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

PLAINTIFF JOHN DOE'S STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUSUPPORT OF MOTION FOR SUMMARY JUDGMENT

Pursuant to Local Rule 56.1 Plaintiff John Doe ("Doe") submits this Statement of Undisputed Material Facts in support of his Motion for Summary Judgment:

A. Mutual of Omaha Insurance Company Markets, Offers, and Sells Long-Term Care Insurance to Consumers in Massachusetts.

1. In 2014 and 2015 Mutual of Omaha Insurance Company ("Mutual") was licensed by the Commonwealth of Massachusetts to offer long-term care insurance policies in Massachusetts. Exhibit A, Deposition of Noel Devries pursuant to Fed. R. Civ. P. 30(b)(6), at Appendix ("A") 7 (p. 26).[1]

2. In 2014 and 2015 Mutual accepted applications for long-term care insurance from people in Massachusetts. Devries Dep. at A. 7 (p. 24).

3. In 2014 and 2015 Mutual sold and issued long-term care insurance to people in Massachusetts. Devries Dep. at A. 3 (p. 9).

[1] The referenced documents are contained in the separately filed Plaintiff John Doe's Appendix of Exhibits in Support of Motion for Summary Judgment. The exhibit letter is set forth the first time a source is cited. Subsequent citations to the same source are to the page number of the Appendix (e.g., "at A. ___").

4. In 2014 and 2015 Mutual sold its long-term care insurance, including to people in Massachusetts, through authorized agents or producers. Devries Dep. at A. 4 (p. 15).

5. The terms "producer" and "agent" are used interchangeably and refer to individuals who are authorized or contracted by Mutual to sell its long-term care insurance. Devries Dep. at A. 4 to 5, 8 (pp. 15-16, 19, 29).

6. In 2014 and 2015 Mutual had a division office located in Massachusetts where its producers worked offering its insurance products. Devries Dep. at A. 7 (pp. 26-27).

7. In 2014 and 2015 Mutual maintained a website intended to create awareness about long-term care insurance with the goal of selling it to consumers, including to consumers in Massachusetts. Devries Dep. at A. 3 to 4 (pp. 11, 13-14).

8. In 2014 and 2015 Mutual's website contained a space for consumers, including those in Massachusetts, to input their contact information to be contacted by one of Mutual's authorized agents or producers. Devries Dep. at A. 4 (pp. 14-15).

9. Mutual's authorized agents or producers have access to a password- protected Mutual website which has the rates to Mutual's products from which they run quotes indicating the cost of Mutual's long-term care insurance products for consumers. Producers and agents also assist consumers with filling out applications. Devries Dep. at A. 5 to 7 (pp. 17-18, 22, 24).

B. Doe's Application for Long-Term Care Insurance with Mutual and its Denial.

10. In 2014, Doe's then-partner, now spouse ("Doe's Partner"), contacted his financial advisor, J.D. Loden ("Loden"), about obtaining long-term care insurance for Doe and Doe's Partner. Exhibit B, Deposition of Doe's Spouse, at A. 11 (p. 11).

11. Loden enlisted the assistance of Ash Brokerage. Exhibit C, Deposition of Teresa-Ann Curreri, at A. 15 (pp. 10-12).

12. Ash Brokerage is a marketing company that helps agents find insurance solutions for their clients. Curreri Dep. at A. 14 (p. 6).

13. Loden asked Ash Brokerage to identify companies that offer a spousal discount for a gay couple. Exhibit D, Deposition of John David (JD) Loden, at A. 26 (p. 7).

14. Ash Brokerage identified Mutual as the carrier that offered such a discount. Loden Dep. at A. 26 (p. 8).

15. In 2014 and 2015 and at all times relevant to Doe's application for long-term care insurance from Mutual, Loden was an agent authorized by Mutual to solicit applications for its insurance products. Exhibit E, Defendant's Responses to Plaintiff's Second Set of Interrogatories, at A. 32 to 33 (Response No. 1).

16. In 2014 and 2015 and at all times relevant to Doe's application for long-term care insurance from Mutual, Ash Brokerage was an agent authorized by Mutual to solicit applications from consumers for Mutual's products. Defendant's Responses to Plaintiff's Second Set of Interrogatories, at A. 33 (Response No. 3).

17. On May 15, 2014 Ash Brokerage's representative, Teresa-Ann Curreri, sent an email to Loden stating that "Amy Ash asked that I forward you a care solution for your MA clients, [Doe and Doe's Partner]." Exhibit F at A. 35.

18. Ms. Curreri understood that she was working with prospective clients who were in Massachusetts. Curreri Dep. at A. 21 (p. 47).

19. The May 15, 2014 email also explained: "Mutual of Omaha will require that you hold a non-resident life and health producer's license in MA along with the newly approved long-term care partnership continuing education. By way of this communication I'm asking Cassandra

Reitzel, contracting specialist, to respond with the ltc CE requirements including information regarding CE reciprocity between FL and MA." A. 35.

20. Loden obtained a license to sell insurance in Massachusetts in compliance with Mutual's requirement. Loden Dep. at A. 29 (pp. 34-35).

21. Loden explained that "you have to have a license for that state to write an insurance contract for a resident of that state." He stated that "[y]ou can't solicit or write a contract unless you're licensed" in the state you are writing it for. Loden Dep. at A. 29 (pp. 35-36).

22. Ash Brokerage provided Loden with quotes for three different Mutual long-term care insurance policies, based on premium and benefits information Mutual made available to Ash. Curreri Dep. at A. 16, 20 to 21 (pp. 20, 43-45); Loden Dep. at A. 27 (p. 15).

23. The cover page of each of the three long-term care insurance premium quote documents that Ash Brokerage prepared for Loden and Doe and Doe's Partner has Mutual's logo and states at the top: "Mutual of Omaha Insurance Company, MutualCare Secure Solution Long Term Care Insurance Policy." *See* Exhibit G at A. 36 to 47 (a copy of one of the three identically formatted documents).

24. Ms. Curreri explained that the premium quote documents are "a personalized illustration or proposal that was developed specifically for [Doe's Partner and Doe] based on their ages, their gender, their state of issue and solving for specific long-term care benefits." Curreri Dep. at A. 21 (p. 48).

25. Every single page of all three premium quote documents says at the top: "Issue State: Massachusetts." A. 36 to 47.

26. Doe and Doe's Partner selected one of the premium quotes as the basis for long-term care insurance policy they applied for. Loden Dep. at A. 27 (p. 16).

27. Loden asked Ash Brokerage to assist with Doe and Doe's Partner's application to Mutual. Curreri Dep. at A. 17 (p. 21).

28. Following a process offered by Ash Brokerage called "App Ease," an Ash representative called Doe on the telephone, asked him the questions on the Mutual of Omaha application, pre-populated the electronic application with the answers, and forwarded it to Loden. Curreri Dep. at A. 17, 23 (pp. 21-23, 54-55).

29. In 2014 and 2015 (and presently), Doe split his living time between Rhode Island and Massachusetts. Exhibit H, Deposition of John Doe, at A. 51 (pp. 5-6).

30. Doe owns a home in Rhode Island, and his partner (now spouse) owns a condominium in Boston. Doe Dep. at A. 51 (pp. 5-6).

31. Doe was present during four to five days of the week at the Rhode Island property, and was present three to four days a week at the Boston property. Doe Dep. at A. 51 (p. 6).

32. In the telephone application interview with the Ash Brokerage representative, Doe provided his Rhode Island address to the Ash representative. Curreri Dep. at A. 18 to 19 (pp. 35-36) (indicating that Doe and Doe's Partner gave two different addresses).

33. A question arose as to whether Doe and his partner lived together for purposes of Mutual's partner discount. Curreri Dep. at A. 18 to 19 (pp. 35-38).

34. An Ash Brokerage representative communicated with Loden to discuss the matter of the addresses of Doe and Doe's Partner. Curreri Dep. at A. 18 (p. 36).

35. Loden asked Ash Brokerage to reach out to Doe to "clear up information on the living situation." Curreri Dep. at A. 19, 22 (pp. 37, 51).

36. By email dated September 3, 2014, Brittany Jordan of Ash Brokerage wrote to Loden: "I have connected with [Doe] and received the additional information that was needed.

Attached please find the Mutual of Omaha application for [Doe and Doe's Partner]." Exhibit I at A. 54.

37. Ash Brokerage sent the pre-populated insurance application to Loden who sent it to Doe and Doe's Partner. Jordan email at A. 54 to 55; Doe Dep. at A. 52 (p. 19).

38. The application pre-populated by Ash Brokerage and submitted to Mutual listed the Boston address for both Doe and Doe's Partner. Exhibit J at A. 57 (first page of Doe and Doe's Partner's application for long-term care insurance).

39. After an application for long-term care insurance is submitted to Mutual, Mutual "underwrites" the application, meaning that it "evaluate[s] the case to determine eligibility" for insurance. Devries Dep. at A. 7 (pp. 25-26).

40. Mutual has the sole responsibility for determining whether to issue a long-term care insurance contract to an applicant. Devries Dep. at A. 7 (p. 25); Loden Dep. at A. 29 (pp. 33-34).

41. By letter dated February 9, 2015, Mutual denied Doe's application for long-term care insurance. The letter stated: "We could not offer the coverage you applied for due to your disclosure in your interview of taking Truvada and confirmed in your medical records from Dr. Katz. We do not offer coverage if you are taking this medication regardless of reason as it is on our uninsurable list of medications." Exhibit K at A. 59.

42. The February 9, 2015 denial letter was mailed to Doe at his Boston address. A. 59.

43. Doe appealed Mutual's denial by letter dated March 30, 2015. The letterhead of Doe's appeal used his Boston address. Exhibit L at. A. 62 to 64.

44. By letter dated April 22, 2015, Mutual informed Doe that it would not change its decision. The letter stated: "We do not offer coverage to anyone who takes the medication

Truvada, regardless of whether it is prescribed to treat HIV infection, or is used for pre-exposure prophylaxis. This is in accordance with our underwriting guidelines." Exhibit M at A. 66.

45. The April 22, 2015 letter was mailed to Doe at his Boston address. A. 66.

C. Doe Would Have Received Long-Term Care Insurance From Mutual if He Were Not Taking Truvada.

46. Underwriting an application for long-term care insurance involves an assessment of the risk of an applicant's future need for long-term care services. Exhibit N, Deposition of Lisa Ging, RN pursuant to Fed Re. Civ. P. 30(b)(6), at A. 79 (p. 122).

47. At the time of Doe's application, Mutual's underwriting process involved a review of an application, medical records, a pharmacy check for prescriptions, and a personal health interview. Ging Dep. at A. 69, 79, 80 to 81 (pp. 12, 123, 171-172).

48. The purpose of reviewing those documents is to determine the health of the applicant and if any of the applicant's health conditions are likely to result in impairment in activities of daily living or cognitive impairment. Ging Dep. at A. 79 (p. 123).

49. If Doe had not been taking Truvada as prevention for HIV, Mutual would have issued to him the long-term care insurance policy that he applied for. Exhibit O, Defendant's Responses to Plaintiff's First Set of Interrogatories, at A. 86 (Response No. 18).

D. Truvada and Mutual's Policy and Practice Regarding the Use of Truvada as Pre-Exposure Prophylaxis for HIV.

50. Truvada is a medication that was approved by the federal Food and Drug Administration (FDA) in 2004 for use in combination with other medications to treat HIV infection. Affidavit of Kenneth Mayer, M.D. ("Mayer Aff.") ¶ 16.

51. Mutual placed Truvada on its uninsurable medication list when it was approved as a treatment for HIV disease in 2004. Defendant's Response to Plaintiff's First Set of Interrogatories at A. 85 (Response No. 10).

52. The FDA approved Truvada's use for pre-exposure prophylaxis (PrEP) in at risk HIV-uninfected individuals on July 16, 2012. It is administered as a once daily pill. Mayer Aff. ¶¶ 14-15, 17.

53. Mutual did not conduct any review of whether Truvada should be on its uninsurable list when it was approved as a prophylactic in HIV negative individuals in 2012. Ging Dep. at A. 78 (pp. 108-109) ("We never specifically designated for PrEP. We said if they are taking the medication, regardless of the reason they take it, they are uninsurable."); *see also*, Exhibit P, Deposition of Michael Wilkins, M.D. pursuant to Fed R. Civ. P. 30(b)(6), at A. 90 (p. 83).

54. As of 2014 and 2015, at the time of Doe's application, Mutual had not reviewed the studies and information on the use or efficacy of Truvada as PrEP. Ging Dep. at A. 71 (pp. 53-55).

55. When Mutual received Doe's application, it did not do any investigation into the use of Truvada as PrEP. Ging Dep. at A. 80 (pp. 170-171).

56. Prior to denying Doe's appeal on April 22, 2015, Mutual did not do any research into the medical literature about PrEP. Ging Dep. at A. 82 (pp. 201-202) (further noting that the basis for upholding the denial was that "[h]e's taking Truvada, and we don't insure anyone who takes Truvada").

57. Mutual had, and continues to have, a blanket policy of denying coverage for long-term care insurance to anyone who takes Truvada as PrEP, regardless of the reason. Wilkins Dep. at A. 89 (p. 78); Ging Dep. at A. 70 (pp. 49-51).

58. There are no exceptions to Mutual's categorical policy of denying coverage to individuals who take PrEP. Ging Dep. at A. 70 (p. 50); Wilkins Dep. at A. 89 (p. 78).

59. Mutual's expert, Allen Schmitz, an actuary, testified that following sound actuarial principals for long-term care insurance underwriting, applicants of the same risk should be categorized similarly, and applicants of a lesser risk should not be categorized adversely to an applicant of a higher risk. Exhibit Q, Deposition of Allen Schmitz, at A. 96 (p. 49).

60. If the overall risk for needing long-term care is the same, applicants should receive the same rate classification. Wilkins Dep. at A. 91 (p. 98).

E. Mutual's Inconsistent Rationales for its PrEP Policy.

61. Asked "What are the reasons that Mutual of Omaha excludes from long-term care insurance all individuals who use Truvada as PrEP," Ging answered:

> Because of the indications for the drug. Someone has HIV or they are at high risk of acquiring HIV.

Ging Dep. at A. 72 (p. 61).

62. Ging testified that there are no other reasons that Mutual excludes individuals who take PrEP. Ging Dep. at A. 72 (p. 61).

63. Ging testified that the reason Mutual excludes PrEP users from an underwriting perspective is that "[i]f you develop HIV, you may need to utilize long-term care services." Ging Dep. at A. 73 (p. 65).

64. Asked to compare the risk from a long-term care insurance perspective between someone who has HIV and someone who doesn't have HIV but is on PrEP, Ging answered:

> The individual who is on PrEP has been deemed to be at high risk of acquiring HIV. So if they acquire HIV, then, yes, the risk is the same.

Ging Dep. at A. 80 (pp. 168-169).

65. Mutual's Medical Director and designated expert, Bruce Henricks, M.D, explicitly disclaimed risk of HIV infection as a reason that Mutual excludes PrEP users. Exhibit R, Deposition of Bruce Henricks, M.D., at A. 108 (pp. 81-82) (Q: It didn't have anything to do with a conclusion that he was at substantial risk for HIV? A: No").

66. Henricks testified that "[d]enial was solely based upon the fact that [Doe] was on Truvada … We didn't have robust enough data from our underwriting sources, our reinsurance colleagues, and evidence from our actuarial consultant Milliman and Roberts that Truvada was a drug we could have a comfort level with in underwriting." Henricks Dep. at A. 108 (pp. 81-82).

67. Although Mutual's experts have opined that the blanket exclusion of PrEP users from long-term care insurance is justified because there is insufficient data on the long-term toxicities of Truvada as PrEP (see Statement of Facts, Section J, *infra*), Mutual did not in its interrogatory answers identify the lack of long-term data as a reason to designate the use of PrEP as grounds for uninsurability. *See* Defendant's Responses to Plaintiff John Doe's First Set of Interrogatories at A. 85 (Response No. 10).

F. Scientific and Medical Information About Truvada as Pre-Exposure Prophylaxis for HIV.

68. 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. Mayer Aff. ¶ 7.

69. Exposure to any virus, including HIV, does not necessarily mean that infection occurs. Mayer Aff. ¶ 8.

70. 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. Mayer Aff. ¶ 8.

71. Unprotected, receptive anal sex with an HIV positive 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%). Mayer Aff. ¶ 8.

72. 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 would quickly progress to AIDS, and for many debilitation and death, to a condition that can be controlled similar to many other chronic manageable diseases. Mayer Aff. ¶ 9.

73. The use of oral ARV medications that treat HIV has also transformed the ability to prevent the transmission of HIV. Studies beginning in 2011 have demonstrated that individuals who are infected with HIV, take ARV as prescribed, and have an undetectable viral load, have effectively no risk of transmitting HIV to an HIV-negative partner. Mayer Aff. ¶¶ 10-13.

74. Pre-exposure prophylaxis, or PrEP, is another extraordinary advance in HIV prevention using an ARV medication. Mayer Aff. ¶ 14.

75. 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 access to these CD4 cells, HIV cannot reproduce and make copies of itself. Mayer Aff. ¶ 18.

76. 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. Mayer Aff. ¶ 19.

77. A double blind placebo controlled study is considered the "gold standard" in research design when it is at first 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. Mayer Aff. ¶ 19.

78. 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. Mayer Aff. ¶ 20.

79. Nonadherence occurs because a number of factors work to reduce the motivation of study participants to take the pill. 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). Mayer Aff. ¶ 26.

80. 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 who never took a single dose of the study drug, or who dropped out of the study. Mayer Aff. ¶ 21.

81. The scientific research concept of "intention to treat" 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. Mayer Aff. ¶ 21.

82. "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. Mayer Aff. ¶ 21

83. 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. Mayer Aff. ¶ 21.

84. 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. Mayer Aff. ¶ 23.

85. 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. Mayer Aff. ¶ 23.

86. 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. The Partners PrEP and iPrEPX studies formed the basis for the FDA's approval of PrEP in July 2012. Mayer Aff. ¶ 23.

87. 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. Mayer Aff. ¶ 23.

88. 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. Mayer Aff. ¶ 24.

89. 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. Mayer Aff. ¶ 25.

90. 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. See 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. Mayer Aff. ¶ 25.

91. 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 seven times a week. See* 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. Mayer Aff. ¶ 26.

92. 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.* This study was initially presented at a leading international AIDS conference in February 2015. McCormack S, Dunn D. *Pragmatic Open-Label Randomised Trial of Preexposure Prophylaxis: The PROUD Study*. Conference on Retroviruses and Opportunistic Infections, Seattle, abstract 22LB, 2015 (February 23-26, 2015). The data 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 randomised trial. *Lancet* 2016; 387:53-60. Mayer Aff. ¶

127.

93. 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. The data were later published in 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. Mayer Aff. ¶ 28.

94. The scientific research and data as of April 2015 indicate 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. Mayer Aff. ¶ 29.

95. 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. Mayer Aff. ¶ 30.

96. A study of men who have sex with men initiating 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. 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. Mayer Aff. ¶ 31.

97. Mutual's medical director and designated expert, Dr. Henricks, testified that he is not familiar with the concepts of "intention to treat" versus "as treated" in scientific research trials. Henricks Dep. at A. 119 (p. 148).

98. Dr. Henricks testified that he is "not familiar enough with the trials and how they are structured to understand what that [distinction] means." Henricks Dep. at A. 119 (p. 148).

99. Dr. Henricks testified that he is not sure how the efficacy of PrEP is best indicated by a research study. Henricks Dep. at A. 119 (p. 148).

100. Mutual's expert, Allen Schmitz, who is an actuary, testified that he does not have expertise in assessing the efficacy of PrEP. Schmitz Dep. at A. 97 (pp. 59-60).

101. Based on knowledge available prior 2015, 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. Mayer Aff. ¶ 33.

102. Studies 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. Mayer Aff. ¶ 10.

G. Mutual's Categorical Exclusion of PrEP Users Disproportionally Impacts Gay Men.

103. The individuals who use PrEP are predominantly gay men. Mayer Aff. ¶ 39; Henricks Dep. at A. 126 (p. 178) (agreeing with Mayer).

104. Eighty percent of PrEP users to date are gay men. Mayer Aff. ¶ 39; Henricks Dep. at A. 127 (pp. 179-180) (agreeing with Mayer).

105. Men who have sex with men account for approximately 70% of new HIV infections annually in the United States. Mayer Aff. ¶ 38.

106. 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. *MMWR Morb Mortal Wkly Rep*. 2015;64(46); 1291-1295. Mayer Aff. ¶ 38.

107. Data from Gilead Pharmaceuticals, the manufacturer of PrEP, indicate that in 2014, 84.7% of PrEP users where 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. Mayer Aff. ¶ 39.

108. Virtually all male users of PrEP are gay men who have sex with men. Mayer Aff. ¶ 39.

H. Mutual's Claim That It Excludes PrEP Users Because They are At High Risk for HIV.

109. The primary, and almost exclusive sexual risk indicator for PrEP, is receptive anal intercourse. Mayer Aff. ¶ 39.

110. Most people at risk for HIV are not on PrEP. Mayer Aff. ¶ 41.

111. Mutual's application for long-term care insurance does not inquire about risk factors for HIV, such as whether an applicant engages in receptive anal intercourse, with or without a condom. Henricks Dep. at A. 123 (pp. 164-165); Wilkins Dep. at A. 91 (p. 99) (Mutual has never assessed for the risk of HIV in its underwriting).

112. Mutual's long-term care insurance applicant pool includes individuals who engage in receptive anal intercourse, including without a condom. Henricks Dep. at A. 123 (p. 164).

113. Mutual's Medical Director and expert, Dr. Henricks, testified that comparing two long-term care insurance applicants with identical sexual practices, and one takes PrEP as directed and the other person does not take PrEP, the individual who is not on PrEP presents the higher risk of contracting HIV. Henricks Dep. at A. 119 (pp. 148-149).

114. Mutual's second expert, Allen Schmitz, who is an actuary, testified that if you have two similarly situated individuals with identical sexual practices, and one person takes Truvada as PrEP and the other does not, "it feels like the individual who is not taking PrEP is a higher risk" for HIV. Schmitz Dep. at A. 94 to 95 (pp. 36-37).

115. Dr. Henricks identified in his expert report a concern that "PrEP therapy [may] alter behavior and foster promiscuity" as a reason justifying Mutual's exclusion of PrEP users. Exhibit S, Expert Report of Bruce Henricks, M.D. FACP, at A. 136 (p. 8).

116. Dr. Henricks testified that "[h]eavens no," promiscuous behavior, as he defines it, is not grounds for exclusion from long-term care insurance. Henricks Dep. at A. 122 (p. 162).

117. Dr. Henricks testified that with respect to a person who engages in "promiscuity," as he uses that term in his expert report, and takes PrEP as directed, "[t]he risk [of HIV] is low." Henricks Dep. at A. 122 (p. 161).

118. Dr. Henricks testified that an otherwise qualified individual who is at low risk for HIV is "of course" eligible for long-term care insurance from Mutual. Henricks Dep. at A. 107 (p. 79).

119. Dr. Henricks testified, however, that a person who engages in "promiscuity," as he uses that term in his expert report, and is not on PrEP and does not use a condom, is a high risk for HIV. Henricks Dep. at A. 123 (pp. 164-165).

120. Dr. Henricks agrees with the following statement from a journal article he cited and relied upon in his expert report: "From the trials reviewed, it is evident that PrEP is highly effective against HIV infection when taken as required." Henricks Dep. at A. 124 to 125 (p. 171-172).

121. Dr. Henricks testified that there were benefits to a person taking Truvada as PrEP as directed in 2015. Those benefits were "[t]he prevention of HIV acquisition." Henricks Dep. at A. 116 (p. 124).

122. Dr. Henricks testified that comparing two otherwise qualified individuals with identical sexual practices, one take PrEP and the other does not, he has "no … specific information" to conclude that the person on PrEP is at higher risk for LTC claims. Henricks Dep. at A. 119 to 120 (pp. 151-152).

I. Mutual's Claim That it Excludes PrEP Users Because They Might Not Take PrEP as Directed, Or Comply with Recommended Follow-up.

i. Adherence to Medication.

123. Mutual's experts assert that the question of whether a patient will adhere to taking PrEP daily is one of the reasons that justifies the blanket exclusion of all PrEP users. Henricks Report at A. 135 (p.7); Exhibit T, Expert Report of Allen Schmitz at A. 152 (p. 8).

124. The effectiveness of every medication taken by every patient is influenced by adherence to the recommended regimen. Henricks Dep. at A. 123 (p. 166).

125. Patient nonadherence to medications for a wide range of health conditions in general is a significant problem in medicine. Henricks Dep. at A. 101 (pp. 22-23).

126. Approximately 75 % of Americans have trouble taking their medication as directed. Henricks Dep. at A. 126 (p. 176).

127. Noncompliance with long-term medication for hypertension, high cholesterol, and diabetes is a common problem that leads to compromised health. Henricks Dep. at A. 126 (pp. 176-177).

128. The failure to adhere to medications for any health condition can result in harm to the patient and increase morbidity. Henricks Dep. at A. 101 to 102 (pp. 23-24).

129. Mutual insurers individuals with diabetes insipidus, diabetes type 2, sleep apnea, bipolar/manic depression, and depression, among others, as long as they are controlled by medication and recommended therapy. Ging Dep. at A. 76 to 77 (pp. 96-97, 98-99, 100-102).

130. Mutual determines an applicant's adherence to medications at the time of underwriting the application. Henricks Dep. at A. 106 (p. 68).

131. Mutual assesses whether a patient is adherent to medications at the time of underwriting, according to Dr. Henricks, by "looking at the medical records ... [t]he physician's assessment and documentation of such… [i]t's the only way we really have when you are underwriting the case … It's the best source of data." Henricks Dep. at A. 103 to 104 (pp. 55-56) (discussing in the context of a patient who takes the medication methotrexate); Henricks Dep. at A. 103, 106 (pp. 53, 69-70) (in the context of the medication Imuran, stating that Mutual would "look at the medical records and the physician's assessment" to determine whether the applicant is taking the medication as directed).

132. Mutual does not monitor an applicant's adherence to their medication regimen after the time of underwriting. Ging Dep. at A. 75 (p. 94).

133. Mutual's Medical Director and expert Dr. Henricks acknowledged that Mutual could determine an applicant's adherence to PrEP in the same way it does for other medications. He testified as follows:

> Q: Couldn't [adherence to PrEP] be assessed by an examination of the medical records of the applicant?
>
> A: Possibly. What patients tell their doctor and what they do are two different things.
>
> Q: Is that the same for other medications?
>
> A: Absolutely.

Henricks Dep. at A. 121 (p. 156).

ii. <u>Compliance with Recommended PrEP follow-up</u>

134. Mutual asserts that the question of whether an applicant who takes PrEP will comply with recommend follow-up monitoring justifies the blanket exclusion of all PrEP users.

Henricks Report at A. 135 (p. 7) ("Will the patient comply with the recommended interval follow-up once on PrEP?").

135. Patients on all medications do not always comply with recommended monitoring and follow-up for their medications. Henricks Dep. at A. 101 (p. 23).

136. The failure of patients to comply with recommended monitoring and follow-up for their medications is a significant problem in the field of medicine that can result in harm and increased morbidity to the patient. Henricks Dep. at A. 101 to 102 (pp. 23-24).

137. Dr. Henricks testified that the determination during underwriting of whether an applicant is compliant with follow-up is "fairly simple … if the physician recommends they come back in three months and they come back in three months." Henricks Dep. at A. 100 (p. 13).

138. Henricks testified that Mutual determines whether an applicant is compliant with recommended monitoring and follow-up by looking at the medical records requested by Mutual during the underwriting process. Henricks Dep. at A. 100 (p. 13).

139. For example, people on the medication methotrexate must be monitored for potential serious side effects or toxicities that include pulmonary toxicity, pulmonary fibrosis, and liver toxicity. Henricks Dep. at A. 104 (pp. 56-57).

140. People stay on methotrexate for rheumatoid arthritis long-term. Henricks Dep. at A. 104 (p. 59).

141. People on methotrexate must receive a liver function test every three months or harm can result. Henricks Dep. at A. 104 to 105 (pp. 59-60).

142. Compliance with quarterly liver function testing is assessed at the underwriting stage by looking at the applicant's medical records. Henricks Dep. at A. 105 (p. 60).

143. Pulmonary toxicity for a person on methotrexate would be detected by physical examination initiated by a patient's complaint of symptoms. Henricks Dep. at A. 105 (pp. 60-61).

144. Mutual's Medical Director and expert Dr. Henricks testified that a patient's compliance with the recommended follow-up for PrEP would be assessed by the medical records of an applicant for long-term care insurance "if the physician did a good job of recording it." Henricks Dep. at A. 121 (pp. 157-158).

145. Dr. Henricks agreed that whether a physician does a good job of recording the recommended follow-up would be true for many medications not excluded by Mutual. Henricks Dep. at A. 121 (p. 158).

146. Dr. Henricks also acknowledged that Mutual could also assess whether an applicant on PrEP went through the proper *pre*-PrEP evaluation and testing by looking at the medical records during underwriting. Henricks Dep. at A. 121 (pp. 156-157).

J. Mutual's Claim That the Blanket Exclusion of PrEP Users From Long-Term Care Insurance is Justified Because There is Insufficient Data on the Long-Term Toxicities of Truvada as PrEP.

147. Dr. Henricks asserts that there are "no real conclusions on the long-term implications of Truvada therapy or related toxicities that would allow analysis of their potential influence on morbidity." Henricks Report at A. 135 (p. 7) (also referencing, insufficient "data to answer the questions of long-term toxicities and their impact on morbidity"; lack of data "to assess the long-term, real-world safety profile"; and lack of "time and extensive claims experience"). See also Schmitz Report at A. 152 (p. 8) ("Truvada as PrEP is a relatively new drug and the long term effects of Truvada are not yet known").

148. Mutual does not have a policy or practice of placing all new FDA approved medications on its uninsurable list for a period of time. Henricks Dep. at A. 109 (p. 89).

149. The fact that a drug has just been approved by the FDA does not warrant placing it on the uninsurable list. Henricks Dep. at A. 109 (pp. 89-90).

i. Mutual Does Not Exclude Other New Medications Lacking Long-term Data.

150. The medication Duavee (Conjugated Estrogen/Bazedoxiefene) was approved by the FDA in 2013. Henricks Dep. at A. 114 to 115 (pp. 119-120); Exhibit U, First Page of FDA Drug Information on Duavee, at A. 162.

151. Duavee has never been on Mutual's Uninsurable List.[2]

152. FDA prescribing information for Duavee indicates that the medication can increase the risk of dementia. Hernicks Dep. at A. 115 (pp. 120-121); A. 162 (FDA drug information).

153. Dementia is "absolutely" a concern for long-term care insurance underwriting because "[i]t's one of the highest conditions that cause claim in LTC in the industry." Henricks Dep. at A. 115 (p. 120).

154. Dr. Henricks would be very cautious in long-term care insurance underwriting about anything that would potentially increase somebody's risk for dementia. Henricks Dep. at A. 115 (p. 120).

155. Dr. Henricks does not think Duavee should be a basis to exclude an applicant from long-term care underwriting. Henricks Dep. at A. 115 (p. 120).

[2] Mutual has stipulated that the medications listed in paragraphs 162, 167, 172, 177, 180, 184, 188, and 195 have never been included in the list of "Some Medications Associated with Uninsurable Health Conditions" in any Mutual Underwriting Guide.

156. Dr. Henricks' reasoning is that there may be potential side effects of the use of conjugated estrogen in women which are offset by the benefits of their use. Henricks Dep. at A. 115 (p. 122).

157. Asked if there were benefits to taking Truvada as PrEP, Dr. Henricks testified:

> In my professional opinion, yes. … It has the potential to be quite efficacious in preventing the acquisition of HIV if it's used properly, which properly would be they're adherent to the proper dosage, they go through an initial pretreatment evaluation, and then are rigorous in their follow up as prescribed by the FDA and the package insert on follow up of Truvada's use.

Henricks Dep. at A. 115 (p. 122).

158. Dr. Henricks testified that in January 2015 for a person who had some risk for HIV it was more beneficial to take PrEP than not. Henricks Dep. at A. 116 (p. 125).

159. Dr. Henricks agrees with the statement from a medical article cited in his expert report that: "We would expect based on current evidence that the long-term safety profile [of PrEP] will be within acceptable limits with favorable benefit-risk profiles considering the impact of PrEP on HIV prevention." Henricks Dep. at A. 124 (p. 170).

160. The medication Steglatro (Ertugliflozin) was approved by the FDA tor treatment of diabetes mellitus in 2017. Henricks Dep. at A. 118 (pp. 137-138); Exhibit V, First Page of FDA Drug Information on Steglatro, at A. 164.

161. The fact that Steglatro was approved in 2017 would not be a reason to exclude it from long-term care insurance. Henricks Dep. at A. 118 (p. 138).

162. Steglatro has never been on Mutual's list of uninsurable medications. *See* n.2, *supra*.

163. The FDA prescription information for Steglatro indicates that it can cause kidney impairment and that there have been post-marketing reports of acute kidney injury, some requiring hospitalization and dialysis. Henricks Dep. at A. 118 (p. 138)..

164. Dr. Henricks testified that these reports would not be a reason to exclude the drug from long-term care insurance. Henricks Dep. at A. 118 (p. 139).

165. With regard to reports of acute kidney injury associated with Steglatro, Dr. Henricks testified that he would wait for more data and follow-up studies over time, but would not exclude users of the medication from long-term care insurance underwriting in the meantime. Henricks Dep. at A. 118 (p. 139).

166. The medication Tanzeum (also known as Albiglutide) was approved by the FDA in 2014 for treatment of Type 2 diabetes. Henricks Dep. at A. 109 (pp. 90-91). Exhibit W, First Page of FDA Drug Information on Tanzeum, at A. 166.

167. Tanzeum (Albiglutide) has never been on Mutual's uninsurable medication list. *See* n.2, *supra*.

168. Dr. Henricks acknowledged that in 2014 there would not be data available to assess the long-term real -world safety of Tanzeum (Albiglutide). Henricks Dep. at A. 110 (pp. 94-95).

169. Dr. Henricks acknowledged that in 2014 there would not have been extensive claims experience, or sufficient data to make conclusions about the long-term implications for morbidity, of a drug such as Tanzeum (Albiglutide) that was approved by the FDA in 2014. Henricks Dep. at A. 110 (pp. 94-95).

170. Dr. Henricks testified that the lack of long-term safety data on Tanzeum (Albiglutide) in 2014 would not be a reason to exclude a user of Tanzeum in the underwriting process. Henricks Dep. at A. 110 (p. 93).

171. The medication Trulicity (also known as Dulaglutide) was approved by the FDA in 2014 for type 2 diabetes. Hendricks Dep. at A. 110 to 111 (pp. 95-96); Exhibit X, First Page of FDA Drug Information on Trulicity, at A. 168.

172. Trulicity (Dulaglutide) has never been on Mutual's uninsurable medication list. *See* n.2, *supra*.

173. Dr. Henricks acknowledged that in 2014 there was not extensive claims experience or data available to assess the long-term real-world safety with respect to Trulicity. Henricks Dep. at A. 111 (pp. 96-98).

174. Dr. Henricks acknowledged that in 2014 there would not have been information to make conclusions about Trulicity's long-term toxicities, or long-term data on the safety and efficacy for Trulicity (Dulaglutide). Henricks Dep. at A. 111 (pp. 96-98).

175. Dr. Henricks stated that the lack of long-term data was not a reason to place the medication Trulicity (Dulaglutide) on Mutual's uninsurable list and thereby not a reason to automatically deny long-term care insurance to users of Trulicity (Dulaglutide). Henricks Dep. at A. 111 (p. 98).

176. Dr. Henricks also acknowledged that the medication Farxiga (also known as Dapagliflozin) was approved by the FDA in 2014 for type 2 diabetes, but there was not extensive claims experience over time, data available to assess the long-term real-world safety, or information to make conclusions about the long-term implications of Farxiga's influence on morbidity. Henricks Dep. at A. 111 to 112 (pp. 99-101); Exhibit Y, First Page of FDA Drug Information on Farxiga, at A. 170.

177. Farxiga has never been on Mutual's list of uninsurable medications. *See* n.2, *supra*.

178. Dr. Henricks testified that a statement in a medical journal that Farxiga's (Dapagliflozin's) "long-term safety and efficacy" are unknown was not a reason to place that medication on Mutual's uninsurable list. Henricks Dep. at A. 112 (p. 101).

179. The medication Repatha (also known as Evolocumab) was approved by the FDA in 2015 as an anti-cholesterol treatment. Henricks Dep. at A. 112 (p. 102); Exhibit Z, First Page of FDA Drug Information on Repatha, at A. 172.

180. Repatha has never been on Mutual's list of uninsurable medications. *See* n.2, *supra*.

181. Dr. Henricks acknowledged that in 2015 Mutual did not have extensive claims experience over time with Repatha (Evolocumab), data to assess the long-term real-world safety of the drug, information to make conclusions about the long-term implications of its influence on morbidity, or information to make conclusions about its toxicities. Henricks Dep. at A. 112 to 113 (pp. 102-105).

182. Dr. Henricks testified that the fact that a published medical article indicated that studies on the long-term safety concerns for Repatha (Evolocumab) are limited, was not a reason to exclude users of Repatha from Mutual's long-term care insurance. Henricks Dep. at A. 113 (pp. 104-105).

183. The medication Kynamro (also known as Mipomersen) was approved by the FDA in 2013 as an anti-cholesterol treatment. Henricks Dep. at A. 114 (p. 116). Exhibit AA, First Page of FDA Drug Information on Kynamro, at A. 174.

184. Kynamro has never been on Mutual's list of uninsurable medications. *See* n.2, *supra*.

185. Dr. Henricks acknowledged that Mutual in 2013 did not have extensive claims experience with this drug, or data to assess its real-world safety or long-term impact on toxicities. Henricks Dep. at A. 114 (p. 117).

186. Dr. Henricks testified that the fact that this medication was approved by the FDA in 2013 was not a reason to place it on the uninsurable list in that year. Henricks Dep. at A. 114 (pp. 116-117).

187. The FDA approved the medication Breo Ellipta in 2013 as oral inhalation for asthma. Exhibit BB, First Page of FDA Drug Information on Breo Ellipta, at A. 176.

188. Breo Ellipta has never been on Mutual's list of uninsurable medications. *See* n.2, *supra*.

189. The FDA prescribing information for Breo Ellipta indicates that patients taking this medication should be assessed for bone mineral density. Henricks Dep. at A. 117 (p. 132).

190. Dr. Henricks testified that this is not a reason to exclude users of this medication from long-term care insurance underwriting since it is just monitoring the patient's status. Henricks Dep. at A. 117 (p. 132).

191. The FDA prescribing information also requires "close monitoring for glaucoma and cataracts." Henricks Dep. at A. 117 (p. 133).

192. Glaucoma and cataracts can increase the risk of morbidity and long-term care insurance claims. Henricks Dep. at A. 117 (pp. 133-134).

193. Dr. Henricks testified that the risk of glaucoma is not a reason to exclude users of Breo Ellipta from long-term care insurance. Henricks Dep. at A. 117 (p. 133).

194. FDA prescribing information indicates that the medication Zurampic (also known as Lesinurad) was approved in 2015 for treatment of gout. Henricks Dep. at A. 117 (p. 134); Exhibit CC, First Page of FDA Drug Information on Zurampic, at A. 178.

195. Zurampic has never been on Mutual's list of uninsurable medications. *See* n.2, *supra*.

196. The fact that Zurampic (Lesinurad) was approved by the FDA in 2015 would not be a reason for Mutual to exclude users from long-term care insurance. Henricks Dep. at A. 117 (p. 134).

197. The FDA prescribing information for Zurampic has a black box warning stating: "Warning: Risk of Acute Renal Failure, More Common When Used Without Xanthine Oxidase Inhibitor." Henricks Dep. at A. 117 (p. 135); A. 178 (FDA information).

198. Henricks testified that the warning is not enough to exclude users of this medication from long-term care insurance. Henricks Dep. at A. 117 (p. 135).

ii. The Safety of PrEP

199. No serious adverse events have been reported in the PrEP studies. Mayer Aff. ¶ 35.

200. There have been some cases of mild decrease in creatine clearance (a marker of kidney function). Mayer Aff. ¶ 35.

201. This is easily managed by routine blood tests for kidney function. Mayer Aff. ¶ 35.

202. PrEP is stopped when these minor side effects are detected and in all cases kidney function returned to normal. Mayer Aff. ¶ 35; Henricks Dep. at A. 125 (p. 172) (agreeing with the statement in a medical journal that "observed increases in the serum creatine level return to normal after the discontinuation of PrEP").

203. Dr. Henricks testified with respect to the medication Zurampic that incidence of serum creatine elevations with this drug were not a reason to exclude it from long-term care insurance "[b]ecause it's most of which are reversible, meaning, if you remove the drug, the renal function returns to normal." Henricks Dep. at A. 118 (pp. 136-137) (also agreeing that "if the serum creatine elevations are reversible, that is acceptable from a long-term care insurance underwriting perspective").

204. There have also been cases of small decrease in bone mineral density in PrEP users. Mayer Aff. ¶ 35.

205. None of these minor decreases has risen to the level of osteopenia and are reversed when PrEP is stopped. Mayer Aff. ¶ 35.

206. Dr. Henricks agrees that reduction in bone mineral density in PrEP users is reversible. Henricks Dep. at A. 125 (p. 174).

207. Dr. Henricks testified with respect to the medication Breo Ellipta that the recommendation for monitoring patients on that drug for decease in bone mineral density would not be a reason to exclude users of that drug in long-term care insurance underwriting. Henricks Dep. at A. 117 (p. 132).

208. Dr. Henricks agrees that there is no basis to support monitoring for bone mineral density for patients taking PrEP. Henricks Dep. at A. 125 (p. 174).

209. 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 which have been noted in people who have used PrEP also 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 taking Truvada, but that has not been the case. Mayer Aff. ¶ 37.

Dated: July 18, 2018

Respectfully submitted,
JOHN DOE
By his attorneys,

/s/ Bennett Klein_____
Bennett H. Klein
BBO # 550702
GLBTQ Legal Advocates & Defenders
18 Tremont Street, Suite 950
Boston, MA 02108
617-426-1350
bklein@glad.org

John P. Ward
BBO # 515860
Law Offices of John P. Ward
584 Castro St., No. 802
San Francisco, CA 94114
415-255-4996
johnpward@gmail.com

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.

Brooks R. Magratten, BBO# 650393
Pierce Atwood LLP
One Financial Plaza, 26th Floor
Providence, RI 02903
(401) 588-5113
bmagratten@pierceatwood.com

Mark A. Pogue, BBO# 550807
Pierce Atwood LLP
One Financial Plaza, 26th Floor
Providence, RI 02903
(401) 490-3422
mpogue@pierceatwood.com

Katharine E. Kohm, BBO# 675362
Pierce Atwood LLP
One Financial Plaza, 26th Floor
Providence, RI 02903
(401) 490-3422
kkohm@pierceatwood.com

Nicole Kinsely, BBO # 682528
Foley Hoag LLP
Seaport World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 832-1185
nkinsley@foleyhoag.com

/s/ Bennett H. Klein
Bennett H. Klein
BBO # 550702
GLBTQ Legal Advocates & Defenders
18 Tremont St., Suite 950
Boston, MA 02108
617-426-1350
bklein@glad.org