

United States Senate

WASHINGTON, DC 20510

June 30, 2022

Dear Commissioner Califf:

As you know, we are experiencing a nationwide shortage of iodinated contrast media, commonly used in medical imaging such as computed tomography (CT) scans and X-Rays. This shortage has impacted as many as half the nation's hospitals, and limited the ability of hospitals to provide the estimated 50 million scans performed with contrast media every year in the U.S.¹

Much of this shortage can be attributed to the production of GE Healthcare's *Omnipaque* (iohexol) and *Visipaque* (iodixanol) intravenous contrast media products, which have been significantly impacted by strict restrictions in Shanghai, where these products are primarily produced. GE is one of four major suppliers of contrast media in the U.S., with Bracco, Bayer, and Guerbet also operating in the market. Approximately half of all hospitals and imaging centers in the U.S. use GE contrast media products.²

The current shortage is expected to last through the summer. GE has stated that they returned to full capacity operation at the Shanghai facility, but there will still be lag time in getting the products to medical providers in the U.S.³ To expedite this, GE has flown in shipments from facilities in Shanghai and Cork, Ireland that would normally travel to the U.S. by ship.⁴

At the recent Senate Health, Education, Labor, and Pensions Committee Hearing entitled "Infant Formula Crisis: Addressing the Shortage and Getting Formula on Shelves", I asked what you thought the next supply chain related crisis for critical foods or drugs would be and you answered that it was contrast media. You stated that this shortage is "unbelievable...but it's happening" and expressed concern that a patient experiencing a stroke or heart attack in this country might not be able to receive an angiogram, for example.⁵

Shortages of contrast media were reported to the FDA in May, and given our conversation, it is clear you are aware of the gravity of this issue.⁶ In addition to the infant formula shortage, this is yet another example where our supply chain has shown to be incredibly vulnerable to isolated issues that can quickly become widespread crises impacting both domestic and global supply of critical products and putting people's lives at risk.

¹ <https://www.nytimes.com/2022/05/26/health/dye-contrast-scan-shortage.html>

² <https://www.nbcnews.com/news/us-news/shortage-contrast-dye-hospitals-ration-ct-scans-procedures-rcna29379>

³ <https://www.ge.com/news/press-releases/ge-healthcare-update-on-iodinated-contrast-media>

⁴ <https://www.nytimes.com/2022/05/26/health/dye-contrast-scan-shortage.html>

⁵ <https://www.help.senate.gov/hearings/infant-formula-crisis-addressing-the-shortage-and-getting-formula-on-shelves>

⁶ https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=lodixanol+%28Visipaque%29+Injection&st=c&tab=tabs-4&panels=0#

Given the severity of this situation, we ask that you provide thoughtful responses to the following questions:

1. Is FDA engaging with the other producers of contrast media to try and import and/or approve additional products to ease the shortage?
2. Is FDA working with hospitals and imaging centers to triage shortages so that new contrast media products can be directed to facilities where they are needed most?
3. What steps is FDA taking to ensure that the Agency is aware of supply chain issues early so the Agency can address potential shortages?

We must learn from cases like this contrast media shortage and the infant formula crisis to diversify our supply chains, increase competition in the market, and ensure our federal regulators are responsive to disruptions in the market. We look forward to working with you to address these critical challenges.

Sincerely,



John Hickenlooper
United States Senator



Tina Smith
United States Senator