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June 6, 2022

Re: Iodinated Contrast Media Shortage

Sujeet Rao
White House Supply Chain Disruptions Task Force
Eisenhower Executive Office Building
1650 17th Street, NW
Washington, D.C. 20500

Dr. Patrizia Cavazzoni
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Retired General Lyons
U.S. Department of Transportation
1200 New Jersey Ave. S.E.
Washington, D.C. 20590

Dear Mr. Rao, Dr. Cavazzoni and Retired General Lyons,

Vizient, Inc. respectfully shares information with the White House Supply Chain Disruptions Task Force and the Food and Drug Administration (FDA) regarding the ongoing iodinated contrast media shortage. Vizient appreciates the White House's responsiveness to supply chain disruptions related to the pandemic and FDA's persistence in preventing drug and device shortages, including making information available via the Drug Shortage Database. However, Vizient continues to receive questions from our hospital and health system members regarding the steps the government is taking to mitigate this persistent and impactful shortage of iodinated contrast media. As such, Vizient provides recommendations for consideration to help increase transparency and, most importantly, support patient care.

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.

While Vizient trusts FDA is actively considering options to mitigate the current iodinated contrast media shortage (i.e., Iodixanol (Visipaque) Injection, Iohexol (Omnipaque) Injection), we also understand the challenges our hospital and health system members face in planning patient care services based on limited information. As the White House and FDA is likely aware, hospitals and health systems have cancelled non-emergent but critical procedures and studies in response to this shortage. While the most important impact is the harm that may come to patients due to such delays, this shortage will also have longer-term implications as greater demand should be anticipated given the growing backlog of services. Thus, it is critical that steps be taken to better ensure anticipated supply will, in fact, meet future demand as options to address this shortage is contemplated.

Vizient regularly shares mitigation strategies with our member hospitals and health systems in the event or anticipation of a shortage. Vizient has been in contact with the primary manufacturer to better understand the scope and extent of the iodinated contrast media shortage and the manufacturer has participated in webinars to attempt to answer questions from hospitals and health systems. Among other information learned, we understand that while production is increasing at plants in China and Ireland, there will be a lag for those products to reach the United States due to transportation challenges. Further, while production improves, it is unclear to Vizient and our members how this will translate to availability in the U.S. as products move through the supply chain.

For example, it is unclear how much product is in transit, undergoing inspection, and within the U.S. distribution channel. As such, Vizient recommends the government consult with the manufacturers of iodinated contrast media products to determine how logistics barriers can be streamlined and more effectively coordinated. Further, as such information is learned, we urge subsequent communications to providers so that they may appropriately schedule procedures.

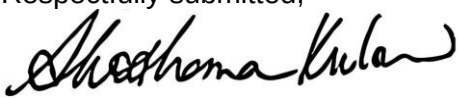
In addition, since FDA has additional authorities (e.g., determining if other manufacturers are willing and able to increase production, expedite inspections and reviews of submission, exercise temporary enforcement discretion for new sources of medically necessary drugs)[1],that may be exercised in the event of a shortage, Vizient request and would appreciate any additional, updated information regarding the agency's plans and response. Our members have emphasized that such information can help providers understand the dynamics of this shortage which, in turn, helps them more effectively prepare to minimize patient harm resulting from the supply disruption.

Based on information Vizient has gathered, we anticipate this drug shortage will impact care delivery until at least August 2022, with the potential for longer-term access issues, particularly as there are three high-use stock keeping units (SKUs)[2] currently being prioritized. Plans for the remaining SKUs remain unclear which creates additional uncertainty regarding the duration and effects of the shortage. We also understand that there may be international supply options, but it is unclear whether these options are being considered for importation.

Vizient encourages the White House and FDA to share additional information regarding the status of different approaches under consideration. Should none of the typical mitigation approaches be applicable to this shortage, we similarly urge the White House and FDA to share this information to provide further clarity and transparency.

We thank you in advance for your prompt attention to this request in the interest of patient care. On behalf of Vizient, I would like to thank FDA for providing us the opportunity to share information regarding contrast media access. 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 this issue.

Respectfully submitted,



Shoshana Krilow
Sr. Vice President of Public Policy and Government Relations
Vizient, Inc.

Cc: FDA Center for Drug Evaluation and Research Drug Shortage Program leaders

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[1] Food and Drug Administration (2018). Fact Sheet: Drug Products in Shortage in the United States, available at: https://www.fda.gov/regulatory-information/food-and-drug-administration-safety-and-innovation-act-fdasia/fact-sheet-drug-products-shortage-united-states, last accessed: June 4, 2022.
[2] The three prioritized SKUs are for the following: Omnipaque 350/100; 350/500; and Visipaque 320/100