

Congress of the United States
House of Representatives
Washington, DC 20515

February 22, 2023

Robert M. Califf M.D.
Food and Drug Administration
U.S. Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

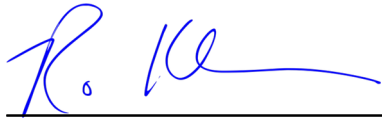
We write to express concern regarding the ongoing shortage of pediatric ibuprofen and acetaminophen. Over the last six months, a drastic increase in children's respiratory illnesses, including Covid-19, influenza and respiratory syncytial virus (RSV), has resulted in an unprecedented demand for over-the-counter pediatric fever-reducing medications. Unfortunately, despite round-the-clock efforts from manufacturers, demand for these medicines is outpacing supply.

We appreciate the steps that the FDA has already taken to combat this shortage, including the agency's recently issued guidance regarding drug compounding for certain ibuprofen suspensions, which allows healthcare providers and pharmacists to make ibuprofen in-house if they have the necessary raw ingredients available. As Congress works to find a legislative solution regarding rates of production, we believe that the FDA can take further actions to address this issue, including the following:

1. Disseminate updated guidance to pharmacists and healthcare providers regarding available alternatives for pediatric ibuprofen and acetaminophen, including dosage conversions. Additional guidance and more intentional communication will help ensure that children's medical needs are being met as efficiently as possible and extra supply is available.
2. Encourage additional transparency from manufacturers to the FDA regarding supply location and the distribution of consumer demand for pediatric fever-relieving medications. With additional data about drugs' location and differences in demand, the FDA can help assist manufacturers distribute supply more evenly, preventing such sudden shortages in different areas around the country.
3. Communicate proactively to caregivers regarding the shortage. Many caregivers have been contending with this shortage for several months, causing understandable distress and confusion. Direct communication from the FDA through a public outreach campaign will help to alleviate concerns and prevent misinformation.

As cases of pediatric illnesses remain steadily high, a stronger response from the FDA is necessary to ensure that children are able to recover safely and swiftly. Once again, we thank you for your leadership during such a challenging time and appreciate your full and fair consideration of our inquiry under all applicable laws and regulations.

Sincerely,



Ro Khanna
Member of Congress



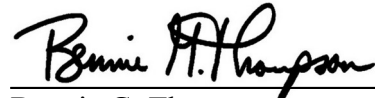
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