

When Condoms Fail: Making Room Under the ACA Blanket for PREP HIV Prevention

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I. INTRODUCTION

There are approximately 50,000 new HIV infections in the United States every year.¹ While the overall frequency of new, diagnosed, and undiagnosed HIV infections—known as “HIV incidence”—has remained relatively unchanged, HIV incidence among certain high-risk groups has actually increased despite nearly thirty years of condom messaging.² For example, from 2008 to 2010, HIV incidence among men who have sex with men (MSM³) increased twelve percent in the United States.⁴ The federal government acknowledges that it has failed to make any significant progress toward reducing sexual risk among certain high-risk populations, particularly MSM.⁵ In fact, the Centers for Disease Control and Prevention (CDC) found, as of 2013, no change or potential movement away from targeted decreases in risk reduction among high-prevalence groups.⁶ Research and anecdotal evidence tells us that as perceptions about HIV mortality are evolving, traditional approaches to HIV prevention rooted in education, behavioral modification, and risk reduction are becoming less effective strategies.⁷ In the words of HIV/

1. CTRS. FOR DISEASE CONTROL AND PREVENTION, PREEXPOSURE PROPHYLAXIS FOR THE PREVENTION OF HIV INFECTION IN THE UNITED STATES—2014: A CLINICAL PRACTICE GUIDELINE 13 (2014) [hereinafter CDC GUIDELINES], <http://www.cdc.gov/hiv/pdf/PrEPguidelines2014.pdf> [<http://perma.cc/P8YN-NB9M>]; *HIV in the United States: At a Glance*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hiv/statistics/basics/ataglance.html> [<http://perma.cc/NDS6-PK93>] (last updated Nov. 25, 2014).

2. See *HIV Incidence*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hiv/statistics/surveillance/incidence/index.html> [<http://perma.cc/76BS-ZGGW>] (last updated May 22, 2013).

3. For the purpose of this Article, MSM includes any man who has sex with another man; this high-prevalence group includes those who self-identify as homosexual, heterosexual, bisexual, and transgender. See *Policy Brief: HIV and Sex Between Men*, UNAIDS 1 (Aug. 2006), http://data.unaids.org/pub/BriefingNote/2006/20060801_policy_brief_msm_en.pdf [<http://perma.cc/U22P-RDVV>] (noting that the umbrella term MSM “encompasses a range of sexual and gender identities among people in various sociocultural contexts”).

4. *HIV in the United States: At a Glance*, *supra* note 1 (stating that the estimated number of new HIV infections among MSM increased from 26,700 in 2008 to 29,800 in 2010); see also CTRS. FOR DISEASE CONTROL & PREVENTION, NATIONAL HIV PREVENTION PROGRESS REPORT, 2013, at 17 (2013) [hereinafter PROGRESS REPORT], http://www.cdc.gov/hiv/pdf/policies_NationalProgressReport.pdf [<http://perma.cc/HNH5-KHRZ>] (finding that unchanged risk behavior among MSM from 2008 to 2011 coupled with increasing numbers of new HIV infections among MSM is “especially worrisome”).

5. See PROGRESS REPORT, *supra* note 4, at 2.

6. See *id.*

7. See, e.g., Junjun Jiang et al., *Pre-Exposure Prophylaxis for the Prevention of HIV Infection in High Risk Populations: A Meta-Analysis of Randomized Controlled Trials*, PLOS ONE 1 (Feb. 3, 2014), <http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0087674&representation=PDF> [<http://perma.cc/>

AIDS activist Peter Staley: “Because we don’t have the death and dying that forced a drastic change in sexual behavior . . . in the mid-‘80s, which was largely sustained until the early ‘90s, the safe-sex condom code that we created then has collapsed.”⁸

Abandoning condom advocacy is not the answer for the majority of HIV/AIDS advocates.⁹ Reducing condomless sex—the primary route of HIV transmission¹⁰—continues to be a priority in HIV prevention and in the prevention of other sexually transmitted infections.¹¹ However, attention has rapidly shifted to developing new HIV prevention modalities and to integrating these new modalities into more traditional prevention

CBN5-LQCD] (finding that “[t]raditional interventions have been known to be poorly effective in HIV prevention”); Mary Jane Rotheram-Borus et al., *The Past, Present, and Future of HIV Prevention: Integrating Behavioral, Biomedical, and Structural Intervention Strategies for the Next Generation of HIV Prevention*, 5 ANN. REV. CLINICAL PSYCHOL. 143, 149 (2009) (stating that although barrier methods such as condom usage can reduce HIV incidence by as much as ninety-five percent, “most persons do not use condoms consistently or correctly, so effectiveness falls to about 70%” (citing Anna F. Foss et al., *Condoms and Prevention of HIV Are Essential and Effective but Additional Methods Are Also Needed*, 329 BMJ 185, 185 (2004))); see also Andrew M. Seaman, *Men at High Risk for HIV May Misjudge Their Vulnerability*, REUTERS (June 26, 2014, 12:07 PM), <http://www.reuters.com/article/2014/06/26/us-gay-men-hiv-truvada-idUSKBN0F120120140626> [<http://perma.cc/SR8P-9MH3>] (discussing a recent study finding decreased perception of HIV risk in MSM attending bathhouses and sex clubs).

8. Mark Joseph Stern, “*I Have Learned Not to Underestimate the Stigma*”: Peter Staley on Truvada, Condoms, and HIV Prevention, SLATE (May 22, 2014, 9:00 AM), http://www.slate.com/blogs/outward/2014/05/22/peter_staley_talks_about_truvada_hiv_and_stigma.html [<http://perma.cc/WV69-8LKR>].

9. In this Article, I am not suggesting that condom advocacy is not a wise use of resources in light of declining usage trends. I seek to investigate the challenges that will shape the scaling up of HIV pre-exposure prophylaxis as a second and third line of defense in combination with condoms and behavioral interventions. See Sunnive Brydum, *Is PrEP the End of HIV in the U.S.?*, ADVOCATE (Oct. 30, 2014, 7:00 AM), <http://www.advocate.com/31-days-prep/2014/10/30/prep-end-hiv-us> [<http://perma.cc/IE6E-Y3L5>] (noting that “most doctors and activists—in addition to overarching agencies like the Centers for Disease Control and Prevention and the World Health Organization—urge that PrEP be used in conjunction with existing strategies”). I also seek to investigate these challenges in the context of individuals who use PrEP as a primary means of HIV prevention in lieu of condoms.

10. See *Who’s at Risk for HIV*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hiv/risk/index.html> [<http://perma.cc/D5B2-FAMA>] (last updated Oct. 30, 2014).

11. See PROGRESS REPORT, *supra* note 4, at 17 (stating that although “the majority of MSM have tried to lower their HIV risk,” there remains “an urgent need to improve the effectiveness of HIV prevention efforts” for MSM and other high-risk populations).

models.¹² Antiretroviral drugs (ARVs), which were introduced to suppress the virus in HIV-positive individuals, are now being used as a pharmacological prevention modality for HIV-negative individuals.¹³ In pharmacological prevention, medication is prescribed to someone with specific risk factors for an illness that has not occurred or is asymptomatic. Pharmacological preventions are by no means new in the medical community.¹⁴ Examples of well-established, FDA-approved pharmacological preventions include the prescription of statin therapy to diabetics who are at risk of developing cardiovascular disease,¹⁵ Malarone for the prevention of Malaria,¹⁶ and contraceptives to prevent pregnancy.¹⁷

In the context of HIV prevention, however, pharmacological prevention is newer to the market. Oral HIV pre-exposure prophylactic medication, known as PrEP or oral PrEP,¹⁸ typically consisting of single or compound ARVs taken by HIV-negative individuals in advance of potential exposure, has been the subject of a deluge of media, public health, and regulatory attention in light of multiple trials showing it significantly reduces the risk of infection.¹⁹ The FDA recently approved the use of an

12. See Rotheram-Borus et al., *supra* note 7, at 150.

13. See *PrEP for HIV Prevention*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/features/stop-hiv-prep> [<http://perma.cc/EPY4-AKCY>] (last updated May 14, 2014).

14. See Diane Anderson-Minshall, *Ask a Doctor: What's Stopping Us from Talking About PrEP?*, ADVOCATE (Oct. 31, 2014, 3:00 AM), <http://www.advocate.com/31-days-prep/2014/10/31/ask-doctor-whats-stopping-us-talking-about-prep> [<http://perma.cc/94D6-VYUX>] (“PrEP itself is not exclusive to HIV. . . . We do PrEP for many other diseases.”).

15. See Am. Diabetes Ass’n, *Standards of Medical Care in Diabetes—2013*, 36 DIABETES CARE S11, S31, S34 (2013), http://care.diabetesjournals.org/content/36/Supplement_1/S11.full.pdf [<http://perma.cc/PP54-HBTR>].

16. See *Medicines for the Prevention of Malaria While Traveling: Atovaquone-Proguanil (Malarone™)*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/malaria/resources/pdf/fsp/drugs/atovaquoneproguanil.pdf> [<http://perma.cc/Y6QZ-HB4Y>] (last visited Mar. 25, 2015).

17. See *Estrogen and Progestin (Oral Contraceptives)*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/druginfo/meds/a601050.html> [<https://perma.cc/VAW2-PY8S>?type=image] (last updated Jan. 26, 2015).

18. Barrier treatments such as condoms are technically a kind of PrEP, as they preventatively reduce the risk of HIV exposure. See Rotheram-Borus et al., *supra* note 7, at 148–49. However, the media, public health officials, and HIV/AIDS advocacy organizations have requisitioned the acronym PrEP to exclusively refer to the use of ARVs as preventive treatment. For the sake of clarity, references to PrEP or oral PrEP in this Article refer solely to oral HIV PrEP.

19. See, e.g., *infra* notes 20–25, 54–58, 66, 104, 115; see also Ume L. Abbas et al., *Antiretroviral Therapy and Pre-Exposure Prophylaxis: Combined Impact on HIV Transmission and Drug Resistance in South Africa*, 208 J. INFECTIOUS DISEASES 224, 224 (2013) (noting there is public concern about the potential emergence and spread of HIV drug resistance arising from the rollout of ARV as PrEP); Michael C. Thigpen et al., *Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana*,

ARV called Truvada[®], and the CDC issued final guidance on the matter, which has thrust oral PrEP into the spotlight. Yet, despite evidence of its effectiveness and concomitant public health and regulatory responses, oral PrEP has proven controversial.²⁰

PrEP intervention has been the subject of notable dissensus, particularly in the lesbian, gay, bisexual, and transgender (LGBT) community.²¹ For example, Larry Kramer, a long-time HIV/AIDS activist, recently stated that people taking Truvada for PrEP must have “rocks in their heads” for risking potential long-term side effects.²² Controversially, Michael Weinstein, President of the AIDS Healthcare Foundation (AHF), analogized oral PrEP to a “party drug” and predicted that it would lead to widespread drug resistance and encourage condomless intercourse.²³ Conversely, a great number of HIV/AIDS advocacy groups, activists, and

367 NEW ENG. J. MED. 423, 423–24 (2012) (reporting the transmission of HIV was reduced in men who have sex with men who took ARVs daily); *PrEP*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hiv/basics/prep.html> [<http://perma.cc/7ZL6-GMQD>] (last updated Jan. 16, 2015) (discussing how PrEP works to prevent the spread of HIV in people who are at high risk of contracting the virus).

20. See, e.g., Michael Weinstein et al., *Discussion: Is PrEP a Good Way to Fight HIV Infections?*, N.Y. TIMES: ROOM FOR DEBATE (June 17, 2014), <http://www.nytimes.com/roomfordebate/2014/06/17/is-prep-a-good-way-to-fight-hiv-infections> [<http://perma.cc/X9Z6-H4VR>]; Associated Press, *Divide over HIV Prevention Drug Truvada Persists*, USA TODAY (Apr. 6, 2014, 6:28 PM), <http://www.usatoday.com/story/news/nation/2014/04/06/gay-men-divided-over-use-of-hiv-prevention-drug/7390879> [<http://perma.cc/Z6B7-VMW2>] (noting that “[t]he discussion can torch emotions like a flame-thrower on a fuel depot”).

21. Compare Mark Joseph Stern, *There Is a Daily Pill That Prevents HIV. Gay Men Should Take It.*, SLATE (Jan. 6, 2014, 12:00 PM), http://www.slate.com/blogs/outward/2014/01/06/truvada_prep_hiv_gay_men_should_take_pre_exposure_prophylaxis.html [<http://perma.cc/B78C-QGXS>] (advocating for the use of Truvada among the gay population), with David Duran, *Truvada Whores?*, HUFFINGTON POST, http://www.huffingtonpost.com/david-duran/truvada-whoers_b_2113588.html [<http://perma.cc/2VFP-659A>] (last updated Jan. 12, 2013, 5:12 AM) (arguing “the FDA is encouraging the continuation of unsafe sex and most likely contributing to the spread of other sexually transmitted infections”).

22. See Patrick Healy, *A Lion Still Roars, with Gratitude*, N.Y. TIMES (May 21, 2014), <http://www.nytimes.com/2014/05/25/arts/television/larry-kramer-lives-to-see-his-normal-heart-filmed-for-tv.html?r=0> [<http://perma.cc/89JR-8XGA>].

23. Michelle Garcia, *Why Michael Weinstein Gets Blamed for PrEP Myths*, ADVOCATE (Oct. 31, 2014, 9:08 AM), <http://www.advocate.com/31-days-prep/2014/10/31/why-michael-weinstein-gets-blamed-prep-myths> [<http://perma.cc/JTK9-SCSJ>]; Curtis M. Wong, *Robert Levithan, AIDS Activist, on the Use of Controversial HIV Prevention Drug Truvada*, HUFFINGTON POST, http://www.huffingtonpost.com/2014/05/27/robert-levithan-aids-truvada_n_5399423.html [<http://perma.cc/4KYG-JF7W>] (last updated May 27, 2014, 4:59 PM).

public health officials have deemed PrEP a necessary safety net, particularly given the existence of a sizeable population of individuals who continue risk-taking activity notwithstanding behavioral messaging.²⁴ In the imagination of some PrEP proponents, PrEP has the potential to usher in an exciting sexual revolution in which the threat of HIV becomes a thing of the past.²⁵ Indeed, those who take oral PrEP have called it “an extra layer of protection,” providing “peace of mind” during sexual intercourse.²⁶

The vigorous debate over PrEP prevention was the genesis of this Article. Why has oral PrEP generated so much debate? What are the barriers to fuller implementation of this pharmacological innovation? How will the post-health reform landscape affect its implementation? Will insurers cover it in the future? Is use of oral PrEP medically necessary? How should advocacy groups, lawmakers, and policymakers act if insurers begin to deny coverage? Will the U.S. Supreme Court’s *Burwell v. Hobby Lobby* ruling affect future PrEP implementation efforts? These are a selection of questions that arose during preliminary research.

There is considerable literature regarding the impact of The Patient Protection and Affordable Care Act (ACA) on access to treatment for HIV-positive individuals.²⁷ However, there is little published legal scholarship focusing *solely* on oral PrEP prevention and the post-ACA challenges facing those seeking fuller implementation.²⁸ In this Article, I

24. Press Release, Leading HIV/AIDS Groups Endorse CDC HIV PrEP Guidelines: Reiterate That PrEP Is a Powerful, Additional Tool in the AIDS Response (June 17, 2014), <http://paperzz.com/doc/1169130/leading-hiv-aids-groups-endorse-cdc-hiv-prep—prepwatch> [<http://perma.cc/VF58-UNNK>]; Aaron Hicklin, *Andrew Sullivan Calls Out Larry Kramer on Truvada*, OUT (May 27, 2014, 1:58 PM), <http://www.out.com/entertainment/popnography/2014/05/27/andrew-sullivan-calls-out-larry-kramer-denigrating-truvada> [<http://perma.cc/3PQP-5NVS>].

25. Tim Vollmer & Doug Sebesta, *Does PrEP = A New Gay Sexual Revolution?*, BAY AREA REPORTER (July 24, 2014), http://www.ebar.com/openforum/opforum.php?sec=guest_op&id=478 [<http://perma.cc/5CT7-XDFG>].

26. Hailey Gilmore, Presentation at 9th International Conference on HIV Treatment and Prevention Adherence: To PrEP or Not To PrEP: Perspectives from US iPrEx Open Label Extension (OLE) Participants (June 9, 2014), http://www.iapac.org/AdherenceConference/presentations/ADH9_OA440.pdf [<http://perma.cc/MJJ9-2G8V>].

27. See, e.g., *Affordable Care Act and Its Impact on People Living with HIV/AIDS*, AIDS ACTION COMMITTEE (Oct. 1, 2013), <http://www.aac.org/media/blog/affordable-care-act-and-its-impact.html> [<http://perma.cc/U5YW-SNKW>]; see also Jennifer Kates et al., *Assessing the Impact of the Affordable Care Act on Health Insurance Coverage of People with HIV*, KAISER FAM. FOUND. (Jan. 7, 2014), <http://kff.org/report-section/assessing-the-impact-of-the-affordable-care-act-on-health-insurance-coverage-of-people-with-hiv-issue-brief> [<http://perma.cc/B5H6-UL3C>].

28. Kristen Underhill’s comprehensive, impeccably researched article, *Paying for Prevention*, pertains to a number of established and emerging biomedical HIV preventions, including (1) oral PrEP, (2) oral post-exposure prophylaxis, known as “PEP”, taken by

argue that in order to effectively incorporate PrEP into existing prevention models and drive down HIV incidence, proponents must overcome fundamental social, political, and legal challenges to ensure sustainable access for the individuals most at risk. I suggest that requiring insurers to cover PrEP and eliminating some of the barriers to access through federal and state action would help resolve acceptability and accessibility barriers to wider implementation that proponents have faced, and will likely face, in the future.

In Part II of the Article, I place PrEP in the broader context of HIV prevention and details recent regulatory responses to PrEP, including the 2012 FDA approval of Truvada for PrEP applications and the recent impactful CDC guidelines. In Part III, I introduce a framework for approaching the implementation of PrEP by dividing current and anticipated challenges into two dimensions: acceptability and accessibility. I argue that the major acceptability challenges involve eliminating stigmas associated with PrEP prevention within high-risk communities and changing attitudes within the medical community. This involves eliminating self-imposed, individual, and institutional biases. With regard to affordability, I highlight the cost of PrEP treatment, discuss the negative effect of prior authorization, and argue that PrEP may be susceptible to future coverage denials based on exclusions in benefit policies. These multidimensional accessibility issues have the potential to render this already underutilized HIV prevention tool, which is even more inaccessible to the people who need it most. In Part IV, I consider a health content regulation solution as one aspect of overcoming these challenges. I discuss options at the federal level under the ACA's "preventive services" provision (PSP) and the possibility of a positive recommendation from the U.S. Preventive Services Task Force (USPSTF or Task Force), which could mandate PrEP coverage at no cost to the insured. In addition, I propose federal regulatory action in connection with the ACA's "essential health benefits" provision (EHBP), which would help streamline some of the barriers to access in the utilization review process. Finally, I explore the possibility of mandated benefit laws at the state level, which could help

HIV-negative individuals after a suspected exposure, (3) ARV-laden microbial gels for vaginal or anal application to prevent infection, (4) male circumcision, and (5) vaccines. See Kristen Underhill, *Paying for Prevention: Challenges to Health Insurance Coverage for Biomedical HIV Prevention in the United States*, 38 AM. J.L. & MED. 607, 610 (2012).

change attitudes toward, ensure access to, and ultimately achieve greater utilization of PrEP prevention.

II. BACKGROUND

An estimated 1.2 million Americans are living with HIV.²⁹ An HIV diagnosis today is by no means the death sentence it was during the early years of the AIDS crisis. HIV is now regarded in the medical and public health communities as a chronic manageable disease.³⁰ In the general population, the urgency of the HIV/AIDS epidemic has waned. According to a 2009 study, only about six percent of the general public indicated that HIV/AIDS was the most urgent health problem facing the nation compared to forty-four percent in 1995.³¹

Nonetheless, the enduring HIV prevention approach remains rooted in the tragic HIV pandemonium of the 1980s. The model for our current message about HIV prevention developed when HIV/AIDS emerged as a leading cause of death in the United States.³² In the 1980s, public fear surrounding HIV/AIDS was at an all-time high, and HIV was regarded as “the most dreaded communicable disease that we know about.”³³ By the mid-1990s, HIV education and awareness campaigns were ubiquitous and seemed to be working.³⁴ HIV prevention experts focused on public health

29. Ctrs. for Disease Control & Prevention, *Vital Signs: HIV Diagnosis, Care, and Treatment Among Persons Living with HIV—United States, 2011*, 63 MORBIDITY & MORTALITY WKLY. REP. 1113, 1113 (2014), <http://www.cdc.gov/mmwr/pdf/wk/mm6347.pdf> [<http://perma.cc/GCN2-S2TJ>].

30. *Chronic Manageable Disease*, AIDS.GOV., <http://www.aids.gov/hiv-aids-basics/just-diagnosed-with-hiv-aids/overview/chronic-manageable-disease> [<https://perma.cc/6UQM-B4SA?type=image>] (last updated Dec. 22, 2009).

31. KAISER FAMILY FOUNDATION, 2009 SURVEY OF AMERICANS ON HIV/AIDS: SUMMARY OF FINDINGS ON THE DOMESTIC EPIDEMIC 3 (2009), <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7889.pdf> [<http://perma.cc/4RS8-BS6R>].

32. Ctrs. for Disease Control & Prevention, *Update: Mortality Attributable to HIV Infection/AIDS Among Persons Aged 25–44 Years—United States, 1990 and 1991*, 42 MORBIDITY & MORTALITY WKLY. REP. 481, 481 (1993), <http://www.cdc.gov/mmwr/PDF/wk/mm4225.pdf> [<http://perma.cc/2ZCD-V7JP>].

33. Images Best Shot, *Aids and Montage of 1980s—Part 1*, YOUTUBE (Oct. 27, 2010), <https://www.youtube.com/watch?v=9oenTf9BUcw> [<https://perma.cc/E6Q5-VF4D?type=live>] (statement of James O. Smith, former Superintendent, Western School Corporation). Smith’s refusal to permit HIV-positive hemophiliac Ryan White to attend school engendered litigation that led to the Ryan White Care Act, which is still very much in force today. *See* Ryan White HIV/AIDS Treatment Extension Act of 2009, Pub. L. No. 111-87, 123 Stat. 2885 (2009).

34. *See* Press Release, Ctrs. for Disease Control and Prevention, 1996 HIV/AIDS Trends Provide Evidence of Success in HIV Prevention and Treatment (Feb. 1996), <http://www.cdc.gov/media/pressrel/aids-d1.htm> [<http://perma.cc/EJ36-379U>]; *A Timeline of AIDS*, AIDS.GOV, <http://www.aids.gov/hiv-aids-basics/hiv-aids-101/aids-timeline>

awareness and educational campaigns, which emphasized modes of transmission, HIV testing and treatment, consistent and proper use of condoms and other barrier methods, and risk-reducing behaviors such as abstinence and monogamy.³⁵ However, traditional approaches to HIV prevention are not keeping up with widespread behavioral changes resulting from factors such as the increase in acceptability of condomless sex, optimism about HIV/AIDS, and condom message fatigue.³⁶ Biomedical prevention—notably oral PrEP—is a much-needed new approach to prevention that has re-energized HIV prevention in the United States and carried it into the twenty-first century.

A. Condoms Today

Condoms are medically effective at preventing HIV, eliminating approximately ninety to ninety-five percent of the transmission risk when used properly and vigilantly.³⁷ But this figure misrepresents the actual efficacy of condoms in practice. Indeed, actual efficacy of condoms is significantly lower due to improper use, intermittent use, or nonuse.³⁸ There are a number of studies that, in the aggregate, suggest a startlingly lower actual efficacy. In one New York study, sixty-six percent of adult New

[<https://perma.cc/CRD9-N65P?type=image>] (last visited Mar. 25, 2014) (noting that in 1996, HIV diagnoses “decline[d] for the first time since the beginning of the epidemic”).

35. See JULIA DAVIS, KAISER FAMILY FOUND., *EVOLUTION OF AN EPIDEMIC: 25 YEARS OF HIV/AIDS MEDIA CAMPAIGNS IN THE U.S.* 13–16 (1996), <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7515.pdf> [<http://perma.cc/XH2L-PPVN>].

36. See Stephen F. Morin et al., *Why HIV Infections Have Increased Among Men Who Have Sex with Men and What To Do About It: Findings from California Focus Groups*, 7 AIDS & BEHAV. 353, 355–56 (2003), http://download.springer.com/static/pdf/293/art%253A10.1023%252FB%253AAIBE.0000004727.23306.20.pdf?auth66=1424998941_4980abdb78ee0793a0bd485895d5c8f6&ext=.pdf [<http://perma.cc/2F3C-H9ZL>]; Barry D. Adam et al., *AIDS Optimism, Condom Fatigue, or Self-Esteem? Explaining Unsafe Sex Among Gay and Bisexual Men*, 42 J. SEX RES. 238 (2005), <http://www.tandfonline.com/doi/pdf/10.1080/00224490509552278>.

37. Steven D. Pinkerton & Paul R. Abramson, *Effectiveness of Condoms in Preventing HIV Transmission*, 44 SOC. SCI. & MED. 1303, 1310 (1997).

38. *Id.* at 1304 (noting that meta-analyses of condom effectiveness in practice suggests sixty to seventy percent effectiveness (citing Susan C. Weller, *A Meta-Analysis of Condom Effectiveness in Reducing Sexually Transmitted HIV*, 36 SOC. SCI. & MED. 1635, 1640 (1993); Laurie Liskin et al., *Condoms—Now More than Ever*, POPULATION REP., Sept. 1990, at 5)); see also *supra* note 7 and accompanying text.

Yorkers surveyed indicated they do not use condoms.³⁹ With regard to youth attitudes, a Durex Global Survey in December 2011 found six out of ten men and women in the United States did not use any form of protection against HIV/AIDS or sexually transmitted infections when they lost their virginity.⁴⁰ Condom usage among American students hit its peak at around sixty percent a decade ago.⁴¹ However, condom usage in this group has stalled since then according to the CDC and a number of recent studies.⁴² In a 2013 study of young African-American MSM, sixty-seven percent of study participants indicated they had engaged in unprotected receptive anal intercourse in the last six months.⁴³ These studies suggest that one cannot judge the legitimacy of new HIV prevention modalities by comparing them to the ninety to ninety-five percent effectiveness rate of condoms. After all, fewer people are using condoms properly, and more people are eschewing them entirely.⁴⁴

Additionally, there is some evidence that increased condom messaging through new technologies in response to the decline in condom usage will not be sufficient to combat the spread of HIV.⁴⁵ One study found the

39. Carl Campanile, *66% of New Yorkers Don't Use Condoms: Survey*, N.Y. POST (Oct. 27, 2013, 11:14 PM), <http://nypost.com/2013/10/27/one-in-three-nyc-adults-use-condoms-survey> [<http://perma.cc/NTB7-PY23>].

40. *When It Comes to Risky Sexual Behavior, Americans Top the List: Durex Global Survey Data Released for World AIDS Day*, PR NEWswire (Nov. 30, 2011), <http://www.prnewswire.com/news-releases/when-it-comes-to-risky-sexual-behavior-americans-top-the-list-134764733.html> [<http://perma.cc/9K78-MPQD>].

41. Katy Steinmetz, *(No) Condom Culture: Why Teens Aren't Practicing Safe Sex*, TIME (Nov. 12, 2013), http://healthland.time.com/2013/11/12/no-condom-culture-why-teens-arent-practicing-safe-sex/?hpt=hp_t3 [<http://perma.cc/GD4H-G83L>].

42. See, e.g., Ctrs. for Disease Control & Prevention, *HIV, Other STD, and Pregnancy Prevention Education in Public Secondary Schools—45 States, 2008–2010*, 61 MORBIDITY & MORTALITY WKLY. REP. 222 (2012), <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6113a2.htm> [<http://perma.cc/RNN4-ABA2>]; M. Lynne Cooper, *Alcohol Use and Risky Sexual Behavior Among College Students and Youth: Evaluating the Evidence*, 14 J. STUD. ON ALCOHOL & DRUGS SUPPLEMENT 101, 104 (2002), <http://www.jsad.com/doi/pdf/10.15288/jsas.2002.s14.101> [<http://perma.cc/5GL9-PHEW>]; Patricia Barthalow Koch et al., *Mixing Sex and Alcohol in College: Female-Male HIV Risk Model*, 24 J. SEX EDUC. & THERAPY 99, 99 (1999).

43. Richard A. Crosby et al., *Acceptability of Condoms, Circumcision and PrEP Among Young Black Men Who Have Sex with Men: A Descriptive Study Based on Effectiveness and Cost*, 2 VACCINES 129, 131 (2014), <http://www.mdpi.com/2076-393X/2/1/129/htm> [<http://perma.cc/F6X3-ZXQ5>].

44. See Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, to Tom Myers, Gen. Counsel, AIDS Healthcare Found. (July 16, 2012), <http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0226-0006> [<http://perma.cc/5HNE-N3TS>] (citing Pinkerton & Abramson, *supra* note 37, at 1306–07).

45. See Brian Mustanski et al., *Effects of Messaging About Multiple Biomedical and Behavioral HIV Prevention Methods on Intentions To Use Among US MSM: Results of an Experimental Messaging Study*, 18 AIDS & BEHAV. 1651, 1656 (2014).

number of informational messages about condom usage on social media neither engenders “differential attitudes and intentions regarding condoms” nor changes attitudes about unprotected intercourse.⁴⁶ Conversely, multiple informational messages regarding PrEP *did* cause increased interest in using the new modality.⁴⁷ Even though consistent and proper condom use is medically effective at preventing HIV transmission and condom messaging remains an important aspect in the prevention of HIV and other sexually transmitted infections,⁴⁸ we need to develop new prevention tools to counterbalance evolving perceptions, disinhibition trends, and educational insouciance.

B. PrEP: A New Approach to HIV Prevention

There is a rapidly growing body of research about the effectiveness of the combination of behavioral prevention and biomedical prevention. One type of biomedical prevention is pharmacological prevention.⁴⁹ In the context of HIV prevention, the discovery of the prophylactic use of ARVs occurred during ARV clinical trials in the 1990s.⁵⁰ Today,

46. *Id.* at 1651.

47. *Id.* at 1656.

48. *Condoms and STDs: Fact Sheet for Public Health Personnel*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/condomeffectiveness/docs/Condoms_and_STDs.pdf [<http://perma.cc/9RKE-E92H>] (last visited Mar. 25, 2015); *Condom Fact Sheet in Brief*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/condomeffectiveness/docs/CondomFactsheetInBrief.pdf> [<http://perma.cc/X29G-UGN5>] (last visited Mar. 25, 2015).

49. Underhill, *supra* note 28, at 621.

50. See Edward M. Connor et al., *Reduction of Maternal-Infant Transmission of Human Immunodeficiency Virus Type 1 with Zidovudine Treatment*, 331 NEW ENG. J. MED. 1173 (1994). In studies of HIV-positive pregnant woman, those who received ARVs had a sixty-eight percent reduction in the risk of perinatal transmission of HIV. *Id.* at 1176. Infants effectively received both PrEP in utero and PEP treatment for six weeks after birth, and the positive results led to further studies of both PrEP and PEP, though studies of PEP, particularly as related to occupational exposure, were more prevalent. *Id.* at 1178. PEP, however, has not proved as controversial as PrEP. See David Tuller, *A Resisted Pill To Prevent H.I.V.*, N.Y. TIMES, Dec. 30, 2013, <http://www.nytimes.com/2013/12/31/health/a-resisted-pill-to-prevent-hiv.html?pagewanted=all&r=0> [<http://perma.cc/Q6LA-LJWP>]. One explanation for this is that whereas PrEP is a daily prophylactic taken in perpetuity, PEP is taken for a discrete period of time—approximately one month—so the risk of long-term side effects is reduced. See David T. Kuhar et al., *Updated US Public Health Service Guidelines for the Management of Occupational Exposures to Human Immunodeficiency Virus and Recommendations for Postexposure Prophylaxis*, 34 INFECTION CONTROL & HOSP. EPIDEMIOLOGY 875, 878 (2013) (recommending ARV

pharmacological HIV prevention includes but is not limited to the following treatments: (1) oral PrEP, (2) oral post-exposure prophylactics, known as “PEP,” taken by HIV-negative individuals after a suspected exposure, (3) ARV-laden microbial gels for vaginal or anal application to prevent infection, (4) ARVs taken by HIV-positive individuals as a means of lowering viral load and thereby preventing infection of others, known as “treatment as prevention” or “TasP,”⁵¹ and (5) vaccines.⁵²

However, no other pharmacological HIV prevention method has exploded onto the clinical research scene like oral PrEP has. As of this writing, there are at least forty clinical studies involving PrEP that are enrolling, recruiting, or in progress.⁵³ Four double-blind, placebo-controlled clinical trials involving Truvada as an oral PrEP in high-risk populations have been published. The first two studied PrEP among MSM.⁵⁴

treatment for four weeks in the case of suspected exposures (citing Ctrs. for Disease Control & Prevention, *Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Postexposure Prophylaxis*, 50 MORBIDITY & MORTALITY WKLY. REP. 1 (2001), <http://www.cdc.gov/MMWR/preview/mmwrhtml/rr5011a1.htm> [<http://perma.cc/5726-AWNW>])).

51. For information about TasP as a method of HIV prevention, see *HIV Treatment as Prevention*, AVERT, <http://www.avert.org/hiv-treatment-as-prevention.htm> [<http://perma.cc/4VMY-ZGFK>] (last updated Jan. 6, 2015).

52. Underhill, *supra* note 28, at 610.

53. See *Clinical Trials*, U.S. NAT’L INSTITUTES OF HEALTH, <https://www.clinicaltrials.gov/ct2/results?term=pre-exposure+prophylaxis+HIV&pg=1> [<https://perma.cc/FB5D-ZDR7>] (last visited Mar. 25, 2015).

54. The first study, published in 2010, is called the iPrEx (Preexposure Prophylaxis Initiative) Trial. This study was a phase III, randomized, double-blind, placebo-controlled trial conducted in Brazil, Ecuador, Peru, South Africa, Thailand, and the United States. See Robert M. Grant et al., *Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men*, 363 NEW ENG. J. MED. 2587, 2588 (2010). The study sample included MSM and male-to-female (MTF) transgender adults who self-reported sex with men during the six months prior to enrollment. *Id.* at 2587, 2592. Noncontrol group study participants received daily oral doses of combination emtricitabine/tenofovir disoproxil fumarate (TDF/FTC). *Id.* at 2588. All participants were seen every four weeks for an interview, HIV testing, risk-reduction counseling, and dispensing of treatment and condoms. *Id.* The iPrEx study yielded an overall forty-four percent reduction in the risk of HIV acquisition among the treatment group (ninety-five percent confidence interval (CI), 15 to 63, $p=0.005$). *Id.* at 2594. The results were more favorable for those who adhered to the protocols by self-reporting and pill counts. See *id.* When adherence was fifty percent, reduction in HIV acquisition was fifty percent, and above ninety percent adherence had a seventy-three percent reduction in risk. *Id.* Importantly, for participants with some detectable level of Truvada in their systems, there was a ninety-two percent reduction of risk. *Id.* at 2596–97. Interestingly, study participants reported a decrease in the number of sex partners and an increase in condom usage. *Id.* at 2590. This finding suggests that mandatory risk-reduction counseling and regular medical checkups associated with the study may have had an impact on risk reduction.

The significant reduction in risk of infection documented in the iPrEx study was confirmed in the second study, the U.S. MSM Safety Trial, published in 2013. Lisa A.

The third studied efficacy in serodiscordant couples.⁵⁵ The fourth completed study pertained to intravenous drug users.⁵⁶ These clinical trials and other studies⁵⁷ suggest the use of antiretroviral drugs could

Grohskopf et al., *Randomized Trial of Clinical Safety of Daily Oral Tenofovir Disoproxil Fumarate Among HIV-Uninfected Men Who Have Sex with Men in the United States*, 64 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 79 (2013). This study was a phase II randomized, double-blind, placebo-controlled study of the clinical safety and behavioral effects of TDF/FTC for HIV prevention in 400 MSM participants in Atlanta, Boston, and San Francisco. *Id.* at 79. In this study, no HIV infections occurred in study participants who were given TDF/FTC. *Id.* at 85.

55. The Partners PrEP Trial was a phase III randomized, double-blind, placebo-controlled study of daily oral TDF or TDF/FTC combination for the prevention of acquisition of HIV by the uninfected partner in 4758 HIV-1 serodiscordant heterosexual couples in Kenya and Uganda. J.M. Baeten et al., *Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women*, 367 NEW ENG. J. MED. 399, 399 (2012); Pamela M. Murnane et al., *Efficacy of Preexposure Prophylaxis for HIV-1 Prevention Among High-Risk Heterosexuals: Subgroup Analyses from a Randomized Trial*, 27 AIDS 2155, 2156 (2013). In thirty-eight percent of the couples, the infected partner was male. *See* Baeten, *supra*, at 401. Among participants of both sexes combined, efficacy estimates for each of the two antiretroviral regimens compared with placebo were sixty-seven percent for TDF (ninety-five percent CI, 44 to 81, $p < 0.001$) and seventy-five percent for TDF/FTC (ninety-five percent CI, 55 to 87, $p < 0.001$). *Id.* at 404. Among women, the estimated efficacy was seventy-one percent for TDF ($p = 0.002$) and sixty-six percent for TDF/FTC ($p = 0.005$). *Id.* Among men, the estimated efficacy was sixty-three percent for TDF ($p = 0.01$) and eighty-four percent for TDF/FTC ($p = 0.005$). *Id.*

56. The Bangkok Tenofovir Study was a phase III randomized, double-blind, placebo-controlled study of the safety and efficacy of daily oral TDF for HIV prevention among 2413 injection drug users receiving drug treatment at clinics in Bangkok, Thailand. Kachit Choopanya et al., *Antiretroviral Prophylaxis for HIV Infection in Injecting Drug Users in Bangkok, Thailand (the Bangkok Tenofovir Study): A Randomised, Double-Blind, Placebo-Controlled Phase 3 Trial*, 381 LANCET 2083, 2083 (2013). Confidence in this study was bolstered by the fact that participants were followed for an average of about five years and received directly observed therapy eighty-seven percent of the time. *See Bangkok Tenofovir Study: PrEP for HIV Prevention Among People Who Inject Drugs*, CENTERS FOR DISEASE CONTROL & PREVENTION (June 2013), http://www.cdc.gov/hiv/pdf/prevention_research_prep_BTSfactsheet.pdf. A post-hoc modified analysis showed the efficacy of TDF in plasma was associated with a 73.5% reduction in the risk for HIV acquisition for this risk group (ninety-five percent CI, 16.6 to 94.0, $p = 0.03$). Choopanya, *supra*, at 2088.

57. *See, e.g.*, Paul W. Denton et al., *Antiretroviral Pre-Exposure Prophylaxis Prevents Vaginal Transmission of HIV-1 in Humanized BLT Mice*, PLOS MED. 84–88 (Jan. 15, 2008), <http://www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.0050016&representation=PDF> [<http://perma.cc/U45Q-4RRK>]; J. Gerardo García-Lerma et al., *Prevention of Rectal SHIV Transmission in Macaques by Daily or Intermittent Prophylaxis with Emtricitabine and Tenofovir*, PLOS MED. 297–98 (Feb. 5, 2008), <http://www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.0050028&representation=PDF> [<http://perma.cc/5JWT-9QC6>]; Jessica E. Haber et al., *Adherence to Antiretroviral Prophylaxis for HIV Prevention: A Substudy Cohort Within a*

“substantially reduce the incidence of HIV transmission in populations at high risk of infection.”⁵⁸ In fact, data from completed trials indicates PrEP is up to ninety-two percent effective in reducing the risk of HIV when taken daily along with other prevention methods such as condom distribution, counseling, and medical oversight.⁵⁹ According to the CDC, PrEP is “a powerful HIV prevention tool” for at-risk groups.⁶⁰ The at-risk groups for whom PrEP prevention has the potential to make a significant impact on risk reduction include the following:

MSM. The MSM category has the highest HIV incidence rate⁶¹—more than fifty percent of new HIV infections⁶²—which makes implementation of new prevention modalities profoundly important for this group. For those MSM who eschew condoms, PrEP would at least provide some layer of

Clinical Trial of Serodiscordant Couples in East Africa, PLOS MED. 1, 8–9 (Sept. 10, 2013), <http://www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.1001511&representation=PDF> [<http://perma.cc/B24S-MURL>]; Shambavi Subbarao et al., *Chemoprophylaxis with Tenofovir Disoproxil Fumarate Provided Partial Protection Against Infection with Simian Human Immunodeficiency Virus in Macaques Given Multiple Virus Challenges*, 194 J. INFECTIOUS DISEASES 904, 909–10 (2006); Robert M. Grant et al., Presentation at the 20th International AIDS Conference: Results of the iPrEx Open-Label Extension (iPrEx OLE) in Men and Transgender Women Who Have Sex with Men: PrEP Uptake, Sexual Practices, and HIV Incidence (July 22, 2014); *Pre-Exposure Prophylaxis (PrEP)*, CENTERS FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hiv/prevention/research/prep> [<http://perma.cc/3TTT-ZXTZ>] (last updated Sept. 30, 2014) [hereinafter *CDC PrEP Research Summary*].

58. Jiang et al., *supra* note 7, at 2 (citing A. David Paltiel et al., *HIV Preexposure Prophylaxis in the United States: Impact on Lifetime Infection Risk, Clinical Outcomes, and Cost-Effectiveness*, 48 CLINICAL INFECTIOUS DISEASES 806, 811–12 (2009); Lynn A. Paxton et al., *Pre-exposure Prophylaxis for HIV Infection: What if It Works?*, 370 LANCET 89, 89 (2007)). Researchers have had some difficulty studying PrEP in the African continent, particularly with women. See Jeanne M. Marrazzo et al., *Tenofovir-Based Preexposure Prophylaxis for HIV Infection Among African Women*, 372 NEW ENG. J. MED. 509, 516–17 (2015) (finding during a randomized, placebo-controlled study of African Women that no tenofovir-based prophylaxes reduced HIV because the study was hindered by low adherence); Donald G. McNeil Jr., *A Failed Trial in Africa Raises Questions About How To Test H.I.V. Drugs*, N.Y. TIMES (Feb. 4, 2015), http://www.nytimes.com/2015/02/05/health/failed-trial-in-africa-raises-questions-about-how-to-test-hiv-drugs.html?_r=0 [<http://perma.cc/A7CV-7PGC>] (indicating that low adherence may have resulted from a combination of financial incentives for participating women, increased access to quality healthcare for participating women, and fear of the drug regimens and researchers’ motives).

59. CDC GUIDELINES, *supra* note 1, at 14–15.

60. *CDC PrEP Research Summary*, *supra* note 57. The CDC maintains an extensive informational webpage devoted solely to PrEP. See *PrEP*, *supra* note 19.

61. Ronald Valdiserri, *HIV Among MSM Examined at CROI*, AIDS.GOV (Mar. 8, 2013), <http://blog.aids.gov/2013/03/hiv-among-msm-examined-at-croi.html> [<http://perma.cc/3UN9-WLVA>].

62. 2020 *Topics & Objectives: HIV*, U.S. DEP’T HEALTH & HUM. SERVICES., <http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicid=22> [<http://perma.cc/9SGK-UTUD>] (last visited Mar. 25, 2015).

protection against HIV infection. For those who do use condoms regularly, providing PrEP would furnish another layer of protection to a group in which HIV incidence is on the rise. It would also reduce the fear associated with condom failure or misuse during anal intercourse.

Serodiscordant Couples. Men and women in serodiscordant relationships—relationships in which one partner is HIV-positive⁶³—are also excellent candidates for an integrated prevention approach that includes PrEP. PrEP is particularly useful for an HIV-negative female to protect her from transmission by her HIV-positive partner during pregnancy attempts, as barrier methods would prevent conception.⁶⁴

Other High-Risk Populations. Other appropriate candidates for PrEP include sex workers,⁶⁵ adult entertainment performers,⁶⁶ intravenous drug users,⁶⁷ and prison populations.⁶⁸ In this catchall group, the risk of

63. See *Mixed-Status Couples*, AIDS.GOV, <http://aids.gov/hiv-aids-basics/staying-healthy-with-hiv-aids/friends-and-family/mixed-status-couples/index.html#tips> [http://perma.cc/W6FW-82YY] (last updated Oct. 27, 2014). Serodiscordant relationships are sometimes called serodivergent, serodifferent, or magnetic relationships.

64. See *Pregnancy & Childbirth*, AIDS.GOV, <http://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pregnancy-and-childbirth/index.html> [http://perma.cc/HM58-B3RR] (last updated Jan. 25, 2012); *Provider Information Sheet—PrEP During Conception, Pregnancy, and Breastfeeding*, CENTERS FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/hiv/pdf/PrEP_GL_Clinician_Factsheet_Pregnancy_English.pdf [http://perma.cc/3NWX-4D7Z] (last visited Mar. 25, 2015).

65. In a 2014 study of female sex workers in China, among the 405 participants, 85.9% indicated they would accept PrEP if it was safe and effective. Li Ye et al., *HIV Pre-Exposure Prophylaxis Interest Among Female Sex Workers in Guangxi, China*, PLOS ONE 1, 5 (Jan. 22, 2014), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3899205/pdf/pone.0086200.pdf> [http://perma.cc/FKU3-LAQL]. Of these 348 participants, 54.3% indicated they would be willing to participate in a clinical trial. *Id.* at 5.

66. See generally Tracy Clark-Flory, *Move Over, Condoms! Porn Has a New Debate: HIV Meds*, SALON (May 14, 2014, 3:58 PM), http://www.salon.com/2014/05/14/move_over_condoms_porn_has_a_new_debate_truvada [http://perma.cc/H7BX-KX9B] (discussing the debate about developing education programs about PrEP in the adult entertainment industry).

67. Injection drug users represented eight percent of all new HIV infections in 2010 and fifteen percent of those living with HIV in 2011. *HIV in the United States: At a Glance*, *supra* note 1 (citing Ctrs. for Disease Control & Prevention, *Estimated HIV Incidence in the United States, 2007–2010*, HIV SURVEILLANCE SUPPLEMENTAL REPORT, Dec. 2012, at 1, 19; Ctrs. for Disease Control & Prevention, *Monitoring Selected National HIV Prevention and Care Objectives by Using HIV Surveillance Data—United States and 6 Dependent Areas—2012*, HIV SURVEILLANCE SUPPLEMENTAL REPORT, Nov. 2014, at 1, 24–25).

68. Prison populations are particularly interesting to consider for oral PrEP because, unlike other risk groups, prisoners' healthcare can be closely monitored to ensure adherence.

transmission immediately upon seroconversion may be greater because detection of, and treatment for, HIV before the next risk-taking activity may not be possible.

1. *Dodging Friendly Fire on the Road to FDA Approval*

The FDA has approved only one medication for oral PrEP called Truvada, which is manufactured by Gilead Sciences, Inc. and is available by prescription.⁶⁹ Gilead retains an exclusive patent and no generics are currently available in the United States.⁷⁰ Despite the FDA's previous approval of Truvada for the treatment of HIV/AIDS, the road to Truvada's FDA approval for pre-exposure applications was not a particularly smooth one. Principal opposition to FDA approval of Truvada as PrEP came from the largest nonprofit HIV/AIDS healthcare provider in the United States, the AHF.⁷¹

Prior to FDA approval, the AHF submitted petitions in response to the FDA's supplemental New Drug Application for Truvada as HIV PrEP.⁷²

69. *Pre-Exposure Prophylaxis (PrEP)*, AIDS.GOV, <https://www.aids.gov/hiv-aids-basics/prevention/reduce-your-risk/pre-exposure-prophylaxis/> [<https://perma.cc/R38D-TH69>] (last updated May 22, 2014). One other Gilead tenofovir combination, Viread, as well as a number of non-Gilead products, such as Lamivudine (Epivir), Maraviroc (Selzentry), Rilpivirine (Edurant), and Raltegravir (Isentress), are being considered for PrEP. See Inge Derdelinckx et al., *Criteria for Drugs Used in Pre-Exposure Prophylaxis Trials Against HIV Infection*, PLOS MED. 2003 (Nov. 7, 2006), <http://www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.0030454&representation=PDF> [<http://perma.cc/MXU4-4Q69>]; C. Preston Neff et al., *Oral Pre-Exposure Prophylaxis by Anti-Retrovirals Raltegravir and Maraviroc Protects Against HIV-1 Vaginal Transmission in a Humanized Mouse Model*, PLOS ONE 2, 4 (Dec. 21, 2010), <http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pone.0015257&representation=PDF> [<http://perma.cc/37LN-8JNB>]; *Epivir (lamivudine, 3TC)*, AIDS MEDS, http://www.aidsmeds.com/archive/Epivir_1579.shtml (last updated May 4, 2014); *Isentress (raltegravir)*, AIDS MEDS, http://www.aidsmeds.com/archive/Isentress_1639.shtml [<http://perma.cc/7AA4-R5QY>] (last updated Dec. 22, 2011); *PrEP Pipeline: Ongoing Research*, PREPWATCH, <http://www.prepwatch.org/prep-research/prep-pipeline-ongoing-research> [<http://perma.cc/46CS-YMXS>] (last visited Mar. 25, 2015).

70. While a generic alternative to Truvada was developed in India by Lupin Limited, Lupin appears to have abandoned the effort. See *Lupin No Longer Trying To Market Generics of Truvada and Viread*, PHARMA LETTER (June 8, 2014), <http://www.thepharmaletter.com/article/lupin-no-longer-trying-to-market-generics-of-truvada-and-viread> [<http://perma.cc/2MYB-UGLA>].

71. AIDS HEALTHCARE FOUND., <http://www.aidshealth.org> (last visited Mar. 25, 2015). According to the AHF's website, the organization provides medical care and/or services in thirty-six countries to more than 404,313 individuals. *Id.*

72. See Citizen Petition from Tom Myers, Gen. Counsel, AIDS Healthcare Found., to the Food & Drug Admin. (Mar. 5, 2012), <http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0226-0001> [<http://perma.cc/L3C2-LLSW>] [hereinafter AHF Petition 1]; Citizen Petition from Tom Myers, Gen. Counsel, AIDS Healthcare Found., to Food &

In its primary petition, the gravamen of the AHF's opposition was that the completed trials failed to demonstrate that the benefits of Truvada as PrEP outweighed the risks.⁷³ The AHF's specific objections to PrEP in its primary petition have become the major talking points against PrEP subsequent to FDA approval. As such, in this subpart, I review these objections to introduce the enduring criticisms of PrEP treatment.

In addition to attacking the body of research to argue the efficacy of Truvada as PrEP has not been sufficiently established, the AHF argued in its primary petition that Truvada's efficacy must be measured against the ninety-five percent efficacy of proper and regular condom usage.⁷⁴ In a response addressing AHF concerns, the FDA rejected this argument, finding that actual efficacy of condoms is "much lower[] because many individuals do not use them correctly or use them at all."⁷⁵

In addition, the organization made a "real world" argument that study conditions did not reflect what regular usage conditions would likely be.⁷⁶ It argued that Truvada, if approved, would not be used as indicated.⁷⁷ The FDA also rejected this argument, finding that proper patient education upon prescription would alleviate adherence concerns.⁷⁸ Furthermore, AHF argued that adherence would be affected by the significant out-of-pocket cost of Truvada,⁷⁹ but the FDA noted cost is not a factor in approval deliberations.⁸⁰

Finally, the AHF made three arguments that the negative, long-term medical and behavioral effects of Truvada are overwhelming. First, the AHF argued that, even if used as directed, Truvada carries with it a "significant—and unacceptable—risk of kidney disease and kidney damage."⁸¹ The FDA rejected this argument, noting that the risk of renal

Drug Admin. (Jun. 8, 2012), <http://www.regulations.gov/#!documentDetail;D=FDA-2012-P-0607-0001> [<http://perma.cc/LL6T-BURM>] [hereinafter AHF Petition 2].

73. See AHF Petition 1, *supra* note 72, at 8–9, 26–29. In its second petition, the AHF argued that the Antiviral Drugs Advisory Committee's members had "intellectual conflicts of interest." AHF Petition 2, *supra* note 72, at 2–3.

74. AHF Petition 1, *supra* note 72, at 16–19.

75. Letter from Janet Woodcock to Tom Myers, *supra* note 44, at 11 (citing Pinkerton & Abramson, *supra* note 37, at 1304, 1306–07).

76. AHF Petition 1, *supra* note 72, at 26.

77. *Id.*

78. Letter from Janet Woodcock to Tom Myers, *supra* note 44, at 14.

79. AHF Petition 1, *supra* note 72, at 10.

80. Letter from Janet Woodcock to Tom Myers, *supra* note 44, at 22.

81. AHF Petition 1, *supra* note 72, at 21.

damage was too infrequent to be significant.⁸² Second, the AHF argued that the use of Truvada would lead to increased drug resistance.⁸³ The FDA, while recognizing this is a serious concern, noted that such instances during clinical studies occurred in participants who were already infected and that proper labeling could mitigate this effect.⁸⁴ Finally, and most memorably, the AHF argued that the use of Truvada as PrEP would increase “risk compensation” among MSM, meaning that users “may [forgo] highly effective and proven protective measures such as condoms in favor of a ‘magic pill’ that is far less effective.”⁸⁵ The FDA rejected this as an empty hypothesis without solid clinical evidence.⁸⁶

On July 16, 2012, the FDA approved the safety and efficacy of once-daily Truvada for HIV prevention in individuals with high risk of sexual exposure for use “as part of a comprehensive HIV prevention strategy that includes other prevention methods, such as safe sex practices, risk reduction counseling, and regular HIV testing.”⁸⁷ As guidance to physicians, Gilead included a list of factors on its package insert to help physicians determine if an individual is at high risk of exposure to HIV. The risks listed include the following:

- has partner(s) known to be HIV-1 infected, *or*
- engages in sexual activity within a high prevalence area or social network *and* one or more of the following:
 - inconsistent or no condom use
 - diagnosis of sexually transmitted infections
 - exchange of sex for commodities (such as money, food, shelter, or drugs)
 - use of illicit drugs or alcohol dependence
 - incarceration

82. Letter from Janet Woodcock to Tom Myers, *supra* note 44, at 15; *see also* Choopanya et al., *supra* note 56, at 2088 (noting that the study “did not find higher rates of increased creatinine or renal disease in participants randomly allocated to tenofovir”). Since FDA approval, at least one double-blind, placebo-controlled study has confirmed that the risk of kidney impairment is small. *See* Kenneth K. Mugwanya et al., *Changes in Glomerular Kidney Function Among HIV-1-Uninfected Men and Women Receiving Emtricitabine-Tenofovir Disoproxil Fumerate Preexposure Prophylaxis: A Randomized Clinical Trial*, 175 JAMA INTERNAL MED. 246, 262–63 (2015).

83. AHF Petition 1, *supra* note 72, at 27–28.

84. Letter from Janet Woodcock to Tom Myers, *supra* note 44, at 21.

85. AHF Petition 1, *supra* note 72, at 24–26.

86. *See* Letter from Janet Woodcock to Tom Myers, *supra* note 44, at 10–11.

87. Press Release, Food & Drug Admin., FDA Approves First Drug for Reducing the Risk of Sexually Acquired HIV Infection (Jul. 16, 2012), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm>.

- partner(s) of unknown HIV-1 status with any of the factors listed above.⁸⁸

The FDA strengthened the package's boxed warning advising healthcare professionals that, among other things, individuals must be confirmed HIV negative and retested every three months during use.⁸⁹ The FDA also required Gilead to establish a program to educate, train, and assist prescribers.⁹⁰

2. Final CDC Guidance

On May 14, 2014, the U.S. Public Health Service, an agency within the U.S. Department of Health and Human Services (HHS) that serves as a parent agency to the CDC, issued an authoritative set of clinical practice guidelines for PrEP.⁹¹ The CDC guidelines are intended for an audience of primary care physicians, clinicians providing substance abuse treatment, infectious disease specialists, and health policymakers.⁹² The CDC's PrEP report recommends oral PrEP for four groups: (1) MSM "at substantial risk of HIV acquisition," (2) heterosexual men and women at substantial risk, (3) serodiscordant couples, particularly when pregnancy is involved, and (4) intravenous drug users.⁹³

Based on a review of published literature, including the major clinical trials referenced herein,⁹⁴ the CDC recommended to primary care practitioners that "clinicians evaluate their male and female patients who are sexually active or who are injecting illicit drugs and consider offering PrEP as one prevention option to those whose sexual or injection behaviors

88. Gilead Sciences, Inc., *Truvada: Package Insert and Label Information*, DRUGINSERTS (last revised Dec. 23, 2013), <https://druginserts.com/lib/rx/meds/truvada-5/> (emphases added).

89. *Important Safety Information*, GILEAD, <http://www.truvadapreprems.com/truva-daprep-safety-profile> [<http://perma.cc/TLB5-AV79>] (last visited Mar. 25, 2015).

90. *See Truvada for a Pre-Exposure Prophylaxis (PrEP) Indication: REMS Information*, GILEAD, <http://www.truvadapreprems.com/online-training> [<http://perma.cc/384T-AH3E>] (last visited Mar. 25, 2015).

91. CDC GUIDELINES, *supra* note 1. These final guidelines incorporated a number of interim reports on the subject. *Id.* at 16–18, 21.

92. *Id.* at 13.

93. *Id.* at 9.

94. *See supra* notes 54–56 and accompanying text.

and epidemiologic context place them at substantial risk of acquiring HIV infection.”⁹⁵

The CDC report is groundbreaking from a public health standpoint, as the CDC guidance encouraging primary care practitioners to consider PrEP for at-risk patients could increase the utilization of PrEP in the mainstream.⁹⁶ Recognizing the opportunity to implement oral PrEP on a broader scale, 164 HIV/AIDS health and advocacy organizations including AIDS Action Committee, amfAR, Gay Men’s Health Crisis, and Lambda Legal endorsed the move shortly after the CDC released its guidelines.⁹⁷

III. CHALLENGES TO PREP IMPLEMENTATION

Since the CDC issued its guidance, interest in oral PrEP has been high.⁹⁸ However, as of this writing, multiple data sets indicate the number of Truvada prescriptions for PrEP is less than 10,000, though exact utilization nationwide is difficult to assess.⁹⁹ With such a slow uptake,

95. CDC GUIDELINES, *supra* note 1, at 12.

96. *See infra* notes 135–136, 217 and accompanying text.

97. Press Release, *supra* note 24, at 1–2.

98. *See, e.g.*, Stephanie E. Cohen et al., *High Interest in Preexposure Prophylaxis Among Men Who Have Sex with Men at Risk of HIV Infection: Baseline Data from the U.S. PrEP Demonstration Project*, 68 J. ACQUIRED IMMUNE DEFICIENCY SYNDROMES (forthcoming Apr. 2015) (concluding that “interest in PrEP is high among a diverse population of MSM at risk for HIV infection when offered in sexually transmitted disease and community health clinics”); Albert Liu et al., *Early Experiences Implementing Pre-Exposure Prophylaxis (PrEP) for HIV Prevention in San Francisco*, PLOS MED. 1, 1 (Mar. 4, 2014), <http://www.plosmedicine.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pmed.1001613&representation=PDF> [<http://perma.cc/3NP5-BAB4>] (noting that “interest in PrEP is high in San Francisco”).

99. A Gilead analysis presented in late 2014 of prescription data from fifty-five percent of pharmacies in the United States identified and studied 3253 people that have been prescribed the drug since January of 2012. Charlene Flash et al., Presentation at the 2014 International Congress of Drug Therapy in HIV Infection: Two Years of Truvada for Pre-Exposure Prophylaxis Utilization in the United States (Nov. 2–6, 2014), http://www.natap.org/2014/GLASGOW/GLASGOW_10.htm [<http://perma.cc/S678-VPM9>]. The 2014 Gilead utilization numbers do not include those receiving PrEP through Medicaid. Email communication with Jim Pickett, Dir. of Prevention Advocacy & Gay Men’s Health, AIDS Found. of Chicago, (Jan. 4, 2015). Another study presented in 2014 indicated that only 2317 prescriptions for Truvada as PrEP were filled in the United States between 2012 and 2013. Robert M. Grant et al., Presentation at the 2014 World AIDS Conference in Melbourne: Pre-Exposure Prophylaxis (PrEP) Initiative: Open Label Extension (July 22, 2014), http://pag.aids2014.org/PAGMaterial/PPT/4961_3462/final.pptx [<http://perma.cc/A56S-JEFJ>]. At the local level, in December of 2014, Kaiser indicated that approximately 500 of its members were taking PrEP in San Francisco. *See* Liz Highleyman, *No New HIV Infections Seen Among Kaiser PrEP Users*, AIDSMAP (Dec. 15, 2014), <http://www.aidsmap.com/No-new-HIV-infections-seen-among-Kaiser-PrEP-users/page/2929303> [<http://perma.cc/KLF7-GKBY>]. Of those taking PrEP, the majority of the users

some PrEP advocates have sounded the alarm.¹⁰⁰ It is particularly irksome to some HIV prevention advocates that the AHF continues to take a wait and see position on PrEP, only recommending its use in “very limited” scenarios, such as in the context of sex workers and serodiscordant couples.¹⁰¹ Yet this is only a small segment of the high-risk population that stands to benefit from the layer of protection that PrEP provides.

Despite the AHF’s objections to PrEP and the growing frustration about its underutilization, efforts to educate high-risk communities,¹⁰² physicians,¹⁰³ and lawmakers¹⁰⁴ have burgeoned. In fact, there has been significant movement recently at the state and local levels. For example, New York Governor Andrew Cuomo recently became the first high-ranking lawmaker to endorse oral PrEP.¹⁰⁵ With Cuomo’s support, the New York City Department of Health and Mental Hygiene developed a PrEP education campaign that provides numerous resources for both patients and providers.¹⁰⁶ According to Cuomo’s administration, the justification for supporting PrEP implementation efforts is the need to provide a basic

between 2012 and 2013 were women. Mark Mascolini, Presentation at the 53rd Interscience Conference on Antimicrobial Agents and Chemotherapy: Almost Half of Early US PrEP Are Women, Often in Southern States (Sept. 10–13, 2013), http://www.natap.org/2013/ICAAC/ICAAC_04.htm [<http://perma.cc/J5GJ-PALS>].

100. See *31 Days of PrEP*, ADVOCATE, <http://www.advocate.com/31-days-prep> [<http://perma.cc/K3JS-Q8U2>] (last visited Mar. 25, 2015) (featuring in-depth articles from PrEP advocates focusing on “why the HIV-prevention drug has not been more widely accepted”).

101. See Principles on Prevention of AIDS Healthcare Foundation, AIDS HEALTHCARE FOUND., <http://www.aidshealth.org/wp-content/uploads/2014/06/AHF-Principles-of-Prevention.pdf> [<http://perma.cc/X5HW-3BTB>] (last visited Mar. 25, 2015) [hereinafter *Principles on Prevention*].

102. See, e.g., *Is PrEP or PEP for You?*, GAY MEN’S HEALTH CRISIS, <http://www.gmhc.org/prep> [<http://perma.cc/9FAT-BHR6>] (last visited Mar. 25, 2015).

103. See, e.g., Howard Grossman, *I’m an HIV Physician. And I’m Starting PrEP*, BODY PRO (July 11, 2014), <http://www.thebodypro.com/content/74724/im-an-hiv-physician-and-im-starting-prep.html?ap=1100> [<http://perma.cc/6KJE-BZE5>].

104. See, e.g., Josh Barro, *With Cuomo’s Plan To Fight AIDS, New Approach Gains a Prominent Backer*, N.Y. TIMES, July 4, 2014, at A15, <http://nyti.ms/1kiDgmC> [<http://perma.cc/SMU7-VT88>].

105. *Id.*

106. See *New Ways To Prevent HIV*, N.Y. CITY DEP’T HEALTH & MENTAL HYGIENE, <http://www.nyc.gov/html/doh/html/living/prep-pep.shtml> [<http://perma.cc/WJR4-YPAH>] (last visited Mar. 25, 2015).

layer of protection from HIV.¹⁰⁷ One official in San Francisco, who publically disclosed his own experience taking PrEP, proposed that the city provide cost-free access to PrEP to anyone who requests the medication.¹⁰⁸ Additionally, Washington State¹⁰⁹ and Illinois¹¹⁰ now operate drug assistance programs for Truvada as PrEP. The support of officials in New York, Washington State, Illinois, and San Francisco is exactly the type of public relations exposure that PrEP proponents need to reach at-risk individuals who are currently unaware of PrEP, who would continue to engage in risk-taking activities with or without it, and who would maintain a high risk of contracting HIV unless introduced to new, attractive, and effective prevention modalities such as PrEP.¹¹¹

However, there are two fundamental challenges to full implementation that advocates will need to address. These challenges are *acceptability* and *accessibility*. PrEP must be acceptable to the high-risk communities who are the targeted users. PrEP must also be acceptable as a legitimate prevention method to the providers who would furnish the medication and

107. Barro, *supra* note 104 (according to a member of Governor Cuomo's administration: "Some people use condoms, some people don't You can't offer condoms to people who don't want them").

108. See Chris Roberts, *SF Supervisor To Call for Free HIV Prevention Medication*, S.F. EXAMINER (Sept. 16, 2014), <http://www.sfexaminer.com/sanfrancisco/sf-supervisor-to-call-for-free-hiv-prevention-medication/Content?oid=2899573> [<http://perma.cc/UF9V-HMRF>].

109. See *Pre-Exposure Prophylaxis Drug Assistance Program (PrEP DAP)*, WASH. STATE DEP'T OF HEALTH, http://www.doh.wa.gov/YouandYourFamily/Illness_andDisease/HIVAIDS/HIVCareClientServices/PrEPDAP [<http://perma.cc/EA42-T6K2>] (last visited Mar. 25, 2015).

110. See *Pre-Exposure Prophylaxis (PrEP)*, ILL. DEP'T PUB. HEALTH, <http://dph.illinois.gov/topics-services/diseases-and-conditions/hiv-aids/pre-exposure-prophylaxis-prep> [<http://perma.cc/775C-YNLZ>] (last visited Mar. 25, 2015).

111. From the perspective of a twenty-one year old African-American taking PrEP as part of a clinical study: "I don't know what I would do without that pill. I would probably have HIV right now. . . . I probably could be dead right now. . . . The pill was a blessing to me." Kimberly Koester et al., Presentation at the 20th International AIDS Conference: Sex on PrEP: Qualitative Findings from the iPrEx Open Label Extension (OLE) in the US (July 22, 2014), http://pag.aids2014.org/PAGMaterial/PPT/1151_2462/sex%20on%20prep%20final.pptx [<http://perma.cc/X8PC-LUTT>]. See HIV incidence among young, African-American MSM in Atlanta is comparable to the general population in high prevalence areas in Sub-Saharan Africa. Holly Korschun, *U.S. Black Gay, Bisexual Men Have Much Higher HIV Infection Rates*, EMORY NEWS CENTER (July 24, 2012), <http://bit.ly/1v9lmaN> [<http://perma.cc/W82F-G33B>] (discussing an Emory School of Public Health study called HPTN 061); *The Atlanta Principles*, ACT UP N.Y., http://actupny.com/actions/files/The_Atlanta_Principles.pdf [<http://perma.cc/L6Q7-3ABF>] (twelve percent of young black gay men in Atlanta are infected with HIV every year) (last visited Mar. 25, 2015). Of all the high-risk populations, the infection risk among young African-American MSM is particularly troubling. In the Emory School of Public Health's HPTN 061 study, researchers found that in the cohort studied, men sexually active at age eighteen run a startling sixty percent chance of contracting HIV by age thirty. *Id.*

monitor treatment. To ensure accessibility, PrEP must be coverable by health plans, affordable to consumers across the socioeconomic spectrum, and procurable with little complication or delay. Those seeking fuller implementation will need to address both acceptability and accessibility to successfully fold PrEP into established HIV prevention methods across the United States and to ensure its sustainability.

A. Acceptability

It takes courage, honesty, and self-awareness to examine one's sexual behavior and make a determination about one's actual risk of HIV infection. Those at risk of HIV infection who are honest about their current and future risk face stigmatization. It also takes courage and honesty to discuss one's risk openly with a medical provider.¹¹² In one activist's frank words, there is a perception that people who actively consider their risk of HIV infection "must be very, very slutty."¹¹³ Just like oral contraception was associated with female debauchery during the rollout of "the pill" in the 1960s, PrEP has been associated with reckless sexual behavior and irresponsibility.¹¹⁴ For example, in a *New York Times* op-ed piece, AIDS activist Larry Kramer suggested that PrEP would contribute to the complacent attitudes of "the lucky uninfected [who] neglect or reject condom use."¹¹⁵ However, there is little evidence that PrEP increases risk-taking activity. In fact, recent research suggests the contrary.¹¹⁶ Unfounded hypotheses that PrEP increases risk-taking activity contribute to public attitudes about the illegitimacy of PrEP, which has harmed implementation efforts.

To make PrEP acceptable, proponents must change social, individual, and systemic biases against those who use it. Stigma, and the discrimination

112. See *HIV Stigma*, UNLOCKING HIV, http://unlockinghiv.com/?page_id=402 [<http://perma.cc/3V2N-NRQT>] (last visited Mar. 25, 2015) (quoting UN Secretary-General Ban Ki-moon as saying that "too many people are afraid to see a doctor to determine whether they have the disease, or to seek treatment if so").

113. Stern, *supra* note 8 and accompanying text.

114. See Duran, *supra* note 21.

115. Larry Kramer, Opinion, *We Don't Know the Full Effects of Truvada Yet*, N.Y. TIMES, <http://www.nytimes.com/roomfordebate/2014/06/17/is-prep-a-good-way-to-fight-hiv-infections/we-dont-know-the-full-effects-of-truvada-yet> [<http://perma.cc/DP7L-QWE8>] (last updated June 18, 2014, 12:07 PM).

116. Koester et al., *supra* note 111 (noting that "PrEP use, in most cases, did not lead to increased condomless sex").

that accompanies it, can occur at the self-imposed, individual, and institutional levels.¹¹⁷ Self-imposed stigma occurs when a person expects the application of a certain stereotype and “a priori acts as if discrimination has already been imposed.”¹¹⁸ In the context of healthcare, self-imposed stigma typically occurs before an individual decides whether to actively seek a practitioner’s advice. By way of example, many women in the 1960s feared that pondering risk of unwanted pregnancy or even considering family planning effectively meant that they were insubordinate and unallied with their husbands’ desires.¹¹⁹ Individual stigma, on the other hand, occurs when one person imposes a negative judgment on another; this stigma is more easily noticeable.¹²⁰ Again, recalling birth control implementation in the 1960s, debate over oral contraception during its early implementation pit men against women and women against themselves. Use of the pill implied that users were currently engaging in, and planning to engage in, immoral behavior.¹²¹ Finally, institutional bias, sometimes known as structural or systemic bias, is more indirect and often appears to be normal behavior.¹²² Such biases occur when institutional practices in the aggregate disadvantage certain groups.¹²³ This could also be seen during early implementation of oral contraception, as the prevalence of male physicians and their traditional assumptions may have had an indirect discriminatory effect on women who were already uncomfortable speaking to a man about contraception.¹²⁴ As a result of these trifold stigmatic forces,

117. Anish P. Mahajan et al., *Stigma in the HIV/AIDS Epidemic: A Review of the Literature and Recommendations for the Way Forward*, 22 AIDS S67, S70 (2008) (citing Bruce G. Link & Jo C. Phelan, *Conceptualizing Stigma*, 27 ANN. REV. SOC. 363, 365 (2001)).

118. *Id.* (citing Link & Phelan, *supra* note 117, at 373–75; Elizabeth C. Pinel, *Stigma Consciousness: The Psychological Legacy of Social Stereotypes*, 76 J. PERSONALITY & SOC. PSYCHOL. 114, 126 (1999); Ronald O. Valdiserri, *HIV/AIDS Stigma: An Impediment to Public Health*, 92 AM. J. PUB. HEALTH 341, 341 (2002)).

119. *See People & Events: The Pill and the Sexual Revolution*, PBS, http://www.pbs.org/wgbh/amex/pill/peopleevents/e_revolution.html [http://perma.cc/EKW5-GJKB] (last visited Mar. 25, 2015).

120. *See* Link & Phelan, *supra* note 117, at 372.

121. *See* LARA V. MARKS, *SEXUAL CHEMISTRY: A HISTORY OF THE CONTRACEPTIVE PILL* 198 (2001).

122. *See* CHRISTA TOBLER, *INDIRECT DISCRIMINATION: A CASE STUDY INTO THE DEVELOPMENT OF THE LEGAL CONCEPT OF INDIRECT DISCRIMINATION UNDER EC LAW 62* (2005) (citing Nicola Lacey, *Legislation Against Sex Discrimination: Questions from a Feminist Perspective*, 14 J.L. SOC’Y 411, 417–18 (1987)).

123. *See* Link & Phelan, *supra* note 117, at 373–74; Mahajan, *supra* note 117, at S70.

124. *See generally* Marks, *supra* note 121, at 116 (noting that “many doctors in the early 1960s were opposed to prescribing the pill”).

procuring the pill in the early years of its introduction took, in the words of one scholar, “a great deal of nerve.”¹²⁵

The similarities between the effect of stigma on women seeking birth control in the 1960s and the effect of stigma on at-risk individuals seeking oral PrEP are uncanny. In the context of pharmacological HIV prevention modalities, like in the context of birth control, stigma is also present at the self-imposed, individual, and institutional levels. Some at-risk individuals fail to even consider taking PrEP, as they believe that actively considering HIV prevention beyond condom usage means that one is promiscuous and reckless. At the conscious level, those seeking PrEP are often concerned about how they will be perceived by their doctors, by their community, and by their sexual partners.¹²⁶ Individual stigma is manifested, like in the birth control context, in the acrimonious debate both within the general population and within the high-risk communities poised to benefit from PrEP prevention.¹²⁷

Negative provider attitudes about PrEP at the individual level also contribute to the stigmatization of those who seek it. Indeed, there is anecdotal evidence that, for an individual who has already decided to seek out PrEP, securing insurance coverage is not the biggest barrier to obtaining a prescription. Rather, it is convincing the medical provider to prescribe PrEP.¹²⁸ The attitudes of medical providers at the individual level negatively impact the utilization of PrEP.¹²⁹ Some medical providers are too unfamiliar with PrEP to prescribe it, and some view prescription of ARVs “as the purview of HIV specialists.”¹³⁰ Even HIV specialist

125. *Id.* at 205.

126. *See* Stern, *supra* note 8.

127. *Id.*; Duran, *supra* note 21 and accompanying text.

128. *See Truvada Track—Monitoring Insurance and Medicaid Coverage of Truvada for PrEP*, MY PREP EXPERIENCE, <http://myprepexperience.blogspot.com/p/truvada-track.html> [<http://perma.cc/WQP9-5LLX>] (last visited Mar. 25, 2015) [hereinafter MY PREP EXPERIENCE].

129. *See, e.g.*, David Tuller, *supra* note 50 (noting that “[s]ome men have reported receiving negative reactions from their health care providers when they brought it up”).

130. Reilly O’Neal, *Getting Comfortable with PrEP: A Provider’s Perspective*, BETA BLOG (Mar. 26, 2014), <http://betablog.org/getting-providers-comfortable-with-prep/> [<http://perma.cc/Z6SA-L5D6>] (interviewing HIV specialist Dr. Joel Gallant, MD, MPH, who relayed the results of a recent think tank meeting with providers); *see generally* S.F. AIDS FOUND., GAY MEN’S SEXUAL HEALTH THINK TANK MEETING (2013), <http://www.sfaf.org/hiv-info/hot-topics/from-the-experts/gay-mens-sexual-health-think-tank-report.pdf> [<http://perma.cc/TF4T-SNDX>] (providing overview of discussions among

willingness to prescribe Truvada for PrEP is on the low side according to a number of studies. In a June 2013 study, for example, 1175 physician members of the Infectious Disease Society of America's Emerging Infections Network (EIN) were given a ten-part questionnaire to evaluate current PrEP attitudes and practices.¹³¹ Although seventy-five percent of responding specialists indicated they were in support of using the prophylactic drug regimen, only nine percent reported they had prescribed it to patients.¹³² The EIN study identified that:

Common reasons for unwillingness to prescribe PrEP included fears about adherence and resistance, concerns about cost and reimbursement, reluctance to use a potentially toxic medication in healthy people and reservations about efficacy. Some physicians raised concerns about risk compensation and there were occasional "moral" objections, one physician stating: "Medicine should not attempt to reverse bad behaviors artificially."¹³³

In addition, a 2013 study of 189 HIV physicians found that although the majority of HIV specialists knew about the existence of PrEP, only one out of five of those specialists reported actually prescribing it.¹³⁴ Other studies support these findings.¹³⁵ The final CDC guidelines represent a significant step forward in changing providers' attitudes about PrEP. In fact, the *New York Times* recently predicted the CDC report could result in a fifty-fold increase in Truvada prescriptions for PrEP—from fewer

more than twenty national leaders and experts about how to best improve provider-client communications around HIV prevention strategies).

131. Maile Y. Karris et al., *Are We Prepped for Preexposure Prophylaxis (PrEP)? Provider Opinions on the Real-World Use of PrEP in the United States and Canada*, 58 CLINICAL INFECTIOUS DISEASES 704, 705 (2014).

132. *Id.*; Barro, *supra* note 104.

133. Michael Carter, *Widespread Support for HIV PrEP Among Infectious Disease Doctors in the US and Canada*, AIDS MAP (Dec. 17, 2013), <http://www.aidsmap.com/Widespread-support-for-HIV-PrEP-among-infectious-disease-doctors-in-the-US-and-Canada/page/2810626> [<http://perma.cc/MTU8-W7D7>].

134. See David Tellalian et al., *Pre-Exposure Prophylaxis (PrEP) for HIV Infection: Results of a Survey of HIV Healthcare Providers Evaluating Their Knowledge, Attitudes, and Prescribing Practices*, 27 AIDS PATIENT CARE & STDs 553, 554 (2013); Mark Mascolini, *Only 1 in 5 US HIV Doctors Surveyed Uses PrEP, Despite High Awareness*, BLACK AIDS INST., <http://www.blackaids.org/news-2013/1899-only-1-in-5-us-hiv-doctors-surveyed-uses-prep-despite-high-awareness> [<http://perma.cc/7F67-VQEY>] (last visited Mar. 25, 2015).

135. See, e.g., Jaclyn M. White et al., *Evolution of Massachusetts Physician Attitudes, Knowledge, and Experience Regarding the Use of Antiretrovirals for HIV Prevention*, 26 AIDS PATIENT CARE & STDs 395, 397 (2012), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3432573/pdf/apc.2012.0030.pdf> [<http://perma.cc/C77Y-5SAL>]. In fact, as of 2013, the majority of prescriptions have been from nonphysician prescribers, such as nurse practitioners and physician assistants. See Mascolini, *supra* note 99.

than 10,000 to 500,000.¹³⁶ Even supposing these numbers are exaggerated, this prediction illustrates the strong effect the CDC report will have on providers who have been hesitant to prescribe PrEP, ambivalent about doing so, simply unaware of the prevention method, or believe it is unavailable to primary care practitioners. At a minimum, the CDC guidelines may be a vehicle for dialogue about high-risk behavior between providers and high-risk patients, as providers often have difficulty beginning these dialogues.¹³⁷

PrEP bias at the institutional level is the most difficult to identify. Institutional bias against those who seek or use PrEP prevention exists by virtue of a healthcare system that is only beginning to support the coding, billing, and medical supervision that PrEP treatment requires.¹³⁸ For example, the current medical coding system, which insurers require physicians to use to track conditions, treatments, services, and medications, makes it difficult for physicians who have never prescribed PrEP to code the treatment. There are sixty billing codes related to HIV prevention that might apply to a PrEP-related clinical profile, but there are no billing codes that specifically pertain to PrEP treatment.¹³⁹ Widespread provider confusion over proper coding can further complicate access, frustrate patients, and may lead to underutilization and future coverage denials.¹⁴⁰

136. Donald G. McNeil Jr., *Advocating Pill, U.S. Signals Shift To Prevent Aids*, N.Y. TIMES, May 15, 2014, at A1, <http://www.nytimes.com/2014/05/15/health/advocating-pill-us-signals-shift-to-prevent-aids.html?r=0> [<http://perma.cc/S9C7-PRU8>].

137. See Jonathan Mermin, *From the CDC: HIV Prevention in the Doctor's Office*, MEDPAGE TODAY (Nov. 30, 2009), <http://www.medpagetoday.com/Columns/And-Now-a-Word/17193> [<http://perma.cc/RPU5-4VSK>] (noting that “many doctors avoid talking about risk behaviors because they assume it makes patients uncomfortable”); see generally Ronald M. Epstein et al., *Awkward Moments in Patient-Physician Communication About HIV Risk*, 128 ANNALS INTERNAL MED. 435 (1998), <http://goo.gl/a8ZZKb> [<http://perma.cc/RX2L-6P45>] (discussing the troubles physicians have communicating with high-risk patients because of inadequate professional, educational, and cultural training to fully assess the risks associated with HIV/AIDS).

138. S.F. AIDS FOUND., *supra* note 130, at 4 (noting that current models of HIV care are “not well suited for PrEP delivery”).

139. S.F. AIDS FOUND., PREP FACTS 10 (2014), http://prepfacts.org/assets/PrEP_Facts_16-pager_brochure_mech_FINAL.pdf (noting that “[c]urrently, there are no official ICD-9 or ICD-10 codes” specifically for PrEP). The most relevant billing code for PrEP is “high risk sexual behavior” (V69.2 and Z72.5, ICD-9 and ICD-10, respectively). See *id.* at 11–13. However, physicians may be using other codes.

140. Some organizations have already begun educating physicians about billing code accuracy pertaining to PrEP. See *Pre-Exposure Prophylaxis (PrEP) for HIV Prevention*, CENTERS FOR DISEASE CONTROL & PREVENTION (May 2014), <http://www.cdc.gov/hiv/>

Additionally, the USPSTF, which directly affects the prescription habits of providers and coverage determinations of insurance issuers, has not yet taken into special consideration the differential healthcare needs of marginalized, high-HIV-incidence communities.¹⁴¹ In the aggregate, these and other institutional factors negatively impact those seeking PrEP and delegitimize their unique preventive healthcare needs.

Just as the self-imposed, individual, and institutional stigmatization of women in the context of birth control has proved a difficult challenge to overcome and continues today, so too will the multidimensional stigmas associated with those who take PrEP.¹⁴² Community education efforts have been, and will continue to be, a key part of the advocacy response,¹⁴³ and the ACA provides grant opportunities that may be appropriate for establishing practitioner, clinician, and community health worker training vis-à-vis oral PrEP.¹⁴⁴ Additionally, in their effort to eliminate the various

pdf/PrEP_fact_sheet_final.pdf [http://perma.cc/24AD-7WZ7]. More information is needed about how insurers identify oral PrEP applications and whether coverage determinations vary based upon the billing codes ascribed.

141. See *infra* note 289 and accompanying text.

142. See, e.g., Maggie Fazeli Fard, *Sandra Fluke, Georgetown Student Called a "Slut" by Rush Limbaugh, Speaks Out*, WASH. POST (Mar. 2, 2012, 11:06 AM), <http://wapo.st/xlpoRt> [http://perma.cc/DQS3-JPFU].

143. Education efforts in the media can incorporate research indicating PrEP usage does not result in decreased condom usage. See, e.g., Julia L. Marcus et al., *No Evidence of Sexual Risk Compensation in the iPrEx Trial of Daily Oral HIV Preexposure Prophylaxis*, PLOS ONE 2, 5, 7 (Dec. 18, 2013), <http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pone.0081997&representation=PDF> [http://perma.cc/4FAH-AH4V]; see also Koester et al., *supra* note 111 (noting that "PrEP use, in most cases, did not lead to increased condomless sex"). Educational efforts directed toward PrEP users can include information about dosage, contraindications, and corequisites to treatment such as routine follow-up visits and HIV testing and counseling on safer-sex practices. At the provider level, educational efforts can focus on training practitioners on how to introduce discussions about HIV risk, accurately explain the risks and benefits associated with PrEP, and properly code the treatment. See Ronald M. Epstein et al., *Talking about AIDS*, 13 AIDS PATIENT CARE & STDs 545, 546 (1999). Additional research will also be a key aspect of changing provider attitudes about PrEP. See Emily A. Arnold et al., *A Qualitative Study of Provider Thoughts on Implementing Pre-Exposure Prophylaxis (PrEP) in Clinical Settings To Prevent HIV Infection*, PLOS ONE 1, 6–7 (July 11, 2012), <http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pone.0040603&representation=PDF> [http://perma.cc/Z9P4-42JD]; see generally Josh Barro, *Is Truvada, the Pill To Prevent H.I.V., 99 Percent Effective? Don't Be So Sure*, N.Y. TIMES (July 16, 2014), http://www.nytimes.com/2014/07/17/upshot/is-truvada-the-pill-to-prevent-hiv-99-percent-effective-dont-be-so-sure.html?_r=3 [http://perma.cc/U8VG-6UD8].

144. The ACA created the Prevention and Public Health Fund, which was established "to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs." 42 U.S.C. § 300u-11 (2012); Corey S. Davis & Sarah Somers, *National Health Care Reform and the Public's Health*, 39 J.L. MED. & ETHICS 65, 66 (Supp. 2011). Under the ACA, the Fund may disburse up to fifteen billion dollars

stigmas attached to oral PrEP on a national scale, PrEP proponents should seek legal and public policy solutions. The stigmatization of PrEP users and its concomitant underutilization may be an appropriate justification for seeking mandatory low cost or cost-free access to PrEP through federal and state laws and regulations.¹⁴⁵

B. Accessibility

In addition to acceptability challenges, challenges related to the accessibility of oral PrEP are a core concern to those seeking fuller implementation.¹⁴⁶ There is anecdotal evidence that major commercial insurers and Medicaid programs are currently covering Truvada as PrEP, which is facilitating more affordable access.¹⁴⁷ United Healthcare, for example, the largest commercial insurer in the United States, is covering PrEP with a prior authorization.¹⁴⁸ However, there is little information about policy coverage of PrEP across the industry, and there are few resources to compare coverage.¹⁴⁹

Because there are currently no federal or state laws or regulations requiring insurers to cover oral PrEP, whether insurers will continue to ride or buck the trend of covering the prevention modality is a great unknown for PrEP proponents. Will some insurers subject PrEP treatment requests to more rigorous utilization review? What is the cost of PrEP treatment? Are there provisions in benefit plans that insurers could invoke to deny coverage for PrEP in the future? Is PrEP medically necessary? Answering these questions will require careful analysis.

to fund education programs for physicians and community prevention programs. *See* Davis & Somers, *supra*, at 66; *Secretary Sebelius Announces \$250 Million To Strengthen the Primary Health Care Workforce*, AM. ASS'N COLLEGES NURSING, <http://www.aacn.nche.edu/government-affairs/archives/secretary-sebelius-announces-250-million-to-strengthen-the-primary-health-care-workforce> [<http://perma.cc/WW6A-SDMV>] (last visited Mar. 25, 2015).

145. *See infra* notes 323–27 and accompanying text.

146. *See* Underhill, *supra* note 28, at 610.

147. *See* MY PREP EXPERIENCE, *supra* note 128.

148. *See id.* Authorization is issued for one month if the beneficiary meets the requirements. *See UnitedHealthcare Pharmacy: Clinical Pharmacy Programs*, UNITEDHEALTHCARE, https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Pharmacy%20Resources/Notification_Truvada.pdf [<https://perma.cc/7L8Q-3PSE>] (last visited Mar. 25, 2015).

149. *See generally* MY PREP EXPERIENCE, *supra* note 128 (indicating that “[w]e have not heard of any insurance company or any Medicaid program outright denying coverage of Truvada as PrEP”).

1. Cost of Oral PrEP Prevention

The entryway to understanding the accessibility challenges that PrEP proponents face is to itemize the various costs associated with PrEP prevention.¹⁵⁰ Few studies have addressed the total cost of providing oral PrEP treatment.¹⁵¹

There are multiple dimensions to oral PrEP treatment in addition to the cost of medication. As part of the “comprehensive HIV prevention strategy” recommended by the FDA, prior to receiving a prescription for Truvada as PrEP, the practitioner must conduct a number of preliminary tests, which include screenings for HIV and other sexually transmitted infections, tests for hepatitis B, and analyses of kidney function.¹⁵² Once treatment begins, cost inputs associated with PrEP prevention include but may not be limited to (1) lab fees in connection with quarterly HIV tests and periodic kidney function analyses, (2) professional fees and services, such as counseling and follow-up visits, and (3) the cost of the medication itself.¹⁵³

In calculating the various insurer outputs to providers, Medicare fee schedules, which list Medicare fees used to pay healthcare providers, are an excellent place to begin because they are “the platform around which insurers and physicians often negotiate.”¹⁵⁴ According to one 2013 study that analyzed the total “cost components” of PrEP using this payment schedule, the aggregate cost associated with PrEP prevention is nearly \$18,000 per year in the United States.¹⁵⁵ This includes the price of

150. See Michael Horberg & Brian Raymond, *Financial Policy Issues for HIV Pre-Exposure Prophylaxis: Cost and Access to Insurance*, 44 AM. J. PREVENTIVE MED. S125, S125 (2013), [http://www.ajpmonline.org/article/S0749-3797\(12\)00696-4/pdf](http://www.ajpmonline.org/article/S0749-3797(12)00696-4/pdf) [<http://perma.cc/TP2W-GFRJ?type=live>].

151. *Id.* (citing two studies: Kamal Desai et al., *Modeling the Impact of HIV Chemoprophylaxis Strategies Among Men Who Have Sex with Men in the United States: HIV Infections Prevented and Cost-effectiveness*, 22 AIDS 1829 (2008), and Paltiel et al., *supra* note 58).

152. See PROJECT INFORM, IS TAKING PREP THE RIGHT CHOICE FOR YOU? 9 (2014), http://www.projectinform.org/pdf/prep_msm.pdf [<http://perma.cc/H742-RQ8D>].

153. See Horberg & Raymond, *supra* note 150, at S126.

154. Jeffrey Clemens, *How Medicare Shapes the US Health Sector*, ECON. ACTION (May 6, 2014), <http://economics.ucsd.edu/economicsinaction/issue-10/headline.php> [<http://perma.cc/AEM5-P5QJ>]; see Lenard I. Lesser et al., *Comparison Between US Preventive Services Task Force Recommendations and Medicare Coverage*, 9 ANNALS FAM. MED. 44, 48 (2011), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3022045/pdf/0090044.pdf> [<http://perma.cc/A4YU-T34V>]; *Medicare-Covered Preventive Services*, AM. C. PHYSICIANS, http://www.acponline.org/advocacy/where_we_stand/assets/iii8-medicare-covered-preventive-services.pdf [<http://perma.cc/8LFV-T4ZH>] (last visited Mar. 25, 2015).

155. See Horberg & Raymond, *supra* note 150, at S126 (citing *Truvada*, BODY (Mar. 2012), www.thebody.com/content/art1331.html [<http://perma.cc/9L8Y-4WZ9>]; PANEL ON

Truvada, which the study estimated at \$1425 per month on average.¹⁵⁶ Using this estimated price for the purpose of illustration, the yearly cost of the medication alone is approximately \$17,125.08.¹⁵⁷ Additionally, the associated costs of FDA-required and CDC-recommended laboratory work are estimated at \$373.50 to \$504.51 per year, which includes an initial HIV screening.¹⁵⁸ Medical services, including the costs of determining eligibility for PrEP, the initial prescription, periodic patient evaluations, and risk-reduction counseling, are estimated at \$309.86 per year.¹⁵⁹ There may also be additional costs in connection with adverse events, such as drug interactions and side effects, should they occur.¹⁶⁰ Thus, the cost of covering PrEP involves more than considering the price of the drug. PrEP is more than a drug, after all, it is a treatment regimen.

Even if actuarial calculations favor coverage and an insurer grants benefits for PrEP treatment, PrEP may still be inaccessible to at-risk patients due to maximum out-of-pocket deductibles, high monthly copays, and coinsurance.¹⁶¹ Private and public copay assistance programs have

ANTIRETROVIRAL GUIDELINES FOR ADOLESCENTS & ADULTS, U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDELINES FOR THE USE OF ANTIRETROVIRAL AGENTS IN HIV-1-INFECTED ADULTS AND ADOLESCENTS K-23 (2014), <http://aidsinfo.nih.gov/contentfiles/lvguidelines/adultandadolescentgl.pdf> [<http://perma.cc/U4WP-3PEA>].

156. *Id.* at S125. For a table containing the various cost inputs, what those inputs include, and the annual cost of each input, see *id.* at S126.

157. *Id.* For a comparable estimate, see Michael Hornberg, Presentation: PrEP: Access and Cost from Private Sector Payor (n.d.), http://www.iapac.org/tasp_prep/presentations/TPSlon12_Panel7_Horberg.pdf [<http://perma.cc/TS7G-BR7H>] (estimating the cost of Truvada at \$16,697.40 per year (citing 2012 *Clinical Diagnostic Laboratory Fee Schedule*, CENTER FOR MEDICARE & MEDICAID (2012), <http://www.cms.gov/apps/ama/license.asp?file=/ClinicalLabFeeSched/downloads/12CLAB.ZIP> [<http://perma.cc/3TSB-T7VF>] [hereinafter *Fee Schedules*])).

158. Horberg & Raymond, *supra* note 150, at S126 (citing *Fee Schedules*, *supra* note 157).

159. *Id.*

160. *Id.* at S127.

161. In fact, some insurers have structured their prescription drug benefit plans to place HIV medications, including Truvada, on specialty drug tiers with high cost sharing, which, according to the AIDS Institute and the National Health Law Program, requires patients to shoulder between forty and fifty percent of the cost of the medication. See Melinda Beck, *Cigna Agrees To Restructure HIV Drug Benefits*, WALL ST. J., <http://www.wsj.com/articles/cigna-agrees-to-restructure-hiv-drug-benefits-1415404871> [<http://perma.cc/4WNR-DPP3>] (last updated Nov. 7, 2014, 7:11 PM); AIDS Found. of Chi., Presentation: Your Six-Month Health Reform Check-Up: Assessing Initial Implementation of Health Reform for People with HIV 16 (June 24, 2014), http://www.hivhealthreform.org/wp-content/uploads/2014/06/6_Month_ACA_Checkup_slides.pdf [<http://perma.cc/5N7M-SLBA>]

helped make PrEP more affordable. For example, Gilead offers copay assistance on a sliding scale to those with qualifying incomes,¹⁶² which has reduced many copays to the \$0 to \$60 range.¹⁶³ On the public side, two states operate their own copay assistance programs.¹⁶⁴ Successful state programs have the potential to be replicated in other states, which could help make PrEP more affordable on a broader scale.

However, there are concerns with conditioning access to HIV prevention on a drug manufacturer's assistance program and even on state programs. First, requiring patients to secure copay assistance from either the manufacturer or a state creates an additional obstacle to procuring the medication, which may dissuade some patients from following through. Second, assistance programs may not be sustainable over time. On the drug manufacturer side, assistance programs could be phased out or qualifying income requirements could change at any time. On the public side, state assistance programs facilitated by health officials can be affected by administration changes and budget cuts. As such, assistance programs should be only one part of the solution to securing affordable access to PrEP treatment in the future.¹⁶⁵

(noting that “[s]ome plans are placing all HIV and HCV medications on tiers that require 50% coinsurance”); Letter from HIV Health Care Access Working Group, to Kathleen Sebelius, Sec’y, U.S. Dep’t of Health & Human Servs. 2 (Dec. 2, 2013), [https://www.aahivm.org/Upload_Module/upload/Advocacy/letter%20to%20HHS%20on%20QHPs%20and%20anti%20retro%20coverage%20concerns\(12%202%2013%20HHS%20Concerns%20Letter%20WAD%20Final\).pdf](https://www.aahivm.org/Upload_Module/upload/Advocacy/letter%20to%20HHS%20on%20QHPs%20and%20anti%20retro%20coverage%20concerns(12%202%2013%20HHS%20Concerns%20Letter%20WAD%20Final).pdf) [<https://perma.cc/F9UL-R2GN>] (listing six examples of “troubling plan cost-sharing designs” that render ARVs unaffordable).

162. See *Paying for Truvada*, GILEAD, <http://www.truvada.com/truvada-patient-assistance> [<http://perma.cc/Q8AS-6HKU>] (last visited Mar. 25, 2015).

163. See *PrEP Facts: Rethinking HIV Prevention & Sex*, FACEBOOK, <https://www.facebook.com/groups/PrEPFacts> [<https://perma.cc/A738-8TJL>] (last visited Aug. 9, 2014) (of over fifty individuals responding to an inquiry about how much their copay for Truvada as PrEP was, the majority cited amounts in the \$0 to \$60 range).

164. Washington State’s assistance program is open to at-risk Washington residents with specific risk factors regardless of need. The program will pay the copay for Truvada for those with insurance and will cover the entire cost of Truvada for those without insurance. WASH. STATE DEP’T OF HEALTH, HIV PREVENTION PROGRAM FOR PEOPLE THAT ARE AT RISK OF HIV INFECTION 2 (2014), <http://www.doh.wa.gov/Portals/1/Documents/Pubs/150-055-PrEPDAPBrochure.pdf> [<http://perma.cc/HL5Z-T5MJ>]. Illinois’ assistance program will cover the entire cost of Truvada for those without insurance who meet specific income criteria. See *Pre-Exposure Prophylaxis (PrEP)*, ILL. DEP’T PUB. HEALTH, <http://dph.illinois.gov/topics-services/diseases-and-conditions/hiv-aids/pre-exposure-prophylaxis-prep> [<http://perma.cc/T6Z5-47R8>] (last visited Mar. 25, 2015).

165. See John Anoyisius Cogan Jr., *The Affordable Care Act’s Preventive Services Mandate: Breaking Down the Barriers to Nationwide Access to Preventive Services*, 39 J.L. MED. & ETHICS 355, 358–59 (2011).

2. Prior Authorization and Medical Necessity

In addition to the cost of PrEP prevention, another accessibility challenge PrEP proponents face is eliminating or streamlining the insurance barriers patients may face subsequent to their provider consultation and before securing the medication. These barriers, which may include prior authorization, paperwork, wait time, and potentially denials based on medical necessity exclusions, typically occur during utilization review, a mechanism that insurers use to evaluate benefit usage.

Utilization review is used, sometimes under different names, in all health insurance programs, including government programs such as Medicare and Medicaid.¹⁶⁶ The utilization review process functions to ensure healthcare benefits are rendered only for services that are covered by the benefit plan, suitable for the treatment, and medically necessary under the circumstances.¹⁶⁷ Types of utilization review are prospective review, often called “prior authorization,”¹⁶⁸ concurrent review,¹⁶⁹ and retrospective review.¹⁷⁰ While classic utilization review of coverage decisions happens retrospectively after the insurer issues the benefit, much of utilization review today occurs prospectively before benefits have been granted.¹⁷¹ This is especially the case with expensive or risky medications, treatments, services, and equipment. In the context of PrEP prevention, which comes at a significant cost to the insurer, the most common form of utilization review that patients experience is the prior authorization.¹⁷²

166. Michael A. Dowell, *Avoiding HMO Liability for Utilization Review*, 23 U. TOL. L. REV. 117, 117 (1991).

167. See *id.*; *Health Utilization Management*, URAC, <https://www.urac.org/accreditation-and-measurement/accreditation-programs/all-programs/health-utilization-management> [https://perma.cc/R9JQ-E6KV] (last visited Mar. 25, 2015).

168. *Answers to Frequently Asked Questions About Utilization Review (UR) for Claims Administrators*, CAL. DEP'T. INDUS. RELATIONS (Mar. 2014), http://www.dir.ca.gov/dwc/UtilizationReview/UR_FAQ.htm [http://perma.cc/73FE-GPG5].

169. See J. Scott Andresen, *Is Utilization Review the Practice of Medicine?: Implications for Managed Care Administrators*, 19 J. LEGAL MED. 431, 434 (1998).

170. Benjamin Saunier, *The Devil Is in the Details: Managed Care and the Unforeseen Costs of Utilization Review as a Cost Containment Mechanism*, 27 ISSUES L. & MED. 21, 33 (2011) (citing Allison Faber Walsh, *The Legal Attack on Cost Containment Mechanisms: The Expansion of Liability for Physicians and Managed Care Organizations*, 31 J. MARSHALL L. REV. 207, 217 (1997)).

171. See INST. OF MED., *CONTROLLING COSTS AND CHANGING PATIENT CARE? THE ROLE OF UTILIZATION MANAGEMENT* 3 (Bradford H. Gray & Marilyn J. Field eds., 1989).

172. See MY PREP EXPERIENCE, *supra* note 128.

Prior authorization is an insurer requirement that medical providers must, except for emergencies, obtain permission before services will be rendered or prescriptions will be filled.¹⁷³ Most insurers maintain a list of drugs requiring prior authorization.¹⁷⁴ Prior authorization policies for Truvada used as PrEP are by no means uniform across private or public healthcare programs. Some insurers require it,¹⁷⁵ while others are covering it without prior authorization.¹⁷⁶ Prior authorizations for Truvada as PrEP can result in “additional delays and treatment interruptions.”¹⁷⁷ Additionally, prior authorizations can place an additional burden on providers “because they require the doctor, rather than other staff to request them monthly.”¹⁷⁸ Prior authorizations also require additional communication between providers and patients¹⁷⁹ and thorough documentation of medical appropriateness¹⁸⁰—why the patient would benefit from the service¹⁸¹—

173. See 5 DOUGLAS DANNER ET AL., *MEDICAL MALPRACTICE: CHECKLISTS AND DISCOVERY* § 36:9 (rev. ed. 2014). For an example of an insurer’s prior authorization policy, see UNITEDHEALTHCARE, *OXFORD PROVIDER REFERENCE MANUAL: COMMERCIAL PLANS 10–12* (2013), <https://www.oxhp.com/secure/materials/providers/prm/PRM.pdf> [<https://perma.cc/7DNZ-8WNV>]; Mark A. Hall & Gerard F. Anderson, *Health Insurers’ Assessment of Medical Necessity*, 140 U. PA. L. REV. 1637, 1654 (1992) (citing INST. OF MED., *supra* note 171, at 3, 17–18, 66).

174. See, e.g., *Drugs Requiring Prior Authorization*, HEALTH NET, https://www.healthnet.com/static/general/unprotected/pdfs/ca/pharmacy/drugs_requiring_pa.pdf [<https://perma.cc/RP7M-BM43>] (last updated Feb. 1, 2015).

175. See MY PREP EXPERIENCE, *supra* note 128; see, e.g., *NYS Medicaid Pharmacy Prior Authorization Programs*, MAGELLAN, https://newyork.fhsc.com/providers/CDRP_truvada.asp [<https://perma.cc/GM9T-QPWN>] (last visited Mar. 25, 2015).

176. See, e.g., *Medication Request Forms (MRF) and Clinical Coverage Criteria*, HARV. PILGRIM HEALTH CARE, https://www.harvardpilgrim.org/portal/page?_pageid=253,234249&_dad=portal&_schema=PORTAL [<https://perma.cc/VL5X-76SG>] (last visited Mar. 25, 2015); *Preferred Drug List*, EMPIRE BLUE (July 2014), http://www.empireblue.com/national/noapplication/f0/s0/t0/pw_e181120.pdf [<http://perma.cc/6D4B-ZDCS>]; *Drug List*, CIGNA, https://my.cigna.com/teamsite/cgi-bin/customer_care/member/drug_list/DrugList.cgi?search_by=name&rxPlanType=&rxPlanDesign=&LeanIndicator=&referrer=&Pid= [<https://perma.cc/E3WU-NN3F>] (last visited Mar. 25, 2015); *Rx Prior Authorization*, ANTHEM, <http://www.anthem.com/pharmacyinformation/priorauth.html> [<http://perma.cc/C5F7-JS7M>] (last visited Mar. 25, 2015).

177. *Barriers to HIV Medication Access*, N.Y. ST. DEP’T HEALTH AIDS INST., https://www.health.ny.gov/diseases/aids/ending_the_epidemic/docs/key_resources/care_committee/medication_access/barriers_to_medication.pdf [<https://perma.cc/EFA8-WE3X>] (last visited Mar. 25, 2015).

178. *Id.*

179. See *id.*

180. See Saunier, *supra* note 170, at 34 (citing Walsh, *supra* note 170, at 217).

181. See, e.g., *Medical Necessity Guidelines*, TUFTS HEALTH PLAN, http://www.tuftshealthplan.com/providers/provider.php?sec=pharmacy&content=pharmacy_medical_necessity_guidelines [<http://perma.cc/SR6A-6MKX>] (last visited Mar. 25, 2015) (“If a physician feels that a patient would benefit from a service, device or equipment requiring

by the provider. Finally, incorrect ARV coding on prior authorization forms resulting from provider confusion may lead to benefit denials.¹⁸² Therefore, it will be important to streamline the prior authorization process for PrEP in the future.

In addition to the administrative prior authorization barrier to PrEP access, another potential barrier to access in the future could be interpretation of policy terms such as medical necessity exclusions.¹⁸³ An insurer may be less inclined to cover an additional layer of HIV prevention if administrators determine that condoms offer a medically effective and less expensive alternative or that PrEP is merely a prevention of comfort or convenience to the patient. It is also possible, particularly after the U.S. Supreme Court's *Burwell v. Hobby Lobby* ruling, that religiously affiliated insurers may rely on policy language to exclude PrEP prevention, a treatment some religious organizations may regard as facilitating or even encouraging promiscuous and unsafe sexual practices.¹⁸⁴ As such, a discussion of benefit policy language that limits coverage, especially medical necessity clauses, is important to understanding some of the accessibility challenges PrEP proponents may face in the future.

The modern definition of medical necessity is a "multidimensional" one containing a number of different elements.¹⁸⁵ Across the industry, there is "widespread consensus" that medical necessity definitions should have specific elements, though these elements may be articulated in different ways depending on the policy.¹⁸⁶ Consider the following pre-ACA Blue Cross Blue Shield definition of medical necessity:

prior authorization, the physician must submit the appropriate clinical documentation for review.").

182. See *Barriers to HIV Medication Access*, *supra* note 177, at 2.

183. See Saunier, *supra* note 170, at 33. Another policy term that may be of some concern in the future is the experimental treatment exclusion. Currently, it is unlikely that an oral PrEP request would be subject to an experimental treatment exclusion, as the FDA's approval of Truvada as PrEP, the CDC's final guidance, and a thorough literature review would likely render the prevention nonexperimental. However, in the future, should physicians experiment with other ARVs as PrEP or with off-label dosage regimens of Truvada, experimental treatment exclusions may indeed come into play.

184. See *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2779 (2014).

185. SARA ROSENBAUM ET AL., U.S. DEP'T OF HEALTH & HUMAN SERVS., MEDICAL NECESSITY IN PRIVATE HEALTH PLANS: IMPLICATION FOR BEHAVIORAL HEALTH CARE 34 (2003), <http://goo.gl/6hFwd6> [<http://perma.cc/LHQ8-W5WA>].

186. *Id.* at 33.

[The plan will use] the following criteria for establishing the medical necessity of a service: appropriate for symptoms, diagnosis, and treatment of a condition, illness, or injury; provided for diagnosis, direct care, or treatment; in accordance with the standards of good medical practice; not primarily for the convenience of the member or member's provider; the most appropriate supply or level of service that can be safely provided to the member.¹⁸⁷

The first element of most modern medical necessity definitions is “contractual scope” language, which limits benefits to certain purposes, such as the treatment of a disease.¹⁸⁸ In the definition above, this may be found in the inclusion of “treatment of a condition, illness, or injury . . . provided for diagnosis, direct care, or treatment.”¹⁸⁹ The second element of most definitions is “professional standard” language, which limits benefits to those that are standard practice in the industry.¹⁹⁰ In the definition above, this element may be found in the language, “in accordance with the standards of good medical practice.”¹⁹¹ The third element is safety and appropriateness language, which limits coverage to treatments that are safe, effective, and appropriate for the particular patient.¹⁹² Also in the definition above, this element may be found in the language, “the most appropriate supply or level of service that can be safely provided to the member.”¹⁹³ The last element contained in most modern medical necessity definitions is convenience language, which limits benefits to treatments that are not made primarily for convenience or “that emanate[] from social or environmental factors.”¹⁹⁴ This element may be seen in the above language, “not primarily for the convenience of the member or member's provider.”¹⁹⁵

In the next subpart, I consider each of these common elements of medical necessity clauses in relation to oral PrEP.

i. Contractual Scope

The first element of a common medical necessity definition is language purporting to limit the scope of the benefit plan. Prior to implementation

187. *Id.* at 50 tbl.2 (reciting Highmark Blue Cross Blue Shield's 2000 medical necessity definition).

188. *Id.* at 33.

189. *See id.* at 50 tbl.2.

190. *Id.* at 33.

191. *See id.* at 50 tbl.2.

192. *See id.* at 33.

193. *See id.* at 50 tbl.2.

194. *See id.* at 33; *see also Medical Necessity Definitions*, CIGNA, <http://www.cigna.com/healthcare-professionals/resources-for-health-care-professionals/clinical-payment-and-reimbursement-policies/medical-necessity-definitions> [http://perma.cc/TC35-T26S] (last visited Mar. 25, 2015) (providing a similar definition of “medical necessity”).

195. *See Rosenbaum et al., supra* note 185, at 50 tbl.2.

of the ACA on January 1, 2014, most commercial insurers included in their medical necessity definitions a threshold requirement that services would be covered only if they treat an illness, injury, condition, or disease.¹⁹⁶ For example, the excerpt of the pre-2014 Blue Cross Blue Shield plan above contains the following language: “[A] service [must be] appropriate for symptoms, diagnosis, and treatment of a condition, illness, or injury.”¹⁹⁷ According to definitions such as this one, treatment in connection with *preventing* a condition, illness, or injury, however, would

196. See Underhill, *supra* note 28, at 641–42 (citing STEVEN PLITT ET AL., 10A COUCH ON INSURANCE 3D §§ 144.32, 144.34 (2005)); see, e.g., AETNA, 2013–2014 STUDENT HEALTH INSURANCE PLAN, UNIVERSITY OF SOUTHERN CALIFORNIA 90 (2012) [hereinafter AETNA USC PLAN], <https://engemannshc.usc.edu/files/2012/12/Aetna-Plan-Document.pdf> [<https://perma.cc/2P4A-NR4C>] (defining “medically necessary” as what is necessary and appropriate “for the diagnosis or treatment of a sickness[] or injury”); KAISER PERMANENTE, A HEALTH MAINTENANCE ORGANIZATION (HIGH, STANDARD AND BASIC OPTIONS) 72 (2014), healthplans.kaiserpermanente.org/federalemployees/wp-content/uploads/sites/2/2013/09/2014_KP_CAN_73-003_FEHB_brochure_131002_1_.pdf [<https://perma.cc/3V7V-HQR8>] (“[W]e will not cover [the service or drug] unless it is medically necessary to prevent, diagnose, or treat your illness, disease, injury, or condition.”). For the minority of plans that have nonperil medical necessity definitions, PrEP may satisfy this threshold language. For example, the Blue Cross Blue Shield’s medical necessity definition states that “[m]edical necessity shall mean . . . care . . . provide[d] to a patient for the purpose of preventing, evaluating, diagnosing, or treating an illness, injury, disease, or its symptoms.” BLUE CROSS & BLUE SHIELD ASS’N, BLUE CROSS AND BLUE SHIELD SERVICE BENEFIT PLAN 144 (2014), <http://www.opm.gov/healthcare-insurance/tribal-employers/plan-information/plan-codes/2014/brochures/71-005i.pdf> [<http://perma.cc/EN2B-JQV4>]; see also AETNA, AETNA HEALTHFUND CDHP/AETNA VALUE PLAN 143 (2014) [hereinafter AETNA HEALTHFUND CDHP], http://www.aetnafeds.com/pdf/2014/2014CDHP_ValueBrochure.pdf [<http://perma.cc/JWR4-SB89>] (“‘Medically necessary’ means . . . for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms . . .”); CIGNA, COLUMBIA UNIVERSITY HR BENEFITS SUMMARY PLAN DESCRIPTION 10 (2013), http://hr.columbia.edu/sites/default/files/document-files/2014/12/05/cigna_pos_100_officers.pdf [<http://perma.cc/TVT2-UVXA>] (defining medically necessary services as those “provided for the purpose of preventing, diagnosing or treating an acute Sickness, Injury, mental disorder”); UHA HEALTH INSURANCE, MEDICAL NECESSITY DECISION POLICY 1 (2013), https://www.uhahealth.com/uploads/forms/form_mis_medical-necessity-decision.pdf [<https://perma.cc/P45D-775U>] (defining medical necessity as “for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms”). Truvada as PrEP would appear to satisfy this threshold language because Truvada is furnished for the purpose of preventing a disease—HIV. However, even if PrEP satisfies one portion of the medical necessity definition contained in a nonperil contract, it may not satisfy other requirements under the plan’s medical necessary definition, such as the requirement that services must “not [be] primarily for the convenience of the patient.” CIGNA, *supra*, at 90.

197. Rosenbaum et al., *supra* note 185, at 50 tbl.2 (reciting Highmark Blue Cross Blue Shield’s 2000 medical necessity definition).

have been susceptible to benefit denials, as insurers could have argued that when treatment occurs in association with an illness that has not yet occurred or when the patient is asymptomatic, the beneficiary cannot be said to be suffering from any condition.¹⁹⁸ PrEP is *pre*-exposure treatment rendered prior to HIV infection. Accordingly, PrEP may have fallen outside the scope of basic policy language in multi-peril contracts pre-2013/2014.¹⁹⁹

However, after implementation of the ACA in 2014,²⁰⁰ all health plans in the individual and small group market, with the exception of grandfathered plans in force on or before March 23, 2010,²⁰¹ must cover a range of categories of treatments, *including* preventive care, under the EHBP.²⁰² In addition, under the PSP, insurers must also cover specific preventive treatments recommended by the USPSTF.²⁰³ Because individual and small group market insurers are required to offer preventive care pursuant to EHBP and PSP, insurers have begun modifying their medical necessity definitions to expressly include the term *prevention* alongside the terms *treatment* and *diagnosis* in their contractual scope language.²⁰⁴ For example, Blue Cross Blue Shield includes the following contractual scope language in one of its 2014 policies: “[W]e will not cover [a service or drug] unless we determine it is medically necessary to *prevent*, diagnose, or treat your illness, disease, injury, or condition.”²⁰⁵ All but one 2013-2014 commercial plan reviewed for this Article contain similar language.²⁰⁶ As a result of this change, oral PrEP could fall within the contractual scope of these post-ACA medical necessity definitions. After all, oral PrEP is prescribed to prevent the disease of HIV, which would likely satisfy the representative language above.

198. See Underhill, *supra* note 28, at 641–42.

199. See *id.*

200. See *infra* text accompanying note 291.

201. See *infra* Part IV.B.

202. See *infra* Part IV.B.

203. See *infra* Part IV.A.

204. See *infra* note 206 and accompanying text.

205. BLUE CROSS & BLUE SHIELD ASS’N, *supra* note 196, at 125 (emphasis added).

206. See AETNA HEALTHFUND CDHP, *supra* note 196, at 14 (“[F]or the purpose of preventing, evaluating, diagnosing, or treating an illness, injury or disease or its symptoms”); CIGNA, *supra* note 196, at 10 (“[P]rovided for the purpose of preventing, diagnosing or treating an acute Sickness, Injury, mental disorder”); UHA, *supra* note 196, at 1 (“[P]rovide to the patient for the purpose of preventing, diagnosing or treating an illness, injury, disease or its symptoms”). But see AETNA USC PLAN, *supra* note 196, at 90 (defining medical necessity as what is necessary and appropriate “for the diagnosis or treatment of a sickness[] or injury”).

On the other hand, some insurers, including Blue Cross Blue Shield, have begun specifically itemizing their covered preventive benefits.²⁰⁷ If PrEP is not a listed preventive treatment, an insurer could determine that PrEP falls outside the scope of the term *prevention* within its medical necessity definition, particularly if the insurer defines *prevention* as limited to the specific itemized preventions on the insurer's covered list. In addition, certain plans, such as grandfathered plans, may not include prevention in their contractual scope language.²⁰⁸ In these circumstances, an insured belonging to a high-risk group could argue that oral PrEP still satisfies the contractual scope element, as his or her increased susceptibility to HIV by virtue of high-risk conduct—or merely belonging to a high-prevalence group—is *itself* a condition for the purpose of satisfying threshold medical necessity language.²⁰⁹ In other words, the insured could argue during the appeals process that simply belonging to a high-risk group, such as the African-American MSM group in which the risk of infection is quite high, makes him or her more susceptible to contracting HIV.²¹⁰ Nonetheless, to argue that potential exposure to HIV by virtue of

207. E.g., GEISINGER HEALTH PLAN, GEISINGER CHOICE PPO WITH NO REFERRAL REQUIRED AND PREVENTIVE SERVICES: SUMMARY OF BENEFITS (2011), <https://www.thehealthplan.com/documents/smallbiz/PPOSOB.pdf>; HORIZON BLUE CROSS BLUE SHIELD OF N.J., HEALTH CARE REFORM: USING PREVENTIVE CARE FOR A HEALTHIER LIFE, (2013), http://www.horizonblue.com/sites/default/files/pdf/Preventive_Care_Guide_4-9-13.pdf [<http://perma.cc/NNP2-38ZD>]; see also CIGNA, A GUIDE TO CIGNA'S PREVENTIVE HEALTH COVERAGE FOR HEALTH CARE PROFESSIONALS 4–11 (2013), <http://www.cigna.com/assets/docs/health-care-professionals/807467h-Preventive-Health-Cov-Guide.pdf> [<http://perma.cc/527M-TXH3>] (listing Cigna's covered preventive benefits).

208. See *infra* note 314 and accompanying text.

209. There is at least one case that supports the idea that susceptibility to a disease can itself be considered an illness, particularly when there is a predisposition that makes the illness more likely and the susceptibility is a diagnosable condition. See *Katskee v. Blue Cross/Blue Shield of Nebraska*, 515 N.W.2d 645, 651 (Neb. 1994). For example, in *Katskee*, the Nebraska Supreme Court found that susceptibility to cancer was a condition, illness, or disease under policy terms. *Id.* at 653. However, the susceptibility in that case involved a genetic predisposition to breast cancer, and the susceptibility was itself a diagnosed condition—breast-ovarian carcinoma syndrome. *Id.* at 651.

210. It would also be possible for the insured to argue that the condition is “contact with and (suspected) exposure to [HIV],” which is a diagnosable condition. See 2015 ICD-10-CM Diagnosis Code Z20.6, ICD10DATA, <http://www.icd10data.com/ICD10CM/Codes/Z00-Z99/Z20-Z28/Z20-/Z20.6> [<http://perma.cc/4TGN-SKK8>] (last visited Mar. 25, 2015). However, a diagnosis of exposure to HIV likely indicates a PEP application and not a PrEP application. A PEP application, though related, is quite distinct. See *Body Fluid Exposure Procedure*, UMASS MEMORIAL 2 (2009), <http://www.umassmed.edu/PageFiles/47836/Body%20Fluid%20Exposure%20Procedure%205%2014%2008.pdf>

belonging to a high-risk group is a disease, illness, or condition may have dangerous consequences.²¹¹ This would risk perpetuating negative attitudes toward members of high-risk groups as it essentially associates membership in a high-risk group with pathology, abnormality, or sickness.²¹² It could be especially damaging to LGBT individuals, whose sexual orientation has been characterized by the medical community as pathological in the past.²¹³

There continues to be a great deal of variation in contractual scope language across benefit plans. For PrEP seekers with benefit plans that include prevention within the contractual scope language and explicitly include PrEP as a covered prevention, it is likely that oral PrEP meets the first element of the medical necessity analysis. On the other hand, for PrEP seekers with benefit plans that exclude prevention in their medical necessity definitions or that do not explicitly cover PrEP as a covered benefit, it is possible that benefits could be excluded based on the contractual scope element, as there are no federal or state laws or regulations requiring PrEP coverage.

ii. Standard Practice in the Industry

A standard practice element in multi-element medical necessity definitions relates primarily to a practitioner's judgment in comparison to practices across the industry.²¹⁴ Some benefit plans may refer to internal guidelines as to what standard practice means for that particular insurer.²¹⁵

The question with regard to oral PrEP here is whether PrEP treatment comports with standard industry practice given that the modality is relatively new and underutilized.²¹⁶ The FDA approval of Truvada for PrEP applications in high-risk groups should be instructive to utilization review administrators. However, the fact that PrEP is FDA approved does not necessarily mean that prescription of Truvada as PrEP is standard HIV prevention for members of high-risk groups. On the other hand, the final CDC guidelines recommending that primary care practitioners prescribe

[<http://perma.cc/AQG6-5ZG7>] (instructing practitioners to use the exposure to HIV/AIDS code for PEP). *But see* Stacey L. Murphy, AIDS Education & Training Centers National Center for HIV Care in Minority Communities Presentation: HIV/AIDS Care: The Diagnosis Code Series 2, at 9 (n.d.), www.healthhiv.org/modules/info/files/files_5152a91c11dde.pdf [<http://perma.cc/LMA7-ZK6S>] (indicating that an "exposure to HIV/AIDS" code may be appropriate for PrEP applications).

211. *See* Underhill, *supra* note 28, at 650.

212. *See id.*

213. *See id.*

214. *See* Rosenbaum et al., *supra* note 185, at 12.

215. *See id.*

216. *Id.* at 1.

PrEP for HIV prevention in high-risk groups have begun to move standard practice in the industry toward PrEP coverage.²¹⁷ If PrEP utilization continues to increase and the introduction of PrEP becomes regular protocol in provider-patient discussions about high-risk conduct, it is likely that an insured would meet this element of a medical necessity definition.

iii. Safety and Appropriateness

Safety and appropriateness language concerns whether the treatment “will be delivered in a manner that the insurer considers to be safe and effective.”²¹⁸ In determining the safety of a prescribed treatment, plan administrators consider whether scientific evidence supports the safety of the treatment for the patient.²¹⁹ Some benefit plans specifically define the term *scientific evidence* to include such evidence as “controlled clinical trials that either directly or indirectly demonstrate the effect of the treatment on health outcomes,” observational studies, peer-reviewed studies published in medical journals, major biomedical compendia, and research conducted in connection with federal institutes or health-related agencies.²²⁰

Although there has been some debate surrounding the actual effectiveness of Truvada as PrEP, potential side effects, and adherence, completed clinical trials of PrEP have indicated at least some appreciable effect of Truvada as PrEP on health outcomes.²²¹ In addition, both the FDA and the CDC have confirmed the safety and efficacy of Truvada.²²² Although

217. See generally *Public Reporting of Hospital-Acquired Infection Rates: Empowering Consumers, Saving Lives: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 109th Cong. 41 (2006) (“CDC guidelines serve as the standard of care in U.S. hospitals and guide the clinical practices of physicians, nurses and other providers.” (statement of Denise Cardo, Chief, Div. of Healthcare Quality Promotion, Centers for Disease Control and Prevention)); see also *supra* Part II.A; notes 147–49 and accompanying text.

218. Rosenbaum, *supra* note 185, at 12–13.

219. *Id.* at 8 (citing Sara Singer et al., *Decreasing Variation in Medical Necessity Decision Making: Final Report to the California HealthCare Foundation* (Aug. 1999) (unpublished manuscript) (on file with Center for Health Policy, Stanford University), <http://www.chcf.org/publications/1999/08/decreasing-variation-in-medical-necessity-decision-making> [<http://perma.cc/KT59-822U>]).

220. See UHA PLAN, *supra* note 196, at 5.

221. See *supra* notes 53–61 and accompanying text. The 2015-published trial of African women, which indicated no reduction in HIV acquisition, was abandoned due to low adherence. See Marrazzo et al., *supra* note 58.

222. See *supra* Parts II.A–B.2.

both agencies recognized some concerns about long-term side effects, subsequent research continues to indicate side effects are minimal. However, research is not complete, and given the continued debate over the safety and appropriateness of PrEP, there is still a risk that some insurers could deny coverage based on safety and appropriateness language.²²³

Utilization review administrators should be encouraged to grant more deference to the physician's determination of whether PrEP is safe and appropriate for the particular patient. A provider's decision to prescribe oral PrEP involves sensitive, in-depth conversations with a patient about contraindications, history of risk-taking behavior, power dynamics in relationships and intimate partner abuse, consideration of the particular risk group to which the patient belongs, history of condom usage, and a number of other factors that may not be easily articulated to insurers by the physician and may not be reflected in medical literature.²²⁴ If insurers give due weight to the provider's assessment of safety and appropriateness for the particular patient, it is likely that oral PrEP would satisfy this element of medical necessity definitions.

iv. Convenience

Under common definitions of medical necessity, a convenience element helps insurers weed out prescribed treatments that are not medical in nature, are meant primarily for the "comfort"²²⁵ or convenience of the patient or the provider, constitute "luxuries,"²²⁶ or result from the patient's "social or environmental" situation.²²⁷ Determinations of convenience are purportedly not based on the insurer's perspective; they involve consideration of the insured's and the provider's perspectives.²²⁸

Given that actual efficacy of condoms in practice is significantly lower than its ninety-five percent medical efficacy and that HIV rates have continued to rise in certain high-risk groups regardless of condom messaging, PrEP is more than a mere convenience for members of these communities; it is a medically necessary treatment.²²⁹ However, insurers

223. See Liz Highleyman, *AHF PrEP Ad Controversy: What Do the Numbers Mean?*, BETA BLOG, Sept. 2, 2014, <http://betablog.org/ahf-prep-ad-controversy-numbers-mean> [<http://perma.cc/37PN-USPH>].

224. See *CDC PrEP Research Summary*, *supra* note 57.

225. KAISER PLAN, *supra* note 196, at 38, 40, 42 (excluding "[c]omfort, convenience, or luxury equipment or features").

226. *Id.* at 38.

227. Rosenbaum, *supra* note 185, at 13.

228. See *id.*; e.g., UHA, *supra* note 196, at 1 ("Not primarily for . . . the convenience of the patient, treating physician, or other health care provider.").

229. See Matt Baume, *Does Hobby Lobby Have To Pay for My PrEP?*, ADVOCATE (Oct. 27, 2014, 7:00 AM), <http://www.advocate.com/31-days-prep/2014/10/27/does->

could argue that because Truvada as PrEP is primarily marketed and CDC recommended as an *extra* layer of protection in addition to condoms, it is unnecessary care because condoms are technically medically effective. Furthermore, if insurers, particularly religiously affiliated issuers, accept the notion that PrEP is a nonessential treatment meant to facilitate the preferred lifestyle choices of individuals seeking to engage in the pleasure of condomless sex or other high-risk conduct, such insurers may be less willing to cover PrEP treatment, even when the patient and provider both believe it is necessary care.²³⁰ High-risk patients who believe their denials are the result of discrimination would probably not be able to rely on the ACA's nondiscrimination provision, Section 1557, because those seeking PrEP are not HIV positive.²³¹

Each element of modern medical necessity clauses presents a different challenge for those seeking to prevent benefit denials. A further complicating factor vis-à-vis medical necessity is the variation in coverage determination processes across the industry and the lack of transparency. Utilization review practices vary widely from insurer to insurer, and insurers provide

hobby-lobby-have-pay-my-prep [<http://perma.cc/PVB9-5XR8>] (quoting Scott Schoettes, HIV Project Director at Lambda Legal, who emphasized that PrEP “is medically necessary care”).

230. In scenarios when condoms cannot be used as a primary line of defense, the insured would have a strong argument that PrEP is not a convenience treatment. For example, condoms cannot be used in the context of heterosexual serodiscordant couples attempting to reduce the risk of transmission to the fetus during conception and childbirth. *See Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions To Reduce Perinatal HIV Transmission in the United States*, AIDSINFO, <http://aidsinfo.nih.gov/guidelines/html/3/perinatal-guidelines/153/reproductive-options-for-hiv-concordant-and-serodiscordant-couples> [<http://perma.cc/Q7W7-LPVA>] (last updated Mar. 28, 2014). Condoms also cannot be used in the case of individuals with latex allergies. *See Latex and Contraception*, AM. LATEX ALLERGY ASS'N, <http://latexallergyresources.org/articles/latex-and-contraception> [<http://perma.cc/4VXF-JWNY>] (last visited Mar. 25, 2015).

231. *See* 42 U.S.C. § 300gg-5 (2012). Those experiencing discrimination in healthcare because of their HIV-positive status may seek protection of the ACA's antidiscrimination provision because this section prohibits discrimination based upon disability. *See id.* However, those taking PrEP are not infected and, hence, not disabled as a result of the HIV status. An argument that the benefit denial is a result of discrimination based upon the patient's sexual orientation would also likely fail because, as it stands, the section does not include discrimination based upon sexual orientation. *See* Ronald O. Valdiserri, Presentation at the Office of HIV/AIDS and Infectious Disease Policy of the U.S. Department of Health and Human Services: The ACA and LGBT Individuals: Delivering Culturally Competent Quality Care in Clinical Settings (May 20, 2014), <https://www.aids.gov/pdf/aca-lgbt-individuals.pdf> [<https://perma.cc/NL4U-STWS>].

little information to the public. The ACA has done little to regularize the prior authorization process or to establish common medical necessity definitions.²³² However, advocates could seek regulatory guidance that would help streamline utilization review across the industry, gain transparency, and help prevent future benefit denials.

IV. PREP IN THE POST-HEALTH REFORM LANDSCAPE

One potential solution to overcoming the multidimensional acceptability and accessibility challenges to fuller implementation of PrEP is health content regulation. This is only one piece of the puzzle, however; I do not argue that mandating benefits is the only answer, or even the best answer, to the problems advocates face in scaling up PrEP. However, mandating benefits would be a step toward gaining acceptability for and securing access to oral PrEP prevention. Given that full implementation of the ACA occurred this past year, I first examine whether there are any mechanisms to ensure access to PrEP under the ACA.²³³

President Barack Obama signed the ACA on March 23, 2010.²³⁴ Preliminary data shows that the ACA is having a remarkable impact on access to more affordable treatment for Americans,²³⁵ including HIV-positive individuals.²³⁶ By eliminating the preexisting condition requirement,

232. See B. Jessie Hill, *What Is the Meaning of Health? Constitutional Implications of Defining “Medical Necessity” And “Essential Health Benefits” Under the Affordable Care Act*, 38 AM. J.L. & MED. 445, 450 (2012).

233. See *Health Reform Implementation Timeline*, KAISER FAM. FOUND., <http://kff.org/interactive/implementation-timeline> (last visited Mar. 25, 2015) (detailing the provisions that took effect on January 1, 2014).

234. Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (codified as amended in scattered section of 42 U.S.C.). The President then signed The Health Care and Education Reconciliation Act of 2010 (HCERA) on March 30, 2010, which amended provisions of the ACA. Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 1124 Stat. 1029 (2010). References to the ACA in this Article refer to the ACA as amended by the HCERA. See Kyle Pettersen-Scott, Comment, *Prevent More, Spend More, Be Well: The Impact of the Affordable Care Act’s Provisions Regarding Preventive Care Coverage, Minimum Medical Loss Ratios, and Wellness Programs*, 4 N.C. CENT. U. BIOTECHNOLOGY & PHARMACEUTICAL L. REV. 26, 26 (2011).

235. Micah L. Berman, *A Public Health Perspective on Health Care Reform*, 21 HEALTH MATRIX 353, 353 (2011).

236. See *Affordable Care Act and Its Impact on People Living with HIV/AIDS*, AIDS ACTION COMMITTEE, <http://www.aac.org/media/blog/affordable-care-act-and-its-impact.html> (last updated Oct. 1, 2013); *The Affordable Care Act and HIV/AIDS*, AIDS.GOV (Nov. 21, 2014), <http://aids.gov/federal-resources/policies/health-care-reform> [<http://perma.cc/ZJ49-T9L8>]; Jennifer Kates & Rachel Garfield, *The ACA and People with HIV: The ACA’s Impact and the Implications of State Choices*, HEALTH AFFAIRS BLOG (Mar. 3, 2014, 4:05 PM), <http://healthaffairs.org/blog/2014/03/03/the-aca-and-people-with-hiv-the-acas-impact-and-the-implications-of-state-choices> [<http://perma.cc/2PHS-DSH3>].

the ACA has the potential to decelerate the spread of HIV by helping HIV-positive individuals gain access to ARVs and lower the virus's communicability.²³⁷ In addition to securing healthcare for HIV-positive individuals, the ACA has the potential to be a game-changer in the HIV prevention context. For example, the ACA requires that insurers offer free HIV testing to at-risk individuals.²³⁸ One analysis concluded that approximately 500,000 people might be tested over the next two years in connection with this requirement.²³⁹ If more states expand Medicaid,²⁴⁰ this number could rise dramatically. Researchers estimate that in the event all states expand Medicaid, HIV testing and diagnosis may increase thirty percent more, to over 1,103,024 people.²⁴¹ A significant increase in cost-free testing could lead to an increase in early HIV diagnosis, treatment, and viral suppression. As such, the impact on HIV incidence at the population level could be substantial.

Beyond facilitating greater access to HIV testing, how might the ACA's mandates affect the implementation of PrEP prevention? Does the ACA help resolve or further frustrate the acceptability and accessibility challenges to fuller implementation? In this Part, I consider the ACA's PSP, and the possibility of federal action under the EHBP.

A. *The ACA's Preventive Services Provision*

Title I of the ACA, which relates to health insurance access, contains a mandate requiring health insurers to provide cost-free access to certain preventive health services.²⁴² This section is often referred to as the

237. See 42 U.S.C. § 300gg-3 (2012).

238. See *infra* notes 276–277 and accompanying text.

239. Zachary Wagner et al., *The Affordable Care Act May Increase the Number of People Getting Tested for HIV by Nearly 500,000 by 2017*, 33 HEALTH AFFAIRS 378, 382 (2014).

240. As of this writing, twenty-eight states and the District of Columbia are expanding Medicaid, nineteen states have not expanded Medicaid, and three have not yet made a decision. *A 50-State Look at Medicaid Expansion*, FAMILIES USA, <http://familiesusa.org/product/50-state-look-medicaid-expansion-2014> [<http://perma.cc/D58C-CEK4>] (last updated Nov. 24, 2014); see also *Medicaid Expansion & What It Means for You*, HEALTHCARE.GOV, <https://www.healthcare.gov/medicaid-chip/medicaid-expansion-and-you/> [<https://perma.cc/98W8-VLHN>] (last visited Mar. 25, 2015) (noting that some states are expanding their Medicaid programs whereas others are not).

241. See Wagner, *supra* note 239, at 378, 382.

242. 42 U.S.C. § 300gg-13 (2012).

“preventive services” provision (PSP).²⁴³ The PSP requires that group health insurance plans and insurance issuers that are not grandfathered cover certain preventive services without cost sharing.²⁴⁴ This means that recommended preventive services must be offered cost-free for those carrying nongrandfathered commercial insurance.²⁴⁵ The ACA neither specifically defines covered services nor designates categories of covered services in this provision. Rather, Congress outsourced this determination. Under the PSP, preventive services offered cost-free must include “[e]vidence-based items or services that have in effect a rating of ‘A’ or ‘B’ in the current recommendations of the United States Preventive Services Task Force.”²⁴⁶

The USPSTF, originally convened in 1984 under the title “U.S. Public Health Service,”²⁴⁷ was established under the ACA for the purpose of “review[ing] the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services.”²⁴⁸ The Task Force consists of a “panel of non-Federal experts” in the areas of “prevention and evidence-based medicine” and is composed of “primary care providers.”²⁴⁹ This body represents the gold standard in preventive medicine guidance and its recommendations are intended for an audience of primary care physicians.²⁵⁰ The USPSTF contains sixteen volunteer

243. See Cogan, *supra* note 165, at 356–57.

244. 42 U.S.C. § 300gg-13. According to Healthcare.gov, a federal government website managed by the U.S. Centers for Medicare & Medicaid Services, cost sharing is the share of total costs, including copayments, deductibles, coinsurance, but not premiums, covered by the insurer that is paid by the insured. *Cost Sharing*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/cost-sharing> [<https://perma.cc/A5VA-9EVY>] (last visited Mar. 25, 2015).

245. See Berman, *supra* note 235, at 369.

246. 42 U.S.C. 300gg-13(a)(1).

247. Solicitation for Nominations for Members of the U.S. Preventive Services Task Force (USPSTF), 79 Fed. Reg. 14,045 (Mar. 12, 2014).

248. 42 U.S.C. § 299b-4(a)(1) (2012); see also Amanda Cassidy, *Health Policy Brief: Preventive Services Without Cost-Sharing*, HEALTH AFFAIRS 2–3 (Dec. 28, 2010), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_37.pdf [<http://perma.cc/FLM9-RNYE>] (“When analyzing a particular preventive service, the USPSTF estimates the benefits and harms based on a review of the clinical evidence.”).

249. *Newsroom*, U.S. PREVENTIVE SERVICES TASK FORCE (Jan. 2015), <http://www.uspreventiveservicestaskforce.org/Page/Name/newsroom> [<http://perma.cc/WY9H-VNHL>].

250. *About the USPSTF*, U.S. PREVENTIVE SERVICES TASK FORCE (Sept. 2014) <http://www.uspreventiveservicestaskforce.org/about.htm> [<http://perma.cc/KM7B-74AA>]; see also Berman, *supra* note 235, at 369 (noting all private health insurance carriers are required to provide full coverage for clinical preventive services recommended by the USPSTF (citing 42 U.S.C. 300gg-13)); Davis & Somers, *supra* note 144, at 66 (noting the USPSTF reviews the evidence base for preventive services and develops recommendations for the health care community); Pettersen-Scott, *supra* note 234, at 31 (discussing that the USPSTF is intended to provide primary care physicians with evidence-based information to aid in providing preventive services to their patients).

members serving four-year terms.²⁵¹ The ACA requires that Task Force members are “independent and, to the extent practicable, not subject to political pressure.”²⁵² Anyone may nominate a Task Force member, and nominations and applications are only viewable in person at the Agency for Healthcare Research and Quality’s (AHRQ) Center for Primary Care, Prevention, and Clinical Partnerships.²⁵³ Stated qualifications for members are “knowledge, expertise, and leadership” in evaluation of research, clinical prevention and primary care, and implementation of recommendations in clinical practice.²⁵⁴ Additionally, the AHRQ seeks members who have expertise in the following areas: (1) public health and reduction of health disparities, (2) women’s health, and (3) health issues affecting minorities.²⁵⁵

Duties of the Task Force include developing recommendations for the healthcare community,²⁵⁶ developing topics for recommendations,²⁵⁷ reviewing previous recommendations,²⁵⁸ providing assistance to healthcare professionals,²⁵⁹ and submitting yearly reports to Congress identifying gaps in research and recommending “priority areas . . . related to populations and age groups not adequately addressed by current recommendations.”²⁶⁰

Each recommendation issued by the Task Force, called a “Recommendation Statement,” receives an A, B, C, D, or I rating “based on the strength of the evidence and the balance of benefits and harms of a preventive service.”²⁶¹ Prior to issuing a final recommendation, the Task Force first drafts a research plan “that guides the recommendation process” and seeks public comment before issuing a final research plan.²⁶²

251. VIRGINIA MOYER ET AL., U.S. PREVENTIVE SERVS. TASK FORCE, HIGH-PRIORITY EVIDENCE GAPS FOR CLINICAL PREVENTIVE SERVICES: THIRD ANNUAL REPORT TO CONGRESS 3 (2013), <http://www.uspreventiveservicestaskforce.org/annlrpt3/annlrpt2013.pdf>.

252. 42 U.S.C. § 299b-4(a)(6) (2012).

253. Solicitation for Nominations for Members of the U.S. Preventive Services Task Force (USPSTF), 79 Fed. Reg. 14,045 (Mar. 12, 2014).

254. *Id.*

255. *See id.*

256. 42 U.S.C. § 299b-4(a)(1) (2012).

257. 42 U.S.C. § 299b-4(a)(2)(A) (2012).

258. 42 U.S.C. § 299b-4(a)(2)(B) (2012).

259. 42 U.S.C. § 299b-4(a)(2)(E) (2012).

260. 42 U.S.C. § 299b-4(a)(2)(F) (2012); *see, e.g.*, USPSTF 2013 Annual Report, *supra* note 251.

261. *About the USPSTF*, *supra* note 250.

262. *Recommendations in Progress*, U.S. PREVENTIVE SERVICES TASK FORCE (NOV. 2014), <http://www.uspreventiveservicestaskforce.org/Page/Name/topics-in-progress> [<http://perma.cc/ZTA3-W2K8>].

The Task Force then drafts an evidence report and a recommendation, for which it also seeks public comment, before issuing a final evidence report and recommendation statement.²⁶³ Comments are not made widely available to the public in electronic format.

As the Task Force considers a preventive treatment, it conducts a balancing of benefits versus harms.²⁶⁴ Among the five ratings, a rating of A or B indicates the health benefits “substantially outweigh [the] harms.”²⁶⁵ For preventive measures garnering these ratings, the USPSTF recommends clinicians offer the service and that patients partake.²⁶⁶ According to the PSP, covered insurers must offer A and B recommended services at no cost to the insured.²⁶⁷ Recommendations rated C indicate the Task Force has found the “net benefit is small,” and providers should “selectively offer[] . . . [the prevention] to individual patients based on professional judgment and patient preferences.”²⁶⁸ Recommendations rated D indicate the preventive service “has no net benefit or that the harms outweigh the benefits.”²⁶⁹ Finally, a rating of I indicates evidence is “insufficient to assess the balance of benefits and harms.”²⁷⁰ Under the PSP, insurers are under no obligation to cover services or treatments garnering C, D, or I recommendations.²⁷¹

263. *Id.* Since 2010, the Task Force has sought public comment on forty-seven draft research plans and recommendations. *Opportunity for Public Comment*, U.S. PREVENTIVE SERVICES TASK FORCE (Nov. 2014), <http://www.uspreventiveservicestaskforce.org/Page/Name/us-preventive-services-task-force-opportunities-for-public-comment> [<http://perma.cc/3UG6-ELHA>]; *Published Recommendations*, U.S. PREVENTIVE SERVICES TASK FORCE (Mar. 2015), <http://www.uspreventiveservicestaskforce.org/BrowseRec/Index> [<http://perma.cc/97NQ-B7VH>].

264. According to the USPSTF, the potential benefits of preventive services may include “reduction of risk factors to prevent disease, early identification of disease leading to earlier treatment, and, ultimately, improved health outcomes such as quality of life and length of life.” MOYER ET AL., *supra* note 251, at 5. Conversely, the potential harms of preventive services may include adverse effects, side effects, and treatment complications, in addition to the harms of “inaccurate test results that may lead to a cascade of additional followup tests (some of which are invasive and could cause harm) and unnecessary treatments.” *Id.* The USPSTF may also consider “the benefits and harms based on age, sex, and risk factors for the disease” when appropriate evidence exists. *Id.* The USPSTF states that it “does not *explicitly* consider costs in its appraisal of the effectiveness of a service[.]” *id.* (emphasis added), but this implies that the USPSTF may consider costs off the record.

265. *Id.*

266. *Id.*

267. 42 U.S.C. 300gg-13(a)(1) (2012).

268. *Grade Definitions*, U.S. PREVENTIVE SERVICES TASK FORCE (Feb. 2013), <http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm> [<http://perma.cc/66EM-M8N6>].

269. *Id.*

270. *Id.*

271. *See* 42 U.S.C. 300gg-13(a)(1).

As of this writing, the Task Force has issued draft or final recommendations on ninety-eight topics.²⁷² Of these, fifty-five evidence-based preventive services or treatments have received A or B recommendations.²⁷³ Of these fifty-five services, six recommendations are pharmacological preventions.²⁷⁴ Most, though not all, of the pharmacological preventions recommended for use with A and B ratings are vitamins, supplements, or over-the-counter pain relievers such as aspirin.²⁷⁵ The USPSTF has only issued two recommendations pertaining

272. *Published Recommendations*, *supra* note 263.

273. *USPSTF A and B Recommendations*, U.S. PREVENTIVE SERVICES TASK FORCE (Oct. 2014), <http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/> [http://perma.cc/D43D-5AWG].

274. *See id.* Three of these pharmacological prevention recommendations pertain to aspirin. *See id.*

275. First, the USPSTF has given a B recommendation to tamoxifen or raloxifene for women at risk of primary breast cancer, and a D recommendation to the same medication for women not at risk. *Breast Cancer: Medications for Risk Reduction*, U.S. PREVENTIVE SERVICES TASK FORCE (Sept. 2013), <http://www.uspreventiveservicestaskforce.org/uspstf13/breastcanmeds/breastcanmedsrs.htm> [http://perma.cc/4PS4-KCQS]. Second, a combination of exercise or physical therapy and vitamin D supplementation for people at risk of falls received a B rating from the USPSTF. *Vitamin D and Calcium To Prevent Fractures: Preventive Medication*, U.S. PREVENTIVE SERVICES TASK FORCE (Sept. 2013), <http://www.uspreventiveservicestaskforce.org/uspstf12/vitamd/finalrecvitd.htm> [http://perma.cc/SGPX-TJZJ]. Third, the USPSTF gave an A rating to the recommendation of folic acid for all women planning or capable of pregnancy to prevent certain birth defects. *Folic Acid to Prevent of Neural Tube Defects: Preventive Medication*, U.S. PREVENTIVE SERVICES TASK FORCE (Sept. 2013), <http://www.uspreventiveservicestaskforce.org/uspstf09/folicacid/folicacidrs.htm> [http://perma.cc/K59F-8DDQ]. Fourth, the USPSTF issued an A recommendation for the prescription of prophylactic ocular topical medication for all newborns for the prevention of neonatal conjunctivitis. *Ocular Prophylaxis for Gonococcal Ophthalmia Neonatorum: Preventive Medication*, U.S. PREVENTIVE SERVICES TASK FORCE (Sept. 2013), <http://www.uspreventiveservicestaskforce.org/uspstf10/gonoculproph/gonocup.htm> [http://perma.cc/BZ8H-MSM2]. Finally, a recommendation for low-dose aspirin for the prevention of preeclampsia in pregnant women received a preliminary rating of B from the USPSTF. *Low-Dose Aspirin for the Prevention of Morbidity and Mortality from Preeclampsia: Preventive Medication*, U.S. PREVENTIVE SERVICES TASK FORCE (Sept. 2014), <http://www.uspreventiveservicestaskforce.org/uspstf/uspsasp.htm> [http://perma.cc/5V59-DZ4J]. Of the other final preventive medication recommendations not garnering an A or B recommendation, aspirin received a D recommendation for the prevention of colorectal cancer. *Final Recommendation Statement: Aspirin/NSAIDs for Prevention of Colorectal Cancer: Preventive Medication*, U.S. PREVENTIVE SERVICES TASK FORCE (Mar. 2007), <http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/aspirin-nsaids-for-prevention-of-colorectal-cancer-preventive-medication> [http://perma.cc/98YV-48EU]. In addition, the Task Force ascribed a D rating to the use of combined estrogen and progestin for the prevention of chronic conditions in postmenopausal women and women who have had a

to HIV prevention. The Task Force recommends HIV screening for all adolescents and adults ages fifteen to sixty-five years old and all individuals at increased risk (rated A), as well as screening for all pregnant women, both those untested and in labor, and those whose HIV status is not known (both rated A).²⁷⁶ As such, covered insurers must offer HIV testing cost-free for those fitting these clinical profiles. According to the Task Force's website, no further recommendations pertaining to HIV are currently under consideration.²⁷⁷

With the passage of the ACA's PSP, the USPSTF has become the sole body that determines preventive healthcare for millions of Americans. Its recommendations not only affect private insurers covered under the provisions but also governmental insurers such as Medicare²⁷⁸ and Medicaid.²⁷⁹ As such, the impact of a USPSTF A or B recommendation

hysterectomy, thereby recommending against its use. *Menopausal Hormone Therapy: Preventive Medication*, U.S. PREVENTIVE SERVICES TASK FORCE (Sept. 2013), <http://www.uspreventiveservicestaskforce.org/uspstf/uspspmho.htm> [<http://perma.cc/7URM-5FSF>]. Finally, the Task Force recommended against the use of Vitamin D for the prevention of fractures and vitamin E for the prevention of cardiovascular disease. These received a rating of D and I (inconclusive), respectively. *Vitamin Supplementation To Prevent Cancer and CVD: Counseling*, U.S. PREVENTIVE SERVICES TASK FORCE (Feb. 2014), <http://www.uspreventiveservicestaskforce.org/uspstf14/vitasupp/vitasuppfinalrs.htm> [<http://perma.cc/VSV7-K4JR>].

276. MOYER ET AL., *supra* note 251, at 9, 25.

277. *Published Recommendations*, *supra* note 263.

278. Medicare is "the largest payer for health services for American adults." Lesser et al., *supra* note 154, at 44. The ACA specifically requires that Medicare cover all preventive services with A or B recommendations without cost-sharing. See Lynda Flowers & Lynn Nonnemaker, *Improvements to Medicare's Preventive Services Under Health Reform*, AARP PUB. POL'Y INST. 1 (2010), <http://assets.aarp.org/rgcenter/ppi/health-care/fs180-preventive.pdf> [<http://perma.cc/N5PJ-7E7R>]. Because the ACA has caused Medicare preventive services to track USPSTF recommendations, a USPSTF recommendation directly impacts whether Medicare will cover a specific prevention cost-free.

279. Under the ACA, A or B recommendation from the Task Force affects access to free preventive care for Medicaid beneficiaries. The federal government pays states with existing Medicaid programs an additional one percent in matching funds to cover costs of the A and B recommended preventive services they offer cost-free. See Cogan, *supra* note 165, at 357. Advocates have called this a "strong financial incentive for states to provide [preventive care] without cost-sharing." *Id.* In addition, states expanding their Medicaid programs must offer all USPSTF A and B recommendations without cost-sharing. See Lindsey Dawson, Pub. Policy Assoc., The AIDS Inst., Presentation at the United States Conference on AIDS: The Impact of the ACA and USPSTF Grade Change on Coverage of HIV Testing (Sept. 9, 2013), www.theaidsinstitute.org/sites/default/files/attachments/Testing_Dawson%20USCA%202013.pdf [<http://perma.cc/9G3K-U963>]. One expert has even predicted that as a result of the change to a uniform set of preventive care standards in Medicare and Medicaid, ninety-five percent of all nonelderly U.S. residents could receive preventive care coverage with no cost-sharing by 2016. See Cogan, *supra* note 165, at 357 (citing CBO's *March 2011 Estimate of the Effects of the Insurance Coverage Provisions*

for Truvada as PrEP would be wide reaching. An A or B recommendation from the Task Force would effectively provide cost-free access to Truvada as PrEP for beneficiaries of most private and all governmental healthcare issuers. This would have a significant impact on utilization of PrEP, as offering PrEP cost-free creates a financial incentive for all high-risk individuals to ask their healthcare providers about it.²⁸⁰ Cost-free access to PrEP would especially impact utilization by high-risk individuals of low socioeconomic status, such as young MSM, intravenous drug users, and sex workers.

In addition, an A or B recommendation for PrEP would be a substantial step toward making PrEP more acceptable to high-risk communities, as the widespread availability and greater utilization of PrEP will help eliminate stigma, and to healthcare providers who might use the recommendation as a means of introducing PrEP as an option for patients who fit the clinical profile. An A or B rating for PrEP would also align the USPSTF with the CDC guidance, which may increase the legitimacy of PrEP as HIV prevention in the minds of providers. Furthermore, such a rating would combat individual and structural stigma, as universal coverage for PrEP would likely require coding and billing changes and help change traditional assumptions about HIV prevention.

Despite the wide-ranging positive impact an A or B recommendation for PrEP would have on implementation efforts, a favorable recommendation for PrEP may not be possible without limiting the scope of the recommendation to certain clinical profiles. There are at least three reasons for this. First, in light of the backlash in the medical community that has resulted from recommendations for politically neutral treatments,²⁸¹

Contained in the Patient Protection and Affordable Care Act (Public Law 111-148) and the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152), CONG. BUDGET OFF. (Mar. 18, 2011), http://www.cbo.gov/sites/default/files/HealthInsuranceProvisions_1.pdf [<http://perma.cc/EPA4-65MN>].

280. Cf. Cogan, *supra* note 165, at 356–57.

281. In the post-health reform environment, even seemingly politically neutral preventions that receive a negative recommendation have engendered debate in both the medical and public health communities due to the recommendation's impact on access to healthcare nationwide. See Berman, *supra* note 235, at 373 (“The general reaction to the USPSTF's recommendations . . . range[] from confusion to intense anger.”); see, e.g., Bradley Anderson, *Scared of Obamacare's IPAB? Meet the USPSTF!*, AM. SPECTATOR (Feb. 27, 2013), <http://spectator.org/articles/33836/scared-obamacares-ipab-meet-uspstf> [<http://perma.cc/BCH5-VL44>]. For example, the Task Force issued a C recommendation for annual mammograms for women between the ages of forty and forty-nine. This rating, effectively meaning that the measure should be “selectively” offered to patients based on

it stands to reason that the Task Force would proceed cautiously with respect to PrEP, which generates controversy even in the high-risk groups who stand to benefit from the prevention. PrEP used in the context of certain clinical profiles, such as in the context of monogamous, serodiscordant couples trying to conceive, may be less controversial than in other contexts. Even the AHF, one of the biggest opponents to broader PrEP rollout, has recommended PrEP in this context.²⁸² Second, the Task Force may perceive that the cost-benefit analysis more clearly supports a positive recommendation for PrEP in certain clinical profiles. Again in the context of heterosexual serodiscordant couples using PrEP during conception attempts, concern about the impact of risk compensation is reduced. In addition, the risk of long-term side effects and concern about viral resistance and long-term adherence are lessened because the HIV-negative female in this context may only undergo PrEP treatment for a finite period of time—before and during pregnancy—whereas PrEP prevention in other risk groups requires treatment in perpetuity.²⁸³ Finally, PrEP treatment comes at a significant cost, and mandating widespread cost-free coverage across all risk groups may not be economically

professional judgment and patient wishes, was met with a great deal of resistance by the medical community. *See, e.g.,* Berman, *supra* note 235, at 371–74; Harold Pollack, *Health Reform and Public Health: Will Good Policies but Bad Politics Combine To Produce Bad Policy?*, 159 U. PA. L. REV. 2061, 2068 (2011); Ben Hartman, *How ACA May Impact Preventive Care*, EVERYDAY HEALTH (Nov. 13, 2013), <http://www.everydayhealth.com/columns/ben-hartman-healthcare-reform-and-you/how-aca-may-impact-preventive-care> [<http://perma.cc/UK6T-Z7X8>]; Emily P. Walker, *AMA Bucks USPSTF on Mammography*, ABCNEWS (June 19, 2012), <http://abcnews.go.com/Health/ama-bucks-uspstf-mammography/story?id=16605261> [<http://perma.cc/AD9F-N3F9>].

282. *See* text accompanying note 101.

283. *See PrEP for HIV Prevention, supra* note 13.

feasible.²⁸⁴ In the pregnancy context, however, issues of cost are lessened because treatment is finite.²⁸⁵

There are at least two drawbacks to this incremental approach. First, seeking cost-free access for one select group that comprises a small percentage of the high-risk pool may have little effect on wider implementation and HIV incidence rates at the population level. Second, focusing on heterosexual serodiscordant couples to the derogation of other risk groups has the potential to further marginalize minority populations, such as the LGBT community, with unique health needs about which the medical community has been skeptical in the past. Nonetheless, should the Task Force grant a favorable recommendation for PrEP in the context of heterosexual serodiscordant relationships, this could increase the acceptability of PrEP and engender a broader PrEP mandate under the PSP in the future.

Regardless of the scope of a PrEP recommendation, advocates should work toward effectuating Task Force reform. Systemic changes to the Task Force are needed to place checks upon an organization that under the ACA now acts under color of federal law. Furthermore, because the USPSTF has the power under the ACA to directly impact access to preventive services for millions of Americans, its members are susceptible to the influence of special interests, including the health insurance industry.²⁸⁶ In fact, Congress appeared to recognize this concern in the text of the ACA itself, as evidenced by the requirement that Task Force members are “independent and, *to the extent practicable*, not subject to

284. There are currently no Task Force recommendations mandating cost-free coverage for medications as costly as Truvada, for which there is no generic equivalent. See *supra* note 70 and accompanying text. Tamoxifen, which received a B recommendation for women at risk of breast cancer, is available in generic form and costs approximately \$100 per month. Alicia Ault, *Will 100% Coverage Spur More Use of Breast Cancer Chemopreventives?*, ONCOLOGY PRAC. (Jan. 22, 2014), <http://www.oncologypractice.com/single-view/will-100-coverage-spur-more-use-of-breast-cancer-chemopreventives/0887cd67af911c29b8a1db55b812d0b3.html> [<http://perma.cc/95H3-QF59>]; *Facts for Life: Tamoxifen*, SUSAN G. KOMEN FOR CURE 2 (last visited Mar. 25, 2015), http://ww5.komen.org/uploadedFiles/Content_Binaries/806-326a.pdf [<http://perma.cc/WQV4-LH97>]; see also Rita Rubin, *Raloxifene or Tamoxifen: Which Is the Right Drug for You?*, USA TODAY (Apr. 17, 2006, 10:01 PM), http://usatoday30.usatoday.com/news/health/2006-04-17-q-and-a-drug_x.htm [<http://perma.cc/WXN7-ADPZ>] (noting that, according to the National Cancer Institute, the average cost of the generic form of tamoxifen is approximately \$100). The average cash price of Truvada is over \$1000 per month. See *supra* note 156 and accompanying text.

285. See *PrEP for HIV Prevention*, *supra* note 13.

286. See text accompanying *supra* note 252.

political pressure.”²⁸⁷ Those seeking Task Force reform should advocate for more transparency. This could be achieved by pushing for (1) a more transparent appointment process by making nominations and applications more widely available and holding public appointment hearings, (2) publication of comments on draft recommendations through a more formal notice and comment procedure, (3) hearings on draft recommendations, and (4) further limitations on member service. Such reforms could potentially be achieved through HHS regulation, executive order, or congressional act.

In addition, the Task Force should be encouraged to broaden the scope of the “special populations” it considers.²⁸⁸ At this time, special populations include only two groups: (1) children and adolescents, and (2) older adults.²⁸⁹ The Task Force should commit to developing preventive care recommendations pertaining to the primary care of members of minority populations, such as LGBT individuals, whose preventive care needs may be different from those of the general population. Broadening the Task Force’s duties to include consideration of minority populations could be achieved through regulation. For example, HHS could provide guidance as to what groups *special populations* should include.

B. The ACA’s Essential Health Benefits Provision

The second major provision of the ACA affecting preventive healthcare is what is often referred to as the “essential health benefits” provision (EHBP).²⁹⁰ Starting in 2014, the ACA mandates coverage of “essential health benefits” in state health insurance exchanges, which includes states opting to expand their Medicaid programs.²⁹¹ In the exchanges, this mandate applies to individual and small group plans.²⁹² All must offer a package containing ten categories of services:

[A]mbulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; *preventive and wellness services* and

287. 42 U.S.C. §299b-4(a)(6) (2012) (emphasis added).

288. See *Special Populations*, U.S. PREVENTIVE SERVICES TASK FORCE (Aug. 2014), <http://www.uspreventiveservicestaskforce.org/populations.htm> [<http://perma.cc/RH3X-XMZE>].

289. *Id.*

290. 42 U.S.C. § 18022 (2012).

291. *Id.* § 18022(a)–(b).

292. 42 U.S.C. § 18021 (2012).

chronic disease management; and pediatric services, including oral and vision care.²⁹³

The ACA and the regulations promulgated thereunder do not specify what services must be covered by insurers in any required category.²⁹⁴ In fact, the ACA specifically forbids HHS from making “coverage decisions.”²⁹⁵ Rather, individual coverage of specific preventions is to be determined at the state level.²⁹⁶ To effect this, HHS implemented a “benchmark plan” mechanism on January 1, 2014.²⁹⁷ States may select a benchmark plan from three of the largest plans operating in their state²⁹⁸ based upon standards established by regulation.²⁹⁹ The benchmark plan “serves as a reference plan” for other insurers operating in the state.³⁰⁰ Under the EHBP, all benchmark plans must cover preventive care³⁰¹ and offer all of the cost-free services required under the PSP³⁰² and any other services required by federal or state law.³⁰³ The benefits packages offered by insurers in the states covered by the EHBP must be “substantially equal” to benchmark plan benefits.³⁰⁴ Insurers may offer additional preventive services or may deny coverage for services not specifically required by federal or state law, as long as their plans remain substantially equal.³⁰⁵

293. *Id.* § 18022(b)(1) (emphasis added); see *Essential Health Benefits*, HEALTH CARE.GOV, <https://www.healthcare.gov/glossary/essential-health-benefits> [https://perma.cc/J3SQ-QKE3] (last visited Mar. 25, 2015).

294. *E.g.*, 45 C.F.R. § 800.105 (2013).

295. 42 U.S.C. § 18022 (b)(4)(B).

296. *E.g.*, CAL. CODE REGS. tit. 10, § 2594.3 (2014).

297. 45 C.F.R. § 800.105(c).

298. 45 C.F.R. §§ 156.100, 156.110 (2013). States that do not select a benchmark plan are assigned the largest plan by enrollment within the state. *Id.* § 156.100. For a list of benchmark plans in all fifty states, see *Additional Information on Proposed State Essential Health Benefits Benchmark Plans*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/CCIIO/Resources/Data-Resources/ehb.html> [http://perma.cc/Q7ZR-992D] (last visited Mar. 25, 2015).

299. 45 C.F.R. § 800.105(c).

300. CTR. FOR CONSUMER INFO. & INS. OVERSIGHT, *ESSENTIAL HEALTH BENEFITS BULLETIN 8* (2011), http://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf [http://perma.cc/EX2C-NNLZ].

301. See 42 U.S.C. § 18022(b)(1) (2012).

302. 45 C.F.R. § 147.130 (2013).

303. See *Additional Information on Proposed State Essential Health Benefits Benchmark Plans*, *supra* note 298.

304. 45 C.F.R. § 800.105(b) (2013).

305. See 45 C.F.R. § 147.130(a)(2) and the conclusion to example 4.

Because PrEP treatment is not a required benefit under the PSP or required under any federal or state law, benchmark plans that decide to cover PrEP do so on their own accord. If they cover PrEP, it is likely that other exchange insurers operating in the state would follow suit. However, it is possible that other insurers in the state could decide not to cover PrEP at all. Insurers who deny coverage outright could argue that denying coverage of PrEP for requesting beneficiaries, who likely comprise a small fraction of their member base, does not affect the value of the prevention package to members in their health plan as a whole. Thus, insurers could argue that essential health benefits offered continue to be substantially equal and actuarially equivalent to the benchmark plan's package, even without PrEP coverage. On the other hand, PrEP proponents could argue that, from the perspective of individual policy members whose plans reject their PrEP benefit requests, denying such benefits leaves their preventive care packages substantially unequal to benchmark plans that cover PrEP. Alternatively, if some benchmark plans begin denying coverage for oral PrEP, this could lead to an onslaught of denials within those state exchanges. Accordingly, it is possible that coverage of oral PrEP in the future could vary from insurer to insurer and from state to state, which could frustrate accessibility to PrEP and further complicate a large-scale rollout. There are actions, however, that HHS could take to create some uniformity in how insurers determine coverage for PrEP.

The ACA explicitly states HHS may not “make coverage decisions,” so it is unlikely HHS could mandate PrEP coverage as an essential health benefit through regulation.³⁰⁶ However, HHS may be able to promulgate regulations that would have the effect of streamlining the utilization review process for those seeking PrEP. The ACA contains a provision that places some limitation on the Secretary's ability to regulate the utilization review process:

Notwithstanding any other provision of the [ACA], nothing . . . shall be construed to—prohibit (or authorize the Secretary of Health and Human Services to promulgate regulations that prohibit) a group health plan or health insurance issuer from carrying out utilization management techniques that are commonly used as of [the date of enactment of the ACA].³⁰⁷

The above limitation on the Secretary's power to regulate utilization review contains several definitional ambiguities. First, the ACA does not define “utilization management techniques,”³⁰⁸ and HHS could promulgate

306. 42 U.S.C. § 18022(b)(4)(B) (2012).

307. 42 U.S.C. § 18120(1) (2012).

308. Sara Rosenbaum et al., *The Essential Health Benefits Provisions of the Affordable Care Act: Implications for People with Disabilities*, COMMONWEALTH FUND 4

regulations defining the term. Second, there is an open question as to which “commonly used” techniques HHS is actually barred from prohibiting, because the ACA also does not define that term.³⁰⁹ This, too, may be an appropriate subject for regulatory guidance. Third, while this provision explicitly states HHS must not promulgate regulations that *prohibit* commonly used utilization management techniques, the provision does not forbid HHS from (a) *promoting* certain baseline utilization techniques, (b) regulating—though not *prohibiting*—the utilization techniques HHS determines are already “commonly used” in the industry, or (c) prohibiting utilization techniques HHS determines are *not* “commonly used” in the industry.³¹⁰

HHS could require that administrators reviewing prior authorization requests for medical necessity take into consideration the specific needs of high-HIV-incidence groups, such as the MSM group, which need other prevention options in light of the uptick of HIV incidence and the decrease of condom usage. This would be a step toward a set of medical necessity standards that are tailored to specific minority populations and their unique healthcare needs. Such action is supported by HHS’s broad discretion under the ACA to ensure nondiscrimination.³¹¹ In fact, the ACA explicitly states that the Secretary must “take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups.”³¹² Furthermore, HHS could add transparency to the process by requiring that insurers disclose more about their utilization review techniques.

There would certainly be objections from healthcare issuers to these regulatory actions. After all, insurers are protective of their own utilization review techniques and hostile to federal interference with a process that has historically been the province of healthcare providers. Insurers could argue that the ACA provision limiting the Secretary’s power vis-à-vis utilization review expresses Congress’s intent to forbid the federal government from interfering in coverage determinations. However, federal guidance pertaining to the utilization review process could increase

(Mar. 2011), https://publichealth.gwu.edu/departments/healthpolicy/DHP_Publications/pub_uploads/dhpPublication_E985318A-5056-9D20-3D44CD4E8D0F288B.pdf [<https://perma.cc/XQA2-4HBL>].

309. See 42 U.S.C. §18120(1).

310. See *id.*

311. 42 U.S.C. § 18022(b)(4)(A)–(C) (2012).

312. 42 U.S.C. § 18022(b)(4)(C).

consumer awareness of coverage policies. Indeed, in the context of PrEP, there is little information about insurers' PrEP coverage policies across the industry. Requiring disclosure of these policies would allow PrEP seekers to make more informed decisions about which insurer to choose—if choice of insurer is even an option—and would give PrEP advocates a means of collecting information and detecting variations in oral PrEP coverage nationwide.

C. State Mandated Benefit Laws

In addition to devising ways to ensure access to benefits for PrEP at the federal level, PrEP proponents should explore mandating benefits for PrEP at the state level through the passage of new mandated benefit laws and the amendment of existing ones.

Mandated benefit laws are laws requiring state-licensed group health insurance plans to cover specific healthcare benefits in their plans.³¹³ These mandates generally do not apply to government payers, such as Medicare and Medicaid, or to self-insured employers who are exempt under the Employee Retirement Income Security Act.³¹⁴ The purpose of a mandated benefit law is to provide access to treatments that employers might not choose to cover and to safeguard reimbursement for healthcare providers.³¹⁵ Examples of benefits subject to state mandated benefit laws include treatments for autism,³¹⁶ chiropractic therapy,³¹⁷ breast reconstruction,³¹⁸ certain cancer treatments in clinical trials,³¹⁹ and off-label use of prescription medication for the treatment of HIV/AIDS.³²⁰

313. See SARA S. BACHMAN ET AL., COMPREHENSIVE REVIEW OF MANDATED BENEFITS IN MASSACHUSETTS: REPORT TO THE LEGISLATURE 1 (2008), <http://mass.gov/chia/docs/r/pubs/mandates/comp-rev-mand-benefits.pdf> [<http://perma.cc/8DTE-W893>]; Mariam J. Laugesen et al., *A Comparative Analysis of Mandated Benefit Laws, 1949–2002*, 41 HEALTH SERVICES RES. 1081, 1083 (2006), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1713218> [<http://perma.cc/3S4J-LMS3>].

314. BACHMAN, *supra* note 313, at 7 (citing Gail A. Jensen & Michael A. Morrissey, *Employee-Sponsored Health Insurance and Mandated Benefit Laws*, 77 MILBANK Q. 425, 426 (1999)).

315. *Id.* at 8 (citing Laugesen et al., *supra* note 313, at 1083–84).

316. See *Insurance Coverage for Autism*, NAT'L CONF. ST. LEGISLATURES (Aug. 2012), <http://www.ncsl.org/research/health/autism-and-insurance-coverage-state-laws.aspx> [<http://perma.cc/H3VH-VYUU>].

317. *E.g.*, WASH. REV. CODE ANN. § 48.43.045 (West 2008); WASH. ADMIN. CODE § 284-43-205 (2014), <http://app.leg.wa.gov/wac/default.aspx?cite=284-43-205> [<http://perma.cc/N6GE-VUEG>].

318. *E.g.*, CONN. GEN. STAT. ANN. § 38a-504c (West 2007).

319. *E.g.*, S.B. 409, 2000 Sess. (N.H. 2000).

320. *E.g.*, MASS. GEN. LAWS ch. 176, § 47P (2011). For a state-by-state list of mandates, see *Additional Information on Proposed State Essential Health Benefits Benchmark Plans*, *supra* note 298.

Mandated benefit laws are not limited to treatment of illnesses, conditions, or diseases, however. There are also numerous preventive services covered by mandated benefit laws, including prenatal HIV prevention, contraception, colorectal cancer screening, and genetic testing.³²¹ In fact, across all mandated benefit laws, coverage of preventive care is the one of the most common types of mandated benefit.³²²

There are several potential justifications for passing new mandated benefit laws for oral PrEP.³²³ If insurers begin to deny coverage for PrEP, the potential adverse impact on HIV prevention within the state may be a justification.³²⁴ The underutilization of PrEP as an HIV prevention tool in a state, especially when it could significantly reduce HIV incidence with a broader uptake, may also be a justification.³²⁵ Additionally, PrEP accessibility issues that are the result of some injustice within the healthcare industry, such as institutional and provider biases against PrEP, expensive specialty drug tiering of ARVs that steers away risk, or outright discriminatory practices, may also be a sufficient justification.³²⁶ Furthermore, failures at the federal level, such as a negative USPSTF recommendation, legislative or regulatory inertia, or other health reform failures, might be a worthy justification for a state mandate.³²⁷ Finally, a favorable cost-benefit financial analysis for PrEP would also justify required coverage.³²⁸

A state-mandated benefit for PrEP would enable greater access to the treatment and could generate more meaningful conversations between

321. See Laugesen et al., *supra* note 313, at 1087–88.

322. As of 2002, there were 295 laws pertaining to preventive care, which covered a range of seventeen benefits. See *id.* at 1081.

323. See Amy B. Monahan, *Value-Based Mandated Health Benefits*, 80 U. COLO. L. REV. 127, 127 (2009) (arguing that mandated benefit laws must be supported by “precise” justifications so that the laws may be “tailored to solving the problem[s] which justify [their] existence”). Another approach to mandating benefits for PrEP treatment at the state level would be amending existing mandates requiring insurers to cover HIV medication for the *treatment* of HIV infection by inserting language that would require insurers to cover HIV medication for the *prevention* of HIV. See, e.g., WIS. STAT. § 632.895(9) (2014); OFFICE OF THE COMM’R OF INS., STATE OF WIS., PI-019, FACT SHEET ON MANDATED BENEFITS IN HEALTH INSURANCE POLICIES 5 (2012), http://oci.wi.gov/pub_list/pi-019.pdf [<http://perma.cc/88XL-QRTD>].

324. See Monahan, *supra* note 323, at 133.

325. See *id.* at 136.

326. See *id.* at 139.

327. See *id.* at 200.

328. A financial analysis of the costs and benefits of a PrEP mandate is beyond the scope of this Article.

patients and providers about HIV risk, which may help eradicate PrEP-related stigma. It would also mitigate, at the state level, the prior authorization and medical necessity issues that PrEP may face in the future. However, those seeking a mandated benefit law for PrEP will need to answer a number of questions. What states should proponents target?³²⁹ Are there not incentives in the system for insurers to cover oral PrEP if it is truly beneficial? Is it economically feasible? Would a PrEP mandate lead to an increase in consumer costs across the plan because premiums could increase? Would a PrEP mandate lead to reduction or abandonment of coverage by employers? Would a PrEP mandate be sustainable in today's political climate?

In addition, proponents of mandated benefits for PrEP will also need to determine whether religious exemptions are necessary after the U.S. Supreme Court's *Burwell v. Hobby Lobby* ruling, in which the Court sustained a free exercise challenge to an HHS oral contraceptive mandate that did not contain such an exemption.³³⁰ Could a religiously affiliated insurance issuer refuse to comply with a PrEP mandate by arguing that requiring coverage substantially burdens the free exercise of religion? As the insurer in *Hobby Lobby* successfully argued in the context of birth control, religiously affiliated insurers could argue that requiring them to cover PrEP makes them complicit in conduct, such as MSM intercourse or intravenous drug use, that their religion proscribes. Although a substantive analysis of the *Hobby Lobby* decision and its potential effect on HIV prevention efforts is beyond the scope of this Article, the decision does suggest that if there is an important public health goal, such as eradicating HIV/AIDS, that cannot be achieved through a less restrictive means other

329. Those preparing to seek a mandated benefit for PrEP should focus on states that have (1) moved progressively on mandated benefit laws in the past, and (2) high rates of HIV incidence. As of 2011, states with the highest HIV incidence were California (5965, 11.9%), Florida (5394, 10.8%), Texas (5044, 10.1%), New York (4944, 9.9%), and Georgia (2520, 5.0%). *The HIV/AIDS Epidemic in the United States*, KAISER FAM. FOUND. (Apr. 7, 2014), <http://kff.org/hivaids/fact-sheet/the-hivaids-epidemic-in-the-united-states> [http://perma.cc/4T9S-AVU9]. As of 2002, Maryland had the most mandated benefit laws (52), then California (45), then Texas (41). Laugesen, *supra* note 313, at 1089. Northeastern states tend to mandate more preventive services than other states. MARIS A. BONDI & MOLLY E. FRENCH, P'SHIP FOR PREVENTION, PREVENTIVE SERVICES: HELPING STATES IMPROVE MANDATES 4 (2002), www.prevent.org/downloadStart.aspx?id=29 [http://perma.cc/B7U9-3R99].

330. *Burwell v. Hobby Lobby Stores, Inc.*, 134 S. Ct. 2751, 2779 (2014); *see also* Baume, *supra* note 229 (noting that “[i]n the wake of the *Hobby Lobby* ruling, gay men may be vulnerable to employers who would attempt to block access to HIV drugs” for religious purposes).

than mandating coverage without religious exemptions, then such a mandate need not contain a religious exemption.³³¹

V. CONCLUSION

HIV PrEP is not a “magic pill” to prevent HIV infection. However, even as an interim solution on the road to a vaccine and a cure, PrEP has remarkable potential—to arrest the increase in HIV incidence, to mitigate the effects of condom decline, and to eliminate the omnipresent prevention fatigue among high-risk communities.

As PrEP advocates continue efforts to scale up utilization, a number of challenges follow them. PrEP stigma continues at the self-imposed, individual, and institutional levels. In addition, PrEP advocates are working to modernize a healthcare system that developed its approach to HIV prevention during the 1980s and 1990s and that does not yet have the scaffolding to provide efficient and affordable access to this new prevention modality. As advocates work to remove accessibility barriers, they should not ignore the possibility of benefit denials. These acceptability and accessibility challenges must be approached from multiple angles to achieve greater, sustainable utilization.

One solution, though there are certainly more, is health content and utilization review regulation. Governmental action requiring insurers to cover PrEP and help streamline the barriers to access is an option that would thrust PrEP into the mainstream, make it easier to obtain, and provide an economic incentive for members of high-risk groups to actually obtain it. Of course, analysis of the economic feasibility of these proposals is needed, as is additional scholarship brainstorming other post-health reform law and policy solutions to eliminating acceptability and accessibility hurdles to PrEP implementation.

Nonetheless, the government has an obligation to sustain the new dynamism in HIV prevention discourse brought about by oral PrEP. PrEP has injected new energy into the fight against HIV, which incidence we desperately need to reduce. High-risk communities are engaged in a

331. See *Hobby Lobby*, 134 S. Ct. at 2783 (“Our decision should not be understood to hold that an insurance-coverage mandate must necessarily fall if it conflicts with an employer’s religious beliefs. Other coverage requirements, such as immunizations, may be supported by different interests (for example, the need to combat the spread of infectious diseases) and may involve different arguments about the least restrictive means of providing them.”).

vigorous and productive debate about PrEP in a way they have never engaged in HIV prevention before—on social media, in public gathering spaces, at rallies, in the doctor’s office, among friends, and in the bedroom. In the words of PrEP advocate Jim Pickett: “PrEP gives us an entry point to talk about [condomless sex] in a way that’s helpful. We can talk about effectiveness and reframe condoms. We can reframe how we talk about protection and safer sex.”³³² Indeed, PrEP has actually increased at-risk individuals’ eagerness to get involved in public health issues. Moreover, PrEP has the potential to give at-risk individuals more control over and more investment in their health.³³³ Our government must ensure that this revolution continues.

332. S.F. AIDS FOUND., *supra* note 130, at 10.

333. *See id.* (“PrEP is a tool that empowers individuals to be proactive, take control, and plan ahead . . .”).