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March 8, 2024

Supreme Court of California
350 McAllister Street, Room 1295
San Francisco, California 94102

Re: Letter Brief on Behalf of Amici Curiae ALLvanza, Global Coalition on Aging, HIV and Hepatitis Policy Institute, Liver Coalition of San Diego, National Minority Quality Forum, Partnership to Fight Chronic Disease, and Phill Wilson, *Gilead Sciences, Inc. v. Superior Court of the City and County of San Francisco and Gilead Tenofovir Cases*, Case No. S283862

Dear Chief Justice Guerrero and Associate Justices:

Amici curiae ALLvanza, Global Coalition on Aging, HIV and Hepatitis Policy Institute, Liver Coalition of San Diego, National Minority Quality Forum, Partnership to Fight Chronic Disease, and Phill Wilson (together, Amici) offer this amicus letter pursuant to California Rule of Court 8.500(g). On behalf of the patient populations for whom they advocate, Amici respectfully urge the Court to grant review in the above-referenced case and make clear that the "duty to innovate" recognized by the Court of Appeal is not cognizable under California law. This unprecedented legal theory stands to chill the development of a future generation of drugs, including much-needed potential treatments and cures for a wide range of diseases. It will also have a chilling effect on innovation generally, and will therefore adversely affect the investment environment in California—especially for sectors where innovation is critical.

Amici recognize that tort law has long helped ensure prescription drug safety by imposing liability on manufacturers of defective drugs. But the Court of Appeal's recent decision would impose liability for *non-defective* drugs, if the manufacturer was researching and developing another product that it "knew" was even "safer" than the drug

in question. Hence, if the decision is allowed to stand, research related to *improvements* in patient safety could serve as a basis to impose civil liability on pharmaceutical companies. The decision thus discourages research, innovation, and investment in potential new treatments and cures. And even worse, the decision may mean that breakthrough medicines are not available for patients suffering from debilitating and even deadly diseases. Moreover, this approach effectively challenges the FDA itself as it pre-empts and overrides FDA decisions on drug development, which already take account of these matters. This is profoundly disturbing and unsettling due to the effects on settled national policy relative to drug development.

Amici submit this letter because they share an interest in promoting safe and effective future drug development on behalf of patient groups and care-givers in California, across America, and worldwide—in particular, older adults and individuals with HIV/AIDS, hepatitis, and other diseases in acute need of pharmaceutical breakthroughs. Amici respectfully submit that the law should incentivize and promote—and never impede—the development of future treatments and cures, particularly ones that stand to benefit underserved or disadvantaged populations.

Amici are at the vanguard of global health initiatives:

ALLvanza is a nonpartisan, forward-thinking, policy and action nonprofit organization that advocates for the success of Latinos, and other underserved communities, in our innovation- and technology-based society.

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 accomplish this through community-based education, linkages to care, advocacy, and research programs.

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. Our 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.

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 co-founder 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.

Older adults around the world—as well as people with HIV/AIDS, hepatitis, and other diseases—benefit from improved access to affordable, safe pharmaceutical drugs. New medicines prevent HIV;[1] others help those with HIV live normal and healthy lives

[1] https://www.cdc.gov/hiv/risk/prep/index.html

without risk of transmitting HIV.[2] Work is underway to develop long-acting treatment and prevention medications so that people with HIV do not need to take a pill every day.[3] Similarly, numerous drugs have helped people who have contracted Hepatitis B live healthy, normal lives.[4] And cures for Hepatitis C now exist.[5] In short, new drugs come to market every year that improve the lives of people with a wide variety of health conditions.[6] This is within the context of existing nationally directed policies from the FDA, which already has effective regulations that would be superseded and overridden by California law. In that case, California would deny those living in the other 49 states their rights currently and formally ensured through the FDA.

To ensure that older adults and people with HIV/AIDS, hepatitis, and other diseases have the highest quality of life, it is vital to optimize conditions for the ongoing and continuous development of new treatments and cures, including innovations for more effective treatment options such as dosage. This means incentivizing pharmaceutical companies to invest in research and development of safe and effective new drugs. The enormous expense of bringing new drugs to market is well known; Deloitte recently estimated that, in 2022, bringing a pharmaceutical product to market cost over $2 billion.[7] 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."[8]

Given the importance—and immense cost—of developing new treatments and cures, Amici have a profound interest in ensuring that the law not disincentivize innovation. Amici were accordingly concerned to learn of the new legal duty recognized by the Court of Appeal in this case, which would impose liability on manufacturers of drugs that are *undisputedly* safe and effective as approved by the FDA itself. The new duty is indifferent to the safety of the existing product, imposing liability if a manufacturer "knew" it could potentially make an even "safer" alternative.

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[2] https://www.hiv.gov/tasp; https://www.nih.gov/news-events/news-releases/newer-anti-hiv-drugs-safest-most-effective-during-pregnancy; https://www.cdc.gov/hiv/basics/prep/about-prep.html

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9936705/

[4] https://www.hepb.org/treatment-and-management/treatment/approved-drugs-for-adults/

[5] https://www.nhs.uk/conditions/hepatitis-c/treatment/#:~:text=Hepatitis%20C%20is%20treated%20using,more%20than%2090%25%20of%20people.

[6] https://www.uptodate.com/contents/whats-new-in-drug-therapy#H143184

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

[8] https://www.cbo.gov/publication/57126

Amici wish to impress upon the Court that this new-fangled duty creates a disincentive to develop new treatments and cures, to the detriment of their patient populations—even as it would supersede the FDA regulatory approval process on which all Americans currently rely.

The Court of Appeal's decision imposes litigation risk on potentially life-saving drugs in a way that is contrary to the public good and the interests of all patients, including the most vulnerable. In unprecedented fashion, this new litigation risk attaches to drugs that are concededly safe and effective. In the vein of no good deed goes unpunished, a manufacturer could face potential liability for undertaking rigorous scientific research and pursuing expensive clinical trials aimed at developing the next generation of therapeutic treatments and cures. The decision thus inhibits—and potentially punishes—innovators (including companies) for pursuing drug development, to the detriment of all, including Amici's patient populations.

Moreover, under this ruling, a manufacturer would be forced to develop drugs that are improvements over existing drugs, focusing on minimizing side effects of drugs that are already on the market and that benefit a patient population. This would mean fewer research and development resources to develop new drugs for patient populations that do not have any drug available to them. This would particularly harm individuals with rare diseases. This suboptimal incentive structure would fail to provide the best health care outcomes for patients, demonstrating why the courts should not interfere with how companies allocate their resources when there are competing needs for those resources.

To be clear, Amici's patient populations would ultimately suffer the most profound consequences if the Court of Appeal's decision is allowed to stand. Amici's patient groups would be the ones deprived of ground-breaking medications that are needed to treat and cure serious diseases. Amici respectfully urge the Court not to overlook these patients in deciding whether to grant review.

Respectfully submitted,

John M. Potter (SBN 165843)

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I, Stephen Moore , declare that I am not a party to the action, am over 18 years of age and my business address is: 626 Wilshire Blvd., Suite 820, Los Angeles, California 90017; ca@counselpress.com

On 3/8/2024 declarant served the within: Letter Brief on Behalf of Amici Curiae **upon:**

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