



NEW YORK STATE SENATE

August 9, 2022

Robert Califf, MD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Re: The Urgent Need to Improve Access to Mifepristone

Dear Commissioner Califf,

We write with a great sense of urgency in light of the Supreme Court's decision in *Dobbs* and our commitment as State Senators to ensure that New York State can provide safe abortion care without unnecessary restrictions. Specifically, we urge the FDA to remove burdensome regulations surrounding the prescription, dispensing, and pharmaceutical distribution of Mifeprex® (mifepristone), an essential option for those seeking abortions, through the removal of the Risk Evaluation and Mitigation Strategy (REMS) and Elements To Assure Safe Use (ETASU) requirements.

In New York State, we have taken strong steps to ensure we remain one of only several safe haven states for women seeking an abortion. We are concerned that, notwithstanding the safety and efficacy of mifepristone for use in medical abortions, the FDA's current limitations on prescribers and planned restrictions on pharmacies place unwarranted limits on who can prescribe, dispense and obtain mifepristone. These limits are not acceptable given the safety and efficacy of this medication, the unique applicability of the medication for medical abortion, and the urgent need for action. As some of us have already requested prior to the *Dobbs* decision, we urge you to reexamine your current rules and move to immediately expand who may prescribe and dispense this medication.

Under the FDA's current policy as amended in December 2021, mifepristone is subject to restrictive Risk Evaluation and Mitigation Strategy (REMS) and Elements to Assure Safe Use (ETASU) requirements normally reserved for drugs with serious safety concerns. These

burdensome requirements mean that those who are pregnant must frequently go to greater lengths to seek out reproductive care specialists and new pharmacies rather than their usual doctor, nurse practitioner or pharmacy. In addition, they are confronted with the impression that serious adverse events resulting from the use of mifepristone occur at a frequency that is not supported by evidence.

As noted by the American College of Obstetricians and Gynecologists (ACOG) and the American Medical Association (AMA) in their letter to you on June 21, mifepristone has been approved as safe for use for more than 20 years and its safety for medication-induced abortion is backed by a significant body of subsequent research. While the FDA did make some changes with respect to prescribers and pharmacies, it continues to impose burdensome rules for both to offer the drug. In the wake of the *Dobbs* decision, we anticipate a surge in unmet need for abortion care and believe it necessary to add our voices to those who have already done so in favor of expanded access.

We appreciate that President Biden was extremely clear in his recent statement when he ordered his health officials “to identify all ways to ensure that mifepristone is as widely accessible as possible.” We write to encourage a greater sense of urgency in meeting this directive. More than half of all abortions are induced through medication. Accordingly, abortion pills such as mifepristone are of preeminent importance in the response to *Dobbs*, and must be treated as such. Every day that passes without swift and sensible changes to increase abortion access means that fewer people receive the care they need.

We fear that the FDA’s current policy does not address the urgency of this moment and represents another example of unique restrictions related to the provision of women’s reproductive healthcare. We urge you to promptly reevaluate and remove burdensome requirements for mifepristone and take strong steps to improve access.

Sincerely,



Senator Shelley Mayer
37th Senate District



Senator Liz Krueger
28th Senate District



Senator Alessandra Biaggi
34th Senate District



Senator Michael Gianaris
12th Senate District



Senator Cordell Cleare
30th Senate District



Senator Brad Hoylman
27th Senate District



Senator Reichlin-Melnick
38th Senate District



Senator Jamaal T. Bailey
36th Senate District



Senator Samra Brouk
55th Senate District



Senator Jabari Brisport
25th Senate District



Senator Peter Harckham
40th Senate District



Senator Zellnor Myrie
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Senator Anna Kaplan
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Senator Jeremy A. Cooney
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Senator James Skoufis
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Senator Timothy M. Kennedy
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Senator Andrew Gounardes
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Senator Toby Ann Stavisky
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Senator John C. Liu
11th Senate District



Senator Gustavo Rivera
33rd Senate District



Senator Robert Jackson
31st Senate District



Senator Julia Salazar
18th Senate District



Senator Jessica Ramos
13th Senate District



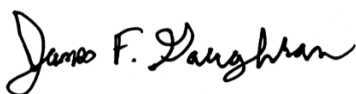
Senator Michelle Hinchey
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Senator Sean Ryan
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Senator Luis R. Sepúlveda
32nd Senate District



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Senator Leroy Comrie
14th Senate District

cc:

Xavier Becerra

Secretary

U.S. Department of Health & Human Services

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