and Innovation Act of 2009.[63] For biosimilars, there can be substantial differences in the chemical makeup of the biological product, and still produce the same result as the original product.[64] In taking this into account, the FDA divides the accelerated application process into two

[58] *Master Files*, U.S FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-approval-pma/master-files (Feb. 14, 2023).
[59] *Id.*
[60] Engelberg, *supra* note 1.
[61] *Id.*
[62] *FDA: User Fees Explained*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/industry/fda-user-fee-programs/fda-user-fees-explained (last updated Oct. 3, 2022).
[63] *See* Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 804 (2010) (codified as 42 U.S.C. § 201).
[64] U.S. FOOD & DRUG ADMIN., BIOLOGICAL PRODUCT DEFINITIONS (2023).

groups.[65] There are those products that are equivalent to the innovator product, and those products that are therapeutically equivalent but chemically or structurally different.[66] Products that are fully equivalent have to meet a higher standard, whereas structurally or chemically different products only have to meet a lower standard.[67]

Given the current state of device approval, and the differing levels of scrutiny dependent on the risk level of that device, this proposal would advocate for the requirement that all devices and biosimilars be completely equivalent to their innovator counterpart. For medical devices, there is no reason to not require this standard for generic device manufacturers, as the information for not only the design of the innovator device, but also the material and composition, will be included in the overall data provided to the generic manufacturer as part of the accelerated process for generic devices described above.[68] Requiring full equivalence would also eliminate the opportunity for innovator manufacturers to create near-equivalent devices in an effort to prevent generics from entering the market were this proposal to go forward.[69]

For biosimilars, the language of the 2009 Act is similar to the language of the 510(k)-clearance process language and, considering the negative effects of the medical device industry regarding generics, that language should be changed to reflect the requirement that biosimilars must meet the full equivalency standard.[70] This would be what is currently considered the "higher" standard for approving biosimilars and considering that all necessary information pertaining to the innovator product would be initially provided to the generic manufacturer through this proposed statutory scheme, there should be no reason why equivalency on all fronts couldn't be achieved.

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[65] *Id.*
[66] *Id.*
[67] *Id.*
[68] Shapiro et al., *supra* note 42, at 621-22.
[69] *Id.*
[70] *See* Biologics Price Competition and Innovation Act of 2009, Pub. L. No. 111-148, 124 Stat. 804 (2010) (codified as 42 U.S.C. § 201).

The implementation of this regulatory structure would give generic manufacturers for devices and biological products the security that their products will not fail in comparison to their innovator counterparts. Innovator manufacturers would be incentivized to innovate, and the overall cost to not just drugs, but medical devices and biological products, can be lowered throughout the market. By bringing an efficient system in place for all FDA-regulated products, this accelerated approval process would reduce the overall costs and approval times, lightening the overall load placed on the FDA. Not only would this system financially benefit the regulatory system and its' manufacturers, but there would be significant costs-savings to healthcare consumers and to its providers.

b. Extending Product Liability Protection to the Entire Industry

As we have seen during the time after the enactment of the Hatch-Waxman Act, the Supreme Court has extended the federal preemption protection to generic drugs that have fully complied with the requirements of the Act in making a generic drug equivalent to an innovator drug.[71] State tort claims against a generic drug for failing to comply to its' state labelling and design requirements are as a result not possible, since federal requirements are supreme to state requirements. Since this proposal would require generic medical devices and biological products to be fully equivalent to their innovator product, this proposal would also push to require language in federal law that protects generic manufacturers from state action when those manufacturers have complied with federal FDA requirements. Like generic drug manufacturing, medical devices and biological products should still be held accountable and face liability claims for potential manufacturing defects. When it comes to alleged design defects or issues with state labeling

[71] *PLIVA, Inc.*, 564 U.S. at 624; *Mutual Pharmaceutical Co.*, 570 U.S. at 493.

requirements, liability should be preempted by federal requirements that were originally satisfied by the innovator device and product manufacturer.

This requirement would bring equal protection under the law for all three product types and would further lower the burden on generic manufacturers to enter the medical device and biological product market. Further, Congress could incentivize generic manufacturers in entering the market by providing product liability protection as stated above in exchange for generic manufacturers' cooperation or requirement to comply with safety data requirements, testing requirements, quality checks, etc.[72] The potential incentives that could be offered to generic manufacturers is something that can be determined through the work of Congress in negotiation with the industry itself, as the benefit of added product liability protection would be invaluable to all future manufacturers.

V. Conclusion

The overall success of the Hatch-Waxman Act came after decades of advocacy by individuals wanting more affordability for drugs and medicines created by the private sector. Since its' inception, there has been an explosion in affordability and access to necessary drugs, and a movement for drug manufacturers to be more innovative to compete with generic drug manufacturers. This system, even with its' downfalls and shortcomings, nonetheless has proved effective in establishing safe, effective drugs for everyone to access.

The same cannot be said for medical devices and biosimilars, equally important and integral parts of the healthcare industry and a major contributor to the ever-increasing costs of healthcare.[73] The current statutory scheme for medical devices puts potential generic devices at a severe disadvantage. To review, the current system allows for an expedited approval process for subtle

[72] U.S. FOOD & DRUG ADMIN., *Postmarket Surveillance Under Section 522 of the Federal Food, Drug, and Cosmetic Act* (2022).
[73] Shapiro et al., *supra* note 42, at 598.

changes to an existing device, regardless of whether the device is equally safe and effective. This allows for innovator manufactures to continuously "create" slightly different devices that effectively keep generic competition out of the market. On top of that, innovators manufacturers have the ability to protect their designs and data from generic manufacturer access through disadvantageous patent law. A final major issue facing generic manufacturers is the lack of product liability protection that comes with creating generic devices and biological products, despite the fact that generic devices are intended to be affordable replicas of their innovator counterparts.

The lack of meaningful reform on the federal level means that healthcare consumers will continue to face the additional costs of a market controlled by name brand manufacturer products. The same applies to the biological products market. Without the statutory changes prescribed, generic medical devices and biological products will continue to lack the diverse and innovative marketplace that the pharmaceutical drug market currently enjoys. The creation, or incorporation, of a uniform generics regulatory system encompassing medical devices, biological products, and pharmaceutical drugs would advance the goals of the FDA in promoting a strong medical market while expanding critical access to the necessary medical products of our time. The goal of this statutory proposal is that the aforementioned solutions can be the next step in achieving equity and access in an ever-growing and more costly healthcare market.