VIA FEDEX & ELECTRONIC MAIL

June 2, 2025

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RE: ***The Defense of the Use of Progesterone in Abortion Pill Reversal & Threatened Pregnancies***

Dear Attorney General Bondi, Secretary Kennedy, Commissioner Makary, Director Maltz, General Counsel Croslow and Deputy Boynton:

I write to you today as the co-founder, President and CEO of 40 Days for Life, the world's largest pro-life organization. With over 1,000,000 volunteers committed to protecting the sanctity of human life from conception to natural death – I ask you to *protect the use of progesterone for women's health care and specifically in cases in which women choose Abortion Pill Reversal ("APR").*

40 Days for Life conducts peaceful, law-abiding vigils in 1,800 cities in all 50 U.S. States and 64 countries. Our prayerful presence in front of thousands of abortion facilities provides unique and deeply concerning insight on the grave harm of abortion on women and the unborn.

As you know, the scope of this issue is vast: Abortion is the leading cause of death, taking the lives of some 1,000,000 unborn Americans each year – with some 60% committed by the Abortion Pill (more than 600,000 unborn babies, annually).

This letter outlines the medical, legal and societal concerns associated with certain radical States' assault on the use of progesterone to aid women who choose Abortion Pill Reversal ("APR").

Every life deserves protection so we must ensure that individuals have access to comprehensive, medically sound options to choose life, including the use of progesterone for threatened pregnancies, including through the use of progesterone and APR.

The increasing efficacy of the use of progesterone to reverse the abortion pill has resulted in concerted legal action by radical pro-abortion states like California, New York and Colorado targeting pro-life organizations and health care providers serving the women seeking APR.

40 Days for Life's position is not mere rhetoric or theory, but stems from our direct engagement with and advocacy for hundreds of thousands of women and families who are most impacted by these policies, settled law and proven science.

Radical, pro-abortion states are actively attempting to block accurate, life-affirming information and medical care. Ironically, they are removing women's "choice" and limiting options to what the government decides is best for women and their babies.
Current lawsuits in California and New York by weaponized attorneys general Bonta and James attempt to limit access to life-affirming interventions and restrict the autonomy of healthcare providers to offer a full spectrum of medically appropriate care. See attached lawsuits.

These weaponized lawsuits are attacks not just on the pregnancy centers and medical care providers but are intentionally aimed at chilling all who adhere to basic science and comprehensive support for pregnant women.

We urge you to implement federal regulation and law that preserve the right of health care professionals to provide progesterone to reverse the effects of the abortion pill, for those women who so choose, without fear or threat of frivolous over-bearing litigation by rogue state and local politicians and lawyers.

Progesterone Is Safe, Effective and Is Good Medicine

The use of progesterone to support pregnancy is ubiquitous, effective and deeply rooted in over a century of extensive scientific inquiry, including:

> *Randomized Trial of Progesterone in Women with Bleeding in Early Pregnancy,* Coomarasamy*, et al.*, New England Journal of Medicine (2019)
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> *Mifepristone Antagonization with Progesterone to Prevent Medical Abortion,* Creinin, *et al.*, Department of Obstetrics and Gynecology, University of California, Davis, Sacramento, CA, (2020)
>
> *The Successful Reversal of the Effects of Mifepristone Using Progesterone, Delgado, et al.,* Issues in Law & Medicine, Volume 33, Number 1, (2018)
>
> *Prenatal Administration of Progesterone for Preventing Preterm Birth,* Dodd, *et al.,* The Cochrane Collaboration (2015)
>
> *Progesterone for Preventing Miscarriage,* Haas, *et al.,* The Cochrane Collaboration (2019)

Progesterone is routinely used in medical care, including to support pregnancies. *We cannot locate any time that a government has ever filed suit or threatened a health care provider – until progesterone was used to support pregnancies threated by the abortion pill. Then the abortion industrial machine jumped to action and suddenly proclaimed: "progesterone doesn't work."*

They are wrong and they know it: *Progesterone is a natural hormone that has been used safely and effectively for over 100 years.*

Pioneering research in the early 20th century established progesterone's crucial role in maintaining a healthy pregnancy by demonstrating its fundamental connection to the uterine lining, influence on uterine activity and necessity for early embryo survival.

By the 1930s, progesterone's structure and diverse roles in the menstrual cycle and pregnancy, including implantation, pregnancy maintenance, and ovulation prevention, were all well established.

The Food and Drug Administration ("FDA") has approved progesterone and progestins for multi-various applications in women's health: Hormone Replacement Therapy ("HRT") for menopause (used in conjunction with estrogen to mitigate endometrial cancer risk); the treatment of amenorrhea and abnormal uterine bleeding; and Assisted Reproductive Technologies ("ART") to support the uterine lining and early pregnancy.

Physicians routinely prescribe progesterone for a myriad of conditions through on and "off-label" uses, dosages and routes of administration. As affirmed in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001), the FDA's labeling requirements "inform a physician of the agency's approval of the product for certain uses, but they do not purport to limit the manner in which a physician may use or prescribe an approved drug."

But these weaponized state lawsuits now threaten not only women's autonomy but physicians' rights to practice. Radical state governments want to tell women and physicians what to do.

The safety profile of progesterone itself is well-established. Studies, including Coomarasamy, *et al.* (2019), indicate no inherent danger in progesterone use, with similar adverse events observed in both progesterone and placebo groups in clinical trials. This robust safety record underscores that progesterone, when prescribed by a licensed medical professional, does not pose significant safety risks.

Progesterone is also widely prescribed for Abortion Pill Reversal ("APR"). All indications are that it is safe and effective. See, Delgado, *et al.* (2018) and Creinin, *et al.* (2020).

Progesterone has a long and proven history of safe off-label use in other high-risk pregnancy scenarios. For instance, the study by Haas, *et al.* (2019), explored its use in preventing recurrent miscarriage. See also, Dodd, *et al.* (2013), detailing progesterone's application in preventing preterm birth in specific high-risk populations: Both suggesting benefits and supporting its use.

The concept of "threatened abortion" is central to APR's rationale, and the practice of using progesterone in such situations is acknowledged in medical literature, even if the overall benefit

in live birth rates for general threatened abortion is not always statistically significant. Coomarasamy, *et al*.

In short, progesterone is safe and effective and widely used in many health care applications – including Abortion Pill Reversal.

The State Lawsuits against Progesterone Providers Are Frivolous and Unlawfully Target Pro-Lifers, Women Who Choose Life and Physician Autonomy

The attempts to limit the medical practice of using progesterone represent an alarming overreach into women's choice, physician autonomy and good medicine.

California and New York Attorneys General are attempting to regulate women's choice and medical speech and practice through absurd applications of commercial laws like "false advertising."

California Attorney General Rob Bonta's lawsuit against Heartbeat International, *People of the State of California v. Heartbeat International, Inc.,* Superior Court of California, County of Alameda, Case No. HG23207915 (Filed Sept. 28, 2023), alleges "false and misleading advertising" regarding APR. California ignores what this law actually says, its application, the effectiveness and use of progesterone and the established principle of physician discretion in off-label prescribing. *In short, it is a complete fiction.*

Similarly, New York Attorney General Letitia James launched investigations and lawsuits under broad consumer protection statutes (New York Executive Law § 63(12)), effectively attempting to use commercial law to dictate medical practice. *People of the State of New York v. Heartbeat International, et al*, (Filed May 6, 2024, in the Supreme Court of New York). These actions disregard the fact that medical professionals are primarily governed by state medical licensing boards, which possess the specialized expertise to regulate medical practice and ensure patient safety. In short, the New York Attorney General is threatening licensed health care providers if they do not "get on board the abortion train."

The bedrock of quality healthcare rests on the principle that patients and physicians must retain their autonomy in medical decision-making. Licensed physicians, with their extensive education, rigorous training, and finely honed clinical judgment, are unequivocally the most qualified to determine appropriate patient care. This fundamental principle is not merely a professional courtesy; it is deeply enshrined in medical practice, allowing doctors to prescribe FDA-approved drugs for off-label uses when they deem it medically appropriate and supported by sound clinical rationale. This has been affirmed by the highest court, as in *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341 (2001), the FDA's labeling requirements "inform a physician of the agency's approval of the product for certain uses, but they do not purport to limit the manner in which a physician may use or prescribe an approved drug."

Medical professionals are primarily governed by state medical licensing boards, bodies specifically designed to ensure physician competence, uphold professional standards, and protect patient safety through expert oversight. Governmental interference in specific medical treatments, like the attempts to ban or criminalize APR-related speech as seen in Colorado's Senate Bill 190, or the highly concerning lawsuits from Attorneys General in California and New York, not only fundamentally undermines this established, expert-driven regulatory system but also leads to compromised patient care, stifles medical innovation, and brazenly politicizes medical practice.

These legal actions frequently target organizations that promote APR, alleging false and misleading advertising, or even aiding and abetting the unlicensed practice of medicine. However, such claims fundamentally disregard the inherent right of free speech, a cornerstone of our democracy. While commercial speech is not absolute, the Supreme Court in *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc*., 425 U.S. 748 (1976) recognized that even commercial speech is entitled to a degree of First Amendment protection. The *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980) test for commercial speech regulation allows for restrictions only if the speech is misleading and the governmental interest is substantial, directly advanced, and narrowly tailored. When discussing medical interventions like APR, especially in the context of offering options to vulnerable individuals, the balance shifts to the public's right to information and the ability to discuss potential medical avenues with their chosen healthcare provider.

40 Days for Life does not practice medicine; our role is to empower women with information and choices. This is precisely why we provide APR brochures (ATTACHED) that are designed to inform expectant mothers of the availability of APR and, crucially, to encourage them to discuss this option with a licensed medical provider.

We do not seek to dictate medical decisions but rather to ensure that women are aware of all potential avenues, particularly when they approach us about reversing a chemical abortion. This approach contrasts sharply with the paternalistic stance of governmental officials who, lacking medical training, seek to restrict information and limit access to care based on political agendas rather than medical best practices.

To assert that providing such information constitutes "false advertising" or "aiding and abetting unlicensed practice" is to stretch consumer protection laws beyond their intent, effectively attempting to silence advocacy and deny women a full spectrum of information in highly personal medical decisions.

The legal actions, such as those initiated by California Attorney General Bonta against Heartbeat International and New York Attorney General Letitia James under New York Executive Law § 63(12), are prime examples of this governmental overreach, attempting to use commercial statutes and absurd executive interpretations to suppress speech and limit the choices available to women and their physicians.

We implore you all to uphold the vital role of physician and patient autonomy and to acknowledge the established medical history and safety profile of progesterone.

While discussions around off-label uses like APR warrant careful and transparent communication - which our organization actively promotes through referrals to licensed providers and informative brochures - the core principle remains that complex medical decisions should rest with licensed professionals, guided by their expertise and unwavering commitment to patient well-being, rather than being dictated by governmental officials, however well-intentioned, who lack medical training.

The attempts by state attorneys general to employ commercial law and absurd executive state laws to limit physicians' ability to practice medicine and discuss legitimate options with their patients set a dangerous precedent.

We urge the federal government to stand against such overreach and champion policies that protect both medical freedom and a patient's right to information, ensuring that crucial aspects of healthcare are not unduly restricted by political agendas.

Sincerely,

Shawn Carney
Shawn Carney (May 30, 2025 13:52 MDT)

Shawn Carney
President & CEO
40 Days for Life

Matt Britton (Jun 2, 2025 08:18 MDT)

Matt Britton
General Counsel
40 Days for Life, Institute of Law & Justice

Donato Borrillo
Donato Borrillo (Jun 2, 2025 09:36 EDT)

Donato Borrillo, JD, MD
Assistant General Counsel & Director of Medicolegal Affairs
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ATTACHMENTS

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ATTACHMENTS

40 DAYS FOR LIFE APR BROCHURE

CASES:

Buchman Co. v. Plaintiffs' Legal Committee

Virginia State Board of Pharmacy, et al v. Virginia Citizens Consumer Council, Inc.

California v. HBI, et al

New York v. HBI, et al

Central Hudson Gas & Electric v. Public Services Commission of New York

LAWS:

New York Executive Law 63

Colorado Senate Bill 23-190 (2023)

ARTICLES:

Randomized Trial of Progesterone in Women with Bleeding in Early Pregnancy, Coomarasamy, *et al.*, New England Journal of Medicine (2019)

Mifepristone Antagonization with Progesterone to Prevent Medical Abortion, Creinin, *et al.*, Department of Obstetrics and Gynecology, University of California, Davis, Sacramento, CA, (2020)

The Successful Reversal of the Effects of Mifepristone Using Progesterone, Delgado, et al., Issues in Law & Medicine, Volume 33, Number 1, (2018)

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Progesterone for Preventing Miscarriage, Haas, *et al.,* The Cochrane Collaboration (2019)