UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JOHN DOE, Plaintiff v. MUTUAL OF OMAHA INSURANCE COMPANY, Defendant	)	No. 1:16-cv-11381-GAO

AFFIDAVIT OF KENNETH MAYER, M.D.

1. I am a Professor of Medicine at Harvard Medical School (2013-present) and prior to that was a Professor of Medicine and Community Health at Brown University's Alpert School of Medicine (1993-2011). I am currently an Attending Physician in the Infectious Disease Division at Beth Israel Deaconess Medical Center in Boston where I am the Director of HIV Prevention Research. From 1987 to 2011 I was the Director of the Brown University AIDS Program. I am the Medical Research Director of Fenway Health, and am co-Director of The Fenway Institute (since 2000).

2. My clinical research career has focused on the natural history and transmission of HIV disease. I have treated patients with HIV and conducted research into HIV since the beginning of the epidemic. Since 1994 I have been the Principal Investigator of the only National Institute of Health (NIH)-funded HIV Prevention Research Clinical Trials Unit in New England focusing on biobehavioral prevention and chemoprophylaxis, as well as more than 20 other active research studies focusing on innovative approaches to HIV prevention. I was the Co-Chair of a National Institutes of Allergy and Infectious Diseases (NIAID)-funded protocol evaluating a community-based prevention intervention for African-American Men who have Sex with Men (MSM) in six

U.S. cities. Between 2006 and 2011, I was the Chair of the Scientific Review Committee of the HIV Prevention Trials Network Executive Committee. I subsequently have been the Chair of the MSM Working Group for the Executive Committee of the HIV Prevention Trials Network [HPTN] since 2011.

3. I am the co-author of more than 800 peer-reviewed scientific publications and have co-edited five academic texts, including "The Social Ecology of Infectious Diseases" and "HIV Prevention: A Comprehensive Approach." I have served as Editor and on the Editorial Board of authoritative medical journals and am currently an Editor-in-Chief of the Journal of the International AIDS Society, and on the editorial boards of the Journal of Acquired Immunodeficiency Syndromes and AIDS Patient Care and STDs. I formerly was an editor of Clinical Infectious Diseases. I have also been a reviewer for many of the world's leading medical journals, including the Journal of the American Medical Association, the New England Journal of Medicine, and the Lancet.

4. My work studying the use of antiretrovirals for HIV prevention extends back almost twenty years. Through the HPTN, I led the first study of topical tenofovir vaginal gel in women, which was subsequently evaluated in several large efficacy trials in Africa. I was the site principal investigator for the CDC's first in human oral safety study of oral tenofovir-emtricitabine (TDF/FTC), known as Truvada, for pre-exposure prophylaxis (PrEP) (Grohskopf, JAIDS, 2011), and was site principal investigator for the iPREX study, which was the first trial to demonstrate the efficacy of Truvada as PrEP (Grant, NEJM, 2010). I have also led 3 investigator-initiated trials of the use of antiretrovirals for post-exposure prophylaxis. I have been involved in studies of use of oral PrEP to protect adolescents against HIV, and have studied

new preventive technologies, including intravaginal rings containing medication and injectable PrEP.

5. A detailed description of my professional background and experience, including all publications authored by me, is detailed in my curriculum vitae which is provided as Exhibit A.

6. Since the beginning of the HIV epidemic, I have regularly attended the leading international medical conferences on HIV and AIDS. In addition, I have regularly followed and been deeply immersed in the medical and research literature about the transmission, treatment, and prevention of HIV disease, including information about the safety and efficacy of HIV pre-exposure prophylaxis. Finally, I have had frequent communication and interaction with clinicians throughout the world who treat people with or at risk for HIV, as well as other leading experts on HIV disease and prevention throughout the world. All of these sources of information and knowledge have informed my opinions set forth in this affidavit.

7. HIV, the human immunodeficiency virus, is a retrovirus that is spread through certain bodily fluids, such as blood, semen, rectal and vaginal fluids, and breast milk. It is the causative agent of Acquired Immune Deficiency Syndrome (AIDS) which is the advanced stage of HIV disease.

8. Exposure to any virus, including HIV, does not necessarily mean that infection occurs. HIV transmission is a low probability event because HIV is a virus of low infectivity, meaning that it takes a large volume of virus to transmit infection. Condomless, receptive anal sex with an HIV-infected partner is estimated to transmit infection at the rate of 138 times per 10,000 instances (1.38%), insertive vaginal intercourse is estimated to transmit in only 4 instances out of 10,000 (0.04%), and oral sex carries an estimated rate of transmission deemed negligible at less than 1 instance out of 10,000 (less than 0.01%). In contrast, HIV transmission through a blood

transfusion from an infected source occurs significantly more efficiently, at an estimated rate of 9,250 per 10,000 exposures. Blood transfusions are no longer a source of transmission due to HIV antibody and RNA testing of the blood supply. Centers for Disease Control and Prevention. HIV Risk Behaviors: Estimated Per-Act Probability of Acquiring HIV from an Infected Source, by Exposure Act. http://www.cdc.gov/hiv/risk/estimates/riskbehaviors.html. Updated December 4, 2015. Accessed November 1, 2017. These estimates were also published by the CDC prior to 2015 and have been widely known and accepted in the medical and scientific community.

9. Treatment for HIV disease has advanced dramatically since the inception of the epidemic. In the late 1990s the advent of oral highly active antiretroviral (ARV) medications (sometimes referred to as antiretroviral therapy, or ART) transformed HIV from a disease in which people could quickly progress to AIDS, and for many debilitation and death, to a condition that can be controlled similar to diabetes or other chronic manageable diseases. Highly active ARV medications suppress HIV replication. ARV medications have resulted in extraordinary changes to the health and longevity of people with HIV. The United States Centers for Disease Control and Prevention has concluded that today with proper medical care, "HIV can be controlled" and "someone diagnosed with HIV and treated before the disease is far advanced can live nearly as long as someone who does not have HIV." Centers for Disease Control and Prevention. About HIV/AIDS: Is there a cure for HIV? https://www.cdc.gov/hiv/basics/whatishiv.html. Updated May 30, 2017. Accessed November 1, 2017.

10. The use of oral ARV medications that treat HIV has also transformed the ability to prevent the transmission of HIV. This is particularly important in light of studies that have reported low rates of consistent condom use among sexually active adults. Centers for Disease

Control and Prevention. Preexposure Prophylaxis for the Prevention of HIV Infection in the United States – 2014 Clinical Practice Guideline, at 28. https://www.cdc.gov/hiv/pdf/prepguidelines2014.pdf. Updated 2014. Accessed November 1, 2017.

11. For example, studies first published in 2011 have demonstrated that individuals who are infected with HIV, take ARV as prescribed, and have a sustained undetectable viral load have effectively no risk of transmitting HIV to an HIV-negative partner. Viral load refers to the amount of virus in blood. Undetectable viral load means that the amount of HIV in blood is so low it cannot be measured by routine RNA amplification technology. Oral ARV medications are highly effective at reducing an HIV-infected individual's viral load to undetectable.

12. Studies looking at whether people with HIV become non-infectious if they are on highly active ARV have examined sero-discordant couples (i.e., couples in which one partner is HIV-positive and the other partner is HIV-negative) who report condomless sex. The first efficacy trial to demonstrate that early initiation of highly active ARV decreased HIV transmission, known as HPTN 052, found a 96% reduction in HIV transmission from HIV-infected persons to their partners. Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 Infection with Early Antiretroviral Therapy. *N Engl J Med*. 2011; 365:493-505. Subsequently, initial results of the PARTNER study, which included greater numbers of gay couples than HPTN 052, were presented at the Conference on Retroviruses and Opportunistic Infections in 2014 and reported in NAM AIDSMAP in March 2014. Those results showed no transmission within couples from a partner with an undetectable viral load in an estimated 16,400 occasions of sex in same-sex couples and 28,000 in heterosexual couples. Cairns G. No-one with an undetectable viral load, gay or heterosexual, transmits HIV in first two years of PARTNER

study. *NAM AIDSMAP*. March 4, 2014. http://www.aidsmap.com/No-one-with-an-undetectable-viral-load-gay-or-heterosexual-transmits-HIV-in-first-two-years-of-PARTNER-study/page/2832748/. Accessed November 1, 2017. The study results were ultimately published in the Journal of the American Medical Association in 2016, and demonstrated that there were no cases of HIV transmission among 1,166 HIV serodiscordant couples, who reported 22,000 condomless sex acts among gay couples and 36,000 condomless sex acts among heterosexual couples. Rodger AJ, Cambiano V, Bruun T, et al. Sexual Activity Without Condoms and Risk of HIV Transmission in Serodiscordant Couples When the HIV-Positive Partner is Using Suppressive Antiretroviral Therapy. *JAMA*. 2016;316(2):171-181.

13. The CDC recently concluded that: "When ART results in viral suppression, defined as less than 200 copies/ml or undetectable levels, it prevents sexual HIV transmission. Across three different studies, including thousands of couples and many thousand acts of sex without a condom or pre-exposure prophylaxis (PrEP), no HIV transmissions to an HIV-negative partner were observed when the HIV-positive person was virally suppressed. This means that people who take ART daily as prescribed and achieve and maintain an undetectable viral load have effectively no risk of sexually transmitting the virus to an HIV-negative partner." McCray E, Mermin JH. Dear Colleague: September 27, 2017. Centers for Disease Control and Prevention, Division of HIV/AIDS Prevention. https://www.cdc.gov/hiv/library/dcl/dcl/092717.html. Published September 27, 2017. Accessed November 2, 2017.

14. Pre-exposure prophylaxis, or PrEP, is another extraordinary advance in HIV prevention using an ARV medication. PrEP is currently administered as a once-daily dose of the ARV medication Truvada™ in HIV-negative individuals at risk for HIV in order to prevent the transmission of HIV.

15. Truvada is a tablet that contains two ARV medications, tenofovir disoproxil fumarate and emtricitabine.

16. Truvada was approved by the FDA in 2004 for use in combination with other medications to treat HIV infection.

17. The FDA approved Truvada as use for PrEP in at risk HIV-uninfected persons on July 16, 2012. Truvada was not a new drug in 2012; rather, the FDA approved it for a new indication.

18. PrEP works by keeping HIV from penetrating certain cells, called CD4 cells, and making copies of itself. CD4 cells are critical to the functioning of the immune system. Without these CD4 cells, HIV cannot reproduce and make copies of itself.

19. The initial series of PrEP research studies were double blind placebo controlled studies in which neither investigators nor the study participants knew who was getting the study drug and who was getting a placebo. A double-blind placebo controlled study is considered the "gold standard" in research design when it is unknown whether a therapy works. These studies are designed to determine whether there is evidence demonstrating that a therapy works to reduce the spread of disease on a population-based level.

20. In any placebo-based study it is expected that there will be nonadherence among participants and that nonadherent study participants will be evenly distributed between the two study groups. Nonadherence occurs because a number of factors may reduce the motivation of study participants to take the pill on a daily basis. For example, study participants are told by the study staff and in the informed consent document that it is unknown whether the therapy works. They are also told that there could be side effects. In addition, participants understand that there is a 50% chance they are not receiving the study drug. Some participants join a study simply to

get free medical care or other benefits, such as HIV testing and other medical monitoring in the PrEP studies, and others may be motivated by modest incentives that are paid to cover participant time in getting to the study site and participating in the study procedures (e.g. filling out questionnaires and having blood drawn).

21. Double blind placebo controlled studies show the effectiveness of a therapy on an "intention to treat" basis, meaning the inclusion of every participant who received the study drug, including those who were nonadherent or never took a single dose of the study drug, or who dropped out of the study. That is distinct from examining the impact of a study drug on an "as treated" basis which refers only to those participants who adhered to the study drug as directed. "Intent-to-treat" analyses are important when it is not established that a new intervention is efficacious, since the blinding and assessment of all study participants minimizes possible confounding. However, once it is established that a new medication works if taken appropriately, then measurement of how well adherent individuals do can best be assessed through "as treated" analyses.

22. The use of antiretrovirals to prevent HIV transmission has long had biological plausibility, i.e. the concept made scientific sense. Almost two decades of animal studies demonstrated that different species could be protected against challenges with retroviruses similar to HIV when antiretrovirals were administered prior to exposure or immediately after exposure. In the late 1990's, studies demonstrated that infants whose HIV-infected mothers used the first antiretroviral, azidothymidine (AZT), at the time of delivery were much less likely to transmit HIV to their offspring.

23. Placebo based trials have demonstrated the effectiveness of PrEP to reduce HIV infection on a population-based "intention to treat" basis. The Iniciativa Profilaxis Pre-

Exposición (iPrEX) study published in 2010 was a large randomized study of 2,499 men and transgender women who had sex with men in the United States, Peru, Ecuador, Brazil, Thailand, and South Africa followed for 3,324-person years (A person-year is a measure of aggregate exposure obtained by multiplying the number of people in a trial by the duration of follow-up. In the case of iPrEX, the number of 3,324-person years for a trial that enrolled 2,499 participants, means that the average follow-up per participant was more than 1 year and 4 months. A large number of person years of follow-up is helpful when looking for the occurrence of uncommon adverse events). The study found a relative reduction of HIV incidence on an "intention to treat basis" of 44%. Grant RM, Lama JR, Anderson PL, et al. Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men. *N Engl J Med*. 2010; 363:2587-99. The 44% decrease in HIV incidence was statistically significant (i.e. there was no likelihood that the finding was accidental) and demonstrated that PrEP could have a population level impact in reducing HIV, especially when men who have sex with men account for approximately 70% of all new HIV infections in the United States. The Partners PrEP trial was another large randomized trial of 4,758 HIV serodiscordant heterosexual couples that showed Truvada reduced the risk of becoming infected by 75% on an intention to treat basis. Baeten JM, Donnell D, Ndase P, et al. Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women. *N Engl J Med*. 2012; 367:399-410. These two studies formed the basis for the FDA's approval of PrEP in July 2012. Subsequent studies continued to demonstrate the effectiveness of PrEP on an "intention to treat" basis. The PROUD study of gay men in England, for example, found an 86% reduction in HIV incidence on an "intention to treat" basis. These findings were first presented at a scientific conference in February 2015. See McCormack S, Dunn D. *Pragmatic Open-Label Randomised Trial of Preexposure Prophylaxis: The PROUD Study*. Conference on Retroviruses

and Opportunistic Infections, Seattle, abstract 22LB, February 23-26, 2015. They were later published in McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomized trial. *Lancet* 2016; 387:53-60.

24. In scientific and medical research, after placebo-based trials demonstrate a statistically significant population based impact, assessment of that data is done to examine the level of dosing required for individual protection.

25. Subsequent to the iPrEX placebo based trial, researchers conducted a post hoc analysis and analyzed blood levels of study participants to determine levels of protection at various drug concentrations associated with the number of doses per week. The results, published in 2012, determined that there was a 76% HIV risk reduction associated with 2 doses per week, a 96% reduction associated with 4 doses per week, and a 99% HIV reduction associated with 7 doses per week. There were no HIV infections among HIV-negative gay men who took Truvada at least four times per week. Anderson PL, Glidden DV, Liu A, et al. Emtricitabine-tenofovir exposure and pre-exposure prophylaxis efficacy in men who have sex with men. Sci Transl Med. 2012 Sep 12;4(151):151ra15.

26. In addition, the iPrEX open label study consisted of a follow-up which enrolled 1603 HIV-negative people who knew they were receiving PrEP in a study intended to replicate the conditions of a clinical setting. There were no HIV infections among those participants who took PrEP at least four times a week, data indicating that reasonable adherence is associated with a very high level of protection with PrEP. Grant RM, Anderson PL, McMahan V, et al. Uptake of pre-exposure prophylaxis, sexual practices, and HIV incidence in men and transgender women who have sex with men: a cohort study. *Lancet Infect Dis*. 2014; 14:820-29.

27. The PROUD study demonstrated the efficacy of PrEP in a real-world setting. It enrolled men who have sex with men in 13 sexual health clinics in England between November 2012 and April 2014. The study had two groups: gay men who wanted and were provided PrEP immediately (the intervention group), and gay men with demonstrated risk for HIV who were placed on a waiting list (the control group). HIV incidence in the control group was 7% whereas HIV incidence in the intervention group was under 1%. There were no HIV infections among participants taking PrEP four to seven times per week. These findings were presented at a scientific conference in February 2015. See McCormack S, Dunn D. *Pragmatic Open-Label Randomised Trial of Preexposure Prophylaxis: The PROUD Study*. Conference on Retroviruses and Opportunistic Infections, Seattle, abstract 22LB, February 23-26, 2015. They were later published in McCormack S, Dunn DT, Desai M, et al. Pre-exposure prophylaxis to prevent the acquisition of HIV-1 infection (PROUD): effectiveness results from the pilot phase of a pragmatic open-label randomized trial. *Lancet* 2016; 387:53-60.

28. The IPERGAY study was a double-blind placebo trial that involved an assessment of pericoital dosing of PrEP. The post hoc analysis of the IPERGAY results showed no HIV transmission among those who were highly adherent. These findings were initially presented in part at the 20th International AIDS Conference, July 20-25, 2014 and at the Conference on Retroviruses and Opportunistic Infections. February 23-25, 2015, in Seattle. Fonsart J, Loze B, Morel S, et al. *Tenofovir and emtricitabine pharmacokinetics in plasma and saliva following a single dose of TDF 600mg/FTC 400mg: implications for on demand PrEP (ANRS Ipergay)*. 20th International AIDS Conference, Melbourne, Australia, abstract LBPE28, July 20-25, 2014. Molina JM, Capitant C, Spire B, et al. *On Demand PrEP With Oral TDF-FTC in MSM: Results of the ANRS Ipergay Trial*. Conference on Retroviruses and Opportunistic Infections, Seattle,

abstract 23LB, February 23-26, 2015. Molina JM, Capitant C, Spire B, et al. On-Demand Preexposure Prophylaxis in Men at High Risk for HIV-1 Infection. *N Engl J Med*. 2015; 373:2237-2246.

29. The scientific research and data as of April 2015 indicates that PrEP has been associated with highly significant decreases in HIV incidence and can reduce the risk of HIV transmission by close to 100% if taken consistently on a daily basis.

30. Scientific and medical studies subsequent to April 2015 bolster the conclusion that PrEP is highly efficacious and reduces the risk of HIV transmission by close to 100% when taken as directed.

31. A study of men who have sex with men who started taking PrEP at Kaiser Permanente Northern California, a large integrated healthcare system in San Francisco, found no HIV seroconversions during PrEP use. In this study over 972 individuals initiated PrEP, accumulating 850 person-years of PrEP use. The study was particularly important, since it was not conducted as part of a clinical trial, but rather reflected PrEP use in a real-world setting. Marcus JL, Hurley LB, Bradley Hare C, et al. Preexposure Prophylaxis for HIV Prevention in a Large Integrated Health Care System: Adherence, Renal Safety, and Discontinuation. *J Acquir Immune Defic Syndr*. 2016; 73:540-546. Volk JE, Marcus JL, Phengrasamy T, et al. No new HIV infections with increasing use of HIV preexposure prophylaxis in a clinical practice setting. *Clin Infect Dis*. 2015; 61:1601-03.

32. Adherence to PrEP is strongly correlated to the level of HIV protection. Based on my direct experience conducting scientific studies of PrEP, my knowledge accumulated from the community of PrEP researchers and infectious disease clinicians, and my own clinical experience, it is my opinion that it is uncommon that an individual seeks out PrEP and does not

take it. First, PrEP is voluntary. Nobody forces a person to take PrEP nor is it prescribed to alleviate any symptoms or disease. Second, the stigma associated with PrEP, and the concern that a provider is judging an individual who seeks PrEP, is a barrier to people accessing PrEP. Thus, individuals who initiate PrEP need to be comfortable enough to disclose to their providers that they are engaging in behaviors that might put them at increased risk for HIV. In addition, PrEP is a simple regimen that consists of one pill a day that is well tolerated. For these reasons people who seek out PrEP are generally strongly motivated to adhere to the medication regimen.

33. PrEP is more effective at preventing HIV than condoms. Studies of the real-world efficacy of condoms in protecting against HIV show a range of protection of seventy to eighty percent. This range of effectiveness of condoms was established and was well known among those knowledgeable about HIV prevention prior to 2015. Since condoms can protect against other STDs, it is reasonable for sexually active people to consider using PrEP AND condoms, but not either/or.

34. I understand that Mutual of Omaha's designated expert claims that "[i]f PrEP is not taken properly to sustain effective blood levels, and HIV is contracted, the resultant HIV infection may harbor varying degrees of drug resistance." However, the data from almost 10,000 participants followed in randomized controlled trials found that the prevalence of transmitted resistance was very rare, in the 0.1% range. Selection for resistance can be avoided by patients adhering to the recommended regimen, which I understand is assessed by Mutual of Omaha in its underwriting process.

35. All of the studies of PrEP demonstrate that Truvada is a medication that is well tolerated by patients with side effects that are modest, easily monitored and managed, and reversible. No serious adverse events have been reported in the PrEP studies. There have been

some cases of mild decrease in creatine clearance (a marker of kidney function). This is easily managed by routine blood tests for kidney function. PrEP is stopped when these minor side effects are detected and in all cases kidney function has returned to normal levels. There have been no reports of kidney issues progressing in people who use PrEP. There have also been cases of small decrease in bone mineral density. None of these minor decreases has risen to the level of osteopenia and are reversed when PrEP is stopped. No fractures have been reported due to PrEP use. Further, unlike other medications with similar or greater risk of side effects, PrEP is not a medication that has to be taken long-term for a chronic condition. It is taken during periods of time when the circumstances of a person's life indicate that they are at higher risk for exposure to HIV.

36. PrEP is as safe, or safer, than many other medications that are currently in common use and are not excluded by Mutual of Omaha. Lithium, for example, is a medication used to treat manic depression and bipolar disorder. It can cause permanent kidney damage. Patients using Lithium must be regularly monitored for kidney function. Dilantin and other medications for epilepsy can cause decreases in bone mineral density and osteoporosis. In addition, hormonal contraception, which like PrEP protects against the unwanted consequences of sexual activity, carries some risk of hypertension and venous thromboembolism, and does not protect against HIV.

37. There is no scientific or medical basis to conclude that the current information about the nature and management of the side effects of PrEP will change in the future. Truvada has been licensed by the FDA since 2004. The same mild and reversible side effects as noted in paragraph 33, have been observed in people with HIV taking Truvada since 2004, without anything further. Different or more significant side effects or toxicities are far more likely to

occur in people with HIV than in HIV negative people talking Truvada, but that has not been the case. There is no scientific or medical basis to exclude PrEP users from long-term care insurance based on an assertion that there is not long-term data on PrEP use. The FDA approves many new medications each year for a wide range of health conditions (e.g., diabetes, high blood pressure) based on an assessment that they are sufficiently safe for use. Based on Mutual of Omaha's underwriting guidelines, it does not appear that all new FDA medications are listed as uninsurable medications simply due to a lack of long-term data.

38. Men who have sex with men account for approximately 70% of new HIV infections annually in the United States. Gay men are therefore particularly likely to seek to minimize their risk of HIV infection by taking PrEP. The CDC estimates that approximately 25% of sexually active men who have sex with men would benefit from PrEP while approximately 0.4% of sexually active heterosexual adults would benefit from PrEP. Centers for Disease Control and Prevention. Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition--United States, 2015. These CDC estimates were compiled from epidemiological and demographic data for years prior to 2014. *MMWR Morb Mortal Wkly Rep*. 2015;64(46);1291-1295.

39. The individuals who use PrEP are predominantly gay men. I base this conclusion on the following considerations. Data from Gilead Pharmaceuticals, the manufacturer of PrEP, indicate that in 2014, 84.7% of PrEP users were men, and that in 2015, the year that Mutual of Omaha denied long-term care insurance to the plaintiff in this case, 89.82% of PrEP users were men. During the period 2012-2016, 84.75% of PrEP users were men. See Mera R, Magnuson D, Trevor H, et al. *Changes in Truvada for HIV pre-exposure prophylaxis utilization in the USA: 2012-2016. 9th International AIDS Society Conference on HIV Science.* Slide: "Men and Women

Starting FTC/TDF for PrEP in US, 2012 to 3rd Quarter 2016." International AIDS Society Conference on HIV Science (IAS 2017), Paris, abstract WEPEC0919, 2017. Virtually all male users of PrEP are men who have sex with men (MSM). The primary sexual risk factors for PrEP use are receptive, and to a lesser extent, insertive anal intercourse. Heterosexual men do not engage in receptive anal intercourse, and uncommonly engage in insertive anal intercourse with female partners. Because MSM by definition are having sex with other MSM, their likelihood of being exposed to HIV is much greater than that of heterosexuals, since they are engaging in behaviors that are most efficient for HIV transmission, with a limited partner pool (i.e. MSM are a small minority of the general population) which has an increased HIV prevalence. I also base this conclusion on my knowledge of HIV treatment and prevention obtained during my years of presentations and attendance at specialized medical conferences, my experience as an editor and reviewer for authoritative journals in the field, and my regular and long-term contact and communication with other clinicians and researchers specializing in HIV and PrEP. In my clinical experience, and the experiences of my colleagues discussed at conferences, most patients who inquire about and are ultimately prescribed PrEP are gay men. It is well-known in the field of HIV medicine and by clinicians and researchers with knowledge of HIV and PrEP that approximately 80 percent of PrEP users to date are gay men.

40. Mutual of Omaha's categorical exclusion of PrEP users from long-term care insurance is irrational and based on a gross misunderstanding of the nature of HIV transmission. Assume that Mutual of Omaha has two identical applicants who have the same risk for HIV and are otherwise eligible for insurance. One applicant uses PrEP and the other applicant does not use PrEP. Mutual of Omaha's policy means that it will insure the applicant with the higher risk

for HIV (since he is not using PrEP) and reject the applicant with the lower risk for HIV, who is trying to protect himself with PrEP.

41. The stated reason for Mutual of Omaha's exclusion of PrEP users is to reduce the prevalence of HIV disease in its insured pool. It is reasonable to assume, however, that Mutual of Omaha's policy will lead to increased prevalence of HIV in its insured pool. Mutual of Omaha's policy is based on the fallacy of PrEP as a proxy for HIV risk. Most people at risk for HIV are not on PrEP. The CDC has estimated that approximately 1.2 million Americans have indications for benefit from PrEP. Centers for Disease Control and Prevention. Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Preexposure Prophylaxis to Prevent HIV Acquisition--United States, 2015. *MMWR Morb Mortal Wkly Rep*. 2015;64(46);1291-1295. To date only about 150,000 individuals have used PrEP. Mutual of Omaha's policy creates a perverse incentive for its applicants not to use a highly effective FDA- and CDC-approved HIV preventative technology without having any way of otherwise validating HIV risk in its applicant pool.

42. Mutual of Omaha's PrEP policy is also dangerous to individuals at risk for HIV and contrary to public health efforts to end the HIV epidemic. I understand that Mutual of Omaha will offer insurance to individuals who have not used PrEP for six months. This provision is based on a false belief about HIV risk and transmission as it appears to assume that an individual who discontinues PrEP for that duration is no longer at risk for HIV. Mutual of Omaha's policy creates an incentive for individuals either to delay PrEP until after the insurance underwriting process is completed, or to stop PrEP in order to obtain insurance. Such a policy increases both individual risk for HIV as well as the prevalence of HIV in Mutual's insured pool.

43. Mutual of Omaha's underwriting guide indicates that it offers long-term care insurance to people with a variety of serious health conditions or risk factors for future morbidity (e.g., tobacco use of unlimited amount and duration, diabetes, and coronary artery disease). It is not rational or medically sound for Mutual to insure individuals with significant risk for morbidity, while denying insurance to people who take a highly effective preventative with modest, monitorable and reversible toxicities and who are at lower risk for HIV than people that Mutual insures.

SIGNED UNDER THE PENALTIES OF PERJURY THIS 13TH DAY OF JUNE, 2018.

KENNETH MAYER, M.D.

CERTIFICATE OF SERVICE

I certify that the within document was electronically filed with the clerk of the court on July 18, 2018, and that it is available for viewing and downloading from the Court's ECF system. Service by electronic means has been effectuated on all counsel of record.

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