A165558

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA
FIRST APPELLATE DISTRICT, DIVISION FOUR

GILEAD SCIENCES, INC.,
Petitioner,
v.
SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF SAN FRANCISCO,
Respondent,
and
GILEAD TENOFOVIR CASES,
Real Parties in Interest.

Review of a Decision of the Superior Court,
San Francisco County, Case No. CJC-19-005043 (Cheng, J.)

APPLICATION BY THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, THE CALIFORNIA LIFE SCIENCES ASSOCIATION, THE BIOTECHNOLOGY INNOVATION ORGANIZATION, AND THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF GILEAD SCIENCES, INC.

*Ashley M. Simonsen (Bar No. 275203)
Alice L. Phillips (Bar No. 322070)
COVINGTON & BURLING LLP
1999 Avenue of the Stars
Los Angeles, CA 90067
Telephone: (424) 332-4782
Facsimile: (424) 332-4749
asimonsen@cov.com
aphillips@cov.com

Michael X. Imbroscio
COVINGTON & BURLING LLP
850 Tenth Street NW
Washington, DC 20001

Paul W. Schmidt
COVINGTON & BURLING LLP
620 Eighth Avenue
New York, NY 10018

Attorneys for Amici Curiae Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, and Advanced Medical Technology Association

David Gonzalez (Bar No. 215728)
Cher Gonzalez (Bar No. 210026)
GONZALEZ GOVERNMENT CONSULTING
1215 K Street, Suite 1100
Sacramento, CA 95814
Telephone: (916) 281-6981
david@gonzalezconsult.com
cher@gonzalezconsult.com

Attorneys for Amicus Curiae California Life Sciences Association

Pursuant to Appellate Rule 8.200(c), the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the California Life Sciences Association ("CLS"), the Biotechnology Innovation Organization ("BIO"), and the Advanced Medical Technology Association ("AdvaMed") respectfully seek leave to file the accompanying *amicus curiae* brief in support of Defendant Gilead Sciences, Inc.[1]

PhRMA is a voluntary, nonprofit association comprised of the leading biopharmaceutical research and technology companies. PhRMA members produce innovative medicines, treatments, and vaccines that save and improve the lives of countless individuals every day. PhRMA members have invested more than a trillion dollars in R&D since 2010, and in 2020 alone invested an estimated $91 billion in discovering and developing new medicines.[2] PhRMA advocates in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines.

Serving over 1,000 biotechnology, pharmaceutical, medical

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[1] Pursuant to Rule 8.200(c), PhRMA, CLS, BIO, and AdvaMed certify that no party or party's counsel authored this brief in whole or in part. No party or party's counsel made a monetary contribution intended to fund the preparation or submission of this brief, and no person or entity other than *amicus curiae*, its members, or its counsel made such a monetary contribution. Although Gilead Sciences, Inc. is a member of PhRMA, CLS, and BIO, it has not contributed financially to the preparation of this brief.

[2] PhRMA, *2021 Profile: Biopharmaceutical Research Industry* (2020) p. 2 <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Industry-Profile-2021/ 2021-Profile-3.pdf>.

device, and diagnostics companies; research universities and institutes; investors; and service providers, CLS is one of the most impactful life sciences advocacy organizations in California. CLS's members are comprised of the scientists, inventors, entrepreneurs, and leaders that have made California the largest, most innovative and productive life sciences ecosystem in the world. CLS works closely with industry, government, academia, and others to shape public policy, improve access to innovative technologies, and grow California's life sciences economy. In doing so, CLS fulfills its mission to protect and nurture California's life sciences industry, empowering discoveries that lead to healthier lives around the world.

BIO is the principal trade organization representing the biotechnology industry domestically and abroad. BIO has more than 1,000 members, which span the for-profit and nonprofit sectors and range from small start-up companies and biotechnology centers to research universities and Fortune 500 companies. BIO's members devote billions of dollars annually to researching and developing biotechnological healthcare, agricultural, environmental, and industrial products that cure diseases, improve food security, create alternative energy sources, and deliver many other benefits.

AdvaMed is the world's largest medical technology association representing device, diagnostics, and digital technology manufacturers that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Its more than 400 member companies

span every field of medical science and range from cutting-edge startups to multinational manufacturers. AdvaMed's member companies are dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards.

This case presents a question of critical importance to the members of PhRMA, CLS, BIO, and AdvaMed: when the U.S. Food and Drug Administration ("FDA") approves the use of an unquestionably safe, effective, and non-defective medication, can a company be held liable in hindsight for its decision to discontinue development of a *different* pharmaceutical compound. PhRMA, CLS, BIO, and AdvaMed's members must make daily strategic and scientific decisions regarding where to devote research and development resources and how best to pursue regulatory approval of their important products in the face of scientific uncertainty and increasingly massive and costly litigation centering on elements of those decisions. They thus have a unique interest in ensuring that litigation cannot be used to punish a company for developing and marketing a product that FDA has indisputably determined has benefits outweighing its risks, based on an accusation that the company should have pursued approval for an alternate product or done so on a faster timetable.

PhRMA, CLS, BIO, and AdvaMed believe their views will assist the Court in resolving this case by providing a unique perspective on the practical implications of the decision below.

Respectfully submitted,

/s/ Ashley M. Simonsen

Ashley M. Simonsen
Alice L. Phillips
COVINGTON & BURLING LLP
1999 Avenue of the Stars
Los Angeles, CA 90067
Telephone: (424) 332-4782
Facsimile: (424) 332-4749
asimonsen@cov.com
aphillips@cov.com

Michael X. Imbroscio
COVINGTON & BURLING LLP
850 Tenth Street NW
Washington, DC 20001
Telephone: (202) 662-6000
Facsimile: (202) 662-6291
mimbroscio@cov.com

Paul W. Schmidt
COVINGTON & BURLING LLP
620 Eighth Avenue
New York, NY 10018
Telephone: (212) 841-1000
Facsimile: (212) 841-1010
pschmidt@cov.com

Counsel for Amici Curiae Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, and Advanced Medical Technology Association

/s/ David Gonzalez

David Gonzalez
Cher Gonzalez
GONZALEZ GOVERNMENT

CONSULTING
1215 K Street, Suite 1100
Sacramento, CA 95814
(916) 281-6981
david@gonzalezconsult.com
cher@gonzalezconsult.com

Counsel for California Life Sciences Association

Dated: October 3, 2022

PROOF OF SERVICE

I am a resident of the State of California and over the age of eighteen years, and not a party to the within action. My business address is 1999 Avenue of the Stars, Suite 3500, Los Angeles, CA 90067. On October 3, 2022, I served the following document(s) described as:

APPLICATION BY THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, THE CALIFORNIA LIFE SCIENCES ASSOCIATION, THE BIOTECHNOLOGY INNOVATION ORGANIZATION, AND THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION TO FILE AN *AMICUS CURIAE* BRIEF IN SUPPORT OF GILEAD SCIENCES, INC.

on the interested parties in this action as follows:

GRANT & EISENHOFFER P.A. M. Elizabeth Graham
201 Mission Street, Suite 1200
San Francisco, California 94105
Telephone: (415) 229-9720
Email: egraham@gelaw.com

JENNER LAW, P.C.
Robert K. Jenner3600 Clipper Mill Road, Suite 240 Baltimore, Maryland 21211
Telephone: (410) 413-2155
Email: rjenner@jennerlawfirm.com

MOSKOVITZ APPELLATE TEAM Myron Moskovitz
90 Crocker Avenue
Oakland, California 94611
Telephone: (510) 384-0354
Email: myronmoskovitz@gmail.com

KERSHAW, COOK & TALLEY, P.C. William A. Kershaw
401 Watt Avenue
Sacramento, California 95846
Telephone: (916) 779-7000

Email: bill@kctlegal.com

SCHNEIDER WALLACE COTTRELL
KONECKY LLP
Amy Eskin, SBN 127668
2000 Powell Street, Suite 1400
Emeryville, California 94608
Telephone: (510) 740-2936
Email: aeskin@schneiderwallace.com

ESNER, CHANG & BOYER
Andrew N. Chang, SBN 84544
Holly N. Boyer, SBN 221788
234 East Colorado Boulevard, Suite 975
Pasadena, California 91101
Telephone: (626) 535-9860
Email: achang@ecbappeal.com
hboyer@ecbappeal.com

DEBRA E. POLE (SBN 97816)
dpole@sidley.com
JOSHUA E. ANDERSON (SBN 211320)
janderson@sidley.com
SEAN A. COMMONS (SBN 217603)
scommons@sidley.com
DAVID CARPENTER
dcarpenter@sidley.com
COLLIN WEDEL
cwedel@cov.com
SIDLEY AUSTIN LLP
555 West Fifth Street, Suite 4000
Los Angeles, CA 90013
Telephone: (213) 896-6000
Facsimile: (213) 896-6600

ANDREW D. SILVERMAN (SBN 246539)
asilverman@orrick.com
ORRICK, HERRINGTON & SUTCLIFFE LLP 51 West 52nd Street
New York, NY 10015
Telephone: (212) 506-5000

Facsimile: (212) 506-5151

[x] (BY TRUEFILING) By filing and serving the foregoing through Truefiling such that the document will be sent electronically to the eservice list on September 28, 2022; and

San Franscisco Superior Court
Department 613
Hon. Andrew Y.S., Cheng
400 McAllister St.,
San Francisco, CA 94102

[x] (BY MAIL) By causing the document to be sealed in an envelope addressed to the recipient above, with postage thereon fully prepaid, and placed in the United States mail at Los Angeles, California.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this proof of service is executed at Los Angeles, California on October 3, 2022.

/s/ *Mark Shuttlesworth*
Mark Shuttlesworth

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BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, THE CALIFORNIA LIFE SCIENCES ASSOCIATION, THE BIOTECHNOLOGY INNOVATION ORGANIZATION, AND THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION IN SUPPORT OF GILEAD SCIENCES, INC.

*Ashley M. Simonsen (Bar No. 275203)
Alice L. Phillips (Bar No. 322070)
COVINGTON & BURLING LLP
1999 Avenue of the Stars
Los Angeles, CA 90067
Telephone: (424) 332-4782
Facsimile: (424) 332-4749
asimonsen@cov.com
aphillips@cov.com

Michael X. Imbroscio
COVINGTON & BURLING LLP
850 Tenth Street NW
Washington, DC 20001

Paul W. Schmidt
COVINGTON & BURLING LLP
620 Eighth Avenue
New York, NY 10018

Attorneys for Amici Curiae Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, and Advanced Medical Technology Association

David Gonzalez (Bar No. 215728)
Cher Gonzalez (Bar No. 210026)
GONZALEZ GOVERNMENT CONSULTING
1215 K Street, Suite 1100
Sacramento, CA 95814
Telephone: (916) 281-6981
david@gonzalezconsult.com
cher@gonzalezconsult.com

Attorneys for Amicus Curiae California Life Sciences Association

CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

Pursuant to Appellate Rule 8.208, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), the California Life Sciences Association ("CLS"), the Biotechnology Innovation Organization ("BIO"), and the Advanced Medical Technology Association ("AdvaMed") state that they are trade associations with no parent corporations. No entity or person has a 10% or greater ownership interest in PhRMA, CLS, BIO, or AdvaMed. PhRMA, CLS, BIO, and AdvaMed do not know of any person or entity, other than the parties themselves, that has a financial or other interest in the outcome of the proceeding that the Justices should consider in determining whether to disqualify themselves. A list of PhRMA's member companies can be found at http://www.phrma.org/about. A list of CLS's members can be found at https://www.califesciences.org/member-directory. A list of BIO's members is available at https://www.bio.org/bio-member-directory. A list of AdvaMed's members is available at https://www.advamed.org/membership-join/membership-directory.

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INTRODUCTION

Scientific knowledge accumulates over time. Scientists today are making medical breakthroughs never thought possible several decades ago. For good reason, our society does not withhold safe and effective products from patients today on the possibility that an even safer or even more effective product might be developed at some point in the future. Yet Plaintiffs seek to hold innovative biopharmaceutical companies making scientific breakthroughs liable for not making those breakthroughs sooner. According to Plaintiffs, whenever an innovator successfully develops a medicine that improves upon an earlier-approved, non-defective medicine, that innovator can be liable to those who took the first medicine on the theory that the innovator could and should have brought its later innovation to market faster. The law does not, and should not, allow this novel liability theory.

By allowing Plaintiffs to proceed toward trial on this theory, the Superior Court's erroneous decision has the potential to impose unfair and unwarranted liability upon the companies that engage in research to move science forward. The decision must be reversed for three reasons.

First, Plaintiffs cannot make out a viable case for negligence. The medicines Plaintiffs complain about were developed and approved in full compliance with all FDA requirements. Compliance with the FDA's extensive testing and approval process means that, in exercising the care deemed necessary by the FDA's expert scientists, Gilead necessarily

exercised reasonable care. Permitting Plaintiffs' novel theory of negligence to proceed towards trial would empower lay juries to supplant the FDA requirements designed by experts with pure lay conjecture.

Second, as a matter of public policy, making California the only state to expose life sciences companies to negligence liability for developing an otherwise safe and effective treatment whenever someone with the benefit of hindsight can argue that the treatment could have been made even safer sooner will stifle innovation in California's significant life sciences industry and undermine FDA's scientific judgment in ensuring access to life-saving medicines.

Third, the decision is contrary to settled law. The Superior Court permitted Plaintiffs to proceed toward trial on claims that Gilead should have brought TAF-based medicines to market sooner. Since Gilead indisputably could not have sold any TAF-based medicine without FDA's special permission and assistance, state-law claims seeking to hold Gilead liable for the timing of TAF's launch—no matter how they are styled—are preempted. State and federal precedent similarly rejects claims that Gilead could simply stop selling its TDF-based medicines to avoid liability.

The Court should issue a writ reversing the Superior Court's ill-conceived decision.

ARGUMENT

Plaintiffs assert that Gilead should be liable for injuries they allegedly experienced from using Gilead's TDF-based

medications, which they claim occurred because Gilead failed to develop alternative TAF-based therapies more quickly. But all of the TDF-based therapies that are the subject of Plaintiffs' claims were FDA-approved, and so developed with the extensive level of care required to achieve that approval. That level of care is necessarily reasonable. Additionally, imposing such liability for scientific judgment calls that resulted in the development of multiple safe and effective medicines would have a dangerous chilling effect on the biomedical research conducted by the members of PhRMA, CLS, BIO, and AdvaMed. Doing so would impede needed treatments from reaching patients and impact a significant California industry, while in the process casting aside the settled policy judgments embodied in existing tort law. And, in all events, such a claim is squarely preempted by federal law.

I. The extensive development and FDA approval process necessarily means that manufacturers of approved medicines exercised reasonable care.

Bringing a new medicine to market is an "onerous and lengthy" process. (*Mutual Pharm. Co., Inc., v. Bartlett* (2013) 570 U.S. 472, 476.) Before studying a new medicine in humans, a pharmaceutical company must conduct a series of laboratory and animal studies to test how the medicine works and assess its safety. (21 C.F.R. § 312.23(a)(8).) If the results are promising, the company submits an Investigational New Drug application ("IND") to FDA, outlining the preclinical study results and offering a plan for clinical trials in humans. (21 U.S.C. § 355(i)(2); 21 C.F.R. § 312.20(a)–(b).) FDA carefully reviews the IND, under which the company conducts three phases of clinical

trials, each of which must be completed successfully before the potential new medicine may undergo FDA review and approval. (21 C.F.R. § 312.21.) On average, the clinical trial phase takes six to seven years to complete.[3]

If FDA determines that the medicine's benefits outweigh its risks, FDA will permit a manufacturer to market the medicine by approving a New Drug Application ("NDA"). (21 U.S.C. § 355(b).) The NDA must contain, among other things, the results of the clinical and pre-clinical testing, proposals for manufacturing, and proposed labeling for the new medicine. (*Id.* § 355(b)(1).) The processes for developing biologics and medical devices are similarly rigorous. (See 21 C.F.R. § 600 et seq.; *id.* § 814.)

On average, developing a new medicine and obtaining FDA approval takes ten to fifteen years and costs $2.6 billion.[4] Through this process, the candidate medicines are culled dramatically: just one out of every 5,000 to 10,000 compounds under development, and less than one out of every eight medicines entering clinical trials, ultimately obtains FDA

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[3] PhRMA, *Modernizing Drug Discovery, Development and Approval* (2016) p. 1 <http://phrma-docs.phrma.org/sites/default/files/pdf/proactive-policy-drug-discovery.pdf>.

[4] PhRMA, *Biopharmaceuticals in Perspective: Fall 2020* (2020) p. 27 <https://www.phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/A-C/ChartPack_Biopharmaceuticals_in_Perspective_Fall2020.pdf> (hereafter *Biopharmaceuticals in Perspective*); see also DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs* (2016) 47 J. Health Econ. 20.

approval.[5] For example, just three new brain cancer medications achieved FDA approval between 1998 and 2019, with 122 unsuccessful attempts to develop a treatment.[6] Similarly, 268 unsuccessful attempts to develop a lung cancer treatment led to only 32 approved new medicines.[7]

The complexities of developing a new, innovative medication are due in part to the stringent standards that FDA applies to the approval of new medications. As the agency responsible for "protecting the public health by ensuring the safety" of medicines and "helping the public get the accurate, science-based information they need to use medical products,"[8] FDA closely examines extensive scientific and clinical data about a medication as part of the approval process. (See 73 Fed. Reg. 49,603, 49,604 [Aug. 22, 2008] [FDA "makes approval decisions . . . based on a comprehensive scientific evaluation of the product's risks and benefits"].) Indeed, FDA typically reviews and analyzes more than 100,000 pages of preclinical and clinical testing results as part of its approval process.[9] FDA will approve

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[5] PhRMA, *Clinical Trials—So Necessary but More Complex than Ever* (Mar. 3, 2011) <https://catalyst.phrma.org/clinical-trials-so-necessary-but-more-complex-than-ever>; *Biopharmaceuticals in Perspective*, *supra* note 4, at p. 27.

[6] *Biopharmaceuticals in Perspective*, *supra* note 4, at p. 40.

[7] *Ibid.*

[8] FDA, *What We Do* <https://www.fda.gov/about-fda/what-we-do>.

[9] *See* PhRMA, *Biopharmaceutical Research & Development: The Process Behind New Medicines* (2015) p. 14 <http://phrma-docs.phrma.org/sites/default/files/pdf/rd_brochure_022307.pdf>.

a new medicine only if it determines that the anticipated benefits "outweigh their known risks" for the intended patient population.[10]

FDA's close scrutiny continues after a medicine's approval. "[A]fter approval, FDA continuously works to evaluate the latest available scientific information to monitor the safety of products and to incorporate information into the product's labeling when appropriate." (73 Fed. Reg. 2848, 2851 [Jan. 16, 2008].)[11] By law, FDA must independently consider whether labeling remains adequate in light of its continuous monitoring of adverse event

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[10] *See* FDA, *Development and Approval Process (Drugs)* <http://www.fda.gov/Drugs/DevelopmentApprovalProcess> [as of Apr. 24, 2017] [FDA's drug approval process "ensures that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks"].

[11] Manufacturers must also undertake continuous efforts to surveil the safety of their medicines after approval. Once a new medicine is brought to market, NDA holders are required to monitor, review, and report to the FDA all adverse events received from any source, "including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." (21 C.F.R. § 314.80(b); see also Food & Drug Administration, *Reports Received and Reports Entered into FAERS by Year* (2015) <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ucm070434.htm> [stating that FDA received over 1.2 million adverse event reports from pharmaceutical companies in 2014].) NDA holders must also submit to the FDA annual reports summarizing all information received about their medicines, including adverse drug events and clinical trial results. (21 C.F.R. § 314.81(b)(2).)

reports and other research (21 U.S.C. § 355(o)(4)), and it must suspend or withdraw approval if it believes the medicine is unsafe (21 C.F.R. § 314.150(a)(2)). "If new, unanticipated risks are detected after approval, [FDA's Center for Drug Evaluation and Research] takes action to inform the public, change a drug's label, or even remove a product from the market."[12] Additionally, "FDA's MedWatch program enables health care professionals and consumers to report suspected problems with their drugs."[13] FDA brings to bear its expertise at all times to ensure that medications are safe, effective, and accompanied by appropriate warnings.

When a biomedical company spends decades and billions of dollars studying the safety and efficacy of a new medicine in clinical trials involving thousands of patients, and when FDA reviews hundreds of thousands of pages of scientific information to reach the expert conclusion that the benefits of a medicine exceed the risks, no reasonable jury can find as a matter of California law that the manufacturer failed to exercise reasonable care for the safety of others in developing that medicine. (See *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 773 & n.3 [court may hold that no reasonable jury could find the defendant failed to act with reasonable prudence under the circumstances or alternatively can "promulgate relatively clear,

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[12] FDA, *CDER: The Consumer Watchdog for Safe and Effective Drugs* <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/cder-consumer-watchdog-safe-and-effective-drugs>.

[13] *Ibid.*

categorical, bright-line rules of law applicable to a general class of cases"].) When the duly authorized regulatory authority has made a considered determination that the procedures it has imposed to develop and approve new medicines and surveil their safety once approved are sufficient to ensure that a medicine is safe and effective for approved use, permitting lay juries to effectively nullify FDA regulations and guidance by imposing a different standard of care for medicine development under the guise of a simple negligence theory would wreak havoc, as companies would be left to divine some standard of care other than the standard deemed appropriate by this country's expert scientists. (*Id.* at 773 n.3 ["In conducting its duty analysis, the court may take into account factors that might escape the jury's attention in a particular case, such as the overall social impact of imposing a significant precautionary obligation on a class of actors." (quoting Rest.3d Torts, Liability for Physical and Emotional Harm, § 7, com. a, p. 78)].) Plaintiffs' proposed theory of simple negligence cannot be reconciled with modern notions of tort law.

Any contrary holding would subject biomedical companies to virtually limitless liability. Science is always advancing, particularly when a company—like Gilead here—continues to invest in new research despite already having brought a life-saving product to patients. Thus, even for a medicine that by the Plaintiffs' own admission is not defective, interested advocates after the fact can always come up with *something* the company could have done differently—another study the company could

have performed or another formulation the company could have explored—or on a faster timetable. (Cf., e.g., Brief for the United States as Amicus Curiae Supporting Petitioner p. 25, *Wyeth v. Levine* (2009) 555 U.S. 555 (No. 06-1249) <https://www.justice.gov/sites/default/files/osg/briefs/2007/01/01/2006-1249.mer.ami.pdf> [noting the "post hoc imagination of lawyers" in pursuing pharmaceutical lawsuits].) After all, given the risk of failure inherent in the development of new medicines, life sciences companies often develop multiple medications in parallel, and companies must make complicated strategic decisions about where to devote resources based on limited information about which medicines have the most promise. Not surprisingly, over 8,000 potential new medicines are under study today, with PhRMA's members investing nearly one-quarter of their total annual domestic sales in research and development.[14] Juries are ill-equipped to adjudicate this second-guessing of the innovator's decisions by a sympathetic injured plaintiff, and it would be inconsistent with any standard for evaluating negligence to allow it to be found when the FDA has determined (and plaintiffs have not even challenged) that the disputed medication is safe and effective.

[14] *Biopharmaceuticals in Perspective*, *supra* note 4, at p. 20; PhRMA, *2021 PhRMA Annual Membership Survey* (2021) p. 4 tbls. 2–3 <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/M-O/PhRMA_membership-survey_2021.pdf>.

II. The Superior Court's decision harms patients by disincentivizing pharmaceutical development.

The Superior Court's decision endorses a liability framework that permits a company to be held liable for virtually any medicine, regardless of its demonstrated safety and efficacy, whenever a company is thereafter able to develop an arguably better medicine. Imposing such sweeping liability based on hindsight judgments about research that resulted in safe and effective medicines in the first instance will impede pharmaceutical research and development.

A. Second-guessing pharmaceutical research decisions with the benefit of hindsight will stifle innovation.

Because of the slim chances of success for any particular medicine, biomedical companies often develop multiple medicine options in parallel, and depending on early results make decisions about how to devote resources for further development and approval efforts. Because of this unavoidable reality, the entire pharmaceutical industry is exceptionally vulnerable to Plaintiffs' tenuous theory of liability. The Superior Court's decision would dangerously disincentivize biomedical research at all stages of development.

For example, consider the biopharmaceutical company deciding whether to invest resources into researching different compounds for treating a particular disease. While it might make scientific and practical sense to focus on one of those compounds as the best candidate to deliver an effective treatment in the shortest amount of time, the company might have second

thoughts about such a singular focus if it knows it could face liability if it makes the wrong choice and another of the candidates turns out later to be a marginally better option.

Consider alternatively the biopharmaceutical company that has already developed a safe and effective medicine whose benefits outweigh its risks. The medicine has proven itself in clinical trials, and secured FDA approval. But the company knows that the medicine, like all medicines, carries risks. The company could continue research efforts to develop alternative treatments with apparently comparable benefits but perhaps fewer risks. Under the Superior Court's logic, every single patient who took the original medicine is potentially a plaintiff if the company succeeds in making a further medical advance. Against that backdrop, a company might be incentivized either to wait to bring the farthest-ahead compound to market until research into all possible compounds under investigation for a particular treatment has been exhausted, even if that delay lasts years or decades, or to halt research into potentially "better" therapies once the first medicine is approved. Both outcomes would be detrimental to public health. If the innovator elects the former strategy and research into other compounds does not pan out, nothing would stop creative lawyers from accusing it of negligence for delaying beneficial treatments in the interim.[15]

Patient welfare would suffer from those misaligned

[15] If accepted, Plaintiffs' negligent undertaking theory could expose innovators who begin research on a compound to liability whenever they halt or delay research, or prioritize other compounds.

incentives. History is replete with examples of incremental reformulations of FDA-approved medicines that dramatically improved public health. For example, hepatitis C is a chronic viral infection affecting up to 170 million people worldwide that can result in liver failure, liver cancer, and even death. In the 1990s, treatment for hepatitis C often involved conventional interferon alfa, a regimen that required between three and seven weekly injections to achieve cure rates of 38 to 43 percent.[16] Ten years later, scientific discoveries led one manufacturer to modify the conventional interferon alfa molecule to slow down its absorption rate, resulting in once-weekly dosing with a substantially higher efficacy rate (56 percent).[17] Similarly, new formulations for a malaria medicine have decreased dosing from eight daily tablets to two; the combination of two medications into a single dosage form has eased the strict treatment regimen for type 2 diabetes; and research into oral contraceptives has resulted in lower-estrogen formulations with dramatically reduced side effects.[18]

These examples are hardly unusual. On average each

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[16] Int'l Fed. of Pharm. Mfrs. & Ass'ns, *Incremental Innovation: Adapting to Patient Needs* (2016) p. 19 <https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_Incremental_Innovation_Feb_2013_Low-Res.pdf> (hereafter *Incremental Innovation*).

[17] *Id.* at 21; *see also* Lietzan, *Paper Promises for Drug Innovation* (2018) 26 Geo. Mason L. Rev. 168, 175–76.

[18] Lybecher, *Incremental Innovation in the Pharmaceutical Industry* (2014) pp. 46–48 <https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf>.

year, approximately two-thirds of global launches of new molecular entities involve improvements to existing molecules.[19] And a recent study found that 63 percent of medications on the World Health Organization's Essential Drug Lists are follow-on innovations.[20]

These later scientific breakthroughs do not discredit earlier scientific discoveries. Scientific knowledge is ever-evolving, and later scientific discoveries often build on prior advances. California's liability regime should encourage these discoveries, not penalize researchers for continuing to improve on existing treatments. (See *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063 [California public policy "favors the development and marketing of beneficial new drugs," so "the broader public interest in the availability of drugs at an affordable price must be considered" in deciding liability standards].)

The fact that the Superior Court reached its decision in the context of a breakthrough innovation that provided meaningful hope to those suffering from a devastating disease makes the ruling all the more troubling. In the early 1990s, at a time when HIV was the number one cause of death among men aged 25–44,[21] Gilead began research on a number of compounds as

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[19] *Incremental Innovation*, *supra* note 16, at p. 11 fig. 3.

[20] Cohen & Kaitin, *Follow-On Drugs and Indications: The Importance of Incremental Innovation to Medical Practice* (2008) 15 Am. J. Therapeutics 89, 90.

[21] CDC, *Update: Mortality Attributable to HIV Infection/AIDS Among Persons Aged 25-44 Years—United States, 1990 and 1991* (1993) 42 Morbidity & Mortality Weekly Report 481

possible treatments for HIV—among them, TDF. (Petitioner's Appendix at pp. 221–22, 340–41.) The first TDF medication, Viread, was ultimately approved by FDA to treat HIV in October 2001. (*Id.* at p. 146.) Gilead continued to innovate and later secured approval of four additional TDF medications to treat HIV: Truvada, approved in 2004, Atripla, approved in 2006 and hailed by FDA as "a watershed in HIV treatment" because it combined three drugs into a single fixed-dose combination pill,[22] Complera, approved in 2011, and Stribild, approved in 2012. (*Id.* at p. 147.) In approving each of those five medicines, as with every medicine it approves, FDA made the determination that the medicine's benefits in fighting the HIV epidemic outweighed its risks because each medication was safe and effective for its intended use. (*Id.* at pp. 146–48.) All five of these TDF medicines have, since they were approved, been labeled to alert doctors and patients to the possible kidney and bone side effects Plaintiffs complain of. (*Id.* at p. 151.) All five of the TDF medicines remain approved for use. (*Id.* at p. 3103.)

Meanwhile, Gilead continued to research non-TDF based therapies that might improve upon the already life-changing treatments available. In 2002 and 2003, *after* Viread was approved by FDA, Gilead conducted a small Phase 1/2 study of TAF that "showed a safety profile similar to that of tenofovir

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<https://www.cdc.gov/mmwr/preview/mmwrhtml/00022174.htm>.

[22] FDA, *The History of FDA's Role in Preventing the Spread of HIV/AIDS* <https://www.fda.gov/about-fda/fda-history-exhibits/history-fdas-role-preventing-spread-hivaids>.

DF." (App. 2290.) Gilead then discontinued development of TAF in 2004, restarted development in 2010, and ultimately secured FDA approval of a TAF-based HIV medication—Genvoya—in November 2015. (*Id.* at p. 153.) Certainly, nobody would suggest that Gilead should have delayed Viread from the time of its approval in 2001 until the time of Genvoya's approval in 2015 (or even until 2006, the earliest date Plaintiffs' experts opine Gilead could have achieved FDA approval of a TAF-based medication). Gilead was right to bring Viread to market as soon as possible upon FDA's determination that it was a safe and effective treatment whose benefits outweighed its risks. At a time when an HIV diagnosis was a death sentence for many HIV patients, Americans could not afford to wait longer for a theoretically better treatment.[23]

Moreover, Gilead's focus on developing combination therapies such as Atripla was undoubtedly reasonable at a time when FDA was specifically "***encourag[ing] sponsors to develop fixed dose combinations*** (FDC) and co-packaged products for the treatment of [HIV]" because "[c]ombination therapy is essential for the treatment of HIV/AIDS" by better "facilitat[ing] distribution of antiretroviral therapies and improv[ing] patient adherence to the regimens." (69 Fed. Reg. 28931, 28932 [May 19, 2004] [emphasis added]; see also *One-a-Day AIDS Pill Is Termed Holy Grail*, Wash. Post (July 13, 2013)

[23] PhRMA, *Medicines in Development, HIV/AIDS* (2014) p. 7 <http://phrma-docs.phrma.org/sites/default/files/pdf/2014-meds-in-dev-hiv-aids.pdf>.

[FDA Deputy Commissioner Murray Lumpkin: "A single, fixed-dose pill has long been seen as the Holy Grail of AIDS treatment."]; Press Release, State Department, HHS Proposes Rapid Process for Review of Fixed Dose Combination and Co-Packaged Products (May 16, 2004) ["FDA recognizes the public health importance of [combination] products and . . . intends to expedite the development process for these products as much as is practicable."].) It is because of innovators like Gilead and the undersigned's members that death rates from HIV/AIDS are 83 percent lower today than they were in the mid-1990s.[24] But the Superior Court's decision exposes Gilead to liability for getting those patients a safe and effective medicine—including the "watershed" combination pill expressly requested by FDA—as quickly as possible.

The liability framework that results from the Superior Court's decision creates an untenable research environment for innovators, who regularly must make difficult resource allocation decisions. As FDA recognizes, "it is not known whether [a] potential medical treatment offers benefit to patients until clinical research on that treatment is complete."[25] Innovators necessarily make decisions about what medicines to prioritize for development with imperfect information about clinical results. They should not be held liable whenever, in hindsight, a different treatment turned out to be more favorable than the one they

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[24] *Id.* at p. 4.

[25] FDA, *Conducting Clinical Trials* <https://www.fda.gov/drugs/development-approval-process-drugs/conducting-clinical-trials>.

chose initially to develop.

B. The practical consequences of Plaintiffs' proposed theory of liability will be severe.

Were Plaintiffs' new, speculative claim to become widely adopted in California courts, it would be highly damaging to scientific and medical innovation, which is affected by the prospect of litigation. The practical impact of any reduction in pharmaceutical research would be felt globally in the context of the COVID-19 pandemic, the monkeypox Public Health Emergency of International Concern,[26] and countless other urgent contexts—be it urgent for one patient or for millions.

The current scope of litigation against life sciences companies is already immense and rapidly expanding. Last year, 28,880 pharmaceutical product liability lawsuits were filed in federal courts alone, 25% more than the year before and more than eleven times the number filed in 2001.[27]

Without sensible protections from unbounded liability, the

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[26] World Health Organization, *WHO Director-General declares the ongoing monkeypox outbreak a Public Health Emergency of International Concern* <https://www.who.int/europe/news/item/23-07-2022-who-director-general-declares-the-ongoing-monkeypox-outbreak-a-public-health-event-of-international-concern>.

[27] *See* Admin. Office of the U.S. Courts, *Table C-2A: U.S. District Courts—Civil Cases Commenced, by Nature of Suit, During the 12-Month Periods Ending September 30, 2017 Through 2021* <https://www.uscourts.gov/sites/default/files/data_tables/jb_c2a_0930.2021.pdf>; Girion, *State Vioxx Trial Is Set as Drug Suits Boom*, L.A. Times (June 27, 2006) p. C1.

California pharmaceutical industry might well contract, harming patients in need of innovative treatment. (See *Brown v. Superior Court*, *supra*, 44 Cal.3d at pp. 1063, 1065 n.10 [recognizing the "connection between the cost and availability of pharmaceuticals and the liability imposed on their manufacturers for injuries," and noting that "fear of large adverse monetary judgments" makes pharmaceutical companies "reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial"].)[28] California's life sciences industry accounts for nearly one-third of all bioscience patents, and its scientists have received the most National Institutes of Health research funding in the country.[29] The state's biopharmaceutical companies have more than 1,300 therapies in the development pipeline—more than 400 of which are aimed at treating cancer.[30]

If the industry's research capacity were to shrink, it would not only inhibit future emergency research efforts like those

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[28] *See also* Viscusi et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989* (1994) 24 Seton Hall L.Rev. 1418, 1419 ["[T]he net effect of the surge in liability costs ha[s] been to discourage innovation in the pharmaceutical industry."]; Epstein, *Legal Liability for Medical Innovation* (1987) 8 Cardozo L.Rev. 1139, 1153–54 ["If in the aggregate the net gains are wiped out by the liability costs, then the product will no longer be made."].

[29] California Governor's Office of Business and Economic Development, *Biotech* <https://business.ca.gov/industries/biotech>.

[30] CLSA, *California Life Sciences Sector Report* (2020) p. 2 <https://www.califesciences.org/wp-content/uploads/2021/06/CLSA-PWC-2020-Sector-Report.pdf> (hereafter *California Life Sciences Sector Report*).

undertaken to develop COVID-19 therapies and vaccines, but it would leave an economic void in its wake. The pharmaceutical industry accounts for $1 out of every $6 spent on domestic research and development by United States businesses,[31] and employs the largest share of manufacturing research and development workers in the country.[32] To use just one year as an example, "[i]n 2017, biopharmaceutical companies sponsored about 4,500 clinical trials in the United States alone, with trials in all 50 states, the District of Columbia and Puerto Rico."[33] The trials "involved close to 1 million participants and accounted for nearly $43 billion in economic activity."[34]

California would suffer the impacts acutely. As the Governor's Office of Business and Economic Development notes, "California's life sciences industry generates nearly 1 million direct and indirect jobs and over $191 billion in annual revenue."[35] In fact, California's pharmaceutical companies would

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[31] Wolfe, *Businesses Spent $375 Billion on R&D Performance in the United States in 2016*, InfoBrief (Sept. 2018) <https://www.nsf.gov/statistics/2018/nsf18312/nsf18312.pdf>.

[32] National Science Foundation, Business Enterprise Research and Development Survey (2019) tbl. 55 <https://ncses.nsf.gov/pubs/nsf22329/assets/data-tables/tables/nsf22329-tab055.pdf>.

[33] PhRMA, *2021 Industry Profile: The Biopharmaceutical Industry's Role in Fueling the U.S. Economy and Global Competitiveness* <https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/Industry-Profile-2021/The-Biopharmaceutical-Industrys-Role-in-Fueling-the-US-Economy-and-Global-Competitiveness.pdf>.

[34] *Ibid.*

[35] California Governor's Office of Business and Economic

be disproportionately burdened by this theory of liability, because out-of-state plaintiffs who have no such claim under the laws of their home states might flock to litigate these claims in California. The combination of the chilling effect on research in the first instance, compounded by a competitive disadvantage against companies in states that do not recognize this free-floating theory of negligence for pharmaceutical products (and no other state does), could even deter innovative companies from operating in California in the first instance.

* * *

Adopting the liability regime endorsed by the Superior Court would ultimately hurt patients in need of treatment. A company developing two related medicines on roughly parallel tracks might feel compelled to forego seeking approval of the first medicine, farther along the development pathway, for fear that a jury down the road might determine that it should have not sought approval of the first medicine but instead should have waited to seek approval only of the other medicine in co-development. Even when FDA determines that the first medicine is safe and effective and a plaintiff concedes it is not defective, the company could face liability if further clinical study were to reveal the second medicine to be marginally better on some metric of safety or efficacy. Such a "wait and see" incentive would not only stifle innovation, but it would also have the very

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Development, *Biotech* <https://business.ca.gov/industries/biotech>; see also *California Life Sciences Sector Report*, *supra* note 30, at p. 1.

real effect of depriving patients in need of immediate treatment. Delay would be cold comfort to those patients denied a safe and effective treatment today because a marginally better treatment might become available at some unknown later date. No rational liability regime should countenance such an outcome.

III. The Superior Court's decision denying Gilead summary judgment is contrary to settled law.

Aside from the serious policy concerns it raises, the decision below is facially inconsistent with federal preemption jurisprudence, which bars claims based on actions that manufacturers cannot take without FDA approval and prohibits state-law liability based on conduct that federal law expressly allows.

A. Federal law preempts Plaintiffs' claims related to the timing of TAF-based formulations' availability.

The U.S. Supreme Court has repeatedly addressed the preemption of tort claims involving FDA-approved medicines. (*See Merck Sharp & Dohme Corp. v. Albrecht* (2019) 139 S.Ct. 1668; *Mutual Pharm. Co. v. Bartlett*, *supra*, 570 U.S. at pp. 484–86; *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 614–15, 618–19; *Wyeth v. Levine* (2009) 555 U.S. 555, 569–72.) Taken together, the Court's jurisprudence establishes a singular test: "The question for 'impossibility' is whether the private party could independently do under federal law what state law [allegedly] requires." (*PLIVA, Inc. v. Mensing*, *supra*, at p. 620 [citing *Wyeth v. Levine*, *supra*, at p. 573].) "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission

and assistance, which is dependent on the exercise of judgment by a federal agency," claims arising from those duties are preempted. (*Id.* at pp. 623–24.) For instance, applying that test, design defect claims "that place a duty on manufacturers to render a drug safer" by "altering its composition" are preempted, because "[o]nce a drug—whether generic or brand-name[36]—is approved, the manufacturer is prohibited from making any major changes" to the formulation. (*Mutual Pharm. Co. v. Bartlett*, *supra*, at pp. 477, 490.)

That Plaintiffs have disclaimed any intent to "pursu[e] a claim for negligent design defect" does not make their negligence claim any less preempted. (Pls.' Pet. at 37.) In response to this Court's order to "identify the specific theory or theories of negligence [they] intend to pursue at trial," Plaintiffs could not have been clearer: "Gilead's decision to place profits over people when it deliberately delayed the development and *availability* of TAF breached that duty, causing thousands of individuals

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[36] See *Yates v. Ortho-McNeil-Janssen Pharms., Inc.* (6th Cir., 2015) 808 F.3d 281, 296–297 [design defect claims against branded manufacturer preempted]; *Kwasniewski v. Sanofi-Aventis U.S. LLC* (D. Nev., Mar. 30, 2018, No. 2:12–CV–00515) 2018 WL 1567851, at *5 n.4 [same]; *Gustavsen v. Alcon Labs., Inc.* (D. Mass., 2017) 272 F.Supp.3d 241, 253–56 [same], *aff'd*, 903 F.3d 1 (1st Cir., 2018); *Brazil v. Janssen Rsch. & Dev. LLC* (N.D. Ga., 2016) 196 F.Supp.3d 1351, 1363 [same]; *Batoh v. McNeil-PPC, Inc.* (D. Conn. 2016) 167 F.Supp.3d 296, 321–22 & n.19 [same]; *Barcal v. EMD Serono, Inc.* (N.D. Ala., Mar. 21, 2016, No. 5:14-CV-01709) 2016 WL 1086028, at *4 [same]; *Thompson v. Allergan USA, Inc.* (E.D. Mo., 2014) 993 F.Supp.2d 1007, 1013–14 [same]; *Trejo v. Johnson & Johnson* (2017) 13 Cal. App. 5th 110, 154–55.

unnecessary harm." (*Ibid.*) Gilead is powerless to "independently" make TAF "availab[le]"; instead, FDA's "special permission and assistance"—in the form of approval based on FDA's "judgment" that the benefits outweigh the risks—is required. Under those circumstances, preemption attaches. (*Evans v. Gilead Scis., Inc.* (D. Haw., Aug. 31, 2020, No. 20-CV-00123) 2020 WL 5189995, at *9 ["The problem with [plaintiff's] theory is that it was impossible for Gilead to 'independently' distribute a TAF-containing drug. Doing so would have required prior FDA approval of the new drug."]; see also *PLIVA, Inc. v. Mensing*, *supra*, 564 U.S. at p. 624 ["The only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state-law concern."]; *Yates*, *supra*, 808 F.3d at p. 300 [state-law claim preempted where defendants could not have complied with state-law obligation "without ultimately seeking the FDA's approval"]; *Gustavsen*, *supra*, 272 F.Supp.3d at p. 255 [state consumer protection and unjust enrichment claims preempted where dependent on defendants "design[ing] an entirely different product before they sought approval, which may never have been granted"], *aff'd*, 903 F.3d 1 (1st Cir. 2018); *Utts v. Bristol-Myers Squibb Co.* (S.D.N.Y. 2016) 226 F.Supp.3d 166, 185-86 [claim that "defendants had a pre-approval duty to submit a differently designed drug for FDA approval" preempted, because it would require court to "speculate" that "FDA would have approved the alternate design"]; *Boone v. Boehringer Ingelheim Pharms., Inc.* (2020) 335 Conn. 547, 581 ["The possibility that the FDA would have looked

favorably on an earlier application does nothing to alter the fact that, at the time of the decedent's death, the defendants were prevented from unilaterally marketing Praxbind under federal law."].)[37] This Court should not contort California negligence law to allow a novel state-law claim, when that state-law claim is clearly preempted by federal law anyway.

B. Federal law preempts Plaintiffs' claim that Gilead should not have sold TDF-based formulations.

Although Plaintiffs disclaim any such argument (App. 3021), the necessary implication of Plaintiffs' negligence theory is that Gilead should have stopped selling TDF-based formulations (or never begun selling them at all). After all, Plaintiffs' claim is that TAF is "more efficacious *and* less toxic" than TDF. (Pls.' Ret. at 9.) Federal law preempts such "stop selling" claims, and Plaintiffs cannot avoid this result through their artful pleading.

Mutual Pharmaceutical Co. v. Bartlett considered and rejected claims that although a generic pharmaceutical company was powerless to independently add the warning plaintiffs claimed state law required, it could have met its obligations under both state and federal law by ceasing to sell the medication

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[37] See also, e.g., *Chambers v. Boehringer Ingelheim Pharms., Inc.* (M.D. Ga., Jan. 2, 2018, No. 4:15-CV-00068) 2018 WL 849081, at *13 ["Regardless of when [defendant] started the process, [the medicine] approval still required the FDA's 'special permission and assistance.' [Defendant] could not unilaterally offer [the medicine] to physicians. Therefore, initiating the process that may have led to [the medicine's] approval does not enable [defendant] to comply with both federal and state law."].

entirely:

> We reject this "stop-selling" rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be all but meaningless.

(*Mutual Pharm. Co. v. Bartlett*, *supra*, 570 U.S. at p. 488; see also *Yates*, *supra*, 808 F.3d at p. 300 ["[Plaintiff] essentially argues that defendants should never have sold the FDA-approved formulation of [the medicine] in the first place. We reject this never-start selling rationale for the same reasons the Supreme Court in *Bartlett* rejected the stop-selling rationale of the First Circuit."]; *Warren v. Boehringer Ingleheim Pharms. Inc.*, (S.D. Ind., Sept. 8, 2017, No. 1:16-CV-01326) 2017 WL 3970666, at *12 n.6 ["The Manufacturers could have chosen never to market [the medicine] in the first place, but we agree with the *Yates* court that this 'never start selling' argument is indistinguishable from the 'stop selling' argument squarely rejected in *Mensing* and again in *Bartlett*."].)

California courts had occasion to apply *Bartlett*'s holding in *Trejo v. Johnson & Johnson*. *Trejo* addressed an over-the-counter medication, not a prescription one, but the fundamental claim was the same: that the active ingredient in the marketed medication (in *Trejo*, ibuprofen; here, TDF) was less safe than another medication (dexibuprofen and TAF, respectively), and accordingly that defendants should have marketed and sold the

safer product. (*See Trejo* (2017) 13 Cal.App.5th 110.) *Trejo* recognized that such claims are impermissible under the Supreme Court's preemption trilogy of *Levine, Mensing,* and *Bartlett*. Acknowledging at the outset that the defendants could not "unilaterally change the chemical composition of Motrin from ibuprofen to dexibuprofen," *Trejo* then held, consistent with *Bartlett*, that the defendants were not "required to stop selling Motrin in order to avoid state liability." (*Id.* at 154–55.)

Bartlett compels the same holding here. Plaintiffs' claim would require Gilead to have stopped selling TDF—indeed, to never have taken steps to have researched and developed it—in favor of TAF in order to avoid liability under state law. There is no principled distinction between these circumstances and the "stop selling" claims rejected in *Bartlett* and *Trejo*.

* * *

Conflict preemption takes proper account of FDA's supremacy in approving medications and serves as an essential check against absolute tort liability. To subject life sciences companies to liability under state law for not taking action that federal law expressly prohibits, or for acting in ways that federal law expressly allows, would not only be constitutionally infirm, but also disincentivize innovation and harm public health.

CONCLUSION

Expanding tort law to hold biopharmaceutical companies liable for marketing safe and effective products—based on hindsight allegations that a safer scientific discovery could have been made sooner—risks subjecting innovators to unfounded and

unwarranted liability, thereby harming patient care. For the foregoing reasons, the Court should reverse the Superior Court's decision denying Gilead summary judgment.

Respectfully submitted,

/s/ Ashley M. Simonsen

Ashley M. Simonsen
Alice L. Phillips
COVINGTON & BURLING LLP
1999 Avenue of the Stars
Los Angeles, CA 90067
Telephone: (424) 332-4782
Facsimile: (424) 332-4749
asimonsen@cov.com
aphillips@cov.com

Michael X. Imbroscio
COVINGTON & BURLING LLP
850 Tenth Street NW
Washington, DC 20001
Telephone: (202) 662-6000
Facsimile: (202) 662-6291
mimbroscio@cov.com

Paul W. Schmidt
COVINGTON & BURLING LLP
620 Eighth Avenue
New York, NY 10018
Telephone: (212) 841-1000
Facsimile: (212) 841-1010
pschmidt@cov.com

Counsel for Amici Curiae Pharmaceutical Research and Manufacturers of America, Biotechnology Innovation Organization, and Advanced

Medical Technology Association

/s/ David Gonzales
David Gonzalez
Cher Gonzalez
GONZALEZ GOVERNMENT CONSULTING
1215 K Street, Suite 1100
Sacramento, CA 95814
(916) 281-6981
david@gonzalezconsult.com
cher@gonzalezconsult.com

Counsel for California Life Sciences Association

Dated: October 3, 2022

CERTIFICATE OF WORD COUNT

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/s/ Ashley M. Simonsen
Ashley M. Simonsen
Counsel for Amici Curiae Pharmaceutical Research Manufacturers of America, Biotechnology Innovation Organization, and Advanced Medical Technology Association

Dated: October 3, 2022

PROOF OF SERVICE

I am a resident of the State of California and over the age of eighteen years, and not a party to the within action. My business address is 1999 Avenue of the Stars, Suite 3500, Los Angeles, CA 90067. On October 3, 2022, I served the following document(s) described as:

BRIEF OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, THE CALIFORNIA LIFE SCIENCES ASSOCIATION, THE BIOTECHNOLOGY INNOVATION ORGANIZATION, AND THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION IN SUPPORT OF GILEAD SCIENCES, INC.

on the interested parties in this action as follows:

GRANT & EISENHOFFER P.A. M. Elizabeth Graham
201 Mission Street, Suite 1200
San Francisco, California 94105
Telephone: (415) 229-9720
Email: egraham@gelaw.com

JENNER LAW, P.C.
Robert K. Jenner3600 Clipper Mill Road, Suite 240 Baltimore, Maryland 21211
Telephone: (410) 413-2155
Email: rjenner@jennerlawfirm.com

MOSKOVITZ APPELLATE TEAM Myron Moskovitz
90 Crocker Avenue
Oakland, California 94611
Telephone: (510) 384-0354
Email: myronmoskovitz@gmail.com

KERSHAW, COOK & TALLEY, P.C. William A. Kershaw
401 Watt Avenue
Sacramento, California 95846
Telephone: (916) 779-7000

Email: bill@kctlegal.com

SCHNEIDER WALLACE COTTRELL
KONECKY LLP
Amy Eskin, SBN 127668
2000 Powell Street, Suite 1400
Emeryville, California 94608
Telephone: (510) 740-2936
Email: aeskin@schneiderwallace.com

ESNER, CHANG & BOYER
Andrew N. Chang, SBN 84544
Holly N. Boyer, SBN 221788
234 East Colorado Boulevard, Suite 975
Pasadena, California 91101
Telephone: (626) 535-9860
Email: achang@ecbappeal.com
hboyer@ecbappeal.com

DEBRA E. POLE (SBN 97816)
dpole@sidley.com
JOSHUA E. ANDERSON (SBN 211320)
janderson@sidley.com
SEAN A. COMMONS (SBN 217603)
scommons@sidley.com
DAVID CARPENTER
dcarpenter@sidley.com
COLLIN WEDEL
cwedel@cov.com
SIDLEY AUSTIN LLP
555 West Fifth Street, Suite 4000
Los Angeles, CA 90013
Telephone: (213) 896-6000
Facsimile: (213) 896-6600

ANDREW D. SILVERMAN (SBN 246539)
asilverman@orrick.com
ORRICK, HERRINGTON & SUTCLIFFE LLP 51 West 52nd Street
New York, NY 10015
Telephone: (212) 506-5000

Facsimile: (212) 506-5151

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/s/ *Mark Shuttlesworth*
Mark Shuttlesworth