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Recent Development Comment

Access in a Crisis: The Modernization of OTC Drug Regulations — Hundreds of thousands of over-the-counter ("OTC") monograph drugs exist on the market today, and this number is continually growing.[1] Because consumers have the ability to "self-diagnose and self-treat with OTC drugs, these products have a very high rate of exposure to the American public, including children and the elderly."[2] Because OTC drugs are easily accessible, require no prescription, and are used for self-care, it is imperative that there exists effective and efficient regulatory oversight in this area. The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") completely reforms the original OTC drug monograph system—transforming the OTC monograph rulemaking process into an administrative order process, authorizing the FDA to collect monograph user fees for the first time in the FDA's history, introducing a minor changes provision, and introducing the possibility of market exclusivity, among other changes. Each change aims to directly address an identified fault in the original system. The FDA has asserted that the OTC drug monograph reform could be a 'win-win-win'—a win for the public, a win for the FDA, and a win for the industry. The public and industry would benefit from efficient and effective review, while the FDA would finally have the resources to modernize while advancing safety and innovation. Yet, there are currently debates over whether the implementation of this program *is truly* a win for all.[3] Congress' inclusion of the OTC drug monograph reform provisions within the CARES Act reflects years of persistent work toward a regeneration of the system.[4] Yet, as with any system overhaul, there lies important implications for the industry, the FDA, and the general public, to consider. This Comment briefly examines the recently enacted CARES Act, specifically highlighting the OTC monograph drug use fee authorization, and exploring the implications of such a change amidst a public health crisis.

I. THE CARES ACT

On March 27, 2020, the CARES Act was signed into law by the President, making it one of the most comprehensive legislative efforts to date addressing the effects

[1]The FDA defines an OTC monograph as "a 'rulebook' for each therapeutic category establishing conditions, such as active ingredients, uses (indications), doses, labeling, and testing, under which an OTC drug is generally recognized as safe and effective (GRASE) and can be marketed without a New Drug Application and FDA pre-market approval." U.S. Food & Drug Admin., Over-the-Counter (OTC) Drug Monograph Process (Sept. 3, 2020), https://www.fda.gov/drugs/over-counter-otc-drug-monograph-process [https://perma.cc/BDY6-3WFH].

[2]Renu Lal, *User Fees and the Future of the OTC Monograph System*, FDA/CDER SBIA Chron. (July 6, 2016), https://www.fda.gov/media/98905/download [https://perma.cc/VWW9-FX9M].

[3]*See id.*

[4]*See* U.S. Food & Drug Admin., Public Meeting: Over-the-Counter Monograph User Fees (June 10, 2016), https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-over-counter-monograph-user-fees [https://perma.cc/24CL-WJ2B].

of the COVID-19 outbreak. Specifically, the CARES Act responds to the virus's impact on "the economy, public health, state and local governments, individuals, and businesses."[5] The CARES Act also marks the largest economic stimulus package in U.S. history, amounting to roughly ten percent of the total U.S. gross domestic product. The CARES Act is referred to by lawmakers as "Phase 3" of Congress' Coronavirus response, following both the March 6, 2020, $8.3 billion package jumpstarting coronavirus vaccine research[6] and the March 18, 2020, $104 billion dollar package focused on "sick leave and unemployment benefits for workers and families."[7] The CARES Act package totals a staggering $2.3 trillion, and contains a variety of health-related provisions ranging from insurance coverage of coronavirus testing and telehealth, to support for the global pandemic response and workforce issues.[8]

Tucked away among the CARES Act's nearly 900 pages, are amendments to the Food, Drug and Cosmetic Act—specifically, amendments to the antiquated OTC drug monograph system. Subtitle F of the CARES Act drastically reforms and modernizes the regulatory framework for OTC drug monographs, serving as "the most important new law affecting the safety, innovation, and affordability of over-the-counter drugs since the 1970s."[9]

OTC drugs, also referred to as nonprescription drugs, play an increasingly significant role in America's health care system. OTC drugs are drug products that are deemed "safe and effective for use by the general public without seeking treatment by health professionals," providing efficient and low-cost access for millions of Americans.[10] Once heralded as an innovative and efficient process almost fifty years ago, the OTC drug monograph review process has arguably become more of a barrier than a catalyst to drug access largely due to its antiquated processes.[11]

Prior to the CARES Act, a specific set of questions plagued the FDA's OTC drug monograph system—namely, "when and how the FDA should revisit the fundamental judgment about a product's suitability for OTC marketing?"[12] The OTC drug monograph system has struggled to keep up with the times as indicated by the FDA's consistent failure

[5]Coronavirus Aid, Relief, and Economic Protection (CARES) Act, H.R. 748, 116th Congress (2020), https://www.congress.gov/116/bills/hr748/BILLS-116hr748eas.pdf [https://perma.cc/A4UM-VCFK].

[6]The Coronavirus Preparedness and Response Supplemental Appropriations Act, H.R. 6040, Pub. L. No: 116-123 (2019-2020).

[7]The Families First Coronavirus Response Act, H.R. 6201, Pub. L. No: 116-123 (2019-2020); Shelia Burke et. al., *Coronavirus: Key Aspects of $8.3 Billion Spending Package – Overview of Coronavirus Preparedness Response Supplemental Appropriations Act*, Baker Donelson (Mar. 12, 2020), https://www.jdsupra.com/legalnews/coronavirus-key-aspects-of-8-3-billion-81697/ [https://perma.cc/4SEY-VRER].

[8]*See* Kellie Moss et. al., *The Coronavirus Aid, Relief, and Economic Security Act: Summary of Key Health Provisions*, KFF (Apr. 9, 2020), https://www.kff.org/coronavirus-covid-19/issue-brief/the-coronavirus-aid-relief-and-economic-security-act-summary-of-key-health-provisions [https://perma.cc/3JBS-YLU4].

[9]Michael Mezher, *Senate Passes OTC Monograph Reform Bill,* Reg. Focus (Dec. 11, 2019), https://www.raps.org/news-and-articles/news-articles/2019/12/senate-passes-otc-drug-monograph-reform-bill [https://web.archive.org/web/20210603134359/https://www.raps.org/news-and-articles/news-articles/2019/12/senate-passes-otc-drug-monograph-reform-bill].

[10]U.S. Food & Drug Admin, Drug Applications for Over-the-Counter (OTC) Drugs. (Mar. 31, 2020), https://www.fda.gov/drugs/types-applications/drug-applications-over-counter-otc-drugs [https://perma.cc/38X7-LYAQ].

[11]*Modernizing FDA's Regulation of Over-the Counter Drugs*, *Before the H. Energy and Commerce Committee, Subcomm. on Health* (Sept. 13, 2017) (testimony of Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research), https://www.fda.gov/news-events/congressional-testimony/modernizing-fdas-regulation-over-counter-drugs [https://perma.cc/FC3V-LY2D].

[12]Lars Noah, *Reversal of Fortune: Moving Pharmaceuticals from over-the-Counter to Prescription Status*?, 63 Vill. L. Rev. 355, 367 (2018).

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to complete and modify hundreds of monographs, falling behind emerging safety and efficacy issues, evolving scientific and technological data, and market changes.[13]

II. THE OTC MONOGRAPH USER FEE AUTHORIZATION

A comprehensive overview of every change the CARES Act made to the OTC monograph system, along with every legal and practical implication is beyond the scope of one recent development article. As such, this Comment will specifically focus on the FDA's newly granted authority to collect user fees and the corresponding implications. I argue that this immense grant of power given to the FDA in the context of the COVID-19 pandemic will have much broader implications that perhaps fall outside of the scope of the legislation lawmakers agreed upon.

Prior to the CARES Act, oversight of the OTC drug monograph system was supported by "$8.2 million of resources, reflecting approximately 30 full-time employees," yet, "it takes approximately 18 full-time employees to review one NDA."[14] This resource disconnect contributed to decades of backlogged OTC monographs, creating a stalled system.[15] Now, for the first time in the FDA's history, the FDA is authorized to collect user fees for OTC monograph drug products, allowing the OTC industry to join the rest of the drug industry in terms of paying fees.[16]

The CARES Act establishes two types of user fees: facility fees and OTC monograph order request fees. Facilities fees will be assessed for any person or entity who owns a registered OTC monograph drug facility, and will be collected in the form of an annual fee.[17] Specifically, manufacturers are expected to pay "two-thirds of what a site owned by the product holder would owe."[18] While no specific provision of the law sets forth any facility fee total, collections are projected to be "$22 million for FY2021, $22 million for FY2022, $25 million for FY2023, $31 million for FY2024, and $34 million for FY2025."[19] OTC monograph order request fees, will be associated with OTC Monograph Order Requests ("OMORs"), which are now needed to make changes to OTC monographs, and the fees vary between Tier 1 and Tier 2.[20] The fee for a Tier 1 OMOR will be

[13] *See* Theresa M. Michele, M.D., Dir., Monograph Reform is Here!, PowerPoint Presentation at the Office of Nonprescription, Food and Drug Admin. (May 29, 2020), https://www.fda.gov/media/139503/download [https://perma.cc/L349-S2V3].

[14] *See Modernizing FDA's Regulation of Over-the-Counter Drugs*, Hearing Before the Subcomm. on Health, 117th Congress, First Session (Sept. 13, 2017).

[15] *See* Woodcock, *supra* note 11.

[16] *See id.*

[17] Joan Baughan et. al., *FDA's OTC Drug Review Process Modernized by the CARES Act*, Steptoe (Apr. 6, 2020), https://www.steptoe.com/en/news-publications/fdas-otc-drug-review-process-modernized-by-the-cares-act.html [https://perma.cc/8GCL-KFDV] ("For 2021, the facility fee will be due on the later of the first business day of July 2020, or 45 calendar days after publication of a Federal Register notice publishing the fees. Thereafter, the facility fee will be due on the later of the first business day of June, or the first business day after the enactment of an appropriations act providing for the collection and obligation of user fees.").

[18] *COVID-19 Stimulus Legislation Will Cost OTC Manufacturers*, Carmargo (Apr. 2, 2020), https://camargopharma.com/resources/blog/covid-19-stimulus-legislation-will-cost-otc-manufacturers/ [https://perma.cc/KH6P-RNEU] ("Sites which manufacture OTC products are required to self-identify via the electronic Drug Registration and Listing System (eDRLS).").

[19] David C. Spangler and Rachel Rathore, *OTC Monograph Reform Legislation is Now Law—What Does It Do?*, Food and Drug Law Inst. (Summer 2020), https://www.fdli.org/2020/05/otc-monograph-reform-legislation-is-now-law-what-does-it-do/ [https://perma.cc/TXR3-ZBT4].

[20] There exist two types of OMORs: Tier 1 and Tier 2. Tier 1 OMORs are requests for generally more significant changes to an OTC monograph. A Tier 1 OMOR is defined as "any request not determined to be a Tier 2 OMOR." A few examples of a Tier 1 OMOR include: (1) any addition of a new ingredient to an existing monograph that already contains one or more GRASE ingredients; (2) any addition of a new indication to an

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$500,000, while the Tier 2 OMOR fee will be $100,000. Both fees are adjusted for inflation overtime. As with other FDA fee authorizations, this program is expected to be in place for a five-year period.

The FDA has asserted that the additional resources provided by the fees will help the agency "increase its staffing capacity to support OTC-related work and build a necessary information technology platform to efficiently submit and review monograph information."[21] Previously established fee programs[22] evidence how user fees serve as vital resources, enabling more timely and efficient evaluation of product safety and efficacy issues, while allowing regulatory practices to efficiently and effectively modernize. The implementation of user fees may truly serve as a reliable source of funding, but there are a multitude of implications that should be considered regarding this system change, namely the impact such a change could have on consumers.

III. IMPLICATIONS OF THE OTC DRUG MONOGRAPH REFORM

The establishment of the OTC monograph user fee authorization is intended to provide the FDA with a predictable source of funds, yet, charging manufacturers new fees that have never been assessed before will most likely have the effect of transferring costs to the group the OTC system is in place for—the everyday consumer, thereby directly countering the drug products' original purpose, and shrinking affordable healthcare options for poorer consumers. The FDA itself has even publicly acknowledged the possibility of this fee-shifting occurrence, stating "[t]he Agency understands the need to consider possible consequences of OTC monograph user fees on manufacturers' costs and how these might be passed on to consumers."[23] Many critics of the system have voiced that the user fee program should not replace congressionally appropriated dollars, some even suggesting that the costs of the program should be "shared with the public."[24]

In addition to this fee-shifting possibility, various stakeholders, namely those within the drug industry, have urged that the enactment of the OTC monograph user fee authorization will require a certain level of transparency in order to maintain a fair and open market, as the change has the potential to exacerbate the apparent disparity between

existing monograph with one or more GRASE ingredients; and (3) any additional new therapeutic category] Tier 2 OMORs fall under a specific list of changes, specified in the FDA's goals and user fee documents. Tier 2 OMORs are generally less significant, as examples include: (1) a request to reorder "existing information in the Drug Facts Label (DFL)"; (2) a request to add information in the "other information section of the DFL"; (3) a request to modify the "Directions for Use section of the DFL"; and (4) a request to add an "interchangeable term," among other things. *See* Theresa M. Michele, *supra* note 13.

[21] *David C. Spangler, supra* note 19.

[22] The Prescription Drug User Fee Act (PDUFA) was first enacted in 1992 and "authorizes FDA to collect fees from companies that manufacture certain human drugs and biological products in exchange for FDA improving the review process for new drug applications (NDAs) and biologics license applications (BLAs)"; The Generic Drug User Fee Act (GDUFA) was originally enacted in 2012 "to improve access to generic drugs" and provided the FDA with "resources to expedite the review of abbreviated new drug applications (ANDAs), including significant resources to eliminate a substantial backlog of ANDAs that had built up over several years and were awaiting a final FDA decision of approvability"; Like GDUFA, the Biosimilar User Fee Act (BsUFA) was first enacted in 2012 "to enable FDA to collect fees from biosimilar companies to aid in the assessment of development programs and applications for marketing approval"; The medical device user fee program, known as MDUFA, was enacted in 2002 and provides resources to the FDA to effectively and efficiently review medical devices. Aaron L. Josephson, *FDA User Fees: Highlights from FDARA & Our Forecast for the Next Round*, MINTZ (Feb. 3, 2020), https://www.mintz.com/insights-center/viewpoints/2146/2020-02-fda-user-fees-highlights-fdara-our-forecast-next-round [https://perma.cc/J7H8-SFAM].

[23] Lal, *supra* note 2.

[24] *Id.*

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smaller and larger drug developers if not appropriately addressed.[25] Smaller, less equipped drug developers may struggle with these newly mandated facility and OMOR fees. Outside of the user fee, the "changes for safety" exception, is the only other exception available for non-payment of fees. This exception is only available if the facility has undoubtedly ceased "all activities related to" OTC monograph drugs prior to the end of the calendar year.[26] If the fee is not paid within twenty calendar days of the due date, the facility may be placed on an "arrears list" with all drug products effectively deemed misbranded.[27]

Perhaps in recognition of this potential disparity, the CARES Act contains a fee dispute provision, but it is unclear under exactly which situations this provision may be enacted, and it is unlikely Congress had small drug developers in mind since inadequate funds is probably not a reason to dispute fees. The new legislation allows for industry-initiated formal development meetings between drug sponsors and the FDA.[28] These meetings are expected to allow sponsors to obtain advice on matters relevant to the development of new monographs or other information necessary to support their drug activities—possibly equalizing the playground in one way or another.

The CARES Act reform calls for major changes in the way OTC drugs are brought to the market, and as a result, will impose burdens on both drug developers and the FDA itself.[29] Although the legislation aims to modernize the FDA's OTC drug activities, it will also provide new initiation opportunities for both the industry and the FDA, which will require additional resources. Even with the newly authorized user fees "helping to defray" financial constraints, additional personnel and training will be required to both help with the full-on implementation of the reform. These additional administrative requirements and potential subsequent resource shortages will take time, adding additional hurdles to an already uncertain timeline.[30] Despite the fact that the FDA has set various guidelines, instructions and timelines for itself and the industry alike, it is "too early to predict how smoothly the transition" will proceed and adapt to the practical realities of the current drug market.[31]

Lastly, enacting such a large-scale reform—the complete overhaul of a fifty-year system—in the midst of the deadliest pandemic of the twenty-first century, offers its own challenges. The FDA's attention is currently preoccupied, with release of various emergency authorizations and public health guidelines requiring the FDA's utmost attention in an effort to mitigate the spread of COVID-19 and save lives. Along with the realities of the pandemic, the FDA is currently undergoing immense political pressure and scrutiny, with

[25]Stakeholders primarily include "consumer and healthcare professional organizations, industry associations, and members of the scientific community." *Id.*

[26]*See* CARES Act, *supra* note 5. The exception for certain safety changes states, "A person who is named as the requestor in an OTC monograph order shall not be subject to a fee under subparagraph (A) if the Secretary finds that the OTC monograph order request seeks to change the drug facts labeling of an OTC monograph drug in a way that would add to or strengthen — "(i) a contraindication, warning, or precaution; "(ii) a statement about risk associated with misuse or abuse; or "(iii) an instruction about dosage and administration that is intended to increase the safe use of the OTC monograph drug." *Id.*

[27]*Id.* (An "arrears list" is a publicly posted list of "companies have not satisfied the annual program fee as required under the [Act].").

[28]*See* Woodcock, *supra* note 11.

[29]Benjamin M. Zegarelli et. al., *OTC Monograph Reform: Key Takeaways and What Industry Can Expect*, MINTZ (June 10, 2020), https://www.mintz.com/insights-center/viewpoints/2791/2020-06-10-otc-monograph-reform-key-takeaways-and-what-industry-can [https://perma.cc/39GZ-VS9M].

[30]*Id.*

[31]*Id.*

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many calling into question the legitimacy of the FDA itself.[32] This reform, although markedly overdue, has added yet another serving to an already full plate.

IV. CONCLUSION

The FDA stated, in response to the timing of this new reform, that the FDA would be "committed to using [the] new tools to promote innovation and improve the safety and effectiveness of OTC monograph drugs—including products like hand sanitizers and acetaminophen, which are so critical to the public health emergency we face right now."[33] While many provisions of the reform legislation are "relatively clear," "the details of implementation and the potential downstream effects of OTC monograph reform remain to be seen."[34] Many questions remain unanswered, namely: "How can the general public be assured the FDA is completing its monograph due diligence, when it is currently expanding significant resources on testing, treatment and vaccine issues with respect to the coronavirus?"[35]

The CARES Act ushered in a wave of reforms, modernizing and equipping a decades-old system with the infrastructure and resources to keep up with the times. The passage of the OTC drug monograph reform is considered a "landmark step" that will undoubtedly have an impact "lasting long after the current public health emergency."[36] As with any extensive and novel change, especially those that directly affect the health and safety of the general public, the FDA must remain vigilant to system failures. New programs offer new and unforeseen challenges, and faster is not always better. During a time when the FDA's attention is stretched in various directions, implementation may fall through the cracks. It is hard to predict how this system will come together and it will truly be interesting to see how it all pans out in the realities of a pandemic world.

Mia Harris

[32] *FDA faces coronavirus vaccine approval while mired in political controversy*, DEUTSCHE WELLE (Dec. 9, 2020), https://www.dw.com/en/fda-faces-coronavirus-vaccine-approval-while-mired-in-political-controversy/a-55737801 [https://perma.cc/7D58-EBXM].

[33] Press Release, U.S. Food & Drug Admin., FDA on Signing of the COVID-19 Emergency Relief Bill, Including Landmark Over-the-Counter Drug Reform and User Fee Legislation (Mar. 30, 2020), https://www.fda.gov/news-events/press-announcements/fda-signing-covid-19-emergency-relief-bill-including-landmark-over-counter-drug-reform-and-user-fee [https://perma.cc/M7DD-GH6J].

[34] Christine Kirk and Carter Cornick, *Over-the-Counter Drug Monograph Reform Legislation in the 116th Congress*, FOOD AND DRUG LAW INST. (2020), https://www.fdli.org/2019/05/over-the-counter-drug-monograph-reform-legislation-in-the-116th-congress/ [https://perma.cc/8HB6-X47W].

[35] *Id.*

[36] *See* Stephen M. Hahn, *supra* note 33.

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