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April 16, 2023

The Honorable John G. Roberts
 Chief Justice
 The Supreme Court of the United States
 One First Street N.E.
 Washington, D.C. 20543

Dear Chief Justice Roberts,

The Coalition for the Life Sciences (CLS), an organization that represents over 50,000 biomedical researchers from academia, private research institutes, and industry, strongly endorses the expertise and authority of the U.S. Food and Drug Administration (FDA), which is charged with gathering and applying scientific evidence and knowledge to evaluate the safety and efficacy of medicines in the United States. We respectfully urge the Court to reverse the lower court ruling to suspend the FDA’s approval of mifepristone which has been proven to be safe and effective.

We are deeply concerned that the April 7th decision by District Judge Matthew Kacsmaryk fundamentally undermines the bipartisan authority granted to the FDA by Congress, displacing scientific data with apparent judicial whim and political bias. The FDA approval process is painstaking and rigorous, requiring multiple steps that demand extensive pre-clinical research and results from carefully-designed clinical trials, providing quantitative measure of the benefits and risks of drugs and medical devices. Additionally, through ongoing post-market monitoring, the FDA captures effects or concerns undetected prior to widespread use, and inserts warnings or even withdraws approval if merited.

It is an unprecedented step for the district court to invalidate a longstanding approval for a drug with a history of safe and effective use. Allowing the district court’s decision to stand would set a dangerous precedent, inviting political agendas to reverse public access to rigorously researched, FDA-validated life-saving medications.

The FDA’s science-based approach protects public health and promotes public trust in our healthcare system. The CLS strongly supports the FDA review process as the gold

<p>The American Society for Cell Biology (301) 347-9300 www.ascb.org</p>	<p>The American Society for Human Genetics (301) 634-7300 www.ashg.org</p>	<p>Chan Zuckerberg Initiative www.chanzuckerberg.com</p>	<p>Genentech, a Member of the Roche Group (650) 467-6617 www.gene.com</p>	<p>The Genetics Society of America (301) 634-7300 www.genetics-gsa.org</p>	<p>Howard Hughes Medical Institute (301) 215-8500 www.hhmi.org</p>	<p>HudsonAlpha Institute for Biotechnology (256) 327-0425 www.hudsonalpha.org</p>	<p>Society for Neuroscience (202) 962-4000 www.sfn.org</p>
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standard for evaluating and approving medicines, and for ensuring safe and effective therapies that advance public well-being.

Thank you for your attention to this matter of critical importance.

Sincerely,

Keith R. Yamamoto

A handwritten signature in black ink, appearing to read "K. Yamamoto", written in a cursive style.

Keith R. Yamamoto, Ph.D.
Chair, Coalition for the Life Sciences
President, American Association for the Advancement of Science
Vice Chancellor for Science Policy and Strategy, UCSF
Director, UCSF Precision Medicine
Professor, Cellular & Molecular Pharmacology