No. 23-10362

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

v.

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

and

DANCO LABORATORIES, LLC,

On Appeal from the United States District Court for the Northern District of Texas, Amarillo Division Case No. 2:22-cv-00223-Z, Judge Matthew J. Kacsmaryk

CONSENT MOTION OF PATIENT AND PROVIDER ADVOCACY ORGANIZATIONS FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF REVERSAL

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Attorneys For Amici Curiae

CONSENT MOTION OF PATIENT AND PROVIDER ADVOCACY ORGANIZATIONS FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF REVERSAL

In accordance with the Clerk's letter of April 19, 2023, The Leukemia & Lymphoma Society and the additional patient and provider advocacy organizations listed in the Appendix (""") respectfully request leave to file an amicus brief supporting reversal of the district court's April 7, 2023 order granting Plaintiffs-Appellees' motion for preliminary injunction. Counsel for conferred with counsel for the parties by email on April 25, 2023, and all of the parties consent to this motion.

represent millions of patients across the United States who have serious health conditions and depend on FDA-approved drugs for treatment. This case implicates those patients' and their providers' interests in the continued availability of drugs that FDA has determined to be safe and effective. respectfully submit that an explanation of the impact of the district court's preliminary injunction ruling on those interests, not only vis-à-vis Mifepristone but other drugs as well, will assist this Court in deciding the appeal of that ruling.

In accordance Federal Rule of Appellate Procedure 29(a)(4)(E) and (b)(4), undersigned counsel certifies that no party's counsel authored this motion or will author 's proposed brief in whole or in part. No party, or party's counsel, made a monetary contribution intended to fund the preparation or submission of this motion or 's proposed brief. No person other than or their counsel made such a monetary contribution.

's proposed brief is attached.

Respectfully submitted,

/s/ Emily I. Gerry Emily I. Gerry egerry@akingump.com Nathan A. Brown nabrown@akingump.com Craig B. Bleifer cbleifer@akingump.com Caroline L. Wolverton cwolverton@akingump.com Oluwaremilekun O. Mehner rmehner@akingump.com Caroline D. Kessler ckessler@akingump.com Jenna H. Becker jbecker@akingump.com **AKIN GUMP STRAUSS HAUER & FELD LLP** Robert S. Strauss Tower 2001 K Street NW Washington, DC 20006 Telephone: (202) 887-4000 Fax: (202) 887-4288

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May 1, 2023

CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limit of Fed. R. App. P. 27(d)(2) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f) this document contains 235 words, and complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using 14-point Times New Roman font.

/s/ Emily I. Gerry Emily I. Gerry

CERTIFICATE OF SERVICE

I certify that on Monday, May 1, 2023 the foregoing document was served on all parties or their counsel of record through the CM/ECF.

<u>/s/ Emily I. Gerry</u> Emily I. Gerry

awareness, and providing educational resources and innovative comfort programs for children with cancer, survivors, and their families.

American Society of Clinical Oncology

The American Society of Clinical Oncology ("ASCO") is a national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO is committed to ensuring that safe and effective treatments for cancer are available to all Americans with an equitable an evidence-based approach.

American Society of Hematology

American Society of Hematology ("ASH") represents more than 18,000 clinicians and scientists worldwide committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematologic (also known as non-malignant) conditions such as sickle cell disease ("SCD"), thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. ASH believes that all individuals should have access to evidence-based, high-quality, clinically appropriate care, and the Society is committed to fostering high-quality, equitable care, transformative research, and innovative education to improve the

Cancer*Care*

Cancer is the leading national organization providing free, professional support services and information to help people manage the emotional, practical and financial challenges of cancer.

Cancer Support Community

As the largest professionally led nonprofit network of cancer support worldwide, the Cancer Support Community ("CSC") is dedicated to ensuring that all people impacted by cancer are empowered by knowledge, strengthened by action, and sustained by community. CSC delivers more than \$50 million in free support and navigation services to cancer patients and their families. CSC also conducts cutting-edge research on the emotional, psychologic, and financial journey of cancer patients and advocates at all levels of government for policies to help individuals whose lives have been disrupted by cancer.

Council of Medical Specialty Societies

The Council of Medical Specialty Societies ("CMSS") is a coalition of 50 specialty societies representing more than 800,000 physicians across the house of medicine. CMSS works to catalyze improvement through convening, collaborating, and collective action. Together, CMSS addresses critical issues across specialties that influence the future of healthcare and the patients they serve.

Epilepsy Foundation

The Epilepsy Foundation is the leading national, voluntary health organization representing over 3.4 million Americans with epilepsy and seizures. Timely access to quality, affordable, physician-directed care including access to anti-seizure medications is vital for people with epilepsy. Uncontrolled seizures can lead to disability, injury, and death. Epilepsy medications are the most common, cost-effective treatment for controlling and/or reducing seizures.

Friends of Cancer Research

lives while the Society works to stop MS in its tracks, restore what has been lost and end MS forever.

National Organization for Rare Disorders

National Organization for Rare Disorders ("NORD") is a unique federation of voluntary health organizations dedicated to helping people with rare diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services. NORD believes that all individuals with a rare disease should have access to quality and affordable health care that is best suited to meet their medical needs.

RESOLVE: The National Infertility Association

RESOLVE: The National Infertility Association, established in 1974, is dedicated to ensuring that all people challenged in their family building journey reach resolution through being empowered by knowledge, supported by community, united by advocacy, and inspired to act. RESOLVE is the oldest and largest patient advocacy No. 23-10362

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

ALLIANCE FOR HIPPOCRATIC MEDICINE, et al.,

Plaintiff-Appellees,

v.

U.S. FOOD AND DRUG ADMINISTRATION, et al.,

Defendant-Appellants,

and

DANCO LABORATORIES, LLC,

Intervenor-Appellant.

On Appeal from the United States District Court for the Northern District of Texas, Amarillo Division Case No. 2:22-cv-00223-Z, Judge Matthew J. Kacsmaryk

AMICUS BRIEF OF PATIENT AND PROVIDER ADVOCACY ORGANIZATIONS IN SUPPORT OF REVERSAL

*Emily I. Gerry [*counsel of record*] Nathan A. Brown Craig B. Bleifer Caroline L. Wolverton Oluwaremilekun O. Mehner Caroline D. Kessler Jenna H. Becker AKIN GUMP STRAUSS HAUER & FELD LLP Robert S. Strauss Tower 2001 K Street, N.W. Washington, DC 20006 202-887-4107

Attorneys For Amici Curiae

CERTIFICATE OF INTERESTED PERSONS

No. 23-10362, Alliance for Hippocratic Medicine, et al. v. U.S. Food and Drug Administration, et al.

The undersigned counsel of record certifies that—in addition to the persons and entities listed in the Certificates of Interested Persons filed in this matter—the following listed persons and entities, as described in the fourth sentence of Fifth Circuit Rule 28.2.1, have an interest in the outcome of this case. These representations are made in order that the Judges of this Court may evaluate possible disqualification or recusal.

Amici¹

The Leukemia & Lymphoma Society American Cancer Society American Cancer Society Cancer Action Network American Childhood Cancer Organization American Society of Clinical Oncology American Society of Hematology American Urological Association Arthritis Foundation Cancer*Care* Cancer Support Community Council of Medical Specialty SocietieFaFa.35MCID 3 s1 -11.248 S9O (M)4.p.4 (ocd.6 (e)12.1 **Counsel for** *Amici* AKIN GUMP STRAUSS HAUER & FELD LLP Robert S. Strauss Tower 2001 K Street NW Washington, DC 20006

Respectfully submitted,

/s/ Emily I. Gerry Emily I. Gerry

Counsel for Amici

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INTEREST OF AMICI CURIAE

The Leukemia & Lymphoma Society and additional patient and provider advocacy organizations listed in the Appendix represent millions of patients across the United States who have serious health conditions and depend on drugs approved by the Food and Drug Administration ("FDA") for treatment. For many of these patients, their very lives depend on the availability of those medications.

In this brief, *Amici* explain patients' reliance on FDA's expert and detailed drug approval and market removal processes, as established by Congress, and the clinical risks presented by injecting uncertainty into the ongoing availability of FDA-approved drugs. These patient interests are an important part of the public interest component of the preliminary injunction analysis. *Amici* respectfully submit, therefore, that an explanation of the impact of the district court's preliminary injunction ruling on those interests, not only vis-à-vis Mifepristone but as to all FDA approved drugs, will assist this Court in deciding the appeal of the ruling under

their counsel contributed financial support intended to fund the preparation or submission of this brief.

SUMMARY OF ARGUMENT

The district court's preliminary injunction ruling and the flawed rationale underlying it jeopardize patients' access to drugs on which their health and, in some cases, their lives depend. Absent reversal, the ruling would render the drug Mifepristone largely unavailable to patients. But the adverse implications of the district court's decision extend far beyond one drug. If allowed to stand, this decision would cast uncertainty over the continued availability of *all* FDA-approved drugs, any of which could be challenged by litigants who disagree that patients should have access to the drug, whether for business reasons, ideological reasons, or actual clinical disagreement with FDA. Case: 23-10362 Document: 274-2 Page: 11 Date Filed: 05/01/2023

safety and effectiveness from "adequate and well-controlled investigations." 21 U.S.C. § 355(c)(1)(A) and (d); *see also id.* §§ 321(p), 331(d), 355(a).⁴

To obtain FDA approval of a new drug, the drug's sponsor undergoes a lengthy and resource intensive development process that includes: laboratory testing; preclinical (animal) testing; several phases of clinical studies; chemistry, manufacturing, and controls; and product labeling information for prescribers.⁵ Drug sponsors must show that the drug's benefits outweigh any potential risks. Under 21 U.S.C. § 355(d), the agency "shall implement a structured risk-benefit assessment framework in the new drug approval process to facilitate the balanced consideration of benefits and risks, a consistent and systematic approach to the discussion and regulatory decision-making, and the communication of the benefits and risks of new drugs."⁶

⁴ "Well-controlled clinical investigations" include "clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof." 21 U.S.C. § 355(d). Medications that are considered to be biologics are subject to licensure by FDA under the Public Health Service Act. *See* 42 U.S.C. § 262(j). A biologic is defined as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings." 21 U.S.C. § 355(i). FDA considers biologics to be a subset of drugs, and for purposes of this brief, we refer to both drugs and biologics as "drugs" for simplicity.

⁵ See 21 C.F.R. § 314.50; see also FDA, FDA's Drug Review Process: Continued (Aug. 24, 2015), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-processcontinued.

⁶ FDA must also consult patient advocacy groups during the periodic (a)JEMC /Span AMCdv/odi-2 (i)-2 (on-)-

FDA recognizes the central role that patients play in this balancing:

[I]t is important to maximize the potential for such clinical trials to provide interpretable scientific evidence about the drug's benefits and risks beginning from the earliest stages of drug development. Patient contribution is optimized in small sample size studies by minimizing bias and maximizing precision with trial design features such as randomization, blinding, enrichment procedures, and adequate trial duration.⁷

The agency has long utilized multiple avenues to incorporate patient and physician

input in the drug review process.⁸ For example, it consults with expert advisory

committees that include patients and physicians to obtain independent advice and

recommendations on marketing approval of drug products.⁹ Indeed, patients and

physicians affiliated with Amici frequently share their perspectives on drug

applications through these mechanisms.

^{(3); 379}j–43(f)(1) & (3); & 379j-53(f)(1) (requiring agency consultation with representatives of patient and consumer advocacy groups in developing recommendations for the every-five-year reauthorization of the Prescription Drug User Fee Act ("PDUFA"), the Generic Drug User Fee Amendments ("GDUFA"), and the Biosimilar User Fee Act ("BsUFA")).

⁷ See FDA Benefit-Risk Assessment, supra note 3, at 11.

⁸ See FDA, Development & Approval Process / Drugs (Aug. 8, 2022), <u>https://www.fda.gov/drugs/</u> <u>development-approval-process-drugs</u>.

⁹ See FDA, New Drug Application (NDA) (Jan. 21, 2022), <u>https://www.fda.gov/drugs/types-applications/new-drug-application-nda</u>. Similarly, the agency's Patient Focused Drug Development ("PFDD") initiative facilitates programs such as public meetings that allow patients, caregivers, and other stakeholders to share their perspectives and further inform the drug development process. See FDA, FDA-led Patient-Focused Drug Development (PFDD) Public Meetings (Feb. 23, 2023), <u>https://www.fda.gov/industry/prescription-drug-user-fee-amendments/fda-led-patient-focused-drug-development-pfdd-public-meetings</u>.

B. FDA's Withdrawal Procedure Is a Careful, Reasoned Process Heavily Focused on Patient Impact

After a drug is approved, FDA continues to monitor its real-world performance, including safety, to ensure that the drug remains safe and effective for its intended uses according to the conditions under which it was approved.¹⁰ Patients, in particular, play a critical role in the agency's monitoring process. For example, patients and their clinicians are the principal source of post-approval adverse drug experience reports and are therefore crucial to the agency's ongoing understanding of a drug's safety and efficacy. Moreover, patient participation in post-approval clinical studies directly informs the agency's determination of any drug-specific post-approval requirements and conditions, including post-approval studies, labeling warnings, and other protections necessary to ensure safe and effective use of the drug.¹¹

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the conditions it is intended to treat, and the patient population reliant upon the therapy. When a drug is already on the market, FDA gives additional weight to how a change in indication, or removal of the drug from the market, would impact clinical practice and patient care. Depending on the agency's analysis of new information, it may determine that an additional warning or precaution is appropriate.¹² In other

The district court disregarded this robust and well-established process through which drugs are reviewed for marketing approval, necessary adjustments are made to labeling or other conditions of distribution as needed, and drugs are removed from the market by FDA when warranted. The court also failed to account for the fact that FDA specialists with technical expertise in their respective fields undertake this balancing of complex scientific data bearing on drug safety and effectiveness pursuant to a specific grant of authority by Congress.

II. INJECTING UNCERTAINTY INTO THE STATUS OF APPROVED DRUGS WOULD HARM PATIENTS

Amici are extremely concerned that if the district court's decision is allowed to stand, it will encourage private litigants to bring additional lawsuits that secondguess FDA's scientifically-based approval decisions. Compounding this concern, under the lower court's reasoning, the bar for overturning FDA approvals would be improperly low. The adverse impact on patients of such a regime would be strongly contrary to the public interest.

Because Article III judges are not equipped to undertake the clinical and scientific assessment of a drug's risks and benefits, the bar for a court to take the drastic step of effectively removing a drug from the market should be extremely high.¹⁶ Lowering that bar, as the district court has done in this case, would inject uncertainty into the status of approved drugs, which would jeopardize treatment for patients.

A. Sudden Loss of Access to Needed Drugs Jeopardizes Patients

While the district court'

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treatment and surgical intervention¹⁹

These consequences of lost access to therapies are devastating for all patients, but they are particularly devastating for cancer patients.²³ Cancer patients who lose access to a prescribed drug must switch to treatments that are more toxic²⁴ and/or less efficacious and may result in worse prognoses.²⁵ In addition, health plan formularies frequently cover only one therapy in a class, meaning that an alternative treatment, even if legally marketed, is not available to a patient until the health plan updates its coverage policy. For some diseases or conditions, including a number of cancers, there are *no* legally marketed alternative treatments. For these diseases and conditions, removal of a drug from the market could, in effect, be a death sentence.²⁶

^{2023), &}lt;u>https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages</u>.

²³ See, e.g., McBride, *supra* note 19, at e1289; Kehl, *supra* note 19, at e154; McKeever, *supra* note 19, at 490; Gogineni, *supra* note 19, at 2463-64; Hanna, *supra* note 21; *see also* Yoram Unguru, *Second Opinion: In Short Supply*, Hopkins Med. (Winter 2020), https://www.hopkinsmedicine.org/news/publications/hopkins_medicine_magazine/forum/in-short-supply ("Drug shortages have directly harmed countless patients, and those with cancer are particularly vulnerable.").

²⁴ See, e.g., Daniel J. Becker, et al., *Impact of Oncology Drug Shortages on Patient Therapy: Unplanned Treatment Changes*, 9 J. Oncology Practice e122, e124 (2013); McKeever, *supra* note 19, at 493; Monika L. Metzger et al., *Perspective: The Impact of Drug Shortages on Children with Cancer —The Example of Mechlorethamine*, 367 New Eng. J. Med. 2461, 2461 (2012); *see also* McBride, *supra* note 19, at e1293.

²⁵ See Metzger, *supra* note 24, at 2462; *see also* Unguru, *supra* note 22 ("Chemotherapy shortages force my colleagues and me to delay treatments, skip or reduce doses, and select less effective and familiar alternatives."); Kehl, *supra* note 19, at e157; Becker, *supra* note 24, at e125.

²⁶ C. Lee Ventola, *The Drug Shortage Crisis in the United States*, 36 Pharmacy & Therapeutics 740, 751 (2011) ("[T]he shortage of cytarabine raised the possibility that drug shortages would not only cause disruptions in care but could also be a death sentence for [acute myeloid leukemia] patients."); see also Metzger, supra note 24, at 2463; McKeever, supra note 19, at 490 (relating story of an ovarian cancer patient whose disease progressed after her healthcare provider "informed her that her chemotherapy protocol would need to be altered midtreatment" because the drug suddenly became unavailable due to manufacturing issues).

The risks to pediatric cancer patients are especially severe. For many pediatric cancers, there is only one FDA-approved treatment available.²⁷ For others, approved alternatives to standard treatment are inferior—often leading to significantly worse outcomes. One study designed to evaluate the effect of drug shortages on children with cancer found a "dramatic difference in event-free survival" over two years between children with Hodgkin's lymphoma treated with the standard treatment (88%) and those treated with a treatment that had been touted as an alternative (75%).²⁸ The study authors concluded that the unavailability of agents used in pediatric cancer treatment regimens is "likely to have devastating effects on patients with cancer," and that "what might appear to be a suitable alternative regimen may result in an inferior outcome—an intolerable situation for young people with curable

therapy regimen for acute lymphoblastic leukemia, "It is terrifying as a mom that a drug your child needs is not available." ³⁰

Uncertainty about the prospect of lost access to a drug as a result of a lawsuit or lawsuits seeking to remove it from the market—which a decision upholding the district court would encourage—would be an added source of anxiety for patients and families already grappling with battling life-threatening diseases and other as well as costly. For example, chimeric antigen receptor ("CAR") T-cell therapy which uses a type of white blood cell (T cells) from a patient that have been modified to target and destroy cancer cells more effectively than the typical "pillars" of cancer treatment (surgery, chemotherapy, and radiation therapy)—was extremely costly and challenging to develop.³¹ Companies can be expected to spend anywhere from under \$1 billion to more than \$2 billion on research and development ("R&D") for some of these promising new therapies.³² The pharmaceutical industry has invested over \$1.1 trillion in the development of new treatments and cures since 2000, including \$102.3 billion in 2021 alone.³³ Significantly, however, these investments do not 0 Td(-2 (t)-5 (-ly)16.8 2 20)33 Given the complexity and expense of developing a new drug, Congress and FDA actively encourage and support new drug development through a variety of financial incentives,³⁵ while at the same time ensuring that the relevant patient populations, who in many cases are vulnerable, are sufficiently protected.³⁶ For example, some new drugs qualify for a period of marketing exclusivity that reflects the significant investment in R&D.³⁷

for priority review) for companies researching treatments for particular diseases or conditions.³⁹

Congress has also created tax credits to ease some of the expenses of research activities. *See, e.g.*, 26 U.S.C. §§ 21, 174. It has mandated waivers or reductions of drug application fees in situations where the fees might represent a barrier to innovation. *See* 21 U.S.C. § 379h(d)(1). Congress also provides direct funding for research through several programs.⁴⁰

With the benefit of these initiatives, flexibilities, and financial incentives, FDA has shepherded thousands of life-saving drugs through the approval process. Were the lower court' technological or economic reasons, would be upended by researchers' inability to rely on FDA's science-based approval and market removal process as definitive.

C. Future Suits Challenging FDA Approvals Would Create Uncertainty Among Patients, Providers, and Drug Developers

The district court's opinion, including its improperly expansive theory of standing, has the potential to generate a flood of litigation challenging FDA drug approvals.⁴¹ Emboldened advocacy groups can be expected to target the approvals of drugs they disfavor based on their lay understandings of scientific studies, cherry-picked data regarding rare side effects, or other grounds. For example, physicians who believe that the availability of a weight loss drug incentivizes "unhealthy" patient behavior in terms of nutrition and exercise could bring a challenge to the drug's underlying

from the market, or to balance the harm to patients of removing a drug from the market against other considerations such as safety risks. Congress entrusted FDA with that responsibility, subject to the agency's reasonable exercise of its scientific judgment. To fulfill that directive, FDA employs experts in science and medicine who are properly trained and equipped to undertake the rigorous analyses necessary for determinations about drug safety and efficacy

CERTIFICATE OF SERVICE

I hereby certify that I e-filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system on May 1, 2023.

Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

May 1, 2023 Washington, D.C.

/s/ Emily I. Gerry Emily I. Gerry

Counsel for Amici

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limits of Rule 32(a) of the Federal Rules of Appellate Procedure because, according to the word count feature of Microsoft Word, it contains 5512 words. This brief also complies with the typeface requirements and type-style requirements of Federal Rules of Appellate Procedure 32(a) and 5th Cir. Rule 32.1 because it was prepared in Times New Roman, a proportionally spaced typeface, 14-point font, with footnotes in Times New Roman 12-point font.

/s/ Emily I. Gerry Emily I. Gerry *Counsel for Amici*

APPENDIX

LIST OF AMICI CURIAE

The Leukemia & Lymphoma Society

Rye Brook, NY

The Leukemia & Lymphoma Society ("LLS") is the world's largest voluntary health agency dedicated to fighting blood cancer and ensuring that the more than 1.3 million blood cancer patients and survivors in the United States have access to the care they need. LLS's mission is to cure leukemia, lymphoma, Hodgkin's disease, and myeloma, and to improve the quality of life of patients and their families. LLS advances that mission by advocating that blood cancer patients have sustainable access to quality, affordable, coordinated health care, regardless of the source of their coverage.

American Cancer Society

Atlanta, GA

The mission of the American Cancer Society ("the Society") is to improve the lives of people with cancer and their families through advocacy, research, and patient support, to ensure everyone has an opportunity to prevent, detect, treat, and survive cancer. Since 1946, the Society has funded over \$5 billion in cancer research, including giving grants to 50 investigators who went on to win the Nobel Prize. The Society also provides extensive patient support, from housing patients in Hope Lodges across the nation to having a call center open 24-7.

American Cancer Society Cancer Action Network

Washington, DC

The American Cancer Society Cancer Action Network ("ACS CAN") is the nonprofit, nonpartisan advocacy affiliate of the Society, making cancer a top priority for public officials and candidates at the federal, state and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change as well as legislative and regulatory solutions that will reduce the cancer burden.

American Childhood Cancer Organization

awareness, and providing educational resources and innovative comfort programs for children with cancer, survivors, and their families.

American Society of Clinical Oncology

Alexandria, VA

The American Society of Clinical Oncology ("ASCO") is a national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. ASCO is committed to ensuring that safe and effective treatments for cancer are available to all Americans with an equitable an evidence-based approach.

American Society of Hematology

Washington, DC

American Society of Hematology ("ASH") represents more than 18,000 clinicians and scientists worldwide committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical hematologic (also known as non-malignant) conditions such as sickle cell disease ("SCD"), thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. ASH believes that all individuals should have access to evidence-based, high-quality, clinically appropriate care, and the Society is committed to fostering high-quality, equitable care, transformative research, and innovative education to improve the lives of patients with blood and bone marrow disorders.

American Urological Association

Linthicum, MD

The American Urological Association ("AUA") is a globally engaged membership organization with more than 22,000 members practicing in more than 100 countries. Our members represent the world's largest collection of expertise and insight into the treatment of urologic disease. Of the total AUA membership, more than 18,000 are based in the United States and provide invaluable support to the urologic community by fostering the highest standards of urologic care through education, research, and formulation of health policy.

Arthritis Foundation

Atlanta, GA

The Arthritis Foundation, the nation's largest nonprofit organization focusing on arthritis, is boldly pursuing a cure for America's #1 cause of disability championing the fight to conquer arthritis with life-changing science, resources, advocacy and community connections.

Cancer*Care*

New York, NY

Cancer*Care* is the leading national organization providing free, professional support services and information to help people manage the emotional, practical and financial challenges of cancer.

Cancer Support Community

Washington, DC

As the largest professionally led nonprofit network of cancer support worldwide, the Cancer Support Community ("CSC") is dedicated to ensuring that all people impacted by cancer are empo.2 ((33 0 Td()Tjl(s)8.4 ()8.9 (n)12.1 b)12.1

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lives while the Society works to stop MS in its tracks, restore what has been lost and end MS forever.

National Organization for Rare Disorders

Quincy, MA

National Organization for Rare Disorders ("NORD") is a unique federation of voluntary health organizations dedicated to helping people with rare diseases and assisting the organizations that serve them. NORD is committed to the identification, treatment, and cure of rare disorders through programs of education, advocacy, research, and patient services. NORD believes that all individuals with a rare disease should have access to quality and affordable health care that is best suited to meet their medical needs.

RESOLVE: The National Infertility Association

McLean, VA

RESOLVE: The National Infertility Association, established in 1974, is dedicated to ensuring that all people challenged in their family building journey reach resolution through being empowered by knowledge, supported by community, united by advocacy, and inspired to act. RESOLVE is the oldest and largest patient advocacy non-profit for infertility and family building in the United States.

WomenHeart: The National Coalition for Women with Heart Disease

Alexandria, VA

WomenHeart: The National Coalition for Women with Heart Disease is the nation's only patient-centered organization focused solely on providing support, education and advocacy to women living with or at risk for heart disease.