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April 20, 2022

The Honorable Patty Murray
Chairwoman
Senate Committee on Health,
Education, Labor & Pensions
154 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Richard Burr
Ranking Member
Senate Committee on Health,
Education, Labor & Pensions
217 Russell Senate Office Building
Washington, D.C. 20510

The Honorable Frank Pallone
Chairman
House Energy and Commerce Committee
2017 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
House Energy and Commerce Committee
1035 Longworth House Office Building
Washington, D.C. 20515

Dear Chairwoman Murray, Chairman Pallone, Ranking Member Burr and Ranking Member McMorris Rodgers:

Vizient, Inc. would like to take the opportunity to offer our feedback on the discussion drafts of the Medical Device User Fee Amendments (MDUFA) of 2022 (hereinafter, "MDUFA V") and the Prescription Drug User Fee Amendments (PDUFA) of 2022 (hereinafter, "PDUFA VII"). As the leaders of the committees with primary jurisdiction over the reauthorization of all of the User Fee Acts, we thank you for your diligent approach to advancing these critical agreements. An expeditious process to approve both MDUFA and PDUFA before the September 30, 2022 expiration will ensure that patients will be able to access new and innovative medical devices and therapeutics without undue delay, while also offering stability to the Food and Drug Administration (FDA) as user fees, which help support funding to improve the efficiency of FDA's regulatory processes, will continue uninterrupted.

Background

Vizient, Inc. provides solutions and services that improve the delivery of high-value care by aligning cost, quality and market performance for more than 50% of the nation's acute care providers, which includes 95% of the nation's academic medical centers, and more than 20% of ambulatory providers. Vizient provides expertise, analytics, and advisory services, as well as a contract portfolio that represents more than $100 billion in annual purchasing volume, to improve patient outcomes and lower costs. Headquartered in Irving, Texas, Vizient has offices throughout the United States.

Comments and Recommendations on MDUFA V

The user fee reauthorization process is a critical and collaborative arrangement that provides opportunities to ensure that the U.S. remains a world leader in medical

innovation. Vizient offers various recommendations for consideration as MDUFA reauthorization efforts continue.

Draft Commitment Letter

The MDUFA V draft commitment letter ("draft commitment" or "draft agreement") provides key agreements and important, innovative concepts that will help support the development of medical products.

Through the draft commitment, user fees are anticipated to increase each fiscal year (FY) from 2023 to 2027. These user fees offer the FDA and device manufacturers predictability and stability, as well as performance accountability, to ensure responsiveness from the agency. Critically, the draft agreement will help support an estimated 273 new full-time equivalents (FTEs) to meet the expectations under the agreement, with the potential for up to 387 FTEs based on whether program targets are met[1]. In addition to supporting new FDA employees, the draft agreement would ensure that the individuals already working at FDA's Center for Devices and Radiologic Health (CDRH) can continue to protect and promote public health by supporting access to safe and effective medical devices.

The draft agreement also includes the launch of a Total Product Lifecycle Advisory Program (TAP) pilot program. The TAP pilot program will help provide more timely and practical pre-submission communications and guidance from the FDA and device makers to improve the quality of submissions, clarify expectations for evidence generation and improve the efficiency of the premarket review process. The TAP pilot will provide critical insights for how innovators and the FDA can foster greater collaboration to bring safe and effective devices to market more quickly and efficiently. Vizient is supportive of more constructive and collaborative work between innovators and regulators to ensure patients will have timely access to innovative new products.

Vizient supports the goals and procedures included in the draft commitment letter and urges Congress to expeditiously approve MDUFA V legislation to continue to support patient access to innovative medical products. While supportive of a timely approval of MDUFA V, as noted above, Vizient is pleased to offer additional items for consideration as Congress weighs how best to construct the agreement for another cycle.

Additional FDA Authorities Related to Medical Device Shortages

Vizient serves a critical role in the health care supply chain, leveraging data and the collective buying power of our members to achieve competitive pricing on health care services and supplies for our members. Both prior to and during the COVID-19

[1] FDA USER FEE REAUTHORIZATION: ENSURING SAFE AND EFFECTIVE MEDICAL DEVICES; House Energy and Commerce Health Subcommittee Hearing; 117th Congress (2022); (Testimony of Janet Trunzo. Senior Executive Vice President, Technology & Regulatory Affairs Advanced Medical Technology Association)

pandemic, Vizient has focused a significant amount of its sourcing, clinical and analytics expertise on improving the resiliency of the supply chain for medical devices and prescription drugs.

A key lesson learned during the COVID-19 pandemic is the need for a diverse and redundant supply chain. When critical medical supplies are sourced, manufactured, packaged, labeled or sterilized in a single location, whether domestic or overseas, a disruption at any point in this sequence could upend the entirety of the supply chain for any given product or products. A core component to ensuring that stakeholders like group purchasing organizations (GPOs) and health care providers can source and obtain products from a diverse set of manufacturers is transparency into the location of each of these critical steps. Greater transparency into the medical device supply chain is an essential component to fortify it against future disruptions due to pandemics and other hazards. These potential challenges have been highlighted in the recent National Academies of Sciences, Engineering and Medicine's report: "Building Resilience into the Nation's Medical Supply Chains" which described the need for greater transparency across the supply chain. To help prevent shortages and mitigate harm caused by such challenges, Vizient believes Congress should provide the FDA with additional authorities.

Ensuring that FDA and key industry partners, such as GPOs, have information related to the critical links in the supply chain for raw materials, component parts, finishing, sterilization and distribution is vital. Such data would provide constructive opportunities for early identification of supply chain vulnerabilities and allow for mitigation steps to be taken to promote redundant sourcing or alternative manufacturing locations outside of a single geographic location.

Additionally, consistent with the FDA's FY 2023 Budget Request, Vizient recommends the agency be granted additional authorities to provide greater oversight of supply chain disruptions, including requiring manufacturers to perform and provide risk assessments, implement risk management plans and identify alternate suppliers and manufacturing sites. In categories where there is limited competition, this becomes more crucial. With that in mind, we encourage the FDA to implement any requirements in conjunction with additional stakeholder outreach, to lessen any regulatory burden and mitigate any further supply disruption that may occur should manufacturers alternatively choose to exit the market entirely.

In addition to enabling the FDA to access important supply chain information, it should also be offered more clear authorities to take actions to prevent shortages and react to national spikes in demand. Specifically, the FDA should be given authority to ensure manufacturers provide notifications to the agency prior to any potential shortages, including production volume information. This authority was provided in a limited way and duration, specific to devices that are critical to respond to a Public Health Emergency (PHE), as part of the CARES Act. Vizient supports continuing these authorities outside the current PHE to help prevent and mitigate supply chain disruptions.

The FDA should also be granted additional authorities that would improve the access to needed medical devices when in the interest of public health. Specifically, FDA should be provided authority to allow temporary importation of certain unapproved devices so long as clinically appropriate and regulatory controls are adopted. In addition, risks associated with limited access of certain medical devices could be mitigated by authorizing FDA to, in certain circumstances (e.g., with appropriate scientific data), permit devices to be distributed past their labeled shelf-life to prevent or respond to shortages.

Improving Cybersecurity

Vizient also recognizes the growing importance of cybersecurity considerations being taken for medical devices. The interconnected nature of medical devices – particularly networked devices that connect to the internet or the medical record – and the health system makes securing such products from cyber threats and potential device vulnerabilities a crucial consideration. Vizient believes that existing medical devices, as well as new products going through the approvals process, should be prepared to assess the risk of cyber threats and monitor for any vulnerabilities and be able to take action to mitigate those risks throughout the full lifecycle of the product.

Congress should consider including such requirements as a part of the MDUFA V reauthorization process. Bipartisan legislation, the Protecting and Transforming Cyber Health Care (PATCH) Act, has been introduced in both the House of Representatives and the Senate, and would require, as part of pre-market submissions, that device manufacturers submit a Coordinated Vulnerability Disclosure, a software bill of materials and other information required by the Secretary of Health and Human Services necessary to demonstrate a reasonable assurance of the safety and effectiveness of the cyber device. In addition, the bill would require the manufacturer to maintain processes and procedures to provide updates and patches to the device and related systems throughout its lifecycle.

The legislation would take necessary steps and ensure that cybersecurity is a meaningful component of the approvals process and provide ongoing support and protection against future cyber threats. Vizient is supportive of the legislation and would encourage Congress to consider including the bill as part of the MDUFA V legislation.

Comments and Recommendations on PDUFA VII

Recommendation to Protect Patient Access to Affordable Legacy Drugs through Clinical Evidence

Vizient recognizes the significant and ongoing efforts between industry and FDA have been critical in shaping the discussion draft of PDUFA VII. However, as Congress considers whether additional legislative changes would be appropriate to include in PDUVA VII, Vizient recommends the including legislative text (*see* Attachment 1) that would ensure clinical trials are performed by a product sponsor who gains exclusivity for receiving approval of unapproved drugs which were marketed before 1938.

As you are aware, the Food, Drug, and Cosmetic Act (FDCA) grants specified periods of marketing exclusivity to newly approved drugs that meet certain criteria. This grant of marketing exclusivity is intended to reward innovation, and to acknowledge the significant cost of research and development, including the cost and lost patent time involved in conducting multiple phases of clinical trials to evaluate whether a new drug is safe and effective. It is designed to incentivize the development of new therapies, including for unmet needs.

Yet, several commonly available legacy drugs[2] receive exclusivity despite submitting applications that often do not include significant new sponsor-generated clinical data. For example, a 2017 study found that 17 out of 19 longstanding drugs that obtained approval between 2006 and 2015 relied on "literature reviews and bioequivalence to older drug products."[3] However, despite not conducting clinical studies, simply by being the first to obtain an FDA approval, these sponsors receive marketing exclusivity for a specified range of years. As a result, the clinical information about the drug has not been meaningfully enhanced through their approval.

Once they receive exclusivity, other versions of these drugs are statutorily *disqualified* from seeking approval, even those that have already been on the market. Moreover, these sponsors then sometimes use their exclusivity to clear the field of legacy competitors, and significantly raise prices—sometimes exponentially— in a manner that jeopardizes patient access and leads to increased costs in the health care system.[4] The text provided in Attachment 1 would ensure that applicants only receive market exclusivity for a drug already available as a legacy drug if they complete clinical investigations essential to the approval of the drug.

Therefore, by advancing the attached legislative text, Vizient urges Congress to close the loophole that is being used to obtain unjustified monopolies on commonly available legacy drugs.

Additional Feedback for Consideration

As mentioned in our comments on MDUFA V, Vizient strongly supports efforts to enhance transparency in the supply chain – this includes the pharmaceutical supply chain as well. Information, such as the source of active pharmaceutical ingredients, critical components or excipients, may help better predict shortages and support a more

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[2] A “legacy drug” means a drug of the same active ingredient (including any ester or salt of the active ingredient) that is in distribution at the time of approval that qualifies as generally recognized as safe and effective or, if at any time prior to June 25, 1938, such drug was subject to the Food and Drugs Act of June 30, 1906.

[3] https://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.23.10.1066

[4] For example, the approval of one drug that had been available as a legacy drug led to an estimated increase of $50 million per year to the Medicaid program. These are drugs that have been available for many decades—in many cases prior to the current drug approval system. They may be “grandfathered” under the FDCA or are generally recognized as safe and effective. Many of these drugs are chemically well-defined and are widely used in health care settings.

resilient supply chain. At present, different aspects of manufacturing have been and remain vulnerable to numerous disruptions, including quality deficiencies, natural disasters, limitations of raw materials, unanticipated business decisions and pandemics. However, a lack of transparency and visibility regarding key manufacturing and sourcing steps exacerbates the harm that is already associated with any disruption source. As a result, it is extremely challenging for the market to know what elements of supply require additional investment and what actions should be taken to create validated redundancy. Therefore, as Congress continues to work on all User Fee Act reauthorizations, including the Generic Drug User Fee Act and the Biosimilar User Fee Act, we encourage Congress to provide FDA with greater data collection authority related to supply chain manufacturing location and to allow FDA to share this information with other stakeholders, like GPOs.

Conclusion

Thank you for your ongoing leadership and commitment to ensuring continued innovation in medical devices and therapeutics through the UFA reauthorization process. Please do not hesitate to contact me at shoshana.krilow@vizientinc.com or 202-354-2607 if you have any questions about Vizient or if there is any way we can be of assistance in advancing this critical legislation.

Sincerely,

Shoshana Krilow
Senior Vice President, Public Policy & Government Relations

Attachment 1.

Avoiding Unintended Consequences for Patient Access to Affordable Legacy Drugs By Clarifying Marketing Exclusivity

The following proposed minor statutory change would:

(1) ensure that applicants only receive market exclusivity for a drug already available as a legacy drug if they complete clinical investigations essential to the approval of the drug;

(2) allow additional sponsors of legacy drugs to seek and obtain drug approvals without delay;

(3) avoid drastic price increases and access challenges by denying unearned monopolies;

(4) help control costs for the Medicare and Medicaid programs; and

(5) better serve American patients.

Proposed Statutory Language:

Section 505 of the Food, Drug, and Cosmetic Act is amended by adding at the end the following:

"(z) ENHANCED CLINICAL INFORMATION FOR LEGACY DRUGS.—In the event that the Secretary grants approval of an application submitted under section 505 of a drug for which a drug of the same active ingredient (including any ester or salt of the active ingredient) is in distribution at the time of approval that qualifies as generally recognized as safe and effective or, if at any time prior to June 25, 1938, such drug was subject to the Food and Drugs Act of June 30, 1906, as amended, the periods of exclusivity otherwise available to such approved drug under sections 505, 505A, or 527 shall only apply if, in addition to satisfying the requirements identified in such sections, the Secretary certifies that the application contained a new clinical investigation conducted by or sponsored by the applicant that is essential to the approval of the drug."