

1 PHILLIP R. MALONE (SBN 163969)
2 JUELSGAARD INTELLECTUAL PROPERTY
3 AND INNOVATION CLINIC
4 Mills Legal Clinic at Stanford Law School
5 559 Nathan Abbott Way
6 Stanford, CA 94305
7 Telephone: (650) 725-6369
8 Facsimile: (650) 723-4426
9 pmalone@law.stanford.edu

10 Attorneys for *Amici Curiae*

11 **UNITED STATES DISTRICT COURT**
12 **NORTHERN DISTRICT OF CALIFORNIA**
13 **SAN FRANCISCO DIVISION**

14 PETER STALEY, *et al.*,
15 Plaintiffs,
16 v.
17 GILEAD SCIENCES, INC., *et al.*,
18 Defendants.

Case No. 3:19-cv-2573-EMC

**BRIEF OF AMICI CURIAE
HIV RESEARCH, POLICY. AND
ADVOCACY ORGANIZATIONS
IN SUPPORT OF PLAINTIFFS’
OPPOSITION TO
MOTIONS TO DISMISS**

Hearing Date: January 16, 2020
Hearing Time: 1:30 p.m.
Courtroom: 5 – 17th Floor
Judge: Honorable Edward M. Chen

21
22
23
24
25
26
27
28

TABLE OF CONTENTS

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

INTEREST OF AMICI 1

ARGUMENT 2

 I. THE HIV EPIDEMIC IS AN ONGOING CRISIS IN AMERICA 3

 II. AFFORDABLE HIV TREATMENT AND PREVENTIVE THERAPIES ARE
 ESSENTIAL TO ENDING THE HIV EPIDEMIC IN THE UNITED STATES 5

 A. Lack of Generic Competition Results in High HIV Drug Prices 7

 B. Accessible and Affordable HIV Therapies Improve Individual Health Outcomes but
 High HIV Drug Prices Negatively Impact Access 8

 C. Accessible and Affordable PrEP Would Dramatically Improve Public Health
 Outcomes by Preventing the Spread of HIV 12

 III. GILEAD’S ALLEGED CONDUCT PREVENTED AMERICANS FROM
 ACCESSING AFFORDABLE HIV TREATMENT 14

 A. Since at Least 2004, Gilead’s Alleged Actions Have Distorted the American HIV
 Treatment and PrEP Markets 14

 B. Gilead’s Alleged Conduct Deprived Americans of Greater HIV Treatment and
 Preventive Options and Lower Drug Prices 16

CONCLUSION 20

APPENDIX A

TABLE OF AUTHORITIES

Cases

In re NFL’s Sunday Ticket Antitrust Litig., 933 F.3d 1136 (9th Cir. 2019).....2

Other Authorities

AIDS Drug Assistance Programs (ADAPS), Kasier Family Foundation (Aug. 16, 2017), <https://www.kff.org/hivaids/fact-sheet/aids-drug-assistance-programs/>.....9

Alison Brown et al., *HIV in Europe and Central Asia: Progress in 2018 Towards Meeting the UNAIDS 90-90-90 Targets*, Euro Surveill., at 3 (available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6280419/>)..... 11

Andrew Frulich et al., *Rapid Reduction in HIV Diagnoses After Targeted PrEP Implementation in NSW, Australia*, Conf. on Retroviruses and Opportunistic Infections (March 4, 2018), <http://www.croiconference.org/sessions/rapid-reduction-hiv-diagnoses-after-targeted-prep-implementation-nsw-australi>..... 14

Andrew Hill and Anton Pozniak, *How Can We Achieve Universal Access to Low-Cost Treatment for HIV?*, 2 J. of Virus Eradication 193, 194 (2016) 18

Bruce Schackman et al., *The Lifetime Medical Cost Savings from Preventing HIV in the United States*, 53 Med. Care 293 (2015)..... 7

Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection, World Health Org., at 79 (2016), <https://www.who.int/hiv/pub/arv/arv-2016/en/>..... 11, 12

Cost Considerations and Antiretroviral Therapy, U.S. Dept. of Health & Hum. Servs., <https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/459/cost-considerations-and-antiretroviral-therapy> 10, 11

Diana Farrell et al., *Accounting for the Cost of US Health Care*, McKinsey Global Inst. (Dec. 2008), <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/accounting-for-the-cost-of-us-health-care> 20

Dobromir Dimitrov et al., *PrEP Adherence Patterns Strongly Impact Individual HIV Risk and Observed Efficacy in Randomized Clinical Trials*, 72 J. Acquir. Immune Defic. Syndr. 444 (2016) 6

Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV, Centers for Disease Control (Dec. 2018), <https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf> 3

Fast Facts, HIV.Gov (Mar. 13, 2019), <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics> 3

1 *FDA-Approved HIV Medicines*, U.S. Dept. of Health & Hum. Servs. (June 24, 2019),
 2 <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/58/fda-approved-hiv-medicines> 17

3 *Generic Competition and Drug Prices*, U.S. F.D.A., [https://www.fda.gov/about-fda/center-](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices)
 4 [drug-evaluation-and-research-cder/generic-competition-and-drug-prices](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices) 8

5 *Generic Drug Access & Savings in the U.S.*, Assn. for Accessible Meds. (2017)..... 10

6 *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Federal Trade Commission,
 7 at 9 (2002) 7, 8, 15

8 *Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV*,
 AIDSinfo, at 43 (2019), https://aidsinfo.nih.gov/contentfiles/lvguidelines/AA_Tables.pdf..... 8, 18

9 *Half of Black Gay Men and a Quarter of Latino Gay Men Projected to be Diagnosed*
 10 *Within Their Lifetime*, Centers for Disease Control (Feb. 23, 2016),
 11 <https://www.cdc.gov/nchhstp/newsroom/2016/croi-press-release-risk.html> 4

12 *HIV in the United States and Dependent Areas*, Centers for Disease Control (Sept. 9, 2019),
 13 <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>..... 3

14 *HIV Prevention Pill Not Reaching Most Americans Who Could Benefit – Especially People*
 15 *of Color*, Centers for Disease Control (Mar. 6, 2018),
 16 <https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html> 13

17 *Hoehn et al., Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for*
 18 *All*, J. of Int’l AIDS Soc’y, at 7 (2011) 7, 16, 21

19 *How Increased Competition From Generic Drugs Has Affected Prices and Returns in the*
 20 *Pharmaceutical Industry*, Congressional Budget Office, at 73 (1998) 15

21 *Jonathan Volk et al., No New HIV Infections With Increasing Use of HIV Preexposure*
 22 *Prophylaxis in a Clinical Practice Setting*, 61 *Clinical Infectious Diseases* 1601 (2015) 12

23 *Joseph Rwagitinywa et al., Utilization and Costs of HIV Antiretroviral Drug sin Europe*
 24 *During the Last Ten Years: Impact of Generic Antiretroviral Drugs on Cost Reduction*,
 122 *Health Policy* 237, 237 (2018) 17

25 *Kartik Venkatesh et al., Low-Cost Generic Drugs Under the President’s Emergency Plan*
 26 *for AIDS Relief Drove Down Treatment Cost; More Are Needed*, 31 *Health Aff.* 1429,
 27 1432 (2012) 9

28 Letter from the HIV Health Care Access Working Group to Kent Sullivan, Insurance
 Commissioner of Texas 2 (May 16, 2018) (available at
http://www.theaidsinstitute.org/sites/default/files/attachments/TX_HHCAWG%20Letter%20to%20Insurance%20Commissioner%20Copay%20Accumulators.pdf) 9, 10, 11, 13

1 Linda Villarosa, *America’s Hidden H.I.V. Epidemic*, N.Y. Times (June 6, 2017),
 2 <https://www.nytimes.com/2017/06/06/magazine/americas-hidden-hiv-epidemic.html> 4

3 Matej Mikulic, *Branded vs. Generic U.S. Drug Prescriptions Dispensed 2005-2018*, Statista
 4 (Sept. 12, 2019), <https://www.statista.com/statistics/205042/proportion-of-brand-to-generic-prescriptions-dispensed/> 15

5 *Medicaid and HIV*, Kaiser Family Foundation (Oct. 1, 2019),
 6 <https://www.kff.org/hivaids/fact-sheet/medicaid-and-hiv/> 9

7 Michelle Andrews, *Even When HIV Prevention Drug is Covered, Other Costs Block*
 8 *Treatment*, Kaiser Health News (July 15, 2019), <https://khn.org/news/even-when-hiv-prevention-drug-is-covered-other-costs-block-treatment> 13

9 *Pre-Exposure Prophylaxis*, HIV.Gov (June 26, 2019), <https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis> 5, 12

10 Press Release, N.Y. Governor Andrew Cuomo, *Governor Cuomo Announces Plan to End*
 11 *the AIDS Epidemic in New York State* (June 29, 2014) (available at
 12 <https://www.governor.ny.gov/news/governor-cuomo-announces-plan-end-aids-epidemic-new-york-state>) 14

13 *Price Declines after Branded Medicines Lose Exclusivity in the U.S.*, IMS Institute (Jan.
 14 2016), <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf> 8

15 *Progress in HIV Prevention Has Stalled; Need for Immediate Action*, Centers for Disease
 16 Control (Feb. 27, 2019), <https://www.cdc.gov/nchhstp/newsroom/2019/hiv-incidence.html> 3

17
 18 Ryan Lee, *HIV/AIDS Group: Insurance Companies Discriminating Against Georgians*
Living with HIV, Ctr. for Health Law and Policy Innovation (2017) 10

19 Selena Simmons-Duffin, *AIDS Activists Take Aim at Gilead to Lower Price of HIV Drug*
 20 *PrEP*, NPR (May 30, 2019), <https://www.npr.org/sections/health-shots/2019/05/30/727731380/old-fight-new-front-aids-activists-want-lower-drug-prices-now> 13

21 Stephanie Cohen et al., *High Interest in Pre-Exposure Prophylaxis Among Men Who Have*
 22 *Sex with Men*, 68 J. Acquir. Immune Defic. Syndr. 439 (2015) 12

23 *Stopping Senseless Deaths*, Access Campaign (July 2018),
 24 https://msfaccess.org/sites/default/files/2019-02/HIV_Brief_StoppingSenselessDeaths_ENG_2018.pdf 18

25 *Tentatively Approved and Approved Antiretrovirals Eligible for Procurement Under the*
 26 *President’s Emergency Plan for AIDS Relief*, U.S. Food and Drug Administration (Sept.
 27 24, 2019), <https://www.fda.gov/international-programs/presidents-emergency-plan-aids-relief-pepfar/tentatively-approved-and-approved-antiretrovirals-eligible-procurement-under-presidents-emergency> 16

1 *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the U.S.*
 Report, Ass’n for Accessible Medicines (2019),
 2 <https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf>..... 15
 3
 4 *The Part D Donut Hole*, Medicare Interactive (last visited Oct. 25, 2019),
<https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-costs/the-part-d-donut-hole>..... 10
 5
 6 *The U.S. Health System in Perspective: A Comparison of Twelve Industrialized Nations*,
 The Commonwealth Fund, at 6 (July 2011),
 7 https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2011_jul_1532_squires_us_hlt_sys_comparison_12_nations_intl_brief_v2.pdf..... 18
 8
 9 Tina Rosenberg, *H.I.V. Drugs Cost \$75 in Africa, \$39,000 in the U.S. Does it Matter?*,
 N.Y. Times (Sept. 18, 2018), <https://www.nytimes.com/2018/09/18/opinion/pricing-hiv-drugs-america.html> 8
 10
 11 Tina Rosenberg, *H.I.V. Drugs Cost \$75 in Africa, \$39,000 in the U.S. Does it Matter?*,
 N.Y. Times (Sept. 18, 2018), <https://www.nytimes.com/2018/09/18/opinion/pricing-hiv-drugs-america.html>) 18
 12
 13
 14 To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy,
 Federal Trade Commission, at ch. 3, p. 11 (2003),
 15 <https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> 15
 16
 17 U.S. Preventative Services Task Force, *Preexposure Prophylaxis for the Prevention of HIV Infection Recommendation Statement*, 321 JAMA 2203, 2204 (2019) 12
 18
 19 *UK Kills Extension to Gilead’s Patent for Truvada*, Bloomberg Law (Sept. 18, 2018),
<https://news.bloomberglaw.com/ip-law/uk-kills-extension-to-gileads-patent-for-truvada> 17
 20
 21 *Understanding the HIV Care Continuum*, Centers for Disease Control, at 2 (2019),
<https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf> 3, 11
 22
 23 Winston Abara et al., *Adherence to Combination Antiretroviral Treatment and Clinical Outcomes in a Medicaid Sample of Older HIV-Infected Adults*, 29 AIDS Care 441 (2016)..... 6
 24
 25
 26
 27
 28

INTEREST OF AMICI

1
2 Amici – Treatment Action Group (TAG), AIDS Action Baltimore (AAB), The Foundation
3 for AIDS Research (amfAR), AVAC: Global Advocacy for HIV Prevention, Health GAP (Global
4 Access Project), Housing Works, The SERO Project, and The U.S. PLHIV Caucus – are not-for-
5 profit organizations dedicated to improving the lives of people living with HIV (or at risk of
6 acquiring HIV) through research, policy, and advocacy.¹ Ensuring that lifesaving and preventive
7 HIV therapies are accessible and affordable for all who need them is central to the mission of all
8 amici and a fundamental pillar of the strategy to end the HIV epidemic in the United States.² Amici
9 work to accelerate better access to HIV treatments and preventive therapies.

10 As part of this effort, amici have fought against excessive HIV drug prices for years, if not
11 decades. As amici are painfully aware every day, at current high prices, many people living with
12 HIV cannot afford the continuous drug regimens required keep them healthy and their HIV
13 suppressed. Moreover, many people at risk of HIV cannot afford the preventive drugs that
14 dramatically reduce the risk of infection. The well-pleaded allegations in the Complaint detail a
15 multi-pronged effort orchestrated by Defendant Gilead and its co-conspirators to delay and prevent
16 generic competition to many of the most important HIV drugs in use today, resulting in artificially
17 inflated prices. These efforts to maintain supracompetitive drug prices have had profoundly
18 negative consequences for the communities amici serve and for which they advocate.

19
20
21
22 ¹ Detailed descriptions of each amici are provided in the Appendix.

23 ² Plaintiffs and all defendants except Japan Tobacco Inc. have advised that they do not object to the
24 filing of this brief; Japan Tobacco has indicated that it does not consent to the filing. Amici state, as
25 contemplated by the analogous Fed. R. App. P. Rule 29(a)(4)(D), that no party or party's counsel
26 authored this brief in whole or in part, or contributed money that was intended to fund preparing or
27 submitting this brief. No person other than amici or their counsel contributed money that was
28 intended to fund preparing or submitting this brief. Amici note that plaintiff Peter Staley was in
1992 one of the founders and Founding Director of amicus the Treatment Action Group but left that
position in 1997. Staley also served on the board of amicus amfAR but left that role in 2004. Staley
does not have any current role in any of the amici on this brief.

1 The outcome of this case will have huge ramifications for the future of HIV treatment and
2 prevention efforts in the United States. The lives and wellbeing of well over one million Americans
3 depend on this market functioning openly and competitively. Amici have a deep interest in ensuring
4 the Court is fully informed about the broader context of this case as it considers the legal sufficiency
5 of Plaintiffs' allegations. This brief details the effects of exorbitant prices, fewer drug options, and
6 diminished competition on health outcomes for people living with, or at risk of, HIV in America.
7 Amici's unique, informed, and independent perspective brings to the Court's attention critical, real
8 world consequences that the parties will not otherwise provide.

9 ARGUMENT

10 At the motion to dismiss stage, Plaintiffs' allegations of material fact must be taken as true
11 and construed in the light most favorable to the nonmoving party. *In re NFL's Sunday Ticket*
12 *Antitrust Litig.*, 933 F.3d 1136, 1149 (9th Cir. 2019) . Reading Plaintiffs' well-pleaded Complaint
13 in this light, the allegations are sufficient to state a claim that Gilead and its co-conspirators
14 orchestrated anticompetitive schemes to unlawfully prevent and delay generic competition in the
15 U.S. market for HIV drugs. The Complaint adequately alleges that these schemes caused and
16 continue to cause severe harm to consumers through artificially inflated drug prices, fewer drug
17 options, and diminished innovation.

18 The perspective and interest of third-parties who are directly affected by the alleged conduct
19 – namely those living with, or at risk of, HIV in America – are essential as the Court assesses the
20 legal sufficiency of Plaintiffs' claims. Because over 80% of people living with HIV in America take
21 at least one Gilead product every day, it is critical the Court have full information about the impact
22 of this case beyond just the direct parties. *See* Compl. ¶ 2.

23 Section I of this brief describes the current status of the HIV epidemic in the United States.
24 Section II explains the critical role that affordable treatment and preventive drugs play in ending
25 this epidemic. It also traces the connection between high drug costs and poor health outcomes in the
26
27
28

1 U.S. Section III demonstrates how Gilead’s alleged conduct directly contributed to the problems
2 described throughout the brief.

3 **I. THE HIV EPIDEMIC IS AN ONGOING CRISIS IN AMERICA**

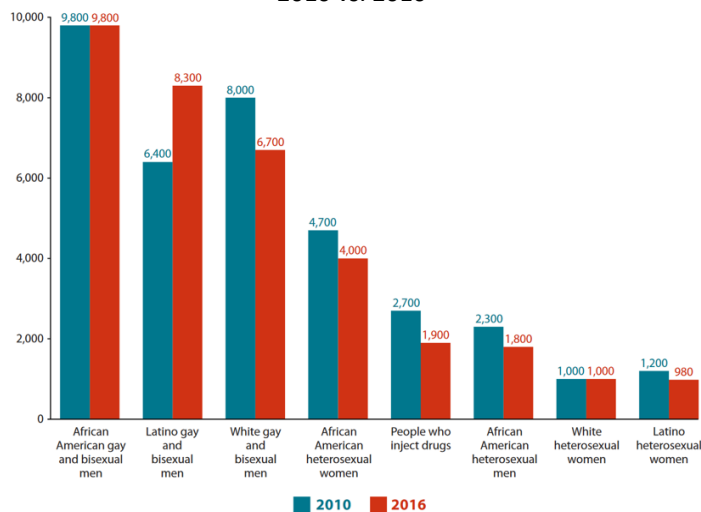
4 Over one million people in the U.S. live with HIV, but about 1 in 7 are unaware they are
5 infected. *HIV in the United States and Dependent Areas*, Centers for Disease Control (Sept. 9,
6 2019), <https://www.cdc.gov/hiv/statistics/overview/ata glance.html>. Every year, approximately
7 40,000 Americans are newly diagnosed with HIV – an average of over 100 per day. *Id.* Of those
8 who live with HIV, only half have been able to access and sustain the antiretroviral treatments
9 required to achieve durable viral suppression, a status that allows people who are HIV-positive to
10 live full and healthy lives. *Understanding the HIV Care Continuum*, Centers for Disease Control, at
11 2 (2019), <https://www.cdc.gov/hiv/pdf/library/factsheets/cdc-hiv-care-continuum.pdf>. Once viral
12 suppression is achieved, the risk of transmitting the virus to others is also effectively eliminated.
13 *Evidence of HIV Treatment and Viral Suppression in Preventing the Sexual Transmission of HIV*,
14 Centers for Disease Control (Dec. 2018), [https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-](https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf)
15 [suppression.pdf](https://www.cdc.gov/hiv/pdf/risk/art/cdc-hiv-art-viral-suppression.pdf). Accessing treatment and achieving viral suppression is critical to preventing new
16 infections and ending the HIV epidemic.

17 Yet, despite the availability of treatments that can ensure viral suppression, more than
18 17,000 Americans progress to AIDS each year – the late stage of HIV infection where the body’s
19 immune system is severely compromised. *Fast Facts*, HIV.Gov (Mar. 13, 2019),
20 <https://www.hiv.gov/hiv-basics/overview/data-and-trends/statistics>. Moreover, despite the existence
21 of highly effective antiretroviral treatment and preventive drugs, the rate of HIV infection in
22 America has not decreased since 2013. *Progress in HIV Prevention Has Stalled; Need for*
23 *Immediate Action*, Centers for Disease Control (Feb. 27, 2019), <https://www.cdc.gov/newsroom/2019/hiv-incidence.html>. Tens of thousands are needlessly infected every year. *HIV in*
24 *the United States, supra.*
25
26
27
28

1 HIV afflicts Americans of all demographics, but some communities are more impacted than
 2 others. Figure 1 below shows the number of new infections across a variety of demographics. At
 3 current rates of diagnoses, the Centers for Disease Control (CDC) estimate that 1 in 2 Black men
 4 who have sex with men and 1 in 4 Latino men who have sex with men could become infected in
 5 their lifetimes, compared to the average U.S. lifetime risk of 1 in 99. *Half of Black Gay Men and a*
 6 *Quarter of Latino Gay Men Projected to be Diagnosed Within Their Lifetime*, Centers for Disease
 7 Control (Feb. 23, 2016), <https://www.cdc.gov/nchhstp/newsroom/2016/croi-press-release-risk.html>;
 8 Linda Villarosa, *America's Hidden H.I.V. Epidemic*, N.Y. Times (June 6, 2017),
 9 <https://www.nytimes.com/2017/06/06/magazine/americas-hidden-hiv-epidemic.html>. Residents in
 10 the South also have markedly higher risks of becoming infected with HIV: In states like Maryland,
 11 Georgia, and Florida the lifetime risk of diagnosis is about 1 in 50. *Half of Black Gay Men, supra.*
 12 While tremendous gains have been made in the fight against HIV in some of its early epicenters, the
 13 high cost of treatment – coupled with racial and geographic disparities in access and outcomes –
 14 makes HIV not just a continuing national crisis, but an ongoing hidden epidemic in large swaths of
 15 America.

16 **Figure 1**

17 New HIV Infections by Race and Transmission Group, U.S.
 18 2010 vs. 2016



25 *Fast Facts, supra.*

1 **II. AFFORDABLE HIV TREATMENT AND PREVENTIVE THERAPIES ARE**
2 **ESSENTIAL TO ENDING THE HIV EPIDEMIC IN THE UNITED STATES**

3 Accessible and affordable drug regimens are critical to stemming the tide of this national
4 epidemic. Modern HIV treatment regimens – called combined antiretroviral therapy (cART) – help
5 to reduce the size and spread of the HIV epidemic in three ways: (1) by enabling people with HIV
6 to live healthy lives with an undetectable viral load; (2) by rendering these people unable to transmit
7 HIV to others once their viral load is undetectable; and, (3) via pre-exposure prophylaxis (PrEP), a
8 treatment taken by people who are HIV-negative to avoid infection.

9 First, **cART as Treatment**: Modern antiretroviral therapies allow people who are HIV-
10 positive to live full and healthy lives. Individuals with HIV must take a cocktail of drugs every day
11 that work together to block replication of the HIV virus. Scientific advancements have increased the
12 convenience of highly effective HIV treatment, culminating in cART regimens that reduce the pill
13 consumption burden to one or two a day. These regimens are a combination of two to four different
14 co-formulated chemical entities packaged either as separate pills or in single fixed-dose
15 combination pills. People with HIV must take cART regimens every day for the duration of their
16 lives. Where HIV was once a death sentence, people with access to health care, insurance, and the
17 support services to sustain daily treatments can now live with HIV as a manageable chronic disease.

18 Second, **Treatment as Prevention**: Taken regularly by a person living with HIV, cART
19 also plays a vital preventive role by reducing the amount of HIV in the bloodstream (the “viral
20 load”) to undetectable levels. This prevents the virus from being transmitted to others.

21 Third, **cART as PrEP**: The spread of HIV is also reduced when people who are HIV-
22 negative but at risk of exposure take PrEP. PrEP are cARTs that have been approved for
23 prophylactic use and have been available in the U.S. since 2012. PrEP is extremely effective at
24 preventing the spread of HIV: A daily pill can reduce sexual infection risk by more than 90% and
25 injection-associated infection risk by more than 70%. *Pre-Exposure Prophylaxis*, HIV.Gov (June
26 26, 2019), [https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-](https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis)
27 [exposure-prophylaxis](https://www.hiv.gov/hiv-basics/hiv-prevention/using-hiv-medication-to-reduce-risk/pre-exposure-prophylaxis).

1 These three transformative treatment and preventive characteristics of modern HIV
2 regimens can play a huge role in ending the HIV epidemic. If the regimens described above were
3 more accessible and affordable, the U.S. could have seen marked declines in the rate of new HIV
4 diagnoses. Instead, the number of new diagnoses has stagnated since 2013 at around 40,000 new
5 infections per year (new infection rates in 1990, six years before the discovery and roll-out of
6 cART, were about 50,000 per year). *Progress in HIV Prevention Has Stalled; Need for Immediate*
7 *Action*, Centers for Disease Control (Feb. 27, 2019), [https://www.cdc.gov/nchhstp/newsroom/2019/](https://www.cdc.gov/nchhstp/newsroom/2019/hiv-incidence.html)
8 [hiv-incidence.html](https://www.cdc.gov/nchhstp/newsroom/2019/hiv-incidence.html).

9 Progress in the fight against HIV has stalled because the significant personal and public
10 health benefits promised by modern HIV drugs can only be realized if they are financially
11 accessible to all who need them. If people living with HIV cannot afford to access and sustain
12 antiretroviral treatment, they will have difficulty, through no fault of their own, adequately adhering
13 to their drug regimens. Without achieving over 90% treatment adherence, HIV replication may not
14 be durably suppressed. The risk of transmission, drug resistance, and morbid and mortal health
15 outcomes – including opportunistic infections and cancers, wasting syndrome, and central nervous
16 system complications – is increased. Winston Abara et al., *Adherence to Combination Antiretroviral*
17 *Treatment and Clinical Outcomes in a Medicaid Sample of Older HIV-Infected Adults*, 29 AIDS
18 Care 441, 445 (2016). While PrEP can be taken more intermittently, overall adherence across pill-
19 taking patterns is determinative of efficacy. See Dobromir Dimitrov et al., *PrEP Adherence*
20 *Patterns Strongly Impact Individual HIV Risk and Observed Efficacy in Randomized Clinical*
21 *Trials*, 72 J. Acquir. Immune Defic. Syndr. 444, 450 (2016). Though many factors inform
22 successful treatment adherence, accessible and affordable medicines are fundamental and
23 determinative. Unfortunately, the cost of HIV treatment has risen to sky-high levels in the United
24 States.³

26
27 ³ U.S. prices are among the highest, if not the highest, in the world. For more, see *infra* Section
28 III.B.

1 **A. Lack of Generic Competition Results in High HIV Drug Prices**

2 According to a 2015 study, lifetime treatment costs for people who are HIV-positive in the
3 U.S. approach \$400,000,⁴ most of which goes toward antiretroviral medications. Similarly, lifetime
4 costs for people who are HIV-negative and need PrEP are nearly \$100,000,⁵ almost all of which
5 goes toward procuring necessary medicines. Bruce Schackman et al., *The Lifetime Medical Cost*
6 *Savings from Preventing HIV in the United States*, 53 *Med. Care* 293, 297-98 (2015). The high
7 costs associated with treating and preventing HIV can be an unsurmountable barrier to starting,
8 continuing, or adequately adhering to medically necessary treatment.

9 One primary reason why HIV treatment is so expensive in the U.S. is the artificially low
10 level of generic competition. In the case of PrEP, there is no generic competition. The U.S. market
11 for cART is dominated by branded drugs. The vast majority of this market is controlled by Gilead,
12 the defendant in this case, which has patent exclusivity on four of the five most-prescribed cART
13 regimens. Compl. ¶ 389. More than 80% of people on HIV treatment regimens take one or more
14 Gilead product every day. Compl. ¶ 2. Gilead also markets the only two PrEP regimens available in
15 the U.S.

16 This lack of generic competition keeps prices high. Generic competition “has consistently
17 proven to be the most powerful and reliable way to reduce drug prices to their lowest sustainable
18 levels.” Hoen et al., *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for*
19 *All*, *J. of Int’l AIDS Soc’y*, at 7 (2011). The availability of generic alternatives can, on average, cut
20 the cost of treatment in half. *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, Federal
21 Trade Commission, at 9 (2002). The few generics that have managed to enter the U.S. HIV drug
22 market prove the point. For example, branded Atripla costs \$32,000 a year while its generic
23 competitor, Symfi, sells at \$19,200, more than 40% cheaper. Tina Rosenberg, *H.I.V. Drugs Cost*
24
25

26 ⁴ This figure is the discounted mean lifetime cost assuming infection at age 35 and estimated life
expectancy of an additional 29.5 years.

27 ⁵ This figure is the discounted mean lifetime cost assuming that 35 as the age where cost
28 accumulation begins and a life expectancy of an additional 38.1 years.

1 \$75 in Africa, \$39,000 in the U.S. Does it Matter?, N.Y. Times (Sept. 18, 2018),
 2 <https://www.nytimes.com/2018/09/18/opinion/pricing-hiv-drugs-america.html>.

3 The larger the number of generic competitors, the lower the market prices can go. As a study
 4 of generic drug prices from 1999 to 2004 showed, products that attracted a large number of generic
 5 manufactures saw their average prices slashed by 80% in the U.S. market. *Generic Competition and*
 6 *Drug Prices*, U.S. F.D.A., [https://www.fda.gov/about-fda/center-drug-evaluation-and-research-](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices)
 7 [cder/generic-competition-and-drug-prices](https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices). A more recent study of the impact of generic competition
 8 also found that – between 2002 and 2014 –prices for oral medicines, like cART, fell 80% within
 9 five years of generic entry. *Price Declines after Branded Medicines Lose Exclusivity in the U.S.*,
 10 IMS Institute (Jan. 2016), [https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-](https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf)
 11 [after-branded-medicines-lose-exclusivity-in-the-us.pdf](https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf). In short, generic competition, “lead[s] to
 12 substantial benefits for consumers of prescription drugs.” *Generic Drug Entry*, *supra*, at 9.

13 If there were greater generic competition in the U.S. HIV treatment market, cheaper
 14 therapies could expand access, improve treatment adherence, and free up money that could be spent
 15 on other essential services. These developments, currently restrained by Defendants’ alleged
 16 conduct, are critical to ending the HIV epidemic in America.

17 **B. Accessible and Affordable HIV Therapies Improve Individual Health Outcomes**
 18 **but High HIV Drug Prices Negatively Impact Access**

19 Achieving viral suppression allows people living with HIV to live full, healthy lives. But
 20 without accessible and affordable HIV drugs, patients have a difficult time consistently accessing
 21 the treatment regimens and essential care – including laboratory work and adherence support
 22 services – they need to reach and maintain viral suppression. This leads to poor health outcomes.
 23 *See Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV*, AIDSinfo,
 24 at 43 (2019), https://aidsinfo.nih.gov/contentfiles/lvguidelines/AA_Tables.pdf.

25 Despite the medical necessity of these drugs, their cost remains “one of the greatest
 26 obstacles facing HIV-positive people.” Letter from the HIV Health Care Access Working Group to
 27 Kent Sullivan, Insurance Commissioner of Texas 2 (May 16, 2018) (available at
 28 http://www.theaidsinstitute.org/sites/default/files/attachments/TX_HHCAWG%20Letter%20to%20

1 Insurance%20Commissioner%20Copay%20Accumulators.pdf). If cheaper generics were available,
2 it could “allow for greatly increased drug procurement” across various health systems, a crucial step
3 to ensuring that all who are diagnosed with HIV in America can have immediate and sustained
4 access to critical antiretroviral medicines. Kartik Venkatesh et al., *Low-Cost Generic Drugs Under*
5 *the President’s Emergency Plan for AIDS Relief Drove Down Treatment Cost; More Are Needed*,
6 31 Health Aff. 1429, 1432 (2012).

7 Not only does the high cost of treatment affect individual patients, in the aggregate it also
8 ties up tremendous sums of money that could otherwise be spent expanding access to treatment to
9 more people. In the U.S., 42% of people living with HIV are covered by Medicaid, 12% by
10 Medicare and other government programs, 35% by private insurance, and 11% are uninsured.
11 *Medicaid and HIV*, Kaiser Family Foundation (Oct. 1, 2019), [https://www.kff.org/hiv/aids/fact-](https://www.kff.org/hiv/aids/fact-sheet/medicaid-and-hiv/)
12 [sheet/medicaid-and-hiv/](https://www.kff.org/hiv/aids/fact-sheet/medicaid-and-hiv/). Even though most individuals have insurance and thus avoid paying the
13 full sticker price of drugs, they still experience the effects of high prices through large healthcare
14 premiums, co-pays, co-insurance, and other out-of-pocket costs. And while low-income individuals
15 may be shielded from high costs through Medicaid or programs like the AIDS Drug Assistance
16 Program (ADAP), government payors must absorb the high costs. *AIDS Drug Assistance Programs*
17 *(ADAPS)*, Kaiser Family Foundation (Aug. 16, 2017), [https://www.kff.org/hiv/aids/fact-sheet/aids-](https://www.kff.org/hiv/aids/fact-sheet/aids-drug-assistance-programs/)
18 [drug-assistance-programs/](https://www.kff.org/hiv/aids/fact-sheet/aids-drug-assistance-programs/). Cheaper HIV drug prices would lower systemwide procurement costs
19 across public and private insurance systems. This benefits individual consumers through lower out-
20 of-pocket costs. It would also make government programs more cost-effective, freeing up money
21 that could be used to expand and improve existing programs and services.⁶

22 Most insurance programs, including Medicare and private employer-provided insurers,
23 require some degree of consumer cost sharing: The patient is responsible for a portion of the cost of
24 medication, usually through copayments. These copayments are often tiered, meaning patients are
25 responsible for a different percentage of the cost of medication depending on the drug they need.

26 _____
27 ⁶ In fiscal year 2019, federal Medicaid spending on HIV totaled \$6.3 billion; state Medicaid
28 spending on HIV was \$3.8 billion. *Medicaid and HIV*, *supra*.

1 Tiering of copays is commonly based on the sticker price of the drug and are thus “often higher for
 2 branded medications than for generic medications.” *Cost Considerations and Antiretroviral*
 3 *Therapy*, U.S. Dept. of Health & Hum. Servs., [https://aidsinfo.nih.gov/guidelines/html/1/adult-and-](https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/459/cost-considerations-and-antiretroviral-therapy)
 4 [adolescent-arv/459/cost-considerations-and-antiretroviral-therapy](https://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv/459/cost-considerations-and-antiretroviral-therapy). Indeed, 90% of generic drugs fall
 5 into \$20 or under co-pay buckets, compared to only 39% of branded drugs. *Generic Drug Access &*
 6 *Savings in the U.S.*, Assn. for Accessible Meds. (2017). Studies have found that insurance providers
 7 “place[] most, if not all, of their HIV/AIDS medications on a tier that requires the most out-of-
 8 pocket contribution from consumers.” Ryan Lee, *HIV/AIDS Group: Insurance Companies*
 9 *Discriminating Against Georgians Living with HIV*, Ctr. for Health Law and Policy Innovation
 10 (2017). This is “particularly true given that the vast majority of medications used to treat HIV... are
 11 not available in generic form.” HIV Health Care Letter, *supra*, at 2.

12 In concrete terms, this means that people who need HIV treatment and are not on Medicaid
 13 or ADAP regularly need to pay substantial out-of-pocket costs or high premiums and co-pays. For
 14 example, Blue Cross Blue Shield, Alliant, and Kaiser all require 40-50% co-insurance payments
 15 each month for HIV drugs costs. Lee, *supra*. Individuals covered through Medicare must contend
 16 with the so-called “donut hole”: Once they exceed their initial coverage limit (in 2019, \$3820 in
 17 total yearly drug costs paid between the individual and the plan), but before they qualify for
 18 catastrophic coverage (in 2019, \$5100 in total yearly out-of-pocket costs), they must pay a sizeable
 19 percentage of the sticker cost of drugs (generally 25-37% depending on whether the drug is branded
 20 or a generic). *The Part D Donut Hole*, Medicare Interactive (last visited Oct. 25, 2019),
 21 [https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-](https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-costs/the-part-d-donut-hole)
 22 [d/medicare-part-d-costs/the-part-d-donut-hole](https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-costs/the-part-d-donut-hole). Even when Medicare patients are outside the donut
 23 hole, they still face out-of-pocket copayments, deductibles, and coinsurance costs.

24 High treatment costs exacerbate the HIV crisis in many ways, but two stand out most
 25 clearly. First, high costs are a categorical barrier to treatment, which is especially pernicious given
 26 that antiretroviral drugs are the key not just to treating HIV, but also to preventing its spread
 27 through viral suppression and increased PrEP adoption. On a global level, if everyone living with
 28

1 HIV received antiretroviral therapy, at least 21 million fewer people would die and at least 28
2 million new infections could be prevented by 2030. *Consolidated Guidelines on the Use of*
3 *Antiretroviral Drugs for Treating and Preventing HIV Infection*, World Health Org., at 79 (2016),
4 <https://www.who.int/hiv/pub/arv/arv-2016/en/>. Second, high costs can be an impediment to
5 treatment adherence, reducing or even altogether eliminating the benefits of antiretroviral therapy.
6 “In one comprehensive review, increased patient cost sharing resulted in decreased medical
7 adherence and more frequent drug discontinuation.” *Cost Considerations, supra*. Even for people
8 with insurance, “the financial burden of increasingly high deductibles and high co-insurance
9 reduces the affordability, and thus the adherence rates, to these drugs.” HIV Health Care Letter,
10 *supra*, at 2. Without sufficient treatment adherence, viral suppression cannot be achieved, resulting
11 in poor health outcomes, unnecessary mortality, increased risks of HIV transmission, and higher
12 long-term costs from preventable infection, illness, and death.

13 In the U.S., only 53% of people living with HIV have achieved durable, ongoing viral
14 suppression. *Understanding the HIV Care Continuum, supra*, at 2. In contrast, 74% of people living
15 with HIV in Western Europe have achieved viral suppression. Alison Brown et al., *HIV in Europe*
16 *and Central Asia: Progress in 2018 Towards Meeting the UNAIDS 90-90-90 Targets*, Euro
17 *Surveill.*, at 3 (available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6280419/>). These
18 striking disparities in population-level outcomes are due, at least in part, to differences in the
19 accessibility and affordability of HIV treatments. While the United States and Western Europe
20 report diagnosed HIV at comparable rates (86% and 87%, respectively), only 64% of those
21 diagnosed in the U.S. receive antiretroviral treatment, compared to 91% in Western Europe. Brown,
22 *supra*, at 3; *Understanding the HIV Care*, *supra*, at 2. This gap is dangerous: Early initiation of
23 antiretroviral therapy “results in reduced mortality, morbidity and HIV transmission outcomes.”
24 *Consolidated Guidelines, supra*, at 75. In fact, initiating treatment as early as possible could result
25 in 6-14% fewer people dying from HIV in the next decade. *Consolidated Guidelines, supra*, at 78.

1 **C. Accessible and Affordable PrEP Would Dramatically Improve Public Health**
 2 **Outcomes by Preventing the Spread of HIV**

3 PrEP is a combined antiretroviral therapy that can be taken by people who are HIV-negative
 4 to reduce their risk of infection. PrEP, when properly adhered to, can reduce infection risk from anal
 5 or vaginal sex by more than 90% and infection risk from injections by more than 70%. *Pre-*
 6 *Exposure Prophylaxis, supra*. PrEP is an especially potent tool for preventing the spread of HIV in
 7 high risk networks, and field studies have shown that people living within these networks are very
 8 interested in adopting PrEP when they are informed about its efficacy. *See, e.g.,* Stephanie Cohen et
 9 al., *High Interest in Pre-Exposure Prophylaxis Among Men Who Have Sex with Men*, 68 J. Acquir.
 10 Immune Defic. Syndr. 439, 446 (2015); Jonathan Volk et al., *No New HIV Infections With*
 11 *Increasing Use of HIV Preexposure Prophylaxis in a Clinical Practice Setting*, 61 Clinical
 12 Infectious Diseases 1601, 1603 (2015). Increasing PrEP’s availability in such communities is
 13 essential to ending to the HIV epidemic. The World Health Organization strongly recommends the
 14 practice, citing “high-quality evidence.” *Consolidated Guidelines, supra*, at 52. The U.S. Preventive
 15 Services Task Force also recommends clinicians offer PrEP to people at high risk of HIV exposure,
 16 stating that “PrEP is of substantial benefit for decreasing the risk of HIV infection.” U.S.
 17 Preventative Services Task Force, *Preexposure Prophylaxis for the Prevention of HIV Infection*
 18 *Recommendation Statement*, 321 JAMA 2203, 2204 (2019).

19 Only two FDA-approved PrEP regimens are available today in the U.S: Truvada (TDF/FTC)
 20 and its successor Descovy (TAF/FTC). Truvada has proven effective in both men and women,
 21 while the newer Descovy was only FDA-approved for men and transgender persons with anal
 22 exposure to HIV, since clinical studies did not include women with vaginal exposure to the virus.
 23 Both are branded products manufactured and marketed by Defendant Gilead. This lack of
 24 competition has caused prices to remain extremely high. Especially for many of those most
 25 susceptible to HIV exposure, such as young Black gay men in the South, the regimens can be
 26 prohibitively expensive. Truvada costs \$1,780 per month – more than \$20,000 per year. Selena
 27 Simmons-Duffin, *AIDS Activists Take Aim at Gilead to Lower Price of HIV Drug PrEP*, NPR (May
 28 30, 2019), <https://www.npr.org/sections/health-shots/2019/05/30/727731380/old-fight-new-front->

1 aids-activists-want-lower-drug-prices-now. The sticker price for Truvada in the U.S. is 350 times
 2 more expensive than generic forms of PrEP offered in other countries, and many consumers are
 3 paying a sizeable percentage of the sticker price. Simmons-Duffin, *supra*. According to Kaiser
 4 Family Foundation, “many private health plans have put the drug in a specialty drug tier with high
 5 copayments.” Michelle Andrews, *Even When HIV Prevention Drug is Covered, Other Costs Block*
 6 *Treatment*, Kaiser Health News (July 15, 2019), [https://khn.org/news/even-when-hiv-prevention-](https://khn.org/news/even-when-hiv-prevention-drug-is-covered-other-costs-block-treatment)
 7 [drug-is-covered-other-costs-block-treatment](https://khn.org/news/even-when-hiv-prevention-drug-is-covered-other-costs-block-treatment). The grossly inflated U.S. Truvada prices has attracted
 8 Congressional attention and was the subject of a recent Congressional inquiry.⁷

9 Although at least 1.2 million Americans are at substantial risk of HIV and would benefit
 10 from PrEP, only 90,000 prescriptions were filled in the last year, representing less than 10% of the
 11 total high risk-pool. *HIV Prevention Pill Not Reaching Most Americans Who Could Benefit –*
 12 *Especially People of Color*, Centers for Disease Control (Mar. 6, 2018), [https://www.cdc.gov/](https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html)
 13 [nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html](https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html). African-Americans and Latinos
 14 account for two-thirds of recent HIV infections, especially among young gay and bisexual men, yet
 15 they received the smallest percentage of prescriptions. *Id.* One of the biggest obstacles to greater
 16 adoption is the cost of medications. HIV Health Care Letter, *supra*, at 2. If costs were reduced,
 17 access and adoption would undoubtedly increase. *See Andrews, Even When, supra.*

18 Empirical evidence for this tie between treatment accessibility and better outcomes can be
 19 found in the public health gains achieved by countries, states, and cities that have either generic
 20 PrEP or targeted PrEP programs designed to increase accessibility and adoption. For example, in
 21 New York – where advocacy groups (including amici TAG and Housing Works) successfully
 22 persuaded the state Medicaid program to negotiate significant price reductions from five of the six
 23 biggest cART manufacturers (including Gilead) – 32,000 people took PrEP in 2018, a 32% increase
 24 from the previous year. Press Release, N.Y. Governor Andrew Cuomo, Governor Cuomo
 25 _____

26 ⁷ Amicus Treatment Action Group submitted testimony to the U.S. House Committee on Oversight
 27 and Reform about the impact of these extremely high prices on May 16, 2019. A copy of the
 28 testimony is available at [http://www.treatmentactiongroup.org/sites/default/files/](http://www.treatmentactiongroup.org/sites/default/files/tag_testimony_congressional_corp_billions_prep_hearing.pdf)
[tag_testimony_congressional_corp_billions_prep_hearing.pdf](http://www.treatmentactiongroup.org/sites/default/files/tag_testimony_congressional_corp_billions_prep_hearing.pdf).

1 Announces Plan to End the AIDS Epidemic in New York State (June 29, 2014) (available at
 2 [https://www.governor.ny.gov/news/governor-cuomo-announces-plan-end-aids-epidemic-new-york-](https://www.governor.ny.gov/news/governor-cuomo-announces-plan-end-aids-epidemic-new-york-state)
 3 [state](https://www.governor.ny.gov/news/governor-cuomo-announces-plan-end-aids-epidemic-new-york-state)) . A recent study in Australia, where generic PrEP is available, found a 35% decline in HIV
 4 infection in the first six months after targeted introduction of PrEP. Andrew Frulich et al., *Rapid*
 5 *Reduction in HIV Diagnoses After Targeted PrEP Implementation in NSW, Australia*, Conf. on
 6 Retroviruses and Opportunistic Infections (March 4, 2018), [http://www.croiconference.org/](http://www.croiconference.org/sessions/rapid-reduction-hiv-diagnoses-after-targeted-prep-implementation-nsw-australia)
 7 [sessions/rapid-reduction-hiv-diagnoses-after-targeted-prep-implementation-nsw-australia](http://www.croiconference.org/sessions/rapid-reduction-hiv-diagnoses-after-targeted-prep-implementation-nsw-australia).

8 Affordable and accessible PrEP is a key pillar in the strategy to end the HIV epidemic, both
 9 globally and in the U.S. Despite the transformative role that PrEP must play in preventing the
 10 spread of HIV moving forward, currently only a small percentage of the people who could most
 11 benefit from PrEP are able to access it. Just as with HIV treatment regimens, the high cost of PrEP
 12 is hampering efforts to keep people healthy and safe from infection. Ensuring that the HIV drug
 13 market is competitive is a key prerequisite to comprehensively and successfully addressing the HIV
 14 epidemic in America.

15 **III. GILEAD’S ALLEGED CONDUCT PREVENTED AMERICANS FROM** 16 **ACCESSING AFFORDABLE HIV TREATMENT**

17 **A. Since at Least 2004, Gilead’s Alleged Actions Have Distorted the American HIV** 18 **Treatment and PrEP Markets**

19 Taking the allegations in the Complaint as true, Gilead’s anticompetitive conduct distorted
 20 the market for HIV drugs by skirting regulations that were carefully designed balance the public and
 21 private interests in the pharmaceutical patent system. Patents incentivize companies to undertake
 22 costly research and development, but they have to be limited in time and scope to enable the
 23 competition that ensures drug prices do not remain exorbitantly high forever. Congress has
 24 recognized the importance of this balance for consumer welfare. In response to stagnating
 25 competition and high drug costs, it passed the 1984 Hatch-Waxman Amendments to “balance
 26 incentives for continued innovation by research-based pharmaceutical companies and opportunities
 27 for market entry by generic drug manufacturers.” *To Promote Innovation: The Proper Balance of*
 28 *Competition and Patent Law and Policy*, Federal Trade Commission, at ch. 3, p. 11 (2003),

1 [https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-](https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf)
2 [competition-and-patent-law-and-policy/innovationrpt.pdf](https://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf).

3 For decades, the Hatch-Waxman framework fostered a competitive pharmaceutical market.
4 By changing the process for developing and marketing generic drugs, the Amendments dramatically
5 increased generic competition in the pharmaceutical industry. Generics accounted for only 19% of
6 the pharmaceutical market in 1984, but that share has risen exponentially since then, greatly
7 increasing consumer welfare. *See Generic Drug Entry, supra*, at i; Matej Mikulic, *Branded vs.*
8 *Generic U.S. Drug Prescriptions Dispensed 2005-2018*, Statista (Sept. 12, 2019),
9 <https://www.statista.com/statistics/205042/proportion-of-brand-to-generic-prescriptions-dispensed/>.
10 “The generic competition spurred by Hatch-Waxman... [also] forced brand-name firms to come up
11 with new products to replenish their revenue streams,” spurring innovation across the entire
12 industry. *To Promote Innovation, supra*, at ch. 3, p 11; see also *How Increased Competition From*
13 *Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, Congressional
14 Budget Office, at 73 (1998).

15 The increasing number of products “fostered significant price competition in those markets
16 with generic entry.” *To Promote Innovation, supra*, at ch. 3, p 11. Thirty-five years after passage of
17 the Amendments, estimated savings from generics in the U.S. were a whopping \$293 billion in
18 2018 alone. *The Case for Competition: 2019 Generic Drug & Biosimilars Access & Savings in the*
19 *U.S. Report*, Ass’n for Accessible Medicines (2019), [https://accessiblemeds.org/sites/default/files/](https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf)
20 [2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf](https://accessiblemeds.org/sites/default/files/2019-09/AAM-2019-Generic-Biosimilars-Access-and-Savings-US-Report-WEB.pdf). Critically in
21 the context of cARTs, the Congressional Budget Office found increased competition “helped hold
22 down the average price of a multiple-source prescription drug by *encouraging the substitution of*
23 *lower-priced generic drugs for brand-name ones.*” *How Increased Competition, supra*, at 34-35
24 (emphasis added). But the alleged No-Generics Agreements orchestrated by the Defendants and the
25 pay-to-delay agreements between Gilead and some generic manufacturers delayed and prevented
26 market entry of at least 28 co-formulated and fixed-dose combination cART treatments, inflating
27 market prices. *See Compl.* ¶¶ 191-92.

1 The Complaint alleges that Gilead and its co-conspirators schemed to prevent and delay
 2 generic substitution in HIV treatments, keeping prices artificially high by suppressing competition.
 3 By agreeing not to use generics in fixed-dose combination pills even after the patents on constituent
 4 brand-name components expire, Gilead subverted the careful balance of the patent system and
 5 distorted the cART market. *See* Compl. ¶¶ 132-33, 152-54, 167-68. As the Complaint alleges, these
 6 agreements have nearly destroyed competition in the market: Over 75% of sales of NRTIs (one of
 7 the three main components of antiretroviral therapy) were covered by Gilead’s anticompetitive
 8 agreements in 2018. Compl. ¶ 6.

9 The alleged “No Generics” agreements, along with the intentional degradation of certain
 10 products and offers of “favored entry” status to generic manufacturers, allowed – and continue to
 11 allow – Gilead to delay generic competition in the antiretroviral therapy market. These allegedly
 12 unlawful schemes have directly reduced treatment options for people living with HIV and kept the
 13 cost of medications excessively high, resulting in “ongoing access barriers and serious ethical
 14 concerns.” Hoen, *supra*, at 7.

15 **B. Gilead’s Alleged Conduct Deprived Americans of Greater HIV Treatment and**
 16 **Preventive Options and Lower Drug Prices**

17 Gilead’s alleged campaign to artificially delay the market entry of generics, *see, e.g.*, Compl.
 18 ¶¶ 172, 310, resulted in U.S. consumers having far fewer treatment options than people anywhere
 19 else in the world. In fact, the FDA itself has approved hundreds of generic antiretroviral drugs and
 20 drug combinations for use in developing countries as part of the President’s Emergency Plan for
 21 AIDS Relief (PEPFAR) program. These drugs meet “all safety, efficacy, and manufacturing quality
 22 standards for marketing in the U.S., and, *but for the legal market protection*,... would be on the
 23 U.S. market.” *Tentatively Approved and Approved Antiretrovirals Eligible for Procurement Under*
 24 *the President’s Emergency Plan for AIDS Relief*, U.S. Food and Drug Administration (Sept. 24,
 25 2019), [https://www.fda.gov/international-programs/presidents-emergency-plan-aids-relief-](https://www.fda.gov/international-programs/presidents-emergency-plan-aids-relief-pepfar/tentatively-approved-and-approved-antiretrovirals-eligible-procurement-under-presidents-emergency)
 26 [pepfar/tentatively-approved-and-approved-antiretrovirals-eligible-procurement-under-presidents-](https://www.fda.gov/international-programs/presidents-emergency-plan-aids-relief-pepfar/tentatively-approved-and-approved-antiretrovirals-eligible-procurement-under-presidents-emergency)
 27 [emergency](https://www.fda.gov/international-programs/presidents-emergency-plan-aids-relief-pepfar/tentatively-approved-and-approved-antiretrovirals-eligible-procurement-under-presidents-emergency) (emphasis added). PEPFAR has transformed the fight against the HIV/AIDS epidemic
 28

1 in over 50 developing countries, supporting treatment to 14.6 million people out of the 23.3 million
2 people receiving treatment worldwide, principally by enabling the widespread dissemination of
3 generic HIV regimens. In the U.S., however, the FDA has approved only 44 drugs or drug
4 components to fight HIV (and many of those drugs are no longer used because they have been
5 supplanted by newer-generation therapies). *FDA-Approved HIV Medicines*, U.S. Dept. of Health &
6 Hum. Servs. (June 24, 2019), [https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/58/fda-](https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/58/fda-approved-hiv-medicines)
7 [approved-hiv-medicines](https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/21/58/fda-approved-hiv-medicines).

8 Americans also have fewer generic options than people in comparable markets that have
9 similar patent systems. For example, in Denmark, the rate of generic substitution for branded
10 antiretroviral treatment has reached nearly 100%. Joseph Rwagitinywa et al., *Utilization and Costs*
11 *of HIV Antiretroviral Drug sin Europe During the Last Ten Years: Impact of Generic Antiretroviral*
12 *Drugs on Cost Reduction*, 122 *Health Policy* 237, 239 (2018). In the United Kingdom, the number
13 of people taking generic HIV medications increased by more than 25% in the three years following
14 a push to switch to generics by the National Health Service. Tina Rosenberg, *Britons Pay Hundreds*
15 *for H.I.V. Drugs. Why Do Americans Pay Thousands?*, N.Y. Times (Sept. 25, 2018),
16 [https://www.nytimes.com/2018/09/25/opinion/britons-pay-hundreds-for-hiv-drugs-why-do-](https://www.nytimes.com/2018/09/25/opinion/britons-pay-hundreds-for-hiv-drugs-why-do-americans-pay-thousands.html)
17 [americans-pay-thousands.html](https://www.nytimes.com/2018/09/25/opinion/britons-pay-hundreds-for-hiv-drugs-why-do-americans-pay-thousands.html). Recently, the England and Wales High Court of Justice invalidated
18 Gilead's patent on Truvada, opening the way for increased use of generic antiretroviral therapy. *UK*
19 *Kills Extension to Gilead's Patent for Truvada*, Bloomberg Law (Sept. 18, 2018),
20 <https://news.bloomberglaw.com/ip-law/uk-kills-extension-to-gileads-patent-for-truvada>.

21 Amici do not argue that all possible generics should be available in the United States.
22 Rather, amici emphasize that – based on the allegations in the Complaint – there are a substantial
23 number of generic combinations that would be available to U.S. consumers but for the co-
24 conspirators' actions. Gilead and its co-conspirators agreed not to use generic components in their
25 products. These agreements have at least two effects: they (1) actively prevent the creation of
26 combination pills that contain generic components; and (2) aggressively disincentivize generic
27 competitors from challenging patents by refusing to use any resulting generic products in fixed-dose

1 combinations with their branded drugs. Based on the allegations in the Complaint, Gilead delayed
 2 or prevented the development of at least 28 identifiable combined antiretroviral therapies that
 3 otherwise would be available to U.S. consumers. Compl. ¶¶ 191-92. If these drugs were available,
 4 the cART market would be twice its current size. *Id.*

5 Based on the historical impact of generic entry, this generic competition would have
 6 dramatically lowered drug prices. Instead, Gilead's alleged anticompetitive conduct stifled generic
 7 competition, ensuring that HIV drug prices are higher in the U.S. than most anywhere else in the
 8 world.⁸

9 How much higher? The recommended first-line antiretroviral drug regimen in the United
 10 States (a combination of dolutegravir, emtricitabine, and tenofovir) commonly costs \$35,000 per
 11 person per year. *Guidelines for the Use of Antiretroviral Agents, supra*, at 55. In at least 94 low- and
 12 middle-income countries, a generic equivalent of that same drug regimen cost only \$75. *Stopping*
 13 *Senseless Deaths*, Access Campaign (July 2018), [https://msfaccess.org/sites/default/files/2019-](https://msfaccess.org/sites/default/files/2019-02/HIV_Brief_StoppingSenselessDeaths_ENG_2018.pdf)
 14 [02/HIV_Brief_StoppingSenselessDeaths_ENG_2018.pdf](https://msfaccess.org/sites/default/files/2019-02/HIV_Brief_StoppingSenselessDeaths_ENG_2018.pdf) at 18.⁹ Even looking only at comparable
 15 developed countries, HIV treatments are categorically more expensive in the United States. *See*
 16 David Squires, *The U.S. Health System in Perspective: A Comparison of Twelve Industrialized*
 17 *Nations*, The Commonwealth Fund, at 6 (July 2011), [https://www.commonwealthfund.org/sites/](https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2011_jul_1532_squires_us_hlt_s)
 18 [default/files/documents/___media_files_publications_issue_brief_2011_jul_1532_squires_us_hlt_s](https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2011_jul_1532_squires_us_hlt_s)
 19 [ys_comparison_12_nations_intl_brief_v2.pdf](https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2011_jul_1532_squires_us_hlt_s). In the United Kingdom, for example, the exact same
 20 HIV drugs are anywhere from 3 to 10 times less expensive than in the U.S. Andrew Hill and Anton
 21 Pozniak, *How Can We Achieve Universal Access to Low-Cost Treatment for HIV?*, 2 *J. of Virus*
 22 *Eradication* 193, 194 (2016). Two of Gilead's most popular medications are illustrative: Tenofovir

23 _____
 24 ⁸ Gilead's alleged anticompetitive practices also have negative impacts on HIV treatment and
 25 prevention markets in other countries. Many middle-income countries are currently excluded from
 26 Gilead's license with the Medicines Patent Pool and Gilead uses its exclusivities to extract high
 prices on cART and PrEP products in those countries, thereby limiting access and options.

27 ⁹ For an analysis of the vast disparities in global HIV treatment costs, see Tina Rosenberg, *H.I.V.*
 28 *Drugs Cost \$75 in Africa, \$39,000 in the U.S. Does it Matter?*, *N.Y. Times* (Sept. 18, 2018),
<https://www.nytimes.com/2018/09/18/opinion/pricing-hiv-drugs-america.html>).

1 (TDF/FTC) sells for \$21,120 in the U.S. but only \$5,553 in the U.K. Atripla (TDF/FTC/efavirenz)
 2 sells for \$34,428 in the U.S. but only \$8,314 in the U.K. *Id.* As shown in Figure 2 below, in 2016,
 3 every single HIV medication was more expensive in the United States compared to the U.K. and the
 4 global lowest price. It remains impossible for Americans with HIV to access treatment at the prices
 5 available in other countries.

6 **Figure 2**

7 Prices for Antiretrovirals in the USA, UK, and Low-Income Countries (2016)

Antiretroviral	Patent expiry	Price per person-year (US\$)*		
		USA	UK	Global lowest
Nucleos(t)ide analogues				
Abacavir	Generic/2016 (Europe)	\$7,236	\$2,778	\$123
Lamivudine	Generic	\$3,408	\$483	\$18
Tenofovir	2017–8	\$14,464	\$3,182	\$39
Zidovudine/3TC	Generic	\$10,536	\$1,107	\$46
Abacavir/3TC	2016	\$18,600	\$4,664	\$161
Tenofovir DF/3TC	2017–8	not sold	not sold	\$47
Tenofovir DF/FTC	2021	\$21,120	\$5,553	\$67
Tenofovir DF/FTC/EFV	2021	\$34,428	\$8,314	\$110
Non-nucleosides				
Nevirapine	Generic	\$7,776	\$1,825	\$28
Efavirenz	Generic/2017 (USA)	\$12,120	\$1,606	\$38
Rilpivirine	2021	\$12,900	\$3,120	\$40
Etravirine	2021	\$15,696	\$4,695	\$438
Protease inhibitors				
Atazanavir	2017–9	\$19,872	\$4,726	\$219
Lopinavir/r	2016	\$13,272	\$4,446	\$243
Darunavir/r	2017–19	\$19,584	\$4,648	\$658
Integrase strand inhibitors				
Dolutegravir	2027	\$20,484	\$7,768	\$600*
Raltegravir	2025	\$18,540	\$7,347	\$973
Elvitegravir	2027	\$37,116	\$8,314	No data

* Using a conversion rate of 1.3 US dollars to 1 UK pound.

19 *Hill, supra*, at 194.

20 Higher drug prices in the United States are the result of a number of factors, including: legal
 21 limits on the biggest provider programs, such as Medicare, which prevent them from negotiating
 22 drug prices with manufacturers; the highly fragmented health care market; higher corporate
 23 spending on marketing; and the high costs of private insurance intermediaries in the health care
 24 market. But none of these drivers can fully explain the huge price difference between the exact
 25 same branded drugs in the U.S. and other wealthy countries. *See generally* Diana Farrell et al.,
 26 *Accounting for the Cost of US Health Care*, McKinsey Global Inst. (Dec. 2008),
 27 <https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/accounting-for->

1 the-cost-of-us-health-care. Without generic competition, pharmaceutical companies have no
2 incentive to reduce their prices in the United States.

3 Gilead's alleged artificial inflation of drug prices has dire consequences for people living
4 with HIV in the U.S., both those who require antiretroviral therapy every day for the rest of their
5 lives and for people who would benefit from PrEP. Because 80% of people with HIV take at least
6 one Gilead product every day and because 100% of people needing PrEP can only use Gilead
7 products at present, Gilead's alleged schemes to ensure the continued high cost of medications
8 despite patent expirations makes treatment and preventive therapies costly and inaccessible for
9 people living in the United States.

10 CONCLUSION

11 As alleged in the Complaint, Gilead abused its market power to orchestrate anticompetitive
12 strategies that delayed the timely entry of generic treatment and preventive HIV regimens. Had
13 these artificial restraints not existed, the timely entry of generics could have lowered costs,
14 increased aggregate treatment adherence, and reduced HIV transmission. While Gilead and its co-
15 conspirators enriched – and continue to enrich – themselves, they did so at the expense of patients,
16 people at risk for HIV acquisition, and the public.

17 America faces an ongoing HIV epidemic. Outside of well-resourced enclaves that have the
18 political will and resources to comprehensively address HIV in their communities, the fight against
19 HIV is stalling. Pharmaceutical companies like Gilead were once stalwarts in this fight, developing,
20 licensing, and marketing drugs that saved millions of lives. But today, driven by billion-dollar
21 profits and with fewer and fewer serious market competitors, these companies have little incentive
22 to innovate. Instead, they act anticompetitively to maintain the status quo through a web of bilateral,
23 anticompetitive schemes that prevent or delay competition even once the originally patented
24 molecules go off patent, thus establishing and perpetuating monopoly pricing. This status quo – in
25 which Americans with HIV find treatment options limited or unaffordable – has unacceptable costs
26 in the form of ongoing HIV transmission, illness, and death, particularly in disenfranchised
27 communities.

1 The allegations in the Complaint carefully detail how Gilead’s self-serving conduct created
2 this harmful state of affairs. If this lawsuit is dismissed, Gilead and its co-conspirators will be able
3 to continue their anti-competitive practices that restrain meaningful generic competition. “Without
4 generic competition, prices for newer drugs will not come down the same way that they did for the
5 first generation of [HIV] medicines.” Hoen, *supra*, at 8. This “treatment timebomb” keeps effective
6 treatment and prevention strategies out of the hands of Americans who need them most. *Id.*

7 The Complaint seeks to stop and prevent Gilead and its co-conspirators from continuing to
8 distort the HIV treatment market. Gilead’s dominance in this market cannot be overstated – again,
9 80% of people living with HIV in the U.S. take at least one Gilead product every day. Gilead makes
10 several drugs that are critical components of an effective HIV regimen. Some of these drugs should
11 have faced competition already, and many should face generic competition soon. But without
12 injunctive relief, Gilead will be able to continue using the alleged No Generics agreements, pay-to-
13 delay settlements, and other tactics to stifle competition. Allowing Gilead to continue its existing
14 course of action will prevent the entry of new generic options, keep the cost of drugs exorbitantly
15 high, and prolong an epidemic that continues to devastate communities across America. Gilead’s
16 alleged anticompetitive actions are not only unlawful, but harmful to the health of millions of
17 Americans.

18 The allegations in the Complaint are more than sufficient to state plausible claims upon
19 which relief can be granted. Accordingly, the Court should deny the Motions to Dismiss and allow
20 the case to proceed.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

/s/ Phillip R. Malone

PHILLIP R. MALONE
(SBN 163969)
Juelsgaard Intellectual
Property and
Innovation Clinic
Mills Legal Clinic
at Stanford Law School
559 Nathan Abbott Way
Stanford, CA 94305
Telephone: 650-724-1900
Facsimile: 650-723-4426
pmalone@law.stanford.edu

Attorney for Amici Curiae

APPENDIX

The following are detailed descriptions of each of the amici.

Treatment Action Group

Founded in 1992 and based in New York City, Treatment Action Group (TAG) is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis, and the hepatitis C virus. TAG works to ensure that all people with HIV, TB, or HCV receive lifesaving treatment, care, and information. We are science-based treatment activists working to expand and accelerate vital research and effective community engagement with research and policy institutions. TAG catalyzes open collective action by all affected communities, scientists, and policy makers to end HIV, TB, and HCV. See www.treatmentactiongroup.org.

AIDS Action Baltimore, Inc.

(AAB) is the oldest surviving AIDS service organization on Maryland, incorporated in 1987. AAB initially provided services such as case management and financial assistance to people with HIV/AIDS. Shortly after our inception, we began working in the HIV research arena, including drug development, treatment and access advocacy for drugs before FDA approval and post-approval pricing as well as other access issues. AAB continues to participate with other local and national community advocates on many government and industry Community Advisory Boards (CABs). We work with industry and academia continually to change the standard of care by ensuring that their new drug pipelines remain robust, and by replacing more older toxic drugs with more effective, better tolerated drugs and new long acting drugs that will not require daily dosing. AAB is also involved in HIV education, including research literacy in the areas of HIV cure and treatment research, treatment, PrEP as well as other other HIV prevention services both locally and nationally. In addition, we administer three local programs that promote empowerment, stigma reduction, outreach and navigation services, linkage to care and adherence support programs in the Baltimore

1 African-American same gender loving community (SGL) and the transgender community. See
2 <http://www.aidsactionbaltimore.org/>.

3
4 **The Foundation for AIDS Research (amfAR)**

5 The Foundation for AIDS Research (“amfAR”) is a Not-for-Profit organization operating
6 with the purpose of ending the global AIDS epidemic through innovative research, public education,
7 and public policy. With the freedom and flexibility to respond quickly to emerging areas of
8 scientific promise, amfAR has played a catalytic role in accelerating the pace of HIV/AIDS research
9 and achieving real breakthroughs since 1985. At the core of its mission, amfAR seeks to fund and
10 advocate for the research, development, and access to life saving treatments. See www.amfar.org.

11
12 **AVAC**

13 Founded in 1995, AVAC: Global Advocacy for HIV Prevention is a non-profit organization
14 that uses advocacy, communication, education, policy analysis and a network of global
15 collaborations to accelerate the ethical development and global delivery of AIDS vaccines, male
16 circumcision, microbicides, PrEP, dual purpose and other emerging HIV prevention options as part
17 of a comprehensive response to the pandemic. See www.avac.org.

18
19 **Health GAP (Global Access Project)**

20 Health GAP is an international advocacy organization dedicated to ensuring that all people
21 living with HIV have access to life-saving medicines, that there is sufficient funding to ensure
22 access, and that treatment programs deliver quality care. Our team pairs pragmatic policy work with
23 bold grassroots action to win access to quality HIV treatment, care, and prevention for all who need
24 it, particularly for the poorest and most marginalized communities in the world. See
25 <https://healthgap.org/>.

1 **Housing Works**

2 Housing Works is a healing community of people living with and affected by HIV/AIDS.
3 Our mission is to end the dual crises of homelessness and AIDS through relentless advocacy, the
4 provision of lifesaving services, and entrepreneurial businesses that sustain our efforts. See
5 www.housingworks.org.

6
7 **The SERO Project**

8 Sero centers People Living with HIV (PLHIV) leadership to end HIV criminalization, mass
9 incarceration, racism and social injustice by supporting inclusive PLHIV networks to improve policy
10 outcomes, advance human rights and promote healing justice. Sero is focused on ending
11 inappropriate criminal prosecutions of PLHIV, including for non-disclosure of their HIV status,
12 potential or perceived HIV exposure or HIV transmission and on building and supporting PLHIV
13 networks. See www.seroproject.com.

14
15 **The U.S. PLHIV Caucus**

16 The US PLHIV Caucus (also known as “the HIV Caucus” or “Caucus”) is comprised of
17 organizations, coalitions, networks and client groups of people living with HIV, and independent
18 advocates living with HIV. The HIV Caucus collectively speaks with a unified voice for people
19 living with HIV in the U.S. At present the HIV Caucus is an unincorporated association of interested
20 parties and does not have a corporate non-profit status. See www.hivcaucus.org.