

United States Senate

WASHINGTON, DC 20510

December 7, 2023

Vimal Kavuru
President and Chief Executive Officer
Rising Pharmaceuticals
2 Tower Center Blvd.
Suite 1401A
East Brunswick, NJ 08816

Dear Mr. Kavuru:

I write regarding reports of a pricing decision made by Rising Pharmaceuticals that is leading to compromised patient care for those suffering from the most severe cases of lead poisoning. Specifically, Rising has priced its Edetate Calcium Disodium Injection, a generic drug to treat elevated blood lead levels, at \$32,000 per course of treatment, reportedly leading to hospitals no longer being able to afford to stock this drug.

The U.S. Food and Drug Administration gave Rising Pharmaceuticals approval to manufacture and commercially produce this drug to alleviate a shortage of this critical treatment. Rising's decision to price this generic injectable at ten times the price of the imported version from France is leading to avoidable and dangerous delays in patient treatment and compromising patient care.

Your company's September 19 announcement of the opening of its previously closed U.S. manufacturing facility, which produces calcium disodium ethylenediaminetetraacetic acid (EDTA), stated that "Rising Pharmaceuticals is proud to play a significant role supporting the healthcare system." However, Rising's pricing decision does not appear to support this goal. As a result of Rising's actions, Americans diagnosed with elevated blood lead levels must wait days - an intolerably long time - before their hospital is able to source this critical drug.

Rising Pharmaceuticals boasts one of the broadest portfolios of any U.S. generics company, producing more than 180 commercialized generic medicines. Rising's website states that the company is "always looking ahead to continue providing new and affordable generic medications of the highest quality." Given the company's broad revenue base and apparent focus on the affordability of its products, please explain the reasoning behind Rising Pharmaceuticals' decision to adopt a price for its generic that well exceeds the price of many expensive brand products on the U.S. market.

In your response, please answer the following questions:

1. What were the biggest factors influencing Rising Pharmaceuticals' decision to price its calcium disodium EDTA at \$32,000 per course of treatment, a higher price than the average name-brand injectable sold in the U.S.?

2. Is Rising Pharmaceuticals pricing its calcium disodium EDTA to capitalize on the shortage of this drug in the United States?
3. Does Rising Pharmaceuticals' pricing decision of \$32,000 per course of treatment compromise timely access to treatment for patients with elevated blood lead levels who need treatment? Is Rising Pharmaceuticals surprised by this outcome and does the company find this pricing ensures efficacious distribution to the public?
4. Why has Rising Pharmaceuticals chosen to not follow a similar U.S. pricing strategy as that of a manufacturer of calcium disodium EDTA in France selling the same product in the U.S. market? Would Rising Pharmaceuticals be able to make a healthy profit off of its U.S. production of calcium disodium EDTA if it followed a similar U.S. pricing strategy for calcium disodium EDTA as that of its competitor product made in France?
5. As a company with such a broad and large product portfolio, please explain why Rising's calcium disodium EDTA product must be priced at ten times the price of the competitor generic imported from France.
6. Does Rising Pharmaceuticals believe they are helping to provide timely access to Edetate Calcium Disodium Injection, as stated in the September 19 announcement, compared to before there was a shortage of this medication?
7. In deciding its price that is reportedly leading to dangerous delays in patient access to calcium disodium EDTA, how did Rising Pharmaceuticals factor in the circumstances that maximize the clinical effectiveness of the drug?
8. Why is this generic drug that was developed decades ago priced at ten times the amount of the same generic product in France? France pays more for generics on average than other comparable European countries.

I know from the statements on your website that your company understands the importance of prescription drugs being affordable and accessible. We must optimize the market for patients and our health system. I look forward to your response.

Sincerely,



Amy Klobuchar
United States Senator