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Submitted via the Federal eRulemaking Portal: http://www.regulations.gov

Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comments (Docket No. FDA-2021-N-0891)

Dear Acting Commissioner Woodcock:

Vizient, Inc. appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) request for comments (RFC) regarding reauthorization of the seventh Prescription Drug User Fee Act (PDUFA). Vizient applauds FDA for hosting the virtual public meeting on September 28, 2021, which allowed stakeholders to share views on PDUFA as the Agency considers changes, enhancements and other refinements for PDUFA VII.

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.

Recommendations

In our comments, we offer several considerations for FDA as it provides proposed recommendations to Congress for PDUFA reauthorization.

Modernize the Unapproved Drugs Initiative (UDI)

As FDA is aware, the Department of Health and Human Services' November 2020 announcement[1] spurred questions regarding FDA's approach to approving long-used, unapproved, marketed products (hereinafter "legacy drugs"). On May 27, 2021, FDA officially

[1] 85 FR 75331

withdrew the November notice, “Termination of the Food and Drug Administration’s Unapproved Drugs Initiative; Request for Information Regarding Drugs Potentially Generally Recognized as Safe and Effective” and indicated that the agency “plans to issue guidance on this topic consistent with good guidance practices”.[2]

While Vizient has raised concerns regarding cost implications associated with UDI, we recognize the benefits of FDA approval and oversight regarding legacy drugs and support the overall safety-related goals of the UDI program. As such, in response to the November 2020 notice and related regulatory uncertainty, Vizient developed various regulatory approaches and provided comments for the agency and HHS to consider to support its review process and oversight of legacy drugs. In addition, in response to the May withdrawal notice, Vizient still continues to share feedback with the agency regarding legacy drugs.

In recent years, the approval of one version of a legacy drug has often been accompanied by substantial price spikes and a rapid winnowing of suppliers — leading to severe access issues in some cases. Vizient believes FDA’s approach to the UDI program could potentially be refined to mitigate this detrimental impact, while continuing to incentivize drug applications. However, statutory exclusivity entitlements for drug approvals are a major element leading to these substantial price spikes. Unlike applications for truly novel drugs, applications for legacy drugs frequently lack the type of costly clinical data development that justifies a statutory exclusivity period, relying instead on literature reviews or other evidence already in existence for a type of drug that has been on the market for decades. As such, Congressional action would be warranted to provide appropriate limits on exclusivity in cases in which a legacy drug is approved with limited new clinical data. Therefore, Vizient recommends that as part of the PDUFA VII reauthorization process, greater attention be paid to the circumstances in which marketing exclusivity is granted to products that are approved as new drugs, particularly those utilizing the 505(b)(2) pathway, where the sponsor does not necessarily have to conduct new clinical trials.

Under the current framework, a sponsor may receive exclusivity, such as new chemical entity (NCE) exclusivity, for a drug approved through the 505(b)(2) pathway by relying on preexisting clinical data from the literature related to a legacy drug. Yet, as in the example of NCE exclusivity, FDA would recognize the newly approved product as innovative, without regard to the unapproved marketed product that was studied in the sponsor-submitted clinical data. As a result, this circumstance does not fulfill one of the goals of the UDI, namely generation of new clinical data, nor does it seem to correlate with the more routine characterization of an NCE where the chemical entity is new. Vizient is concerned this unique circumstance of providing such exclusivity is a means by which sponsors receive substantial benefit beyond their level of investment by bypassing critical clinical trial requirements.

As such, Vizient recommends FDA work with Congress to ensure that exclusivities for legacy products are only granted when the sponsor generates new clinical trial data. Given FDA’s and other stakeholders’ learned experiences with the UDI, there is a significant opportunity to reconsider and refine the incentives for approval. Vizient reiterates our support of FDA’s efforts to approve products and ensure that marketed products do not pose a risk to patients, and we believe there is an opportunity for FDA and Congress to ensure the incentives to

[2] 80 FR 28605

approves legacy products are not disproportionate to the resources invested to receive different types of exclusivities.

Supply Chain Resiliency and Transparency

Like FDA, Vizient supports efforts to enhance transparency in the supply chain because more specific and robust information, such as the source of active pharmaceutical ingredients or excipients, may help better predict shortages and support a more 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 to take to create validated redundancy. Until such time as there is greater clarity, it will remain nearly impossible to know which components of the supply chain require further reinforcement against potential threats. Therefore, as FDA works with industry and Congress on efforts to enhance data collection and pharmaceutical quality, we encourage the agency to ensure that FDA can share this information with other stakeholders, such as group purchasing organizations.

Conclusion

Vizient welcomes FDA's public meeting and RFC, which provides a significant opportunity for stakeholders to inform the agency on how specific proposals will impact our members. On behalf of Vizient, I would like to thank FDA for the opportunity to comment on PDUFA reauthorization. Please feel free to contact me at (202) 354-2600 or Jenna Stern, Sr. Director of Regulatory Affairs and Government Relations (Jenna.Stern@vizientinc.com), if you have any questions or if Vizient can provide any assistance as you consider these issues.

Respectfully submitted,

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Vizient, Inc.