No. 24-2069

United States Court of Appeals
for the Federal Circuit

UNITED STATES,

Plaintiff-Appellant,

v.

GILEAD SCIENCES, INC., GILEAD SCIENCES IRELAND UC,

Defendants-Appellees.

Appeal from the United States District Court for the District of Delaware in Case No. 1:19-cv-02103-MN (Hon. Maryellen Noreika, Judge)

AMICI CURIAE BRIEF OF PROFESSORS OF LAW, MEDICINE, AND PUBLIC HEALTH IN SUPPORT OF APPELLANT AND REVERSAL

Christopher J. Morten
NEW YORK UNIVERSITY SCHOOL OF LAW
(WASHINGTON SQUARE LEGAL SERVICES, INC.)
Furman Hall, 245 Sullivan Street, 5th Floor
New York, New York 10012
cjm531@nyu.edu
(212) 998-6430

Counsel for Amici Curiae

DECEMBER 19, 2024

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 24-2069

Short Case Caption United States v. Gilead Sciences, Inc.

Filing Party/Entity Professors of Law, Medicine, and Public Health

Instructions:

1. Complete each section of the form and select none or N/A if appropriate.
2. Please enter only one item per box; attach additional pages as needed, and check the box to indicate such pages are attached.
3. In answering Sections 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance.
4. Please do not duplicate entries within Section 5.
5. Counsel must file an amended Certificate of Interest within seven days after any information on this form changes. Fed. Cir. R. 47.4(c).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 12/19/2024

Signature: /s/ Christopher J. Morten

Name: Christopher J. Morten

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☑ None/Not Applicable
See Appendix A (attached)		

☑ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Christopher J. Morten New York University School of Law (Washington Square Legal Services, Inc.)		

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

☐ Yes (file separate notice; see below) ☐ No ☑ N/A (amicus/movant)

If yes, concurrently file a separate Notice of Related Case Information that complies with Fed. Cir. R. 47.5(b). **Please do not duplicate information.** This separate Notice must only be filed with the first Certificate of Interest or, subsequently, if information changes during the pendency of the appeal. Fed. Cir. R. 47.5(b).

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

APPENDIX A

List of Signatories
(Amici Curiae Professors of Law, Medicine, and Public Health)

(Amici sign on their own behalf. Institutions are listed for identification only.)

Charles Duan, JD
Assistant Professor of Law, American University Washington College of Law

Gregg Gonsalves, PhD
Associate Professor of Epidemiology, Yale School of Public Health

Cynthia M. Ho, JD
Clifford E. Vickrey Research Professor, Loyola University Chicago School of Law

Amy Kapczynski, JD, MA, MPhil
Professor of Law, Yale Law School

Jordan Paradise, JD
Georgia Reithal Professor of Law, Loyola University Chicago School of Law

Reshma Ramachandran, MD, MPP, MHS
Assistant Professor of Medicine, Yale School of Medicine

Joseph S. Ross, MD, MHS
Professor of Medicine and Public Health, Yale School of Medicine

Jason M. Schultz, JD
Professor of Clinical Law, New York University School of Law

Michael S. Sinha, MD, JD, MPH, FCLM
Assistant Professor of Law, Saint Louis University School of Law

Anthony D. So, MD, MPA
Distinguished Professor of the Practice, Johns Hopkins Bloomberg School of Public Health

Liza Vertinsky, JD, MA, PhD
Professor of Law, University of Maryland Francis King Carey School of Law

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

IDENTITY AND INTERESTS OF THE *AMICI CURIAE*[1]

Amici are professors of law, medicine, and public health who are experts in patent law, medical innovation, pharmaceutical policy, and health justice. Amici are

Charles Duan, JD, Assistant Professor of Law, American University Washington College of Law;

Gregg Gonsalves, PhD, Associate Professor of Epidemiology, Yale School of Public Health;

Cynthia M. Ho, JD, Clifford E. Vickrey Research Professor, Loyola University Chicago School of Law;

Amy Kapczynski, JD, MA, MPhil, Professor of Law, Yale Law School;

Jordan Paradise, JD, Georgia Reithal Professor of Law, Loyola University Chicago School of Law;

[1] Amici submit this brief pursuant to Federal Rule of Appellate Procedure 29(a)(2) and state that all parties have consented to its timely filing. Amici further state that no counsel for any party authored this brief in whole or in part, and no entity or person, aside from the amici curiae and their counsel, made any monetary contribution intended to fund the preparation or submission of this brief. Amici file this brief in their individual capacities as scholars; they provide institutional affiliations solely for the purpose of identification. Four professors in particular have guided the research, drafting, and editing of this brief: Gregg Gonsalves, Amy Kapczynski, Reshma Ramachandran, and Anthony D. So.

Reshma Ramachandran, MD, MPP, MHS, Assistant Professor of Medicine, Yale School of Medicine;

Joseph S. Ross, MD, MHS, Professor of Medicine and Public Health, Yale School of Medicine;

Jason M. Schultz, JD, Professor of Clinical Law, New York University School of Law;

Michael S. Sinha, MD, JD, MPH, FCLM, Assistant Professor of Law, Saint Louis University School of Law;

Anthony D. So, MD, MPA, Distinguished Professor of the Practice, Johns Hopkins Bloomberg School of Public Health; and

Liza Vertinsky, JD, MA, PhD, Professor of Law, University of Maryland Francis King Carey School of Law.

We have studied the extensive contributions that public research makes to breakthrough pharmaceutical inventions in the United States. We provide this brief to aid the Court in protecting the United States' world-leading system of pharmaceutical innovation, which relies on research and development conducted by the U.S. Department of Health and Human Services (HHS) and its constituent agencies, including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC). HHS's research and development often result in highly innovative pharmaceutical inventions and patents on those

inventions. The government licenses those patents to private industry partners on reasonable terms as part of HHS's vigorous and generous technology transfer process, designed to get inventions to the public as quickly as possible.

I. INTRODUCTION

This brief provides the Court with background on U.S. government patenting and technology transfer practices, with a focus on HHS and two of its constituent agencies, NIH and CDC. These well-established practices result in robust public-private partnerships that transform taxpayer investment in research into pharmaceutical inventions that reach vulnerable populations and benefit society as a whole.

HHS requested that Gilead discuss licensure of the government's presumptively valid patents concerning the use of a combination of emtricitabine and tenofovir as HIV pre-exposure prophylaxis (PrEP) pursuant to HHS's comprehensive project of technology transfer and public-private partnership. HHS's request was reasonable and conformed with past practice, whereas Gilead's refusal to engage in good-faith negotiation with the government was extraordinary, unreasonable, and aberrant.

Gilead has not only declined to license HHS's patents on PrEP; the company apparently refused good-faith discussion of even the *possibility* of patent licensure

and mutually beneficial public-private partnership.[2] This is so even though HIV PrEP is one of the most important pharmaceutical breakthroughs of the 21st century and even though HHS's goal is and has always been to get HIV PrEP to patients as quickly and broadly as possible.

An endorsement of Gilead's behavior could subvert the status quo of public-private partnership in pharmaceuticals, hinder future breakthroughs invented in HHS laboratories from reaching patient populations, and ultimately harm public health. For these reasons, we hope that Gilead will acknowledge HHS's role in the invention of PrEP, come back to the negotiation table, and discuss an appropriate license.

II. ARGUMENT

A. Government-conducted research is a cornerstone of pharmaceutical innovation.

Government support for biomedical research is indispensable to the ecosystem of pharmaceutical innovation in the United States. HHS's constituent

[2] We recognize that if HHS's patents on PrEP are ultimately held invalid, Gilead and other entities that practice the patents will owe no royalties to the government. Of course, there can be no liability for infringement of an invalid patent. At the same time, we find it notable that Gilead refused to discuss patent licensing and partnership with the government years before the company challenged any of the relevant patents. Moreover, HHS's patents on PrEP survived inter partes review challenges at the Patent Trial & Appeal Board, strengthening their presumption of validity and making Gilead's refusal to engage with the government all the more striking.

laboratories invest tens of billions of dollars every year in the discovery and development of new drugs, vaccines, medical devices, treatment methods, and more. *See* United States Government Accountability Office (GAO), *National Institutes of Health: Better Data Will Improve Understanding of Federal Contributions to Drug Development* (GAO-23-105656), May 4, 2023, at 14.[3] For example, NIH is "the largest public funder of biomedical research in the world." NIH, *Grants & Funding*.[4] NIH's funding has contributed to 354 of 356 drugs (99.4%) approved by the Food and Drug Administration from 2010 to 2019, illuminating the breadth and significance of government investment in drug development and biomedical research at large. *See* Ekaterina Galkina Cleary et al., *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010-2019*, 4 JAMA Health Forum e230511 (2023) at 4.[5]

A critical portion of government investment in pharmaceutical research and development is conducted by the government itself, or "intramurally." Out of an almost $48 billion annual budget for FY 2023, "approximately 11 percent of the

[3] https://www.gao.gov/products/gao-23-105656.

[4] https://www.nih.gov/grants-funding (last visited Dec. 9, 2024).

[5] https://jamanetwork.com/journals/jama-health-forum/fullarticle/2804378.

NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories . . . ." NIH, *Budget*.[6] Other constituent agencies of HHS have in-house laboratories and research portfolios of their own. For example, CDC's laboratories invent medical technologies such as "diagnostics assays, early therapeutics, vaccine candidates, research tools . . . and occupational safety and health products." CDC, *About the Technology Transfer Office* (Oct. 3, 2024).[7] CDC's technology transfer website currently describes over 200 medical technologies recently developed within the agency's laboratories. CDC Office of Science, *Technologies Available for Licensing and Collaboration*.[8] Exemplary CDC technologies include vaccine candidates against rotavirus and polio. *See* NIH Technology Transfer, *Novel Human Rotavirus Vaccine CDC-6 Strain for Impacted Subgroup, the Lewis Negative Population*;[9] NIH Technology Transfer, *Codon*

[6] https://www.nih.gov/about-nih/what-we-do/budget (last visited Dec. 9, 2024).

[7] https://www.cdc.gov/os/offices/technology-transfer.html (last visited Dec. 9, 2024).

[8] https://www.cdc.gov/os/technology/techtransfer/industry/licensing/technologies.htm (last visited Dec. 9, 2024).

[9] https://www.techtransfer.nih.gov/tech/tab-3253 (last visited Dec. 9, 2024).

Deoptimized (CD) Poliovirus Seed Strains for Use in an Inactivated Poliovirus Vaccine.[10]

Through this intramural research, HHS and its agencies have invented and developed important medications with tremendous impact on the lives of patients. The Government Accountability Office (GAO) has documented that between 1980 and 2019 HHS licensed 94 patents to pharmaceutical companies, which contributed to the development of over 30 products approved by the Food & Drug Administration (FDA) that address a wide range of public health needs affecting patient populations across the country and around the world. GAO, *Biomedical Research: NIH Should Publicly Report More Information about the Licensing of Its Intellectual Property* (GAO-21-52), Nov. 20, 2020 at 17, Table 1.[11] These HHS-invented products include both therapeutic interventions and preventive care that protect patients' health. They include the anti-cancer medications Fludara, Lumoxiti, Taxol, Velcade, Yescarta, and Zevalin; the respiratory syncytial virus treatment Synagis; the HIV-protease inhibitors Prezcobix and Prezista; and vaccines such as Gardasil, Gardasil 9, and Cervarix to prevent the transmission of

[10] https://www.techtransfer.nih.gov/tech/tab-3839 (last visited Dec. 9, 2024).

[11] https://www.gao.gov/products/gao-21-52.

HPV, LYMErix to prevent Lyme disease, and Havrix to prevent hepatitis A. *See id.* at 65-66, Appendix II.

Pharmaceutical inventions emerging from HHS's laboratories were critical to the national and global response to the COVID-19 pandemic. For example, NIH scientists at the National Institute of Allergy and Infectious Diseases (NIAID), working with academic collaborators, invented a way to stabilize coronavirus spike proteins, creating potent and precise engineered immunogens for coronavirus vaccines. Daniel Wrapp et al., *Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation*, 367 Science 1260 (2020).[12] Most of the leading COVID-19 vaccines that have played a pivotal role in mitigating the COVID-19 pandemic on a global scale, including those by Pfizer/BioNTech, Moderna, J&J, and Novavax, used NIH's engineered immunogen. Public Citizen, *Leading COVID-19 Vaccine Candidates Depend on NIH Technology*, Nov. 10, 2020.[13]

HIV PrEP, the medical breakthrough at issue in this appeal, is a paradigmatic example of valuable intramural government research. In the early 2000s, government scientists at CDC's Division of HIV/AIDS Prevention invented a prophylactic regimen using two antiretroviral drugs that could, for the first time,

[12] https://www.science.org/doi/10.1126/science.abb2507.

[13] https://www.citizen.org/wp-content/uploads/USG-Spike-Protein.pdf.

prevent the transmission of HIV. *See* Appx02001-02013 (U.S. Patent No. 9,044,509). CDC's PrEP regimen was hailed by TIME magazine as the number one medical breakthrough of 2010. POZ, *Time Names Truvada for HIV Prevention No. 1 Medical Breakthrough of 2010*, Dec. 16, 2010.[14] Per a 2012 TIME article, FDA approval of HIV PrEP "mark[ed] a big step toward controlling the spread of HIV and AIDS, not just in the U.S. but worldwide as well." Alice Park, *Truvada: 5 Things to Know About the First Drug to Prevent HIV*, TIME, Jul. 17, 2012.[15]

B. The government routinely obtains pharmaceutical patents and licenses them to private companies as part of a comprehensive, generous, and successful system of public-private partnership.

The United States' world-leading system of pharmaceutical innovation relies on publicly funded research conducted in HHS's laboratories. But although the government plays an important role in research and development, it does not participate substantially in the manufacture and commercialization of its pharmaceutical inventions; instead, the government relies on commercial partners to get medications and other healthcare products into the hands of doctors and

[14] https://www.poz.com/article/Truvada-HIV-Prevention-19610-2311.

[15] https://healthland.time.com/2012/07/17/truvada-5-things-to-know-about-the-first-drug-to-prevent-hiv/.

patients. NIH National Cancer Institute (NCI) Technology Transfer Center, *Intellectual Property*.[16]

The current system of public-private partnership in the United States took shape in the 1980s. Congress passed the Stevenson-Wydler Technology Innovation Act in 1980 "to promote [] technological innovation for the achievement of national economic, environmental, and social goals . . . ." Stevenson-Wydler Technology Innovation Act of 1980, Pub. L. No. 96-480, 94 Stat. 2311 at Preamble. The Act encouraged the U.S. government to "ensure the full use of the results of the Nation's Federal investment in research and development," by obtaining patents on government inventions. 15 U.S.C. § 3710(a)(1). In 1986, Congress passed the Federal Technology Transfer Act, amending Stevenson-Wydler in part to encourage the government to transfer federally owned or originated technology to State and local governments and to the private sector by "negotiat[ing] licensing agreements" on reasonable terms. *See id*.; 15 U.S.C. § 3710a(a)(2). *See also* 35 U.S.C. § 207 (provision of U.S. patent law, enacted as part of the Bayh-Dole Act of 1980, expressly authorizing federal agencies to obtain U.S. and foreign patents).

[16] https://techtransfer.cancer.gov/investigators/intellectual-property (last visited Dec. 10, 2024).

Federal agencies within HHS have undertaken the congressional mandate. CDC pools its technology transfer operations with NIH,[17] and both agencies focus their expertise and resources on the invention and development of technologies that improve public health, rather than manufacturing and commercialization. *See, e.g.*, NIH NCI Technology Transfer Center, *Intellectual Property*.[18] As NIH explains, agency scientists rely on "commercial partners to get [] new discoveries/technologies to the patient populations [they] serve." *Id.* Just as Congress instructed, "[t]he NIH . . . relies on patents as its primary form of IP protection for inventions and discoveries originating from scientists and laboratories." *Id*. In the words of a technology transfer official at NIH, patenting NIH inventions "protects the invention and reduces the risk for a party that licenses [] those patents and make it [] more likely they'll actually develop the

[17] "CDC technology transfer services are provided by [the] NIAID Technology Transfer and Intellectual Property Office." NIH, *CDC - Centers For Disease Control And Prevention*, https://www.techtransfer.nih.gov/tdc/cdc-centers-for-disease-control-and-prevention (last visited Dec. 10, 2024). CDC's own Technology Transfer Office explains that it works with its "NIH partners [to] evaluate, protect, market, license, monitor, and manage the wide range of CDC's scientific discoveries." CDC Office of Science, *About the Technology Transfer Office*, https://www.cdc.gov/os/offices/technology-transfer.html (last visited Dec. 10, 2024).

[18] https://techtransfer.cancer.gov/investigators/intellectual-property (last visited Dec. 10, 2024).

technology"—all for the "goal of getting products out to the public." *See* Appx32671 (Testimony of Dr. Tara L. Kirby).

HHS agencies then license these patents to commercial partners, transferring the "rights to make, use and/or sell a technology . . . to for-profit entit[ies] for commercial development and/or use." Appx37375 (slide from presentation by NIH Office of Technology Transfer official Dr. Tara L. Kirby describing licensing and patenting practices at NIH). According to the GAO, HHS licenses patents on reasonable terms; recent royalties on licensees' net sales ranged from less than 1 percent to over 10 percent of sales. *See* GAO-21-52 at 23.[19] This range conforms with customary royalty rates in the pharmaceutical industry. *See* IPRA, ROYALTY RATES FOR PHARMACEUTICALS & BIOTECHNOLOGY (9th ed.), Preface (2022) (stating that the most common private sector patent royalty arrangement is 5% of net sales and that about 70% of patent licenses involved royalties of 10% or less of net sales).

Crucially, technology transfer from HHS's agencies to private companies is often more than a bare license to a government-owned patent and much more than

[19] In the same report, GAO also found that, "[a]ccording to NIH, as of February 2020, [NIH] licenses had generated up to $2 billion in royalties, including three licenses that had generated more than $100 million each" and that "[b]ecause royalties are typically based on sales, some of the licenses' high royalties reflect the commercial success of the drugs associated with these licenses." *Id.*

a one-time discussion. As NIH has explained, government experts in technology transfer seek to "guide[] the interactions of [] partners from the point of discovery, to patenting, through invention development to licensing," and "play a key role in helping to accelerate development of cutting-edge research by connecting [] partners to NIH's world-class facilities, resources, and discoveries." NIH NCI Technology Transfer Center, *Success Stories*.[20] Further, to "ensure that federal technologies are developed and used and brought to the public," HHS "track[s] [companies'] progress through progress reports, and [] also include[s] in the license specific requirements for benchmarks [the companies] need to meet along the way." *See* Appx32670 (Testimony of Dr. Tara L. Kirby).[21] Thus, the success of HHS's system of public-private partnership is founded not only on HHS's groundbreaking research but also on its stewardship throughout development and commercialization.

The remainder of this section provides a non-exhaustive summary of groundbreaking pharmaceutical inventions that began in HHS laboratories and then

[20] https://techtransfer.cancer.gov/about/success-stories (last visited Dec. 10, 2024).

[21] An NIH technology transfer official testified that HHS's benchmarks are "often [] related to the process of getting a drug approval" including "when [a company] appl[ies] for the right to develop the drug, when [they] go through clinical trials, [and] when [they] apply for or maybe even receive approval from the FDA." Appx32672 (Testimony of Dr. Tara L. Kirby).

reached patients via public-private partnerships facilitated by NIH's technology transfer office.

The development of palivizumab (Synagis), an antibody used to prevent serious Respiratory Syncytial Virus (RSV) in infants, is, per NIH, "a prime example of how government-industry partnerships benefit the public." NIH Office of Technology Transfer, *Synagis® Helping Infants and Parents Breathe Easier: A Case Study* (Oct. 23, 2002) at 2.[22] Synagis was developed through a nine-year relationship between NIH and MedImmune, Inc. *Id.* Government scientists invented a novel antibody directed against RSV, and then industry partners conducted the additional tests, trials, and strategy development necessary to produce the medication on a commercial scale. *Id.* In the words of NIH, the Synagis story demonstrates that "linking federal laboratories with private corporations allow[s] for the introduction of innovative products to the market place that can be used to improve the public health." *Id*.

Similarly, Havrix, an important vaccine to prevent hepatitis A, was developed through collaboration between scientists at SmithKlineBeecham (SKB) and government researchers at NIH, and CDC. NIH Office of Technology Transfer, *Havrix® Waging War Against a Common Enemy: A Case Study* (Oct. 22,

---

22 https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/SynagisCS.pdf.

2002).[23] Per NIH, "[t]hese federal labs conducted investigations in part through Cooperative Research and Development Agreements (CRADA) with SKB," and now Havrix is used globally to prevent hepatitis A epidemics. *Id*.

Paclitaxel (Taxol), a powerful medication for treating cancer, including ovarian and breast cancer, was developed as part of a CRADA between NCI and Bristol Myers Squibb (BMS). *See* GAO, *NIH-Private Sector Partnership in the Development of Taxol* (GAO-03-829), June 2003, at 9-10.[24] According to the GAO, these public-private partners "collaborate[d] on . . . clinical studies to obtain FDA approval for the marketing of paclitaxel . . . ." *Id* at 9. As a result, "[t]he NIH-BMS collaboration provided BMS access to NIH research results that were critical for BMS's quick commercialization of Taxol," and the collaboration "provided other benefits for both parties and for the health of the public as well," with BMS providing supplies of paclitaxel to NIH and NIH conducting clinical trials and other research. *Id* at 10.

Fludarabine (Fludara), a highly effective chemotherapy agent for chronic lymphocytic leukemia, was developed through a close partnership between the National Cancer Institute (NCI) and Berlex Laboratories. NIH Office of

---

[23] https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/HavrixCS.pdf.

[24] https://www.gao.gov/assets/gao-03-829.pdf.

Technology Transfer, *Fludara™ The New Benchmark: A Case Study* (Sep. 2003).[25] Per NIH, NCI invented the drug compound, "performed the early pre-clinical testing of this compound, submitted an [investigational new drug application], and sponsored early clinical testing and the two phase 2 clinical trials on which FDA approval was based." *Id.* at 1. For its part, "[t]he Berlex team worked closely with the NCI as soon as the license was signed. Fludara is difficult to manufacture, and the NCI needed increasing amounts. Berlex was responsible for supplying the drug to the NCI for use in a variety of clinical studies, and also for ensuring that NCI had sufficient Fludara to provide to compassionate use patients." *Id* at 2. NIH licensed its patents not just to Berlex but to a second company, to increase the odds of successful commercialization; ultimately "only Berlex Laboratories was able to develop a drug." *Id.* at 1.

HHS scientists and industry partners also collaborated on thyrotropin alfa (Thyrogen), an injectable biologic used as a diagnostic to identify thyroid disease in patients with thyroid cancer. NIH Office of Technology Transfer, *Thyrogen® Increasing Patient Compliance: A Case Study* (Sep. 2004).[26] Thyrotropin alfa

---

25 https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/FludaraCS.pdf.

26 https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/ThyrogenCS.pdf.

allows patients to continue taking thyroid hormone medication and avoid the effects of thyroid hormone withdrawal. *Id.* at 1. According to NIH, the CRADA between NIH and the company Integrated Genetics (now Genzyme Therapeutics) "allow[ed] rapid transfer of scientific innovation[] and development of biological products used to treat patients," and "[u]nder this agreement, both parties collaborated to improve upon the findings of the [NIH] scientists." *Id*. at 2.

Another example of a successful public-private partnership resulting in breakthrough medication is bortezomib (Velcade). NIH Office of Technology Transfer, *Velcade®, New Science and New Hope: A Case Study* (Sep. 2003).[27] According to NIH, this valuable medication, "a completely new approach to treating cancer" that "give[s] extra months of life to patients for whom no other therapy is effective," was brought to market "just four and a half years after treating the first human patient." *Id*. at 1, 2. NIH has stated that "[t]his remarkable speed stems from [the government's industry partner Millennium Pharmaceuticals'] willingness to commit enormous resources to drug development, and its early collaboration with the NIH and the FDA." *Id*. at 2.

---

27 https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/VelcadeCS.pdf .

HHS's laboratories do not limit their work to early-stage research. To the contrary, HHS's laboratories also do important late-stage research on already-approved drugs. For example, HHS laboratories sometimes discover new uses of existing medicines, patent those uses, then transfer the technology to the original manufacturer of the medicines. *See, e.g.*, GAO-03-829 at 12 (documenting Bristol-Myers Squibb's (BMS's) licensure from NIH of patented methods of using paclitaxel in cancer treatment; BMS had already been marketing paclitaxel for treatment of ovarian cancer).

In one notable instance, NIH invented and patented a method of treating drug-resistant strains of HIV that reduced the likelihood of further drug resistance when using the antiretroviral drug darunavir (Prezista). *See* GAO-21-52 at 19. NIH then licensed its patent and transferred the technology to the pharmaceutical company that manufactured darunavir, Tibotec Therapeutics, which was later acquired by Janssen. *See id.* at 19 n.49. The darunavir scenario is reminiscent of the story of HIV PrEP: Like Gilead, Tibotec and Janssen held patent rights on the drug itself, but government scientists discovered and patented a novel, highly useful method of using the same drug to improve patient health. *Id.* at 19 & n.49. With darunavir, NIH successfully licensed and transferred the method of use to Tibotec and Janssen, yielding benefits for the companies and patients alike. *See id.* at 75 (Table 9) & 76 (Table 10) (documenting billions of dollars in spending on

darunavir by Medicare and Medicaid alone in the years 2014-18); Eric Palmer, *Tivicay marks beginning of end in growth of HIV branded market, forecast says*, Fierce Pharma, Aug. 14, 2013 (describing Prezista (darunavir) as a "blockbuster[]").[28]

C. Gilead's refusal to discuss public-private partnership with HHS on HIV PrEP, including patent licensure, was extraordinary and unreasonable.

This section will trace the history of HHS's efforts to cultivate a public-private partnership with Gilead to develop HIV PrEP, along with Gilead's persistent refusal to engage in good faith discussions with the government.

Over a documented history spanning more than fifteen years, Gilead was notified of the government's research on, patenting of, and licensing efforts around the use of emtricitabine and tenofovir as PrEP. This saga began no later than 2004, when Gilead and CDC signed a series of material transfer agreements (MTAs)[29] obligating CDC to promptly disclose or notify Gilead of research results or

---

[28] https://www.fiercepharma.com/sales-and-marketing/tivicay-marks-beginning-of-end-growth-of-hiv-branded-market-forecast-says.

[29] A material transfer agreement (MTA) is a contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use it for his or her own research purposes. The MTA defines the rights of the provider and the rights and obligations of the recipient with respect to the materials and any progeny, derivatives, or modifications. Berkeley Sponsored Projects, *Quick Guide to Material Transfer Agreements at UC Berkeley*, https://spo.berkeley.edu/guide/mtaquick.html (last visited Dec. 11, 2024).

inventions derived from the combination of tenofovir disoproxil fumarate and emtricitabine (TDF/FTC). *See* Appx03031 (Complaint ¶¶ 119-23). Gilead sells pills combining these two drugs under the brand name Truvada, and Gilead provided samples to CDC that CDC used in its testing. *Id.*

Even at this early stage, the MTAs contemplated the possibility of CDC scientists creating new inventions in the course of their research, HHS patenting those inventions, and CDC inviting Gilead to license those patents. *See* Appx03031-03032 (Complaint ¶ 124).

In the course of its research, CDC subsequently invented the use of the combination of emtricitabine and tenofovir as PrEP and, as expected under the MTA, informed Gilead. Early results from CDC's research were first made publicly available in February 2006, when Dr. Heneine, a named inventor of HHS's patents on PrEP, presented data at the Conference on Retroviruses and Opportunistic Infections (CROI). Appx03035 (Complaint ¶ 135). Later, in February 2008, CDC officials sent Gilead's Drs. James Rooney and William Lee an email containing a draft of an article to be published later that month in an issue of the medical journal *PLoS Medicine*. Appx03033 (Complaint ¶ 131). This article documented the results of CDC's research on HIV PrEP, discussing "the potential high effectiveness of daily or intermittent PrEP against sexual HIV transmission." J. Gerardo García-Lerma et al, *Prevention of Rectal SHIV Transmission in*

Macaques by Daily or Intermittent Prophylaxis with Emtricitabine and Tenofovir, 5 PLoS Medicine 0291, 0298 (2008).[30]

CDC notified Gilead of its intent to patent its invention of HIV PrEP. The *PLoS Medicine* article notified readers, including the two Gilead doctors, that some of the article's authors were "named in a US Government patent application related to methods for HIV prophylaxis." *Id*. at 0291. That same year, Dr. Janssen, another named inventor of HHS's patents on PrEP, accepted employment at Gilead and executed an inventions agreement, requiring him to disclose prior inventions relevant to the subject matter of employment to Gilead. Dr. Janssen listed the publication of a pending patent application, WO 2007/092326, linked to the patent applications that ultimately issued as HHS's patents on PrEP. Appx32708 (uncontested facts). According to HHS, Gilead was given notice at least eleven more times between 2010 and 2016 through pre-publication review of CDC-authored scholarship which identified the same pending government patent application. Appx03033 (Complaint ¶ 133).

Even with knowledge of CDC's—and later NIH's—research on use of emtricitabine and tenofovir as PrEP, Gilead did not initially intend to seek the FDA's approval of a new PrEP indication for Truvada. Appx32447-32448

[30] https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0050028.

(Testimony of Dr. Debra Birnkrant). Although Gilead, in the words of then-general counsel Gregg Alton, had little doubt that "Truvada would work for PrEP" as early as 2009 (having seen results from then-ongoing clinical trials), the company did not intend to promote the drug for this valuable use. Appx32747-32748; Appx32761-32762.

In February 2009, Gilead met with FDA officials, who stressed the great potential to advance public health by securing a PrEP indication for Truvada and recommended Gilead work with the sponsors of those ongoing clinical trials to prepare supporting evidence. Appx32446-32449, Appx32452 (Testimony of Dr. Debra Birnkrant); *see also* Appx32746-32747 (Testimony of Gregg Alton). FDA approval of a PrEP indication was all the more important given the recent failure of an HIV vaccine candidate from Merck and surrounding pessimism about the viability of any HIV vaccine. *See* Clare Wilson, *Safer Sex in a Pill*, New Scientist, Nov. 22, 2008, at 42. Yet, months later, Gilead still remained opposed to seeking an indication. *See* Appx32765 (Testimony of Gregg Alton). Years passed before Gilead made efforts toward securing a PrEP indication for Truvada, which it finally applied for in December 2011. *See* Appx32449, Appx32453 (Testimony of Dr. Debra Birnkrant). Gilead's waffling occurred while approximately 50,000 HIV

transmissions per year occurred in the United States. CDC, *HIV Infection — United States, 2008 and 2010* (Nov. 22, 2013).[31]

When Gilead finally pursued FDA approval for Truvada as PrEP, Gilead did not shoulder the onerous burden of funding and conducting clinical trials required to obtain approval. Instead, in its supplemental new drug application, Gilead relied on the iPrEx and Partners PrEP clinical trials. *See* Appx03044-03045 (Complaint ¶ 171). These trials, costing over $135 million in total, were funded primarily by grants from NIH, with additional contributions from the Bill and Melinda Gates Foundation; Gilead contributed no funding. *See* Gilead, *U.S. Food and Drug Administration Approves Gilead's Truvada® for Reducing the Risk of Acquiring HIV* (Jul. 16, 2012) (Gilead Press Release)[32]; Appx03040, Appx03041 (Complaint ¶¶ 154, 158). When the FDA approved the new indication of Truvada as PrEP in 2012, the then-Executive Vice President of Research and Development and Chief Scientific Officer at Gilead acknowledged the importance of public research to the development of PrEP, announcing that "[t]his advancement in the field of HIV prevention was made possible due to the leadership and commitment of the FDA and the Department of Health and Human Services." Gilead Press Release.

---

[31] https://www.cdc.gov/mmwr/preview/mmwrhtml/su6203a19.htm.

[32] https://www.gilead.com/news/news-details/2012/us-food-and-drug-administration-approves-gileads-truvada-for-reducing-the-risk-of-acquiring-hiv.

Academic researchers later concluded that "the US government spent an estimated $143 million" on development and clinical testing of Truvada as PrEP and that "Gilead would not have been able to so readily market this drug for PrEP without the groundbreaking publicly funded work conducted or supported by the CDC and the NIH . . . ." Frazer A. Tessema et al., *Federal Funding for Discovery and Development of Costly HIV Drugs Was Far More Than Previously Estimated*, 42 Health Affairs 642, 642, 647 (2023).

After approval, the government continued to play a crucial role in the rollout of PrEP to American patients, acting as a powerful counterweight to Gilead's skepticism of PrEP's commercial potential. In 2013, Jim Rooney, then-VP of medical affairs at Gilead, stated that the company "[did] not view PrEP as a commercial opportunity," finding that "[t]he role of antiretrovirals in H.I.V. prevention [was] not yet defined and not yet broadly accepted." Christopher Glazek, *Why Is No One On the First Treatment to Prevent H.I.V.?*, The New Yorker, Sep. 30, 2013.[33] Yet sales of Truvada for PrEP accelerated in 2014, after CDC and the World Health Organization (WHO) issued clinical guidelines recommending that daily PrEP be considered for HIV prevention in all people who are at substantial risk. *See* Appx03046 (Complaint ¶¶ 175-76). Even still, as late as

[33] https://www.newyorker.com/tech/annals-of-technology/why-is-no-one-on-the-first-treatment-to-prevent-h-i-v.

2015, a spokesperson for Gilead stated that the company "[did] not view PrEP as a commercial opportunity and [was] not conducting marketing activities around Truvada as PrEP." Michela Tindera, *Gilead Said PrEP To Prevent HIV Was 'Not A Commercial Opportunity.' Now It's Running Ads For It*, Forbes, Aug. 8, 2018 (Tindera, *Gilead Said*).[34]

Once finally aware of its financial windfall, Gilead moved aggressively to maximize revenues on PrEP, and it did so without consulting or collaborating meaningfully with the HHS laboratories responsible for the breakthrough invention. Following growing patient demand for PrEP,[35] Gilead decided to increase dramatically the prices it charged for Truvada. *See* Shefali Luthra & Anna Gorman, *Rising Cost Of PrEP To Prevent HIV Infection Pushes It Out Of Reach For Many*, NPR News, Jun. 30, 2018.[36] Gilead increased the list price of the drug

---

[34] https://www.forbes.com/sites/michelatindera/2018/08/07/gilead-said-prep-to-prevent-hiv-was-not-a-commercial-opportunity-now-its-running-ads-for-it/.

[35] In the mid-2010s, patient demand for PrEP grew not just due to work by CDC, the WHO, and other public agencies and nongovernmental organizations but also due to work by HIV/AIDS advocacy organizations. *See, e.g.*, My PrEP experience, *UPDATED NUMBER - 116 Leading HIV/AIDS groups (and allied orgs) endorse CDC HIV PrEP Guidelines*, May 15, 2024, https://myprepexperience.blogspot.com/2014/05/67-leading-hivaids-groups-endorse-cdc.html.

[36]

by about 45% in the six years after its approval for use as PrEP. *Id*. By 2019, Gilead offered Truvada for sale at a retail price about 350 times higher than its manufacturing cost. *See* HIV Prevention Drug: Billions in Corporate Profits after Millions in Taxpayer Investments: Hearing Before the Comm. on Oversight and Reform, Serial No. 116–24 (May 16, 2019) at 5 (Statement of Dr. Robert M. Grant).[37]

Having identified PrEP as an "important growth driver" for its HIV portfolio, Gilead finally began direct-to-consumer promotion and advertising for PrEP medications in 2018. Tindera, *Gilead Said*. On January 6, 2017, Gilead applied to the U.S. Patent & Trademark Office for exclusive use in commerce of the trademark, TRUVADA FOR PREP. Appx03060 (Complaint ¶ 250). Gilead's trademark application was filed *after* the government had provided Gilead notice of issuance of HHS's patents on PrEP and had repeatedly attempted to negotiate a non-exclusive license. Appx03061 (Complaint ¶ 252).

Meanwhile, as early as 2014, HHS went to great lengths to notify Gilead and other pharmaceutical companies of its intention to partner with HIV drug

---

https://www.npr.org/sections/health-shots/2018/06/30/624045995/rising-cost-of-prep-a-pill-that-prevents-hiv-pushes-it-out-of-reach-for-many.

[37] https://www.congress.gov/116/meeting/house/109486/documents/HHRG-116-GO00-Transcript-20190516.pdf.

manufacturers positioned to manufacture and distribute the life-saving medical breakthrough that is HIV PrEP. In October 2014, NIH published a notice in the Federal Register discussing the availability of HHS's then-pending patents on PrEP for licensing, with the aim of increasing awareness of the technology to find potential licensees. *See* NIH, Government-Owned Inventions; Availability for Licensing, 79 Fed. Reg. 59,277, 59,277-78 (Oct. 1, 2014). That same month, the Technology Transfer Office at NIH's NIAID sent multiple emails to a number of Gilead employees, notifying them that Gilead could be a good partner and linking them to the Federal Register notice. *See* Appx32686-32688 (Testimony of Dr. Tara L. Kirby). Gilead never responded. Appx32690 (Testimony of Dr. Tara L. Kirby).

NIAID's Technology Transfer Office renewed outreach efforts in early 2016 after issuance of HHS's patents on PrEP. NIH technology transfer officials, in an effort "to find a contact at Gilead who would respond [] about the CDC PrEP patents," emailed Gilead employees with whom they had been in active contact regarding unrelated matters. *Id*. NIH technology transfer officials were referred to one of the same individuals they had emailed originally in 2014. Appx32691 (Testimony of Dr. Tara L. Kirby). In all, NIH technology transfer officials reached out to Gilead "at least half a dozen" times between 2014 and 2016 regarding licensing of HHS's patents on PrEP. Appx32692 (Testimony of Dr. Tara L. Kirby).

Gilead's pattern of dodging communication with those that had provided the research critical to the commercial success of PrEP continued through 2018. The record shows that by 2019, it was clear that Gilead would not talk with HHS about the possibility of patent licensure and formalized public-private partnership. Appx03058-03059 (Complaint ¶¶ 240-41). Gilead's behavior over this period of years indicated hostility to the very idea of paying for licenses to government inventions.

In 2019, Gilead began expressing publicly the view that HHS's patents on PrEP are invalid. In May 2019, Gilead CEO Daniel O'Day stated before the House Oversight Committee that Gilead viewed the patents as invalid but would not challenge the validity of HHS's patents on PrEP due to how the company valued its "collaborative relationship with the agency." HIV Prevention Drug: Billions in Corporate Profits after Millions in Taxpayer Investments: Hearing Before the Comm. on Oversight and Reform, Serial No. 116–24 (May 16, 2019) at 14 (Statement of Daniel O'Day).[38] Just three months later, Gilead challenged the validity of HHS's patents on PrEP via inter partes review petitions at the Patent Trial and Appeal Board (PTAB), where Gilead lost on all counts. Appx03059 (Complaint ¶ 243); *see also* IPR2019-01453, Paper 14 (Feb. 20, 2020); IPR2019-

[38] https://www.congress.gov/116/meeting/house/109486/documents/HHRG-116-GO00-Transcript-20190516.pdf.

01454, Paper 15 (Feb. 20, 2020); IPR2019-01455, Paper 16 (Feb. 5, 2020); IPR2019-01456, Paper 17 (Feb. 5, 2020) (PTAB decisions denying institution of *inter partes review* in four separate petitions, as Gilead did not "establish[] a reasonable likelihood of prevailing on its assertion that at least one of the challenged claims is unpatentable based on the grounds advanced"). Gilead's IPR challenges predate the government's filing of this suit.

HHS has framed its successful defense of those IPR challenges and its decision to pursue the *United States v. Gilead* suit as an effort to protect the legitimacy of government-owned patents—patents that are paid for by American taxpayers and that undergird HHS's world-leading system of public-private partnership in pharmaceutical research and development, described in Section II.B. Upon filing of the suit, then-HHS Secretary Alex Azar stated, "Gilead must respect the U.S. patent system, the groundbreaking work by CDC researchers, and the substantial taxpayer contributions to the development of these drugs." U.S. Dep't of Justice, *United States Files Complaint against Pharmaceutical Company Gilead for Patent Infringement Related to Truvada® and Descovy® For Pre-Exposure Prophylaxis of HIV* (Nov. 7, 2019).[39]

[39] https://www.justice.gov/opa/pr/united-states-files-complaint-against-pharmaceutical-company-gilead-patent-infringement.

Gilead's refusal to partner with the government is all the more remarkable given the number of other firms that have partnered with HHS and licensed HHS's patents on PrEP. For example, Mylan Pharmaceuticals, a generic manufacturer that manufactures tenofovir disoproxil fumarate and emtricitabine combination tablets for sale in Australia, Canada, Germany, France, and the UK, approached the government seeking to license HHS's patents on PrEP. Appx32679 (Testimony of Dr. Tara L. Kirby). After unsuccessfully challenging the European counterpart to HHS's patents on PrEP, Mylan entered into an agreement with the government in 2016 that included a worldwide non-exclusive license to the rights to HHS's patents on PrEP, as well as related foreign patents. Appx03056-03057 (Complaint ¶¶ 225-29). Mylan also agreed to pay the government royalties for any products that are eventually sold in the United States, after expiry of Gilead's patents on the composition of the tablets. Appx03060 (Complaint ¶ 248).

Several other drug manufacturers have licensed the rights to foreign counterpart patents to HHS's patents on PrEP or are in negotiations to do so. Appx03057 (Complaint ¶¶ 230-31). HHS has executed at least six patent licenses involving HHS's patents on PrEP, all with a royalty of at least 4% of net sales. Appx32680-32681; Appx32710-32717 (testimony of NIH technology transfer officials describing licensing agreements with drug manufacturers involving HHS's patents on PrEP). Given the much higher profit margins that Gilead enjoys

compared to these generic manufacturers, it is all the more remarkable that it has refused to engage with the government to license HHS's patents on PrEP on the same or similarly reasonable terms. Appx33277-80 (Testimony of Dr. Robert DeForest McDuff, damages expert for the government, describing the high profit margins Gilead enjoys and indicating that a "reasonable [royalty] rate for Gilead would be in the five to ten percent range").

In sum, there is a near-15-year history of Gilead's knowledge of the government's research, patenting, and licensing activities around HIV PrEP, and of Gilead's refusal to participate in public-private partnership to get PrEP to patients as quickly and widely as possible. Meanwhile, Gilead has benefited enormously from the government's research on PrEP, to the tune of over $10 billion in sales at a 97% gross profit margin across the life of HHS's patents on PrEP. Appx33274-33277 (Testimony of Dr. Robert DeForest McDuff). Without the government's research and the government's education of doctors and patients about the benefits of PrEP, Gilead would never have realized these immense benefits. Gilead was presented with numerous opportunities to enter into active partnership with HHS and refused to do so at each turn. Instead, Gilead took unilateral steps to capitalize on the low-risk, high-margin financial opportunity that fell into its lap—steps that put the company's bottom line ahead of public health.

HIV PrEP eventually found its way to American patients, but years later than HHS had intended. Today, HIV transmission rates remain stubbornly higher in the United States than its peers—a preventable tragedy. *See* Benjamin Ryan, *U.S. progress in HIV fight continues to trail many other rich nations*, NBC News, May 23, 2023.[40]

D. Allowing Gilead's exploitation to stand risks upsetting the balance of public-private partnership, to the detriment of patients.

If Gilead's exploitation of HHS's research and development of HIV PrEP stands, the precedent set will risk upsetting HHS's successful practices of public-private partnership that companies and patients rely on.

The United States's world-leading system of taxpayer-funded, government-conducted research on pharmaceuticals and generous and active public-private partnership, described in Sections II.A and II.B, has thrived for decades on the expectation that companies should and will deal with HHS in good faith. Gilead has now unsettled that expectation.

Should Gilead succeed in earning billions of dollars from HIV PrEP without ever paying a license to HHS and without ever entering into traditional public-private partnership, other pharmaceutical companies may attempt to copy Gilead's

[40] https://www.nbcnews.com/nbc-out/out-health-and-wellness/us-progress-hiv-fight-continues-trail-many-rich-nations-rcna85683.

playbook. The result could be an unstable and unpredictable new status quo of drug companies looking to exploit HHS rather than partner with it.

If other companies do begin copying Gilead's playbook, HHS's laboratories may change their own practices, with potentially harmful consequences. HHS may be forced to bring further lawsuits to enforce its patent rights, taxing both courts' and agencies' resources. HHS's laboratories may come to view Gilead and other large, sophisticated pharmaceutical companies more skeptically. HHS may worry that these companies will harvest the fruits of government research without paying even a small royalty in return and without active collaboration to ensure successful product development conscious of public health goals. HHS may then enter new partnerships more slowly and less often.

Ultimately, patients are likely to bear the harmful consequences that might flow from disturbing the United States's successful system of public-private partnership in pharmaceutical innovation. If public-private partnership falters and HHS can no longer monitor and guide industry commercialization of HHS scientists' breakthrough inventions, some patients may wait longer for access to those inventions. Other patients may be harmed when drug companies, NIH, CDC, and other HHS agencies no longer work together to design and conduct highest-quality clinical trials to establish the safety and effectiveness of new products.

Our hope is that Gilead will ultimately come back to the negotiating table and pay royalties commensurate with what it would have paid had it entered, in good faith, licensing discussions with HHS years ago. We mean to hold Gilead accountable, protect the United States' world-leading system of pharmaceutical innovation, and demonstrate that companies benefitting from HHS's research breakthroughs must hold up their end of the bargain.

III. CONCLUSION

To protect the United States's world-leading system of pharmaceutical innovation, this Court should reverse the district court and grant the relief sought by the government.

Date: December 19, 2024 *Respectfully submitted,*[41]

/s/ Christopher J. Morten

Christopher J. Morten
NEW YORK UNIVERSITY SCHOOL OF LAW (WASHINGTON SQUARE LEGAL SERVICES, INC.)
Furman Hall, 245 Sullivan Street, 5th Floor
New York, NY 10012
cjm531@nyu.edu
Telephone: 212-998-6430

Counsel for Amici Curiae

[41] Counsel gratefully thanks NYU Law Science, Health & Information Clinic students Ben Anderson and Kiran Zelbo for their many contributions to this brief.

STATEMENT OF PARTY INTEREST & FINANCIAL CONTRIBUTIONS

1. Amici are the sole authors of this brief. No party or party's counsel authored this brief, in whole or in part.
2. No party or party's counsel contributed money that was intended to fund preparing or submitting the brief.
3. No person contributed money that was intended to fund preparing this brief. The costs associated with filing this brief were paid by Washington Square Legal Services, Inc. at New York University School of Law.

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Federal Circuit Rules 29(a) and 32(b)(1). It contains 6,765 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).
2. This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Times New Roman 14-point font in Microsoft Word.

Date: December 19, 2024 *Respectfully submitted*,

/s/ *Christopher J. Morten*

Christopher J. Morten
NEW YORK UNIVERSITY SCHOOL OF LAW (WASHINGTON SQUARE LEGAL SERVICES, INC.)
Furman Hall, 245 Sullivan Street, 5th Floor
New York, NY 10012
cjm531@nyu.edu
Telephone: 212-998-6430

Counsel for Amici Curiae