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Submitted electronically via https://www.regulations.gov/

Dr. Robert Califf
Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Risk Management Plans to Mitigate the Potential for Drug Shortages Draft Guidance (Docket No. FDA-2022-D-0277)

Dear Dr. Califf:

Vizient, Inc. appreciates the opportunity to comment on the Food and Drug Administration's (FDA's) Draft Guidance, Risk Management Plans to Mitigate the Potential for Drug Shortages (hereinafter "Draft Guidance"). Vizient applauds the FDA for taking steps to provide clarity regarding the development, maintenance and implementation of risk management plans (RMPs), as we believe RMPs can help mitigate drug and biological product shortages.

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 97% 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In our comments, we respond to FDA's draft guidance for manufacturer RMPs to mitigate the potential for drug shortages. Generally, to improve access to essential medications and enhance patient care, Vizient prioritizes initiatives focused on transparency, quality, redundancy and production of additional supply. Vizient appreciates the numerous steps the agency outlines in the draft guidance that may help support quality and redundancy, however, we encourage the agency to consider opportunities to increase transparency and the production of additional supply.

Transparency

In the Draft Guidance, FDA "recommends that the primary stakeholder share as much of its RMP as possible with the secondary[1] and other stakeholders of the drug product to enable

[1] According to the Draft Guidance, secondary stakeholders are entities that are expected to have more detailed insight into specific segments of the supply chain for a drug product but may not have an understanding of its entirety. Secondary stakeholders include:

secondary and other stakeholders to incorporate the broad strategies of the primary stakeholder's RMP into their own plans and also contextualize the risks identified in the primary stakeholder's RMP, specifically for the manufacturing facility."[2] In addition, the Draft Guidance provides information regarding "Other Stakeholders" and their development of RMPs. Vizient appreciates that the agency has identified the need to share information with Other Stakeholders to support their efforts to prepare for and understand the potential risks of a drug shortage. Vizient would ask for FDA's consideration of additional specificity around aspects of the "Other Stakeholders" definition.

Vizient recommends that group purchasing organizations (GPOs) be enumerated as an "Other stakeholder" for the specific purposes of accessing RMPs from primary, secondary and other stakeholders. Access to RMPs would add needed transparency to help GPOs prepare themselves and their member providers for drug shortages. GPOs play a critical role in the supply chain as they are the sourcing and purchasing partners for American hospitals and other providers. GPOs work collaboratively with various supply chain stakeholders to address drug shortages and employ a variety of proactive steps to reduce their impact.

In addition, Vizient believes that there are a range of potential "Other Stakeholders", including GPOs, who play a critical role in the supply chain but would not have direct access to the type of information that FDA recommends be considered in an RMP. For example, in the Draft Guidance, FDA provides various risk factors that some secondary and other stakeholders could share that may be useful to the primary stakeholder (and vice versa), such as information regarding limitations for raw materials, intermediaries, components, and drug product containers and closures; communications between contract manufacturing facilities and component suppliers; infrastructure and utilities weakness; and monitoring of vulnerable equipment, among other related topics. However, other stakeholders, such as GPOs, would not be the origination point for such information. Therefore, further differentiation of the responsibilities of the various potential "other stakeholders", including GPOs, hospitals, and other providers would be desired.

In addition to sharing RMP information to the extent possible, Vizient also suggests that supporting documentation and context regarding an RMP be shared, if feasible, as this will provide additional transparency to support mitigation efforts. For example, should an alternative active pharmaceutical ingredient (API) supplier be identified in an RMP, it would be helpful to share information that indicates whether that API supplier has been directly informed of their inclusion in the RMP to ensure plans can be promptly executed should an issue emerge or where multiple stakeholders rely on a single stakeholder for risk mitigation purposes.[3] Vizient believes this additional information will be critical to proactively ensuring coordination.

Finished product manufacturers that are not primary stakeholders …; API manufacturers, as well as those manufacturers that physically process (e.g., 148 milling, coating) or package the API.

[2] FDA (2022), Risk Management Plans to Mitigate the Potential for Drug Shortages, Draft Guidance, available at: https://downloads.regulations.gov/FDA-2022-D-0277-0002/attachment_1.pdf

[3] FDA (2022), Risk Management Plans to Mitigate the Potential for Drug Shortages, Draft Guidance, available at: https://downloads.regulations.gov/FDA-2022-D-0277-0002/attachment_1.pdf, stating, "When a stakeholder … (i.e., a secondary or other stakeholder) develops its RMP, it typically should interpret the broader risks identified in the primary stakeholder's RMP within the context of a specific manufacturing facility, and address unique risks at a manufacturing facility that are unlikely to be identified by the primary stakeholder… The RMP for stakeholders that are not the primary stakeholder should consider the effect of identified risks on the manufacturing facility as well as on the drugs manufactured at that facility."

Regarding the products for which a RMP is required, FDA provides a list of different types of products, including certain APIs and associated medical devices used for preparation or administration in the Draft Guidance. Specific to the prescription drug product types, Vizient encourages FDA include products noted in Vizient's Essential Medicines list which is updated regularly. In addition, we encourage the agency to provide a list of products where the agency believes RMPs are required to provide additional clarity to stakeholders.

Redundancy

Vizient appreciates that the Draft Guidance makes several references to redundancy in the context of an RMP, however, Vizient suggests that more clear recommendations are needed. For example, regarding risk reduction, FDA provides that a strategy to mitigate or avoid risks "can include building redundancy into manufacturing operations, establishing adequate controls on the supply chain, strengthening relationships with suppliers (e.g., contract manufacturers, ingredient suppliers), and/or identifying alternative suppliers." Vizient is concerned that these recommendations may be too generally stated such that redundancy may not actually be achieved. For example, Vizient suggests FDA clarify that manufacturers should have established back-up manufacturing capabilities and at least two additional API sources. Based on Vizient's experience, such specificity can help ensure redundancy meaningfully exists. Vizient also encourages FDA to retroactively work with manufacturers to identify when and why redundancy plans may not have been effective so that additional insights can be provided in the future.

Conclusion

Vizient applauds FDA's efforts to release the Draft Guidance and provide an opportunity for stakeholder input. Vizient has engaged in numerous efforts to support access to medications, including publishing a regularly updated essential medicines list and a bi-annual Pharmacy Market Outlook, as we are committed to ending drug shortages. In closing, on behalf of Vizient, I would like to thank FDA for providing the opportunity to respond to this Draft Guidance. Please feel free to contact me, or Jenna Stern at jenna.stern@vizientinc.com, if you have any questions or if Vizient may provide any assistance as you consider these recommendations.

Respectfully submitted,

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