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In the

Supreme Court

of the

State of California

GILEAD TENOFOVIR CASES

AFTER A DECISION BY THE CALIFORNIA COURT OF APPEAL
FIRST APPELLATE DISTRICT, DIVISION FOUR, CASE NO. A165558
SAN FRANCISCO COUNTY SUPERIOR COURT, CASE NO. CJC-19-005043
HON. ANDREW Y.S. CHENG, TRIAL JUDGE

APPLICATION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF AND *AMICUS CURIAE* BRIEF OF COMMUNITY EDUCATION GROUP, C. VIRGINIA FIELDS, GLOBAL COALITION ON AGING, HIV AND HEPATITIS POLICY INSTITUTE, LIVER COALITION OF SAN DIEGO, DR. EUGENE MCCRAY, NATIONAL MINORITY QUALITY FORUM, PARTNERSHIP TO FIGHT CHRONIC DISEASE, AND PHILL WILSON IN SUPPORT OF PETITIONER

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IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

GILEAD SCIENCES, INC.,
Petitioner

v.

SUPERIOR COURT OF THE STATE OF CALIFORNIA,
COUNTY OF SAN FRANCISCO,
Respondent.

GILEAD TENOFOVIR CASES,
Real Parties in Interest.

AFTER A DECISION BY THE CALIFORNIA COURT OF APPEAL
FIRST APPELLATE DISTRICT, DIV. 4, CASE NO. A165558
SAN FRANCISCO COUNTY SUPERIOR COURT CASE NO. CJC-19-005043
HON. ANDREW Y.S. CHENG, TRIAL JUDGE

APPLICATION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF SUPPORTING PETITIONER

Under California Rules of Court, Rule 8.520(f), Community Education Group (CEG), C. Virginia Fields, Global Coalition on Aging (GCOA), HIV and Hepatitis Policy Institute (HIV + Hep), Liver Coalition of San Diego, Dr. Eugene McCray, National Minority Quality Forum (NMQF), Partnership to Fight Chronic Disease, and Phill Wilson (the "Amici") respectfully request permission to file the attached *amicus curiae* brief in support of petitioner Gilead Sciences,

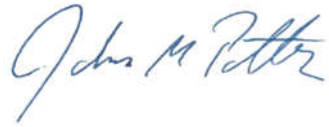
Inc.[1] Amici are advocates for underserved patient populations who have an interest in ensuring that the legal system properly incentivize the development of next-generation treatments and cures for people suffering life-threatening and life-changing diseases. The attached *amicus curiae* brief will assist the Court in better understanding the risk the Court of Appeal's ruling poses to the patients in the communities Amici serve.

Accordingly, Amici respectfully request that the Court accept and file the attached *amicus curiae* brief.

Dated: November 25, 2024

Respectfully submitted,

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By: 

John Potter

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[1] No party or counsel for a party in the pending appeal authored this proposed brief in whole or in part, and no person or entity other than *amici curiae*, their members, or their counsel made any monetary contribution intended to fund the preparation or submission of this proposed brief. (*See* Cal. Rules of Court, Rule 8.520(f)(4).)

AMICUS CURIAE BRIEF OF COMMUNITY EDUCATION GROUP, C. VIRGINIA FIELDS, GLOBAL COALITION ON AGING, HIV AND HEPATITIS POLICY INSTITUTE, LIVER COALITION OF SAN DIEGO, DR. EUGENE MCCRAY, NATIONAL MINORITY QUALITY FORUM, PARTNERSHIP TO FIGHT CHRONIC DISEASE, AND PHILL WILSON

INTRODUCTION

Amici curiae Community Education Group, C. Virginia Fields, Global Coalition on Aging (GCOA), HIV and Hepatitis Policy Institute (HIV + Hep), Liver Coalition of San Diego, Dr. Eugene McCray, National Minority Quality Forum (NMQF), Partnership to Fight Chronic Disease, and Phill Wilson (the "Amici") offer this *amicus curiae* brief to impress upon the Court that the novel duty created by the Court of Appeal risks a future with fewer next-generation treatments and cures for people suffering life-threatening and life-changing diseases—particularly diseases that impact the underserved communities on whose behalf Amici advocate.

Amici additionally wish to place HIV medications in context of the impact they had on people living with HIV and AIDS, turning what was for many people a death sentence into a manageable chronic condition. The fight against HIV has always depended on a steady stream of innovation building on innovation—and today, because of these breakthroughs, HIV is not only manageable, but preventable. But

groundbreaking innovations in HIV and AIDS treatment over the last few decades could be developed only within a legal regime that appropriately balances accountability for manufacturers of defective drugs with the right incentives for innovators to develop new drugs. Amici hope that by better understanding the risk the Court of Appeal's ruling poses to the patients in the communities Amici serve, this Court will better appreciate the danger of letting it stand.

Amici are advocates for underserved patient populations and work at the vanguard of global health initiatives. Certain Amici receive charitable support from donors, including pharmaceutical manufacturers, but Amici are independent organizations and do not act at the direction of their donors.

Since 1992, Executive Director A. Toni Young has led the **Community Education Group (CEG)** in addressing health disparities in underserved communities. Drawing on over 30 years of public health expertise, Toni spearheads initiatives combating HIV, hepatitis C, and opioid use. Under her leadership, CEG delivers community-based health services, capacity building, and advocacy while creating partnerships to drive systemic change. Her work prioritizes equity and resilience, improving health outcomes in marginalized populations.

C. Virginia Fields, MSW, served as President and CEO of the National Black Leadership Commission on Health, NBLCH (formerly known as the National Black Leadership Commission on AIDS, Inc.), from February 2008 – June 2024. She brought to the position over eighteen years of experience as an elected official in New York City, where she won widespread praise as a consensus builder around important city, state and national policy issues.

During her tenure, as President and CEO, NBLCH elevated its presence and influence through affiliate chapters in 11 cities and engaged over 100 active partnerships, nationwide. Her expertise in government and politics led to the successful implementation of noteworthy public policy achievements in domestic and international HIV/AIDS prevention, treatment and care. She served as a member of the New York State AIDS Advisory Council; U.S. Department of Health and Human Services' Region II Health Equity Council, one of ten such regional councils across the nation addressing health disparities and social determinants of health.

Ms. Fields served in elected office as President of the Borough of Manhattan, New York City, from 1998 to 2005, representing 1.5 million residents; and a member of the New York City Council from

1989 -1997. In 2005, she was a Democratic candidate for Mayor of New York City, becoming the first African American woman to seek that office.

Prior to elected office, Ms. Fields established a distinguished career in her professional field of social work, where she served in various positions as a Social Service Administrator for the New York City Work Release Program; Director of Foster Care/Adoption at The Children's Aid Society; and Consultant to the National Board of the YWCA.

A civil rights activist, political leader, educator and philanthropist, Ms. Fields serves as a featured speaker on leadership issues, civil rights, health, government and politics at numerous private industry, governmental, civic and community organization events. In 2004, she addressed the International Business Conference in Beijing, China; and was a speaker at the National Democratic Convention in Boston.

Born in Birmingham, Alabama, Ms. Fields received a Bachelor of Arts Degree from Knoxville College, in Tennessee and served as President of the National Alumni Association and member of the Board of Trustees. A graduate of Indiana University's School of Social Work,

she served as an adjunct lecturer at New York University's Silver School of Social Work and Columbia University Graduate School of Social Work.

Ms. Fields is member of Alpha Kappa Alpha Sorority, Links, Incorporated, Abyssinian Baptist Church, and board member of several nonprofit organizations. She is a recipient of numerous awards, citations and honors of distinction for her leadership on politics, health, education, community and economic issues. Enjoys travelling and resides in New York City.

Global Coalition on Aging (GCOA) is a leader in efforts to help people adapt to a world with longer life expectancies and manage in a world where there are more old than young. It works with major global brands to promote a thoughtful approach to positive and healthy aging. Through various initiatives, it helps governments and policy leaders understand age-related risks. For example, a recent GCOA report detailed the challenge of antimicrobial resistance (AMR)—the natural process by which infectious diseases grow resistant to treatment over time—as well as specific policy initiatives governments can take to address AMR. It addresses other key areas from Oncology and CVD to Bone Health and Elder Caregiving where older adults and the aging

society itself are especially in need of a healthier and more active aging. Through its reports, it has also helped educate policymakers about improving cancer care for older patients.

HIV and Hepatitis Policy Institute (HIV + Hep) is at the forefront of the effort to ensure quality and affordable healthcare for people with HIV and hepatitis. It works with members of the HIV, hepatitis, and other patient communities, as well as policy makers and members of the media to improve access to quality and affordable healthcare. In particular, HIV + HEP has helped to secure funding for HIV/AIDS- and hepatitis-related programs. HIV + HEP further helps educate the public about HIV and hepatitis through reports that showcase important medical developments.

Liver Coalition of San Diego is a local organization formed by medical specialists, transplant surgeons, patients, and caregivers to promote liver health and meet the needs of those affected by liver disease in San Diego County. They support initiatives that prevent liver cancer, the fastest growing cause of cancer death in the United States. Their goal is to prevent and, when necessary, treat the leading causes of liver cancer; such as viral hepatitis, fatty liver disease, alcohol associated liver disease and rare & pediatric liver diseases. The burden

these diseases place on patients is immense, and the need for new and effective treatments is urgent. Innovation in medical research and technology offers the best hope for these patients, many of whom are waiting for the next breakthrough to change their lives. Of the more than 100 different liver diseases, 15 are considered rare. Each liver disease is on a spectrum ranging from 'no relief' to 'effective treatments' and possible someday 'a cure', such is the case with hepatitis C.

Dr. Eugene McCray is an internationally renowned infectious disease epidemiologist and researcher who recently retired from the Centers for Diseases Control and Prevention on September 30, 2020, where he served as the Director of CDC's Division of HIV/AIDS Prevention (DHAP). In this role, he was responsible for leading CDC efforts in U.S. domestic response for HIV prevention including Ending the HIV Epidemic Initiative. More specifically, he oversaw prevention programs, research, surveillance, and communications activities that were designed to have the greatest effect on reducing HIV infections in the United States and improving health equity. Dr. McCray was the first Director for CDC's Global AIDS Program from 2000 to 2004. While Director of the Global AIDS Program, he established international

HIV/AIDS assistance program in 25 countries and three regions around the world (*e.g.*, Africa, Asia and the Caribbean/Latin America regions) and worked closely with Health and Human Services and State Department leaders to develop the blueprint for the President's Emergency Plan for AIDS Relief. Dr. McCray is currently serving as Chair of the Board of Trustees for AIDS United, a national non-profit organization in Washington, DC that is dedicated to ending the AIDS epidemic in the United States. AIDS United exists to amplify the voices of people living with and vulnerable to HIV through our work on policy and advocacy, strategic grant making and capacity building. He is also a member of the Board of Directors for TruEvolution, a local non-profit organization based in Riverside, California whose mission is to fight for health equity and racial justice to advance the quality of life and human dignity of LGBTQ+ people. Finally, Dr. McCray is a member and former Chair of the HIV Leadership Advisory Council to the U.S. Business Action to End HIV, a growing coalition of businesses committed to ending the HIV epidemic in America.

National Minority Quality Forum (NMQF) is a 501(c)(3) not-for-profit research, education and advocacy organization based in Washington, DC. The mission of NMQF is to reduce patient risk by

assuring optimal care for all. NMQF's vision is an American health services research, delivery and financing system whose operating principle is to reduce patient risk for amenable morbidity and mortality while improving quality of life. NMQF strives to center health equity by eliminating policy, structural and systemic barriers that compromise the ability of the American health services enterprise to meet the needs of all population cohorts. NMQF is non-partisan and therapeutic-area agnostic. The education and experience of their staff enable engagement with and across the research, delivery and financing sectors. This enables NMQF to operationalize their values construct at the federal and state levels as the science evolves and where opportunities present. Therapeutic areas with which they have engaged include cardiopulmonary diseases, kidney diseases, diabetes, Alzheimer's disease and related dementia, cancer, sickle cell disease, HIV and AIDS. Examples of their engagements include the development of ICD-10-CM coding, performance measures, data analyses that link administrative claims and census data, primary data collection through surveys, Thought Leaders Roundtables, and legislative, policy and regulatory advocacy. In every instance, for every therapeutic area, NMQF has identified the need for innovation and

additional research to assure that improvements in the quality of care and treatment outcomes redound to the benefit of all patients, families and communities.

Partnership to Fight Chronic Disease is an internationally-recognized organization of patients, providers, community organizations, business and labor groups, and health policy experts committed to raising awareness of the number one cause of death, disability, and rising health care costs: chronic disease.

Phill Wilson is an internationally renowned HIV/AIDS advocate and activist. He is the founder and former President and CEO of the Black AIDS Institute, a think tank whose mission is to stop the AIDS pandemic in African American communities. Prior to founding the Institute in 1999, Mr. Wilson served as the AIDS Coordinator for the City of Los Angeles from 1990 to 1993, and the Director of Policy and Planning at AIDS Project Los Angeles from 1993 to 1996. He was co-chair of the Los Angeles County HIV Health Commission from 1990 to 1995, and was an appointee to the Health Resources & Services Administration AIDS Advisory Committee from 1995 to 1998. Mr. Wilson was the cofounder of the National Black Lesbian and Gay Leadership Forum and the National Task Force on AIDS Prevention.

He has been involved in the founding of a number of other AIDS service organizations and community-based organizations, including the Chris Brownlie Hospice, the AIDS Healthcare Foundation, the National Minority AIDS Council, the Los Angeles County Gay Men of Color Consortium, and the CAEAR Coalition.

ARGUMENT

In finding that drug manufacturers may be held liable for failing to develop safer alternatives to existing, non-defective medicines, the Court of Appeal focused on only a subpopulation of people who rely on medicines to treat HIV or AIDS: those who allege injuries from rare, disclosed side effects of the medicines. This narrow focus elides an equally important, much bigger picture: the overwhelming benefits breakthrough medicines provided and continue to provide to people living with or at risk of contracting HIV or AIDS—including Plaintiffs themselves—and the major risk the ruling below poses to the steady flow of innovation on which this and other patient communities rely.

I. The Breakthroughs in the Decades-Long Battle Against HIV/AIDS.

Just a few decades ago, HIV was a national public health crisis. It proved fatal with tragic regularity. By the end of 1981—at the start of the outbreak—there were already a staggering 130 reported deaths

among the 337 reported cases.[2] New AIDS cases increased 89% from 1984 to 1985; 51% of adults and 59% of children died.[3] During the 1980s, HIV "emerged as a leading cause of death in the United States."[4] By 1993, it was the leading cause of death among Americans aged 25-44 years old.[5] In some communities, those numbers were much higher.

People who contracted HIV had few medical options—in addition to contending with rampant discrimination and prejudice.[6] In the early 1980s, virtually no antiviral drugs existed to treat any disease.[7] An early HIV treatment, Azidothymidine (AZT), resulted in debilitating side effects including severe intestinal problems, damage to the immune system, nausea, vomiting and headaches.[8]

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[2] *See* https://www.hiv.gov/hiv-basics/overview/history/hiv-and-aids-timeline#year-1996.

[3] *Id.*

[4] *Id.*

[5] *Id.*

[6] *See* https://pmc.ncbi.nlm.nih.gov/articles/PMC8493181 ("Obituaries often excluded AIDS as the cause of death, and surviving partners were often not named as bereaved strangers in the absence of a legally executed will, with the families of deceased men refusing to acknowledge partners and taking personal effects and property."); https://news.gallup.com/vault/259643/gallup-vault-fear-anxiety-during-1980s-aids-crisis.aspx ("In two separate polls in 1987, roughly half of Americans agreed that it was people's own fault if they got AIDS (51%) and that most people with AIDS had only themselves to blame (46%)").

[7] *See* https://ccr.cancer.gov/news/landmarks/article/first-aids-drugs

[8] *See* https://time.com/4705809/first-aids-drug-azt/.

Single-drug treatments like AZT had serious limitations because HIV mutates. This allows HIV to become impervious to any single drug.[9] For some, taking AZT alone resulted in drug resistance in a matter of days.[10] Researchers urgently sought a way to avoid such drug resistance by combining drugs.

A breakthrough came in the early 1990s when studies found progress in using a combination of two drugs.[11] Then, in 1996, researchers found that triple-drug therapy could suppress HIV replication to minimal levels and could avoid drug resistance.[12] Highly Active Antiretroviral Therapy (HAART)—a regimen in which one takes three or more drugs at once to treat HIV—became popular.[13]

But HAART's combination approach had its own challenges. It required patients to take multiple pills a day, and some of the medications used, like zidovudine, caused serious side effects.[14] Simply taking the drugs correctly was difficult: patients had to take pills

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[9] *See* https://www.niaid.nih.gov/diseases-conditions/antiretroviral-drug-development.
[10] *See* https://www.niaid.nih.gov/diseases-conditions/antiretroviral-drug-development.
[11] *See* https://www.niaid.nih.gov/diseases-conditions/antiretroviral-drug-development.
[12] *Id.*
[13] *See* https://www.webmd.com/hiv-aids/hiv-treatment-history
[14] *Id.*

at different intervals throughout the day, some with food and others without.[15] For many people, it was challenging to stick to such complex regimens long-term, undermining the effectiveness of their treatment.

To address these medical and practical difficulties with the multi-drug regimens, in 2004, the FDA called on pharmaceutical companies to develop combination drug therapy in a single pill to fight HIV.[16] Reflecting the seriousness of the issue, the FDA noted that it was prepared to expedite review of any such products.[17]

Two years later, in 2006, Gilead was one of the companies that provided the much-needed single-pill breakthrough with a complete HIV treatment regimen "in[] a single fixed-dose combination pill."[18] As the FDA noted, "[i]nstead of a 'cocktail' of multiple medications, HIV treatment could now be simplified into a once-daily single tablet regimen."[19] A single drug that was effective without a complex multi-pill regimen constituted a major advance over prior approaches,

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[15] *See* https://www.niaid.nih.gov/diseases-conditions/antiretroviral-drug-development.

[16] *See* https://www.federalregister.gov/documents/2004/05/19/04-11364/guidance-for-industry-on-fixed-dose-combination-and-co-packaged-drug-products-for-treatment-of-hiv.

[17] *Id.*

[18] *See* https://www.fda.gov/about-fda/fda-history-exhibits/history-fdas-role-preventing-spread-hivaids.

[19] *Id.*

affording the many people living with HIV a safe, easy-to-take, and FDA-approved medicine to effectively treat the disease and significantly lengthen and improve their lifespans.

Medical research has continued to yield breakthroughs in fighting HIV. New medicines effectively treat and control the disease, transforming it into a manageable, non-transmissible chronic illness for many people.[20] Some medicines can now be used prophylactically to prevent partners of people with HIV from acquiring HIV.[21] This peace of mind and freedom for people with HIV cannot be overstated. Prophylactic medicines can reduce one's risk of contracting HIV through sex about 99%, and through injection by at least 74%.[22] People living with HIV can now treat it with a range of combination pills.[23] Now, we are hearing there will be a treatment that may require only two injections a year to achieve "total protection from the virus."[24] This series of breakthroughs shows how innovation builds upon innovation.

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[20] *See* https://www.hiv.gov/tasp; https://www.nih.gov/news-events/news-releases/newer-anti-hiv-drugs-safest-most-effective-during-pregnancy.
[21] *See* https://www.cdc.gov/hiv/risk/prep/index.html.
[22] *See* https://www.cdc.gov/hiv/risk/prep/index.html.
[23] *See* https://www.healthline.com/health/hiv-aids/evolution-of-hiv-treatments#combination-pills.
[24] *See* https://www.nytimes.com/2024/06/21/health/lenacapavir-hiv-prevention-africa.html.

II. The Court of Appeal's Novel Duty Jeopardizes the Next Generation of Breakthrough Treatments and Cures.

The novel duty imposed by the Court of Appeal jeopardizes the next generation of breakthroughs for people with HIV and AIDS, as well as those fighting other diseases, by imposing liability on drug manufacturers for lifesaving and concededly non-defective drugs. By disrupting the current incentive structure for innovation, it threatens to rob the most vulnerable patient populations—including the ones on whose behalf Amici advocate—of new medicines they desperately need. That risk far outweighs any potential benefit of such a duty.

Medical advances like the medicines at issue in this case happen only as the result of enormous investment by pharmaceutical companies in the research and development of safe and effective new drugs. The vast expense and risk of bringing new drugs to market is well known: Deloitte estimated that, in 2022, bringing a drug to market cost over $2 billion.[25] Investment in research and development is enormous: a recent study of investment in new medicines from 2009 to

[25] *See* https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-seize-digital-momentum-rd-roi-2022.pdf.

2018 found that the average capitalized research and development investment to bring a new drug to market was about $1.3 billion.[26] As the Congressional Budget Office has summarized, "developing new drugs is a costly and uncertain process, and many potential drugs never make it to market."[27]

By imposing liability on companies for disclosed side effects of non-defective drugs, the Court of Appeal's rule threatens the approach to drug development that has resulted in countless breakthroughs that have saved and improved the lives of billions of people. The Court of Appeal's duty puts its thumb on the scales of research and development decisions in two unfortunate ways.

First, to avoid liability for injuries caused by already non-defective and reasonably safe medicines, the Court of Appeal's approach incentivizes companies to shift their resources to making marginal improvements on already safe and effective medicines rather than investing in new, breakthrough medicines to treat to existing medicines and to rush those improvements to market quickly, possibly without fully understanding their risks.

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[26] *See* https://pubmed.ncbi.nlm.nih.gov/32125404.
[27] *See* https://www.cbo.gov/publication/57126.

Indeed, under this new duty, if a manufacturer learns about an alternative drug in the process of its research a potential medicine, it will risk future litigation if it does not prioritize bringing the alternative to market as soon as it can—*even if* the initial drug is safe, non-defective, and the alternative has not proven better.

This is not an incentive to produce the best drugs: it is a virtual requirement to prioritize, above all else, bringing to market alternative drugs that may not turn out to be any safer or even similarly effective to those currently on the market. The consequence is that manufacturers might choose to focus on developing drugs that are merely small improvements over existing drugs for some people, rather than on treatments for underserved patient populations and diseases that currently lack effective treatment options.

There are many such populations in dire need of such treatments: one in ten Americans have a rare disease and 95% of known rare diseases do not have an approved treatment.[28] For example, few treatment options are available for Duchenne muscular dystrophy, a rare, serious, debilitating childhood genetic disease characterized by

[28] *See* https://ncats.nih.gov/sites/default/files/NCATS_RareDiseasesFactSheet.pdf.

muscle degeneration that leads to injury and weakness, and a significantly shortened life expectancy.[29] Likewise, Tay-Sachs disease, a rare, fatal, neurodegenerative disorder that most commonly occurs in children, has no cure or effective treatment.[30]

Many such rare or hard-to-treat diseases primarily or disproportionately impact historically disadvantaged or underserved populations. Amicus Global Coalition on Aging, for example, is particularly focused on the need for advancements in treating conditions that affect seniors, including Alzheimer's, antimicrobial resistance, cardiovascular disease, osteoporosis, and communicable diseases in older adults. Amicus HIV and Hepatitis Policy Institute sees a pressing need for cures for HIV and hepatitis B, as well as longer-acting HIV treatments and prevention products.

Further examples abound: Catamenial pneumothorax is a rare condition impacting women, and results in a collapsed lung.[31] Its exact

[29] *See* https://www.pfizer.com/science/focus-areas/rare-disease/research.
[30] *See* https://www.genome.gov/Genetic-Disorders/Tay-Sachs-Disease.
[31] *See* https://rarediseases.org/rare-diseases/catamenial-pneumothorax/.

cause is unknown, making treatment challenging.[32] According to one study, the recurrence rate for patients undergoing surgery to treat this disease can be as high as 40%.[33] Similarly, in the United States, more than 90% of people affected with sickle cell disease—an inherited blood disorder that can cause severe pain, anemia, and stroke—are Black or African-American.[34] Hermansky-Pudlak syndrome, a rare form of albinism that causes visual impairment and excessive bleeding, is most prevalent in people from Puerto Rico.[35] And Kawasaki disease, which is the primary cause of heart disease in children in the United States, mostly frequently affects children of Asian descent.[36]

The novel duty imposed by the Court of Appeal would pressure manufacturers to focus on developing incrementally safer alternatives to existing treatments rather than pathbreaking new treatments for underserved populations or fatal diseases. For example, manufacturers might feel pressured to allocate resources toward developing

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[32] *See* https://rarediseases.org/rare-diseases/catamenial-pneumothorax/.
[33] *See* https://pmc.ncbi.nlm.nih.gov/articles/PMC4971265.
[34] *See* https://rarediseases.org/rare-diseases/sickle-cell-disease/; https://www.cdc.gov/sickle-cell/data/index.html.
[35] *See* https://rarediseases.org/rare-diseases/hermansky-pudlak-syndrome/.
[36] *See* https://rarediseases.org/rare-diseases/kawasaki-disease/.

incrementally safer alternatives for common, non-fatal conditions like psoriasis over researching desperately needed treatments for conditions like Alzheimer's, hepatitis B, sickle cell disease, or Kawasaki disease.

A second possible consequence of the Court of Appeal's new duty is to create a disincentive for pharmaceutical companies to investigate and learn of potential improvements to existing products—and to market those improvements—because doing so will create liability for the manufacturer for injuries caused by the earlier iteration of the medicine. Indeed, the premise of the Court of Appeal's duty is that manufacturers can be liable if they "know" of an even safer version of their product. Pharmaceutical companies could therefore avoid liability by *not* undertaking rigorous scientific research and pursuing expensive clinical trials aimed at discovering improvements and developing the next generation of therapeutic treatments and cures.

This is particularly problematic because manufacturers often research backup candidates even while continuing to move ahead with a "lead" drug development candidate. Because such transformative research would entail the possibility of finding drugs along the way that enterprising plaintiffs' lawyers, with the benefit of hindsight, could later allege to be "safer," companies might decide not to conduct that

research purely for litigation-based reasons. And even if a pharmaceutical company learned of an improvement, it would have to think twice about marketing it on the risk that releasing an improvement over an existing medicine might lead to lawsuits against the earlier medicine and claims that the improvement could have and should have been released earlier. This decision thus inhibits—and potentially punishes—innovators for pursuing drug development.

Patients of course deserve to be safe from defective drugs. But that does not mean allowing tort liability for side effects that were adequately warned about, and that are concededly outweighed by the benefits of the medications. Existing law already provides multiple layers of protection for patients: the FDA rigorously evaluates new drugs before they come to market and individuals injured by defective drugs can seek redress in the courts. By imposing liability on makers of *non-defective* drugs, the novel duty imposed by the Court of Appeal unnecessarily supersedes and supplements the role of the FDA and current tort law—even as it threatens to disrupt the incentive structure for the development of breakthrough treatments and cures.

In short, less innovation means the vulnerable patient populations on whose behalf Amici advocate are less likely to see the

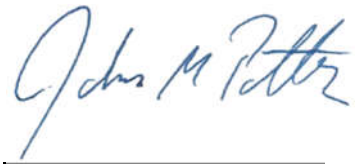
breakthrough improvements their lives depend on. Any potential benefit of the Court of Appeal's novel duty—and Amici see none for the patient populations they serve—pales in comparison.

CONCLUSION

For the foregoing reasons, this Court should hold that the novel duty created by the Court of Appeal is not cognizable under California law.

November 25, 2024

Respectfully submitted,



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CERTIFICATE OF COMPLIANCE

Pursuant to California Rules of Court Rule 8.520, subd. (c), I hereby certify that, according to the word count feature of the software used, this Amicus Curiae Brief contains 4,425 words, exclusive of materials not required to be counted under Rule 8.520, subd. (c).

November 25, 2024

/s/ John Potter
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)

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