

# Congress of the United States

Washington, DC 20515

November 14, 2023

The Honorable Xavier Becerra  
Secretary  
US Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 20101

Robert M. Califf, MD  
Commissioner  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993

Melanie Fontes Rainer  
Director  
Office for Civil Rights  
U.S. Department of Health and Human Services  
200 Independence Avenue, SW Room 509F, HHH  
Building  
Washington, D.C. 20201

Dear Secretary Becerra, Commissioner Califf, and Director Fontes Rainer:

Thank you for your leadership and collaboration in spurring adequate supply and nondiscriminatory distribution of critical medications. The dual threats of short supply and unintended chilling effects of abortion restrictions and bans have in some circumstances made accessing certain medications for chronic conditions and reproductive health particularly difficult, if those medications can also be used for or cause an abortion. We are reaching out today because these factors continue to hinder access to the medications methotrexate and misoprostol.

Methotrexate is a commonly prescribed medication used to treat rheumatoid arthritis (RA), other autoimmune disorders, and some cancers, including breast cancer, lymphoma and leukemia, among other conditions. It is an antimetabolite which alleviates RA by reducing the activity of the immune system. It is Food and Drug Administration approved and often the first line of defense against RA, being used to treat inflammation which cannot be controlled by a biologic alone. Its injectable form is used to treat ectopic pregnancy. Misoprostol is a medication used to prevent gastric ulcers, for miscarriage management, and for abortion.

Since the Supreme Court's *Dobbs v. Jackson Women's Health Organization* decision in June 2022, people across the country have been denied access to methotrexate and misoprostol. In many states, physicians, other types of providers, and pharmacists must comply with extreme and often confusing abortion bans and restrictions. These laws have created a chilling effect in which providers are fearful to offer medications like methotrexate and misoprostol to manage chronic conditions or for miscarriage management, because they could under another use be used for or cause an abortion.<sup>1</sup> While we appreciate the statement on July 13, 2022, from

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<sup>1</sup> <https://www.reuters.com/world/us/state-abortion-bans-prevent-women-getting-essential-medication-2022-07-14/>

the Department of Health and Human Services reminding retail pharmacies of their obligation to supply prescribed medications in a nondiscriminatory manner, this issue persists.<sup>2</sup>

Further, the supply chain for methotrexate is at risk, and manufacturers have not kept up with demand.<sup>3</sup> In Spring 2023, Akorn Pharmaceuticals, the largest manufacturer of generic methotrexate filed for Chapter 7 bankruptcy and closed. This has left a gap in the market, which has contributed to the shortage of the medication.

Without access to this critical medication, people's lives are at risk. In response to this shortage, we request answers to the following:

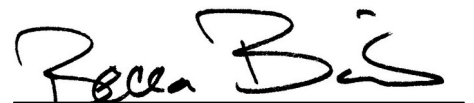
1. What steps are HHS and the FDA taking to strengthen the supply chain for methotrexate, and ensure an adequate supply of this medication?
2. What barriers to the manufacture and distribution of methotrexate remain?
3. What Congressional support or assistance do HHS and the FDA need to address these barriers and ensure adequate supply and distribution of methotrexate?
4. In addition to monitoring and enforcement actions, what proactive steps is the Office for Civil Rights taking to ensure that all pharmacy retailers are dispensing reproductive health medications and medications for chronic conditions, like methotrexate and misoprostol, in a nondiscriminatory manner?

We request your prompt response to these questions and appreciate your collaboration in restoring access to care for people across the country.

Sincerely,



Sean Casten  
Member of Congress



Becca Balint  
Member of Congress

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<sup>2</sup> <https://www.hhs.gov/civil-rights/for-individuals/special-topics/reproductive-healthcare/pharmacies-guidance/index.html>

<sup>3</sup> <https://www.the-rheumatologist.org/article/methotrexate-shortage-why-its-happening-potential-solutions/>



Valerie P. Foushee  
Member of Congress



Jill Tokuda  
Member of Congress



Nikki Budzinski  
Member of Congress



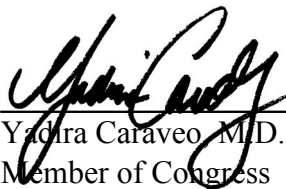
James P. McGovern  
Member of Congress



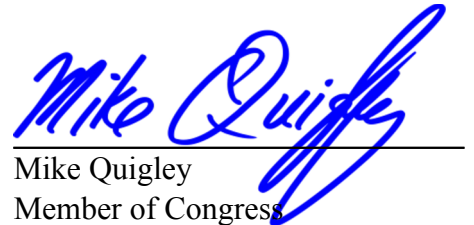
Yvette D. Clarke  
Member of Congress



Paul Tonko  
Member of Congress



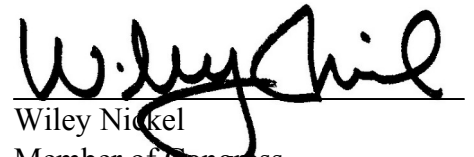
Ysaira Caraveo, M.D.  
Member of Congress



Mike Quigley  
Member of Congress



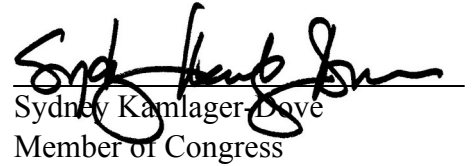
Seth Moulton  
Member of Congress



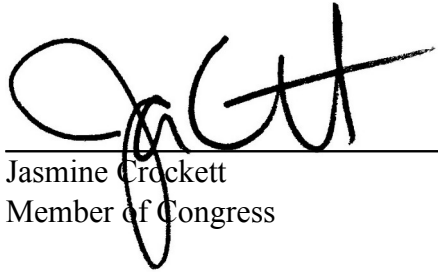
Wiley Nickel  
Member of Congress



Eleanor Holmes Norton  
Member of Congress



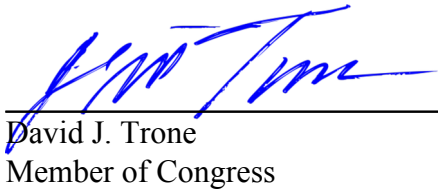
Sydney Kamlager-Dove  
Member of Congress



Jasmine Crockett  
Member of Congress



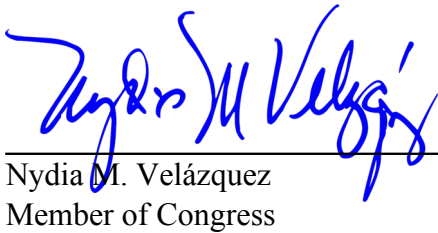
Kevin Mullin  
Member of Congress



David J. Trone  
Member of Congress



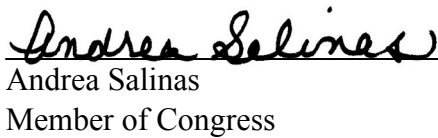
Raúl M. Grijalva  
Member of Congress



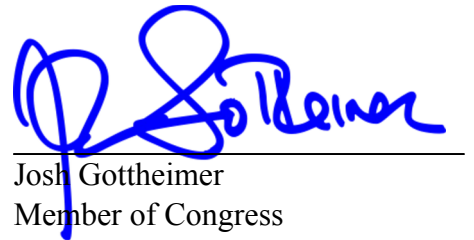
Nydia M. Velázquez  
Member of Congress



Katie Porter  
Member of Congress



Andrea Salinas  
Member of Congress



Josh Gottheimer  
Member of Congress



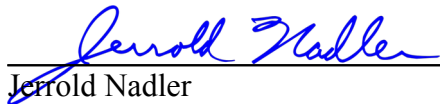
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Susie Lee  
Member of Congress



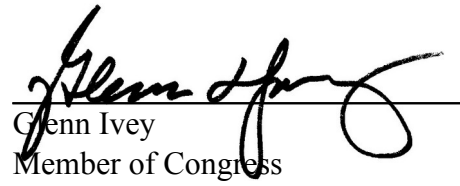
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Bradley Scott Schneider  
Member of Congress



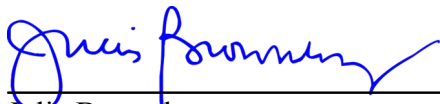
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Jerrold Nadler  
Member of Congress



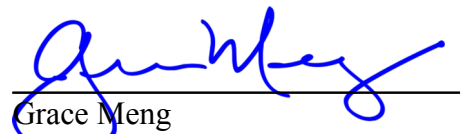
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Glenn Ivey  
Member of Congress



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Julia Brownley  
Member of Congress



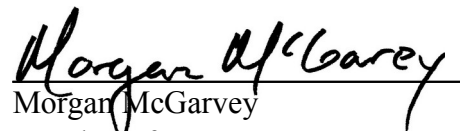
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Grace Meng  
Member of Congress



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Betty McCollum  
Member of Congress



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Morgan McGarvey  
Member of Congress



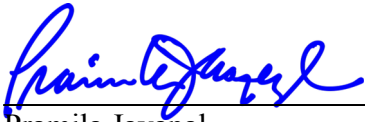
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Dan Goldman  
Member of Congress



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Ted W. Lieu  
Member of Congress



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Pramila Jayapal  
Member of Congress



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Brittany Pettersen  
Member of Congress



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Deborah K. Ross  
Member of Congress



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Steve Cohen  
Member of Congress



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Alma S. Adams, Ph.D.  
Member of Congress



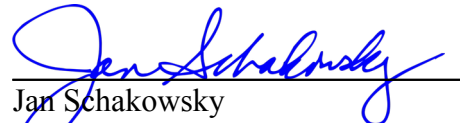
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Jeff Jackson  
Member of Congress



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Gregory W. Meeks  
Member of Congress



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Jan Schakowsky  
Member of Congress



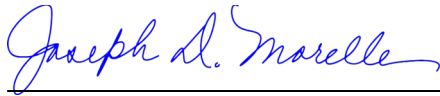
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Kathy Castor  
Member of Congress

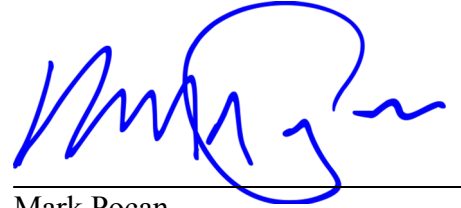


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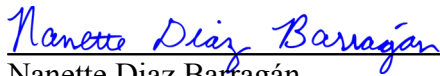
Angie Craig  
Member of Congress



Joseph D. Morelle  
Member of Congress



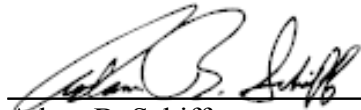
Mark Pocan  
Member of Congress



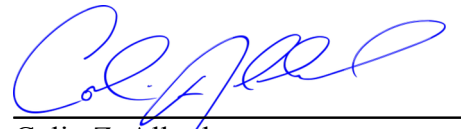
Nanette Diaz Barragán  
Member of Congress



Troy Carter  
Member of Congress



Adam B. Schiff  
Member of Congress



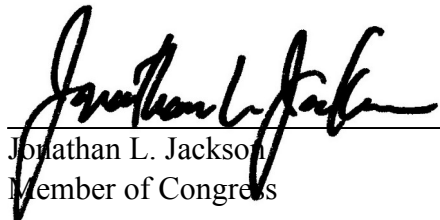
Colin Z. Allred  
Member of Congress



Madeline Dean  
Member of Congress



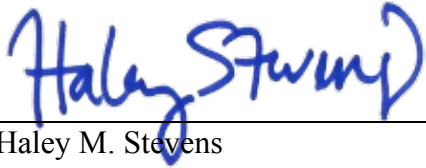
Salud Carbajal  
Member of Congress



Jonathan L. Jackson  
Member of Congress



Ruben Gallego  
Member of Congress



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Haley M. Stevens  
Member of Congress



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Dina Titus  
Member of Congress