Daniel M. Weiskopf, WSBA No. 44941
McNaul Ebel Nawrot & Helgren PLLC
600 University Street, Suite 2700
Seattle, WA 98101
(206) 467-1816
dweiskopf@mcnaul.com

Shannon Rose Selden,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
srselden@debevoise.com

Megan McGuiggan,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
801 Pennsylvania Avenue
Washington, DC 20004
mmcguiggan@debevoise.com

Adam Aukland-Peck,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
aauklandpeck@debevoise.com

Molly Meegan,
pending *Pro Hac Vice*
American College of Obstetricians
and Gynecologists
409 12th Street SW
Washington, DC 20024
mmeegan@acog.org

Jessica Morris,
pending *Pro Hac Vice*
American College of Obstetricians
and Gynecologists
409 12th Street SW
Washington, DC 20024
jmorris@acog.org

Attorneys for Amici Curiae

Hon. Thomas O. Rice

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT SPOKANE

STATE OF WASHINGTON, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

No. 1:23-cv-3026-TOR

UNOPPOSED MOTION OF MEDICAL AND PUBLIC HEALTH SOCIETIES FOR LEAVE TO FILE AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS' AMENDED COMPLAINT & MOTION FOR PRELIMINARY INJUNCTION

March 30, 2023
Without Oral Argument

Proposed *amici* (as set forth in Section I below) respectfully move this Honorable Court for leave to file the attached brief as *amici curiae* in support of Plaintiffs' Amended Complaint and Motion for Preliminary Injunction. *See* ECF Nos. 3, 35. Plaintiffs and Defendants have consented to *amici* filing the attached brief.

I. IDENTITIES OF *AMICI*

Amici are leading professional organizations of physicians and public-health experts, including the leading professional societies of physicians and obstetricians-gynecologists. Specifically, *amici* include:

American College of Obstetricians and Gynecologists (ACOG): Representing more than 90% of board-certified OB/GYNs in the United States, ACOG is the nation's premier professional membership organization for obstetrician-gynecologists dedicated to access to high-quality, safe, and equitable obstetric and gynecologic care. ACOG maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. ACOG is committed to ensuring access for all people to the full spectrum of evidence-based quality reproductive health care, including abortion care, and is a leader in the effort to confront the maternal mortality crisis in the United

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

States. ACOG opposes medically unnecessary laws or restrictions that serve to delay or prevent care and the criminalization of evidence-based medicine. ACOG has previously appeared as *amicus curiae* in various courts throughout the country, and ACOG's briefs and guidelines have been cited by numerous courts as an authoritative voice of science and medicine relating to obstetric and gynecologic health care.

American Medical Association (AMA): The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state, including Washington.

Society for Maternal-Fetal Medicine (SMFM): Founded in 1977, SMFM is the medical professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies. SMFM represents more than 5,500 members who care for high-

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

risk pregnant people and provides education, promotes research, and engages in advocacy to advance optimal and equitable perinatal outcomes for all people who desire and experience pregnancy. SMFM and its members are dedicated to ensuring that all medically appropriate treatment options are available for individuals experiencing a high-risk pregnancy.

American Academy of Family Physicians (AAFP): Founded in 1947, the American Academy of Family Physicians is one of the largest national medical organizations, representing 127,600 family physicians and medical students nationwide. AAFP seeks to improve the health of the public and by supporting its members in providing continuous comprehensive health care to all.

American Academy of Pediatrics (AAP): The American Academy of Pediatrics was founded in 1930 and is a national, not-for-profit professional organization dedicated to furthering the interests of child and adolescent health. Since AAP's inception, its membership has grown from 60 physicians to over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 90 years, AAP has become a powerful voice for child and adolescent health through education, research, advocacy, and the provision of expert advice. Among other things, AAP has worked with the federal and state governments, health

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

care providers, and parents on behalf of America's adolescents to ensure the availability of effective reproductive health care.

American College of Nurse-Midwives (ACNM): The American College of Nurse-Midwives is the professional association that represents Certified Nurse-Midwives and Certified Midwives in the United States. ACNM's members provide evidence-based midwifery care for women and gender nonconforming people throughout the lifespan, with an emphasis on pregnancy, childbirth, gynecologic and reproductive health care.

American Gynecological & Obstetrical Society (AGOS): The American Gynecological & Obstetrical Society advances the health of women by providing dedicated leadership and promoting excellence in research, education and medical practice. The AGOS is an organization composed of individuals attaining national prominence in scholarship in the discipline of Obstetrics, Gynecology and Women's Health.

American Society for Reproductive Medicine (ASRM): The American Society for Reproductive Medicine is dedicated to the advancement of the science and practice of reproductive medicine. Its members include approximately 8,000 professionals.

Council of University Chairs of Obstetrics and Gynecology (CUCOG): The Council of University Chairs of Obstetrics and Gynecology

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

was established for the charitable and educational purposes of promoting excellence in medical education in the fields of Obstetrics and Gynecology. Today, the organization promotes and supports leadership development of current and future chairs, and encourages excellence in medical student, resident, and fellowship training; clinical practice; research; and advocacy in women's health. CUCOG provides a forum for chairpersons to address issues relevant to academic obstetrics and gynecology, and provides opportunities to share ideas and network with colleagues.

North American Society for Pediatric and Adolescent Gynecology (NASPAG): The mission of the North American Society for Pediatric and Adolescent Gynecology is to provide multidisciplinary leadership in education, research and gynecologic care to improve the reproductive health of youth. NASPAG pursues scientific and educational goals including serving and being recognized as the leader in pediatric and adolescent gynecology education, research and clinical care, conducting and encouraging multidisciplinary and inter-professional programs of medical education and research in the field, and advocating for the reproductive well-being of children and adolescents and the provision of unrestricted, unbiased and evidence-based practices.

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

Society of General Internal Medicine (SGIM): The Society of General Internal Medicine is a member-based international association of over 3,600 of the world's leading academic general internists, who are dedicated to improving access to care for vulnerable populations, eliminating health care disparities and enhancing medical education. The members of the Society advance the practice of medicine through their commitment to providing comprehensive, coordinated, and cost-effective care to adults, educating the next generation of outstanding physicians, and conducting cutting-edge research to improve quality of care and clinical outcomes of all patients.

Society of Gynecologic Oncology (SGO): The Society of Gynecologic Oncology contributes to the advancement of women's cancer care by encouraging research, providing education, raising standards of practice, advocating for patients and members, and collaborating with domestic and international organizations.

Society of Gynecologic Surgeons (SGS): The Society of Gynecologic Surgeons' mission is to promote excellence in gynecologic surgery through acquisition of knowledge and improvement of skills, advancement of basic and clinical research, and professional and public education.

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

Society of OB/GYN Hospitalists (SOGH): The Society of OB/GYN Hospitalists is a rapidly growing group of physicians, midwives, nurses, physician assistants and other individuals in the health care field who support the OB/GYN Hospitalist model. SOGH is dedicated to improving outcomes for hospitalist women and supporting those who share this mission. SOGH's vision is to shape the future of OB/GYN by establishing the hospitalist model as the care standard.

Washington State Medical Association (WSMA): The Washington State Medical Association ("WSMA") is the statewide association of physicians, surgeons, and physician assistants, with over 12,000 members. WSMA provides physician-driven, patient-focused advocacy as a knowledgeable and interested party in matters impacting the practice of medicine and the availability of health services for patients. WSMA works with Washington's lawmakers on legislation and has participated in court cases as a party and as amicus curiae on issues affecting the practice of medicine.

II. ANALYSIS

A "district court has broad discretion to appoint *amici curiae*." *Hoptowit v. Ray*, 682 F.2d 1237, 1260 (9th Cir. 1982), *abrogated on other grounds by Sandin v. Conner*, 515 U.S. 472 (1995).

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

The "classic role" of *amici curiae* is "assisting in a case of general public interest, supplementing the efforts of counsel, and drawing the court's attention to law that escaped consideration." *Miller-Wohl Co. v. Comm'r of Labor & Indus.*, 694 F.2d 203, 204 (9th Cir. 1982). "District courts frequently welcome *amicus* briefs from non-parties concerning legal issues that have potential ramifications beyond the parties directly involved or if the *amicus* has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide." *Chong Yim* v. *City of Seattle*, No. C18-0736-JCC, 2018 WL 5825965, at *1 (W.D. Wash. Nov. 7, 2018) (internal quotations and citation omitted).

Amici seek to file a brief in this case because they have significant interest in the issues involved and ensuring that the safety of medication abortion is correctly understood. Collectively, *amici* represent hundreds of thousands of American physicians and other health professionals, including thousands of physicians in the Plaintiff States. *Amici* are well-versed in mifepristone's safety and efficacy given their experience as practicing medical professionals or working closely with the same. It is in *amici*'s interest to protect access to vetted, safe medications, both as a matter of policy and as a matter of practice. Ensuring access to evidence-based health care and promoting healthcare policy that improves patient health is central

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

to each of *amici*'s missions. *Amici* believe that all patients are entitled to treatment that is medically and scientifically sound without unnecessary barriers that are not medically justified. Additionally, *amici* have a strong interest in ensuring that legal decisions are based on sound scientific evidence. *Amici* therefore seek to file this brief to provide a medical perspective on the issues in this case, with a specific focus on the real-world practice of medicine. The proposed brief seeks to demonstrate mifepristone's proven safety and efficacy.

Amici will provide this Court with a unique medical and scientific perspective and data to help contextualize and resolve the present issues, and may provide supplemental authority and argument beyond that advanced by Plaintiffs. Specifically, *amici* will provide and cite scientific and medical data not present in the parties' briefs, and will also offer the perspective of medical professionals who both prescribe and monitor the effects of mifepristone, drawn from real-world experience and peer-reviewed studies. This information is highly relevant to the Court's determination of whether the Food & Drug Administration should remove the January 2023 restrictions (i.e., the "REMS," as defined in the brief attached) on mifepristone, as well as to the balance of the equities and the public interest in the requested injunction.

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

Accordingly, *amici* respectfully request that the Court enter the attached proposed order and grant leave to file the attached proposed brief.

DATED this 24th day of March 2023.

McNAUL EBEL NAWROT & HELGREN PLLC

By: s/Daniel M. Weiskopf
Daniel M. Weiskopf, WSBA No. 44941

600 University Street, Suite 2700
Seattle, Washington 98101
(206) 467-1816
dweiskopf@mcnaul.com

Shannon Rose Selden,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
(212) 909-6082
srselden@debevoise.com

Megan McGuiggan,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
801 Pennsylvania Avenue
Washington, DC 20004
(202) 383-8087
mmcguiggan@debevoise.com

Adam Aukland-Peck,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
(212) 909-6703
aauklandpeck@debevoise.com

Molly Meegan,
pending *Pro Hac Vice*
American College of Obstetricians and Gynecologists
409 12th Street SW
Washington, DC 20024
(202) 638-5577
mmeegan@acog.org

Jessica Morris,
pending *Pro Hac Vice*
American College of Obstetricians and Gynecologists
409 12th Street SW
Washington, DC 20024
(202) 638-5577
jmorris@acog.org

Attorneys for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record who receives CM/ECF notification.

DATED this 24th day of March, 2023.

By: s/Daniel M. Weiskopf
Daniel M. Weiskopf, WSBA No. 44941

LAW OFFICES OF
McNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

Daniel M. Weiskopf, WSBA No. 44941
McNaul Ebel Nawrot & Helgren PLLC
600 University Street, Suite 2700
Seattle, WA 98101
(206) 467-1816
dweiskopf@mcnaul.com

Hon. Thomas O. Rice

Shannon Rose Selden,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
(212) 909-6082
srselden@debevoise.com

Megan McGuiggan,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
801 Pennsylvania Avenue
Washington, DC 20004
(202) 383-8087
mmcguiggan@debevoise.com

Adam Aukland-Peck,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
(212) 909-6703
aauklandpeck@debevoise.com

Molly Meegan,
pending *Pro Hac Vice*
American College of Obstetricians
and Gynecologists
409 12th Street SW
Washington, DC 20024
(202) 638-5577
mmeegan@acog.org

Jessica Morris,
pending *Pro Hac Vice*
American College of Obstetricians
and Gynecologists
409 12th Street SW
Washington, DC 20024
(202) 638-5577
jmorris@acog.org

Attorneys for Amici Curiae

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT SPOKANE

STATE OF WASHINGTON, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

No. 1:23-cv-3026-TOR

BRIEF OF AMICI CURIAE MEDICAL AND PUBLIC HEALTH SOCIETIES IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

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LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

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Other Authorities

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

I. INTERESTS OF *AMICI CURIAE*

Amici curiae are leading medical and public health societies representing physicians, clinicians, and public health professionals who serve patients in Washington and nationwide. Among other organizations, they include the American College of Obstetricians and Gynecologists ("ACOG"), the nation's leading organization of physicians who provide health services unique to people seeking obstetric or gynecologic care; the American Medical Association ("AMA"), the largest professional association of physicians, residents, and medical students in the country; and the Society for Maternal-Fetal Medicine ("SMFM"), the professional society for maternal-fetal medicine subspecialists, who are obstetricians with additional training in high-risk pregnancies.[1]

Amici believe that all patients are entitled to prompt, complete, and unbiased healthcare that is medically and scientifically sound. Ensuring access to evidence-based healthcare and promoting policy that improves patient health are central to *amici*'s missions. *Amici* submit this brief to explain that mifepristone is exceedingly safe and effective and that the Risk Evaluation and

[1] Additional *amici* are described in the Motion for Leave.

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

Mitigation Strategy's ("REMS") restrictions on mifepristone currently in place, described *infra*, are medically unnecessary.

Continuing to unnecessarily restrict access to mifepristone will deprive patients of lifesaving care and set healthcare back by decades. Mifepristone has undergone rigorous testing and review and has been approved for use in the United States for over 20 years. Accordingly, *amici* have a strong interest in ensuring that the science surrounding mifepristone's safety and efficacy is understood and access to this critical medication is not unduly restricted.

II. PRELIMINARY STATEMENT

Medication abortion including mifepristone is safe and effective—as evidenced by over two decades of medical studies and vast data collection. The Food & Drug Administration ("FDA") based its initial approval in 2000 on robust evidence that showed mifepristone was extremely safe. The evidence collected and studies performed since then have only confirmed mifepristone's safety. Serious side effects occur in ***less than 1%*** of patients, and major adverse events—significant infection, blood loss, or hospitalization—occur in ***less than 0.3%*** of patients. The risk of death is almost non-existent. Medication abortion also offers advantages over

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

procedural abortion because it is less invasive and more accessible, particularly to underserved patient populations.

Mifepristone is also frequently used for the safe and effective management of miscarriage, which can be dangerous and life threatening if left untreated. Recent research has shown that use of mifepristone, in conjunction with misoprostol, improves safety outcomes for patients experiencing pregnancy loss who are treated through medication abortion.

While some progress has been made to increase mifepristone's availability, the FDA continues to limit its accessibility through the REMS without justification. The REMS includes: (1) provider-certification restrictions, mandating that providers be specially certified to prescribe mifepristone; (2) authorization forms requiring the patient to recognize they are "end[ing]" their pregnancy by taking mifepristone; and (3) regulations requiring special pharmacy certification. REMS programs do not apply by default and are used only where necessary to keep patients safe—circumstances not present here. The REMS at issue is only a barrier to access and does nothing to protect patients given mifepristone's proven safety. The relief sought in the Amended Complaint should be granted.

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

A. Mifepristone Is Safe and Effective.

The most common method of medication abortion in the United States is a two-drug regimen: mifepristone is taken in conjunction with misoprostol to end an early pregnancy by emptying the contents of the uterus.[2] Mifepristone followed by misoprostol is used both to induce abortion and to manage miscarriage or early pregnancy loss, which can be life threatening.[3]

There is overwhelming scientific evidence supporting mifepristone's safety and efficacy. The REMS creates medically unnecessary burdens for providers and patients seeking abortion or miscarriage management, particularly in areas where care is already limited.

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[2] Mifepristone-misoprostol regimens are more effective than misoprostol-only regimens. ACOG Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation*, at 4 (Oct. 2020).

[3] *See* ACOG Practice Bulletin No. 200, *Early Pregnancy Loss* (Nov. 2018, *reaff'd* 2021).

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

1. Mifepristone Has Been Thoroughly Studied and Is Conclusively Safe.

Decades of evidence demonstrate that medication abortion is safe and effective, with exceptionally low rates of major adverse events. Mifepristone's safety profile is on par with, or safer than, over-the-counter painkillers like ibuprofen, which more than 30 million Americans take in any given day.[4] Viagra—which is widely prescribed and *not* subject to a comparable REMS program—carries a substantially higher risk of death than mifepristone.[5]

The FDA first approved the use of mifepristone over 20 years ago after determining, based on extensive clinical trials and sound research, that mifepristone is safe, effective, and that the health benefits outweighed the known risks.[6] In the decades since, hundreds of systemic reviews, trials, and

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[4] *See* R. Morgan Griffin, *Making the Decision on NSAIDs*, WEBMD (Oct. 17 2005), https://www.webmd.com/arthritis/features/making-decision-on-nsaids.

[5] Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA 590, 590–93 (Feb. 2, 2000).

[6] *See* 2000 FDA Approval Memo, Compl. Ex. D, ECF No. 1-5; Development & Approval Process: Drugs, FDA (Aug. 8, 2008).

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

observational studies have confirmed the safety and effectiveness of mifepristone up to the 10-week gestational period.[7] As a result, medication abortion is a commonly preferred form of abortion care,[8] accounting for most abortions in the U.S. as of 2020,[9] while maintaining an exceptionally low rate of complications.

Studies have repeatedly concluded that even minor complications arising from medication abortion are rare—yet the REMS inexplicably remains in place without compelling medical justification.[10] Major adverse

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[7] *See* 2016 FDA Mifeprex Summary Review, Compl. Ex. J, ECF No. 1-11, at 6; ACOG Practice Bulletin No. 225, *supra* note 2.

[8] *See* ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report: Mifepristone U.S. Post-Marketing Adverse Events Summary through 6/30/2021*, UNIV. OF CAL., S.F. 1, 1–3 (Nov. 2022).

[9] *See* Rachel Jones et al., *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INST. (Dec. 21, 2022).

[10] *See* Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States*, NAT'L ACADS. PRESS 45, 58 (2018); Dina

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

events—which include hospitalization and serious infection or bleeding—are "exceedingly rare," occurring in approximately 0.3% of cases.[11] Studies have shown an even smaller number, between 0.014% and 0.07% of patients, experience serious infection.[12] The FDA has made clear that the same

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Abbas et al., *Outpatient Medical Abortion Is Safe and Effective through 70 Days Gestation*, 92 CONTRACEPTION 197 (2015).

[11] Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications after Abortion*, 125 OBSTETRICS & GYNECOLOGY 175, 175–83 (2015) (study of over 55,000 abortions found a major complications rate of 0.23% – 0.31% for medication abortion; 0.16% for procedural abortion (i.e., abortion by aspiration)); *see also* Compl. Ex. J, *supra* note 7; FDA Ctr. for Drug Eval. & Research, *Medical Review, Application No. 020687Orig1s020* at 56 (Mar. 29, 2016) ("2016 FDA Medical Review"); ANSIRH, *U.S. Studies on Medication Abortion without In-Person Clinician Dispensing of Mifepristone*, UNIV. OF CAL., S.F. (Oct. 2021); Elizabeth G. Raymond et al., *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 CONTRACEPTION 26, 30 (2013).

[12] 2016 FDA Medical Review, *supra* note 11, at 53–54.

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

complications can be observed following a miscarriage, procedural abortion, or medication abortion—i.e., any time a pregnant uterus is emptied—and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [infections, bleeding, or death] has been established."[13]

The risk of death from medication abortion is near zero.[14] A 2019 analysis of FDA data by the University of San Francisco Medical Center over an 18-year period found only 13 deaths possibly or probably related to medication abortion, yielding an approximate mortality rate of 0.00035%.[15] Indeed, there is a greater risk of complications or mortality for procedures like wisdom tooth removals, tonsillectomies, colonoscopies, or from the use of

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[13] Mifeprex Labeling, Compl. Ex. M, ECF No. 1-14 at 2, 5.

[14] *See* Katherine Kortsmit et al., *Abortion Surveillance – United States, 2019*, 70 CDC MORBIDITY & MORTALITY WKLY. REP. 1, 7, 29 tbl.15 (Nov. 26, 2021); Suzanne Zane et al., *Abortion-Related Mortality in the United States, 1998–2010*, 126 OBSTETRICS & GYNECOLOGY 258, 261 (2015).

[15] ANSIRH, *Analysis of Medication Abortion Risk and the FDA Report: Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018*, UNIV. OF CAL., S.F., 1, 1–2 (Apr. 2019).

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

Viagra, than by any abortion method (medication or procedural).[16] Studies have associated Viagra with 4.9 deaths per 100,000 prescriptions,[17] demonstrated that death from colonoscopy occurs in about 0.03% of cases,[18] and found that the "risk of death associated with childbirth [is] approximately 14 times higher" than the risk associated with an abortion.[19] Put simply, medication abortion is among the safest medical interventions in any category, related to pregnancy or not.

Accordingly, mifepristone's use has only expanded since its initial approval. It is now used for a variety of other health purposes, including to

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[16] ANSIRH, *Safety of Abortion in the United States*, UNIV. OF CAL., S.F. 1, 1–2 (Dec. 2014); ASGE Standards of Practice Committee, *Complications of Colonoscopy*, 74 AM. SOC'Y FOR GASTROINTESTINAL ENDOSCOPY 745, 745 (2011).

[17] Mitka, *supra* note 5.

[18] ASGE Standards of Practice Committee, *supra* note 16, at 747.

[19] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTETRICS & GYNECOLOGY 215, 216 (2012).

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

treat uterine fibroids and endometriosis,[20] to reduce the duration of bleeding or hemorrhaging during certain serious pregnancy complications,[21] to and treat patients with Cushing's Syndrome.[22]

Mifepristone's safety was evident when it was first approved and has not changed for decades after rigorous and ongoing scientific study, testing, and monitoring of post-market data.[23] There is no compelling medical basis to justify continuing its REMS.

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[20] *See* Mario Tristan et al., *Mifepristone for Uterine Fibroids*, COCHRANE DATABASE SYST. REV. (Aug. 2012); Y. X. Zhang, *Effect of Mifepristone in the Different Treatments of Endometriosis*, CLIN. & EXP. OBSTETRICS & GYNECOLOGY 350, 350–53 (2016).

[21] *See, e.g.*, Yanxia Cao et al., *Efficacy of Misoprostol Combined with Mifepristone on Postpartum Hemorrhage and Its Effects on Coagulation Function*, 13 INT. J. CLIN. EXP. MED. 2234, 2234–40 (2020).

[22] *See* Farah H. Morgan & Marc J. Laufgraben, *Mifepristone for Management of Cushing's Syndrome*, 33 PHARMACOTHERAPHY 319, 319–29 (2013).

[23] *See* 2016 FDA Medical Review, *supra* note 11, at 8.

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

2. Medication Abortion Offers Comparative Benefits Against Other Forms of Abortion.

Procedural abortion (sometimes referred to as a "surgical abortion," though it does not involve "surgery" as that term is generally understood) is not an adequate substitute for medication abortion. While both methods are exceedingly safe, procedural abortion and medication abortion are not equivalent in terms of patient care—procedural abortion can be intrusive in a way that medication abortion is not. In *amici*'s experience, patients choose medication over procedural abortion for many reasons, including a desire to avoid physical contact or the distress of having instruments inserted into the vagina due to prior sexual assault or trauma; a desire to be able to have the abortion in the company of loved ones; or simply a desire for privacy. Patients experiencing miscarriage may choose a mifepristone-misoprostol regimen for the same reasons, rather than an in-clinic procedure.

Additionally, medication abortion may be the only option reasonably accessible to patients given the lack of available reproductive care and restrictions many states have imposed or seek to impose on procedural abortion. This is especially true for patients who are from historically marginalized populations, are low income, or are living in rural areas that are

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600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

long distances from medical facilities or otherwise lack trained clinicians.[24] Even when medical facilities are reasonably accessible to patients, a significant number that provide abortion care offer only medication abortion.[25] For patients with certain medical conditions, disabilities, or other extenuating circumstances (such as a lack of access to child care or the inability to take time off work or travel long distances), medication abortion is the safest and most accessible option. Unnecessarily restricting access to mifepristone through the REMS only exacerbates these issues—without reason—for the most vulnerable populations.

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[24] *See* March of Dimes, *Maternity Care Deserts Report* (Oct. 2022), https://www.marchofdimes.org/maternity-care-deserts-report; Lyndsey S. Benson et al., *Early Pregnancy Loss in the Emergency Department, 2006–2016*, 2 J. AM. C. EMERGENCY PHYSICIANS OPEN e12549 (2021); Anthony Mazzeo et al., *Delivery of Emergency Care in Rural Settings,* ACEP EMERGENCY MEDICINE PRAC. COMM. (July 2017).

[25] *See* Rosalyn Schroeder et al., *Trends in Abortion Care in the United States, 2017–2021*, ANSIRH, UNIV. OF CAL., S.F. (2022).

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

B. Restricting Mifepristone Access without Justification Harms Patients.

Unnecessarily restricting access to mifepristone has profound impacts on patients, providers, and our healthcare system on a macro-level in ways that are both related and unrelated to abortion.

For instance, mifepristone is frequently used in the management of miscarriages. Worldwide, one in six recognized pregnancies ends in miscarriage,[26] and when accounting for unrecognized pregnancies (e.g., where the patient is not aware they are pregnant), that number rises to 25%.[27] Without proper care and intervention when needed, miscarriage carries risks of

[26] Siobhan Quenby et al., *Miscarriage Matters: The Epidemiological, Physical, Psychological, and Economic Costs of Early Pregnancy Loss*, 397 LANCET 1658, 1658–67 (2021).

[27] Xiaobin Wang et al., *Conception, Early Pregnancy Loss, and Time to Clinical Pregnancy: A Population-Based Prospective Study*, 79 FERTILITY & STERILITY 577, 577–84 (2003).

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

hemorrhage, sepsis, and death.[28] Pregnant people of color are more likely to experience early pregnancy loss or miscarriage.[29] Restricting the use and availability of mifepristone for miscarriage management deprives patients, including a disproportionate amount of patients of color, of the ability to receive prompt, effective, and critical medical care.

The same is true for induced medication abortions. Abortion care can be lifesaving, especially for people suffering from serious health conditions or complications related to pregnancy. Medication abortion's relative availability makes it more accessible to patients who otherwise face challenges accessing medical care, including low-income patients, rural patients, and patients of color[30]—the very people who are most likely to experience

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[28] Robin R. Wallace et al., *Counseling Women with Early Pregnancy Failure: Utilizing Evidence, Preserving Preference*, 81 PATIENT ED. & COUNSELING 454, 454–61 (2010).

[29] *See* Benson et al., *supra* note 24.

[30] *See* Christine Dehlendorf & Tracy Weitz, *Access to Abortion Services: A Neglected Health Disparity*, 22 J. HEALTH CARE FOR THE POOR & UNDERSERVED 415, 418 (2011); Rachel Jones et al., *COVID-19 Abortion Bans*

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600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

maternal morbidity and more likely to die from pregnancy-related complications.[31]

Even under the best of circumstances, pregnancy and childbirth impose significant physiological changes that can exacerbate underlying preexisting conditions and can severely compromise health, sometimes permanently.[32] Pregnancy, particularly when coupled with a preexisting condition, can

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and Their Implications for Public Health, 52 PERSPS. ON SEXUAL AND REPROD. HEALTH 65, 66–67 (2020); Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, GUTTMACHER INST. (May 2016); Ctr. for Medicare & Medicaid Serv., *CMS Rural Health Strategy*, at 2 (2018).

[31] *See* Ctr. for Medicare & Medicaid Serv., *Advancing Rural Maternal Health Equity*, at 1 (2022); Juanita Chinn et al., *Health Equity among Black Women in the United States*, 30 J. WOMEN'S HEALTH 212, 215 (2021).

[32] *See, e.g.*, ACOG Practice Bulletin No. 222, *Gestational Hypertension and Preeclampsia* (June 2020); ACOG Practice Bulletin No. 183, *Postpartum Hemorrhage* (Oct. 2017); Alison G. Cahill et al., *Obstetric Care Consensus: Placenta Accreta Spectrum*, 132 OBSTETRICS & GYNECOLOGY e259 (2018).

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600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

quickly evolve into a life-threatening situation necessitating critical care, including abortion. This phenomenon is particularly apparent in the U.S., which has the highest maternal mortality rate among developed countries, with rates increasing the most for Black and Hispanic patients.[33]

The harms of unnecessarily restricting mifepristone access disproportionately impact these underserved patient populations. For instance, though people of all races and ethnicities take mifepristone for miscarriage management, Black patients are more likely to need such care. Miscarriage is more common among groups impacted by social inequities, such as pregnant people who are Black, poor, or exposed to environmental pollutants.[34] Black patients are also at an increased risk of experiencing major depression

[33] Roosa Tikkanen et al., *Maternal Mortality and Maternity Care in the United States Compared to 10 Other Developed Countries*, COMMONWEALTH FUND (Nov. 18, 2020).

[34] *See generally* Quenby et al., *supra* note 26.

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

following a miscarriage,[35] the negative outcomes for which are mitigated by providers who empower patient autonomy by offering management strategies, like mifepristone, that are safe and effective. Restricting mifepristone imposes unnecessary burdens on access to essential reproductive healthcare, particularly for the country's most vulnerable patient populations.

C. The REMS at Issue Harms Patients.

The REMS harms patients by imposing logistical and administrative hurdles to health care without any compelling reason. First, the Patient Agreement Form is medically unnecessary and duplicative of informed consent. Such forms are particularly burdensome when compared to protocols for alternative, less-preferred forms of miscarriage management—i.e., misoprostol-alone management—which have a similar safety profile but do *not* require patients to sign any form. Patients are, confusingly, required to jump through this additional, repetitive, and unnecessary administrative hurdle to receive the same treatment via a more effective regimen (involving

[35] *See* Jade Shorter et al., *Racial Disparities in Mental Health Outcomes Among Women with Early Pregnancy Loss*, 137 OBSTETRICS & GYNECOLOGY 156 (2021).

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600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

mifepristone). At minimum, any mandatory forms should be amended to be tailored to the specific medical needs of the patient. The present form requires patients to attest that they "have decided to take mifepristone and misoprostol to *end* [their] pregnancy,"[36] which is not accurate in all circumstances. During miscarriage, pregnancy loss is already in process or has already occurred in many cases. Requiring miscarriage patients to attest to terminating a pregnancy is confusing, at best, and harmful, at worst, due to the prevalence of abortion stigma.[37] It could also put patients who seek miscarriage care in jurisdictions hostile to reproductive care and abortion access in legal jeopardy.

Second, the clinician "Certified Provider Requirement" does not meaningfully benefit patients. Clinicians who commonly provide early pregnancy care, such as emergency medicine specialists, obstetrician-gynecologists, family physicians, women's health nurse practitioners, and

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[36] *See* Mifepristone Patient Agreement Form, Compl. Ex. Q, ECF No. 1-18 (emphasis added).

[37] *See generally* Alison Norris et al., *Abortion Stigma: A Reconceptualization of Constituents, Causes, and Consequences*, 21 WOMEN'S HEALTH ISSUES S49 (2011).

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600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

certified nurse midwives are already trained in pregnancy dating, ectopic risk factors, and general care, rendering the additional certification redundant and unnecessary. This requirement does nothing to improve care, creating yet another administrative burden discouraging clinicians from using mifepristone and complicating their ability to do so.[38] Clinicians may also be wary of undergoing the mifepristone certification process due to the stigma and potential legal ramifications associated with providing abortions and the violence and harassment they risk as a result,[39] even if those clinicians prescribe mifepristone solely for miscarriage management.[40] It is not surprising that providers have described the REMS as a barrier to integrating

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[38] *See* Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 644 (2022).

[39] *See id.*; *see also* Danielle Calloway et al., *Mifepristone Restrictions and Primary Care: Breaking the Cycle of Stigma through a Learning Collaborative Model in the United States*, 104 CONTRACEPTION 24, 25 (2021).

[40] *See* Donley, *supra* note 38.

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

mifepristone in their practice,[41] whether for induced abortion, miscarriage, or other treatments.

Finally, *amici* expect that the "Pharmacy Certification" requirement is harmful for the same reasons as provider certification requirements. Pharmacies are already well-equipped to dispense mifepristone without special certification.[42] Certification will force retail pharmacies to make business decisions weighing the value of distributing mifepristone against the risks—including potential unfounded litigation from anti-abortion groups and unwanted public attention, protests, or boycotts for that same reason.[43] For example, national pharmacy chain Walgreens has already indicated that it will not seek certification, and other large retail pharmacies may follow suit (again,

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[41] *See*, *e.g.*, Calloway et al., *supra* note 39; Na'amah Razon et al., *Exploring the Impact of Mifepristone's Risk Evaluation and Mitigation Strategy (REMS) on the Integration of Medication Abortion into US Family Medicine Primary Care Clinics*, 109 CONTRACEPTION 19 (2022).

[42] *Cf.* Daniel Grossman et al., *Medication abortion with pharmacist dispensing of mifepristone*, 137 OBSTETRICS & GYNECOLOGY 613 (2021).

[43] *See* Donley, *supra* note 38, at 646.

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MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

with rural patients feeling the heaviest impact).[44] Given that the misoprostol-only alternative can be accessed at *any* pharmacy regardless of certification status, this certification requirement actually incentivizes pharmacies to carry the *less preferred* regimen that offers no safety benefit to patients. Pharmacies that do not seek certification (after weighing the considerations above) will be unable to provide their customers the more effective regimen for medication abortion and will be limited in the types of miscarriage management they can offer—ultimately harming patients by restricting the availability of a safe medication.

In sum, eliminating the REMS expands access to a safe and effective drug with virtually no other impact. Removing unnecessary barriers to access this safe, effective, and commonly-used drug will only serve to help patients and the providers who care for them in the long term.

III. CONCLUSION

For these reasons and those articulated in Plaintiffs' Brief, we strongly urge the Court to grant the relief sought in the Amended Complaint.

[44] *Cf. id.* at 665.

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

DATED this 24th day of March 2023.

McNAUL EBEL NAWROT & HELGREN PLLC

By: s/Daniel M.Weiskopf
Daniel M. Weiskopf, WSBA No. 44941

600 University Street, Suite 2700
Seattle, WA 98101
(206) 467-1816
dweiskopf@mcnaul.com

Shannon Rose Selden,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
(212) 909-6082
srselden@debevoise.com

Megan McGuiggan,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
801 Pennsylvania Avenue
Washington, DC 20004
(202) 383-8087
mmcguiggan@debevoise.com

Adam Aukland-Peck,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
(212) 909-6703
aauklandpeck@debevoise.com

Molly Meegan,
pending *Pro Hac Vice*
American College of Obstetricians
and Gynecologists
409 12th Street SW
Washington, DC 20024
(202) 638-5577
mmeegan@acog.org

Jessica Morris,
pending *Pro Hac Vice*
American College of Obstetricians
and Gynecologists
409 12th Street SW
Washington, DC 20024
(202) 638-5577
jmorris@acog.org

Attorneys for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that on March 24, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record who receives CM/ECF notification.

DATED this 24th day of March, 2023.

By: s/Daniel M. Weiskopf
Daniel M. Weiskopf, WSBA No. 44941

LAW OFFICES OF
MCNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816

Daniel M. Weiskopf, WSBA No. 44941
McNaul Ebel Nawrot & Helgren PLLC
600 University Street, Suite 2700
Seattle, WA 98101
(206) 467-1816
dweiskopf@mcnaul.com

Shannon Rose Selden,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
srselden@debevoise.com

Megan McGuiggan,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
801 Pennsylvania Avenue
Washington, DC 20004
mmcguiggan@debevoise.com

Adam Aukland-Peck,
pending *Pro Hac Vice*
Debevoise & Plimpton LLP
66 Hudson Boulevard
New York, NY 10001
aauklandpeck@debevoise.com

Molly Meegan,
pending *Pro Hac Vice*
American College of Obstetricians
and Gynecologists
409 12th Street SW
Washington, DC 20024
mmeegan@acog.org

Jessica Morris,
pending *Pro Hac Vice*
American College of Obstetricians
and Gynecologists
409 12th Street SW
Washington, DC 20024
jmorris@acog.org

Attorneys for Amici Curiae

Hon. Thomas O. Rice

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON
AT SPOKANE

STATE OF WASHINGTON, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

No. 1:23-cv-3026-TOR

[PROPOSED]ORDER GRANTING MOTION OF MEDICAL AND PUBLIC HEALTH SOCIETIES FOR LEAVE TO FILE AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS' AMENDED COMPLAINT AND MOTION FOR PRELIMINARY INJUNCTION

On March 24, 2023, certain medical and public health societies filed a Motion for Leave to File Amicus Brief in Support of Plaintiffs' Complaint and Motion for Preliminary Injunction. Having considered the pleadings and papers filed in connection therewith, and all other matters presented to the Court, and good cause having been shown:

It is hereby ORDERED that the Motion for Leave to File Amicus Brief in Support of Plaintiffs' Complaint and Motion for Preliminary Injunction is GRANTED. The Amicus Brief lodged is deemed filed and served.

IT IS SO ORDERED this ____ day of _____, 2023.

_____

Hon. Thomas O. Rice
United States District Judge
Eastern District of Washington

LAW OFFICES OF
McNAUL EBEL NAWROT & HELGREN PLLC
600 University Street, Suite 2700
Seattle, Washington 98101-3143
(206) 467-1816