

August 16, 2022

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

**Re: Drug shortages of bupivacaine, bupivacaine with epinephrine, lidocaine, lidocaine with epinephrine, ropivacaine, and mepivacaine**

Dear Dr. Cavazzoni,

Thank you for the Food and Drug Administration's (FDA's) commitment to responding to drug shortages. We are writing today to emphasize the urgent need to identify strategies to increase the supply of certain medications, particularly bupivacaine, bupivacaine with epinephrine, lidocaine, lidocaine with epinephrine, ropivacaine and mepivacaine. While these medications have all experienced shortages over the last several years, Vizient notes that the situation has worsened more recently as all are now simultaneously on shortage.

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.

Vizient notes that recent fill rates<sup>1</sup> for bupivacaine, bupivacaine with epinephrine, lidocaine, lidocaine with epinephrine and ropivacaine are particularly low, ranging from 19.2 percent to 51 percent, despite there being numerous suppliers in the market for these products. Vizient has heard concerns from our provider members, indicating that although mitigation strategies are being employed, the volatility of medication availability has led to frequent, high-impact changes within hospitals and health systems. These high-impact changes include adjusting how much of these medications are administered and who receives them, leading to reports of higher patient-reported pain scores and a greater reliance on other modalities, particularly opioids. Some of Vizient's members indicated that they are reserving these medications solely for epidurals and planned C-sections. As a result, some health systems have been forced to remove "caine" medications from certain multimodal pain pathways to conserve inventory. Should these shortages persist or worsen, patient-reported pain scores may continue to increase, resulting in a greater reliance on opioids and a potential for further increases in lengths of stay.

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<sup>1</sup> Fill rates referenced do not include preservative free products and are presented as an average from the past three months.

We appreciate FDA's ongoing efforts to respond to drug shortages. Regarding the previously noted shortages, Vizient encourages the agency to consider alternative options to improve access, such as potential importation. To the extent the agency needs additional information, Vizient hopes to be a resource for the agency.

Again, Vizient is deeply appreciative of the opportunity to share information with FDA, and we thank FDA for considering of our recommendations. We remain available to answer any questions and/or discuss other potential solutions to prevent further supply chain disruption. Please do not hesitate to contact me at [Shoshana.Krilow@vizientinc.com](mailto:Shoshana.Krilow@vizientinc.com). We look forward to working with you to protect the health of our nation and we thank you for your leadership.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Shoshana Krilow". The signature is fluid and cursive, with the first name being more prominent.

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

CC: [drugshortages@fda.hhs.gov](mailto:drugshortages@fda.hhs.gov)