Pre-Exposure Prophylaxis:
Results of Studies as of May 2015
And CDC Guidelines

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Press Release

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New guidelines recommend daily HIV prevention pill for those at substantial risk

Could have significant impact on the U.S. epidemic if targeted and used as directed

Health care providers should consider advising the use of anti-HIV drugs by uninfected patients who are at substantial risk of infection, according to new clinical guidelines.

PrEP, or pre-exposure prophylaxis, could reduce HIV infection rates. When taken daily as directed, PrEP can reduce the risk of HIV infection by more than 90 percent. Inconsistent use results in much lower levels of protection.

"HIV infection is preventable, yet every year we see some 50,000 new HIV infections in the United States," said CDC Director Tom Frieden, M.D., M.P.H. "PrEP, used along with other prevention strategies, has the potential to help at-risk individuals protect themselves and reduce new HIV infections in the US."

PrEP should be considered for HIV-uninfected patients with any of the following indications:

- Anyone who is in an ongoing sexual relationship with an HIV-infected partner.
- A gay or bisexual man who has had sex without a condom or has been diagnosed with a sexually transmitted infection within the past six months, and is not in a mutually monogamous relationship with a partner who recently tested HIV-negative.
- A heterosexual man or woman who does not always use condoms when having sex with partners known to be at risk for HIV (for example, injecting drug users or bisexual male partners of unknown HIV status), and is not in a mutually-monogamous relationship with a partner who recently tested HIV-negative.

- Anyone who has, within the past six months, injected illicit drugs and shared equipment or been in a treatment program for injection drug use.

The guidelines were developed by CDC in partnership with other federal health agencies, public health experts and community leaders.

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- Anyone who has, within the past six months, injected illicit drugs and shared equipment or been in a treatment program for injection drug use.

“While a vaccine or cure may one day end the HIV epidemic, PrEP is a powerful tool that has the potential to alter the course of the U.S. HIV epidemic today,” said Jonathan Mermin, M.D., M.P.H., director of CDC’s National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention. “These guidelines represent an important step toward fully realizing the promise of PrEP. We should add to this momentum, working to ensure that PrEP is used by the right people, in the right way, in the right circumstances.”

The guidelines offer providers specific advice on how to give people the support they need to take their pills regularly. Given the need for high adherence and the lack of complete protection from HIV with PrEP or any other single strategy, the guidelines encourage providers to promote and support its use in combination with condoms and other proven risk-reduction strategies. Accompanying the guidelines is a supplement that includes checklists and interview guides to assist clinicians with PrEP prescribing and counseling.

The guidelines build on interim guidance issued by CDC following the release of research findings on PrEP for men who have sex with men (MSM), heterosexuals, and people who inject drugs. In 2012, the U.S. Food and Drug Administration (FDA) approved the drug combination of 300 milligrams tenofovir disoproxil fumarate and 200 milligrams emtricitabine (TDF/FTC) for use as PrEP in combination with safer sex practices.

Consistent with FDA labeling, the guidelines stress the importance of HIV testing before PrEP is prescribed and at three-month intervals while a patient is using PrEP. Regular testing ensures that anyone on PrEP who becomes infected with HIV discontinues PrEP use in order to minimize the risk that the virus could become resistant to the drugs. Such patients then can begin receiving HIV treatment.

“PrEP is a new approach to HIV prevention that requires continuing collaboration between patients and providers, as effectiveness requires adherence to daily medication and regular medical visits for monitoring, counseling and testing,” said Dawn K. Smith, M.D., M.P.H., the epidemiologist in CDC’s Division of HIV/AIDS Prevention who led the development of the guidelines. “Individuals will have to decide with their doctor if PrEP is right for them, but for some, this may offer a much-needed strategy to help protect themselves from HIV infection.”

In addition to providing guidelines and tools to assist providers in effectively prescribing and supporting PrEP use, CDC and other organizations are conducting pilot implementation studies and demonstration projects throughout the country. These projects aim to identify the most effective ways to deliver PrEP in community settings that can reach those at high risk for HIV infection.

The guidelines were announced today in CDC's Morbidity and Mortality Weekly Report. The 67-page guidelines and 43-page clinical providers' supplement are published in full at http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf (http://www.cdc.gov/hiv/pdf/guidelines/PrEPguidelines2014.pdf) and http://www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf (http://www.cdc.gov/hiv/pdf/guidelines/PrEPProviderSupplement2014.pdf) .

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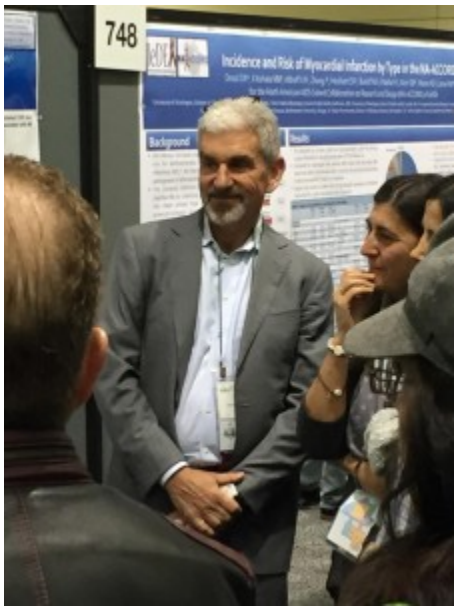

By Richard Elion

Senior Director of Evidence Based Practices

There are moments when the science becomes so vocal and clear that it is impossible not to hear the message.

The 1996 International AIDS Conference in Vancouver was such a moment in time. It became clear that the new developments of "HIV cocktails" would keep HIV-positive patients alive for long periods of time. It happened again four years later in Durban, South Africa, when we realized that it was really possible to treat all HIV-positive people.

February 24, 2015 was such a day for HIV prevention. There were four separate papers presented at the Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle hat created a tsunami of support for the importance of preventing HIV through the use of once daily medication. The first two studies were clinical trials that had to be stopped prematurely since the results were so overwhelmingly supportive for the use of PrEP (pre-exposure prophylaxis).

The PROUD study in England enrolled 545 men who have sex with men (MSM) and transgender women – half of whom received daily medication for PrEP immediately and the other half who received it one year after enrolling. It showed such a significant benefit in such a short period of time that the study was terminated. There were 3 HIV infections in the group on PrEP and 2 of the three were most likely infected prior to study entry compared to 19 infections in the deferred arm. The impact of PrEP can be better understood thusly: only 13 men needed to be treated to prevent every new HIV infection.

The second study in France and Canada, Ipergay, evaluated an alternative strategy called intermittent PrEP that was based on your need to use protection if you were going to have sex. This event based strategy utilized two pills of the medication Truvada 2-14 hours before sex and then one pill a day for two days after sex, resulting in a net dosing of four pills for every sexual encounter. This study was also stopped after noticing a significant number of new infections in the control group compared to the group that got Truvada. These investigators found that by treating 18 men with PrEP, they were able to prevent a new infection.

These two studies add to a growing body of evidence that makes denial of the benefit of PrEP akin to those who are against vaccines or climate change, according to Dr. Joel Gallant of Johns Hopkins University.

Also announced at CROI were the results of two studies that evaluated the role of PrEP in controlling the HIV epidemic. Dr. Bob Grant of UCSF demonstrated that PrEP in San Francisco is currently used by only 29 percent of eligible users and that if this could increase to 90 percent of eligible users, then the city could accomplish a 70 percent reduction of new HIV cases. Dr. Jared Baeten of University of Washington showed that new infections could be drastically reduced from 39 new cases yearly to 2 per year in a group of heterosexual couples where one person was HIV-positive and the other was not.

The combination of clinical data and the models that showed how the application of these approaches would alter the landscape of HIV was striking. All in the audience could grasp that the combination of rolling out effective therapies coupled with effective prevention could potentially end the spread of HIV. There are obviously great challenges in the integration and application of these approaches to populations, and the devil will lie in the details. But for a moment, we could finally see through the history and haze of suffering and deaths. We could envision a world with a purpose and resources to use these technologies to begin ending the war on AIDS. Let's see if we have the will and resources to see this through.

To view Dr. Elion's presentation at CROI, click here: **http://www.croiwebcasts.org/console/player/25776?mediaType=slideVideo&**

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HIV/AIDS

Time to expand use of PrEP to prevent spread of HIV infection

The Pharmaceutical Journal, 7 MAY 2015 **By Oliver Bacon**

There is growing evidence that pre-exposure prophylaxis is efficacious, safe and cost-effective in preventing high-risk individuals from getting HIV.

Source: Alamy / Shutterstock / Pharmaceutical Journal

It has been nearly three years since the US Food and Drug Administration (FDA) approved daily emtricitabine/tenofovir (FTC/TDF, marketed as Truvada) as pre-exposure prophylaxis (PrEP) to prevent HIV infection in adults at increased risk of infection.

In 2014, the World Health Organization (WHO) recommended that men who have sex with men (MSM) should consider taking antiretroviral (ARV) medicines as an additional precaution against contracting HIV. Emerging evidence now adds further weight to the concept that PrEP, when used appropriately, could help halt the spread of infection among individuals at increased risk of HIV infection.

The time has come for governments and health bodies to adopt policies that incorporate the use of PrEP to protect people at risk of infection and help fight the spread of HIV, as they have done in countries such as the United States.

The ARVs tenofovir and emtricitabine have long been used in combination with other ARVs to treat HIV. When someone is exposed to HIV, emtricitabine/tenofovir can keep the virus from establishing a permanent infection — treatment can be combined with condoms and other prevention methods to provide even greater protection than when used alone.

When properly adhered to, PrEP has been shown to reduce the risk of HIV infection by up to 92% in men who have sex with men (MSM), and in heterosexuals at increased risk of HIV infection, including those in serodiscordant relationships[1],[2],[3].

Safety and tolerability

Critics of PrEP have expressed concerns that a healthy person should not be taking powerful drugs normally used to treat those infected with HIV because of the adverse effects associated with their use. However, an analysis of the safety profile of PrEP disproves this concern.

Tenofovir, when used in combination antiretroviral therapy (ART), especially with a protease inhibitor, is well known to cause a small drop in creatinine clearance and bone density in some HIV-infected persons (emtricitabine, the other drug in FTC/TDF, seems to have few side effects). A small but clinically unremarkable decrease in creatinine clearance versus placebo has been demonstrated in randomised trials of FTC/TDF for PrEP, which usually appears by week four, remains steady, and resolves after drug is stopped[4],[5].

Similarly, although FTC/TDF used for PrEP is associated with a small but significant decrease in bone mineral density, there is no increase in fractures[6]. A “start-up syndrome”, most commonly consisting of mild nausea, bloating, and loose stools, has been observed in approximately 10% of PrEP trial participants, usually resolving in several days to a week[1],[2],[3]. Unlike ARVs from the protease inhibitor and non-nucleoside reverse transcriptase inhibitor classes, the nucleotide reverse transcriptase inhibitors (NRTIs) FTC/TDF have almost no known drug interactions.

Halting new infections

Beyond efficacy and safety data, another justification for implementing PrEP is that it may fill gaps in the current methods in use to shrink the epidemic, such as HIV testing, condom promotion and treatment of HIV-infected persons with ART.

An analysis by the US Centers for Disease Control and Prevention estimates that condoms, when used 100% of the time, reduce HIV risk from an HIV-infected partner by 70% for anal sex to 87% for vaginal sex. When used inconsistently, they are no more protective, statistically, than sex without condoms — only 16% of MSM reported 100% use with partners regardless of HIV status[7].

PrEP is not going to encourage people to stop using condoms consistently. Many people have already stopped, even if they know they should use them or would like to use them. PrEP will also protect people when condoms break, or slip off, or when they are not an option, as in some cases of non-consensual sex.

The remarkable degree of protection afforded by testing and treatment (also known as treatment as prevention, or TasP) — a 96% risk reduction shown in the HPTN052 randomised trial of ART in serodiscordant heterosexual couples[8] — depends on people knowing their HIV status and starting ART as soon as possible after receiving a positive test. Until testing and immediate treatment are universal (and a look at the current treatment cascade suggests this will take a while), people will continue to get infected with HIV by partners unaware of their own infection, or aware of their positive status and unable or unwilling to access ART.

Around 50,000 new infections occur in the United States each year, an incidence that has not changed in the past 12 years[9], even though condoms have been in use for HIV prevention since the early 1980s when the AIDS epidemic began, and effective ART has been available since 1996.

Even in San Francisco, where I work as an HIV doctor and where ART initiation has been recommended regardless of CD4 count since 2010, there were 467 new infections in 2012, a year when 68% of newly diagnosed persons achieved viral suppression through ART[10]. As a prevention method controlled entirely by the individual, independent of his or her ability to use condoms at the time of intercourse and his or her partner's testing status or viral load, PrEP complements the prevention methods we have.

Latest evidence and cost-effectiveness

Preliminary results of new PrEP trials, released at the Conference on Retroviruses and Opportunistic Infections (CROI) in February 2015, provide hope that approval will soon follow in other countries. It is about time.

On 23 February 2015, CROI attendees heard the preliminary results from the PROUD and IPERGAY studies of PrEP in MSM. Some attendees likened the feeling in the room to that experienced at the 1996 International AIDS Conference in Vancouver, Canada, when it was first shown that three-drug ART led to virologic suppression, immune reconstitution and reduced mortality.

The UK PROUD study[11] randomised 545 MSM at sexual health clinics to start daily FTC/TDF PrEP immediately versus waiting for 12 months, with quarterly follow-up for infections. Intended as a pilot study of PrEP offered in a "real world" setting, the randomised phase of PROUD was halted when interim analysis showed a risk reduction of 86% in the immediate versus deferred arm.

The IPERGAY study[12] randomised 400 MSM in France and Quebec, Canada, to placebo versus "on-demand" FTC/TDF PrEP, consisting of two tablets 2–24 hours before sex, one tablet 24 hours after sex, and another tablet 48 hours after the first dose. As in PROUD, the randomised phase was halted after interim analysis showed a significant reduction in HIV infections (again, 86%) in the active versus placebo arm. In both studies, the only persons who became infected after randomisation to active drug had stopped taking their tablets two months before their estimated date of infection.

Taken together, these two studies show high rates of acceptability and efficacy of FTC/TDF PrEP by MSM at high risk of HIV infection (as demonstrated by infection rates in the placebo arms) and at high risk of inconsistent condom use (as demonstrated by the considerable prevalence of sexually transmitted infections at baseline) in real world settings.

These two studies are also likely to trigger a recalculation of cost-effectiveness estimates of PrEP. Until now, assuming an efficacy of 44% and moderate uptake, these have shown PrEP to be cost-effective, although still expensive, when offered to MSM at increased risk of infection[13],[14],[15]. Improved estimates of cost-effectiveness or, possibly, cost savings should increase pressure on national governments, international funders and pharmaceutical companies to consider including PrEP in national prevention programmes regardless of a county's level of resources.

The road towards zero new infections

As is the case with so many diseases, until there is an effective vaccine or a safe, accessible curative regimen for HIV, both of which are being sought, the realistic strategy for shrinking the epidemic is going to rely on combining the best methods available. Increased testing, improved use of condoms and immediate treatment of newly diagnosed HIV positive cases have gone a great distance towards containing the epidemic in many countries, rich and poor. Now PrEP offers an effective, safe and acceptable way to extend this progress further still.

Oliver Bacon is an associate professor of clinical medicine at UCSF in the HIV Division at San Francisco General Hospital.

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Pre-Exposure Prophylaxis:
Legal Issues

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

JASON POTTER BURDA*

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* © 2015 Jason Potter Burda. Full-Time Lecturer, University of Massachusetts School of Law-Dartmouth. The Author would like to thank University of Massachusetts School of Law Dean Mary Lu Bilek for funding this research project, Professors Hillary Farber and Margaret Drew for their mentorship, Brenna Ferrick for her research assistance, and Aaron David Burda for his inspiration, insight, and support.

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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 (MSM[3]) 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/

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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 transmission[10]—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

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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-idUSKBN0F12012 0140626 [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* Sunnivie 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/JE6E-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

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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-whores_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

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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

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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

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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

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[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

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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*, 61MORBIDITY & 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,

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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]

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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 detectible 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 studies[57] suggest the use of antiretroviral drugs could

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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. Haberer 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 rate[61]—more than fifty percent of new HIV infections[62]—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

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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-positive[63]—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 it 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]

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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)*, AIDSMEDS, 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/#!document Detail;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

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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, s*upra* 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

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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/truvadaprep-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,

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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 lawmakers[104] 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

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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 State[109] and Illinois[110] 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

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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

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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*, AIDSMAP (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]

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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

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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.

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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

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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://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 treatement 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

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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://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 Anoysius 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]

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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 patients[179] and thorough documentation of medical appropriateness[180]—why the patient would benefit from the service[181]—

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=&referer=&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.uftshealthplan.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:

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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

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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 [http://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.

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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

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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

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[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 Preventention)); *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

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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

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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,

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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://families usa.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]

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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]

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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/vitamind/ finalrecvitd.htm [http://perma.cc/5GPX-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/uspsaspg.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 Medicare[278] and Medicaid.[279] As such, the impact of a USPSTF A or B recommendation

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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, *Raloxifine 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 state[298] 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 care[301] and offer all of the cost-free services required under the PSP[302] 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]

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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

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(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]

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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. Morrisey, *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

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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 justif[y] [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

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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 . . . .").

Lowering the Age for HIV Prevention

By Rod McCullom

In May 2014, the Centers for Disease Control and Prevention issued new guidance for HIV prevention, recommending that uninfected people at risk of contracting the virus—including gay and bisexual men, HIV-negative partners in mixed-status relationships, and intravenous drug users—take a daily pill as protection against HIV/AIDS. Truvada, a powerful combination of two antiretrovirals, was approved in 2004 to treat people who are already HIV-positive. It became the first and only medication to be approved for HIV prevention in 2012, after a 2010 study found it to be up to 96 percent effective if taken four or more times a week. Truvada is approved as a treatment for HIV-positive patients as young as 12 years old. But only adults 18 and older are allowed to take Truvada as pre-exposure prophylaxis, or PrEP—and that is a problem, according to a growing number of public-health researchers and advocates.

The number of new HIV infections in the United States has stabilized at around 50,000 per year, according to the CDC, but new infections continue to increase among gay and bisexual men. The trend is particularly acute among black men, and even more so among those between the ages of 13 and 19. New infections among young gay and bisexual black men increased by almost 50 percent between 2006 and 2009, a rate the CDC has called "alarming." An estimated 6 percent of black gay and bisexual men in the United States under the age of 30 are HIV-positive, according to data from a longitudinal study conducted by the HIV Prevention Trials Network.

"That 6-percent prevalence is higher" than the overall adult rate of infection in some countries in sub-Saharan Africa, noted Christopher Chauncey Watson, a public-health researcher at George Washington University who presented the longitudinal data at HIV/AIDS conferences in Melbourne, Australia, and Cape Town, South Africa, last year. "In addition, there are so many other barriers [to healthcare]—poverty, homelessness, unemployment—that these youth face on a daily basis," he said. "We need to consider innovative approaches toward HIV prevention. Pre-exposure prophylaxis could become a powerful tool."

So far, only one study is investigating the potential use of PrEP among adolescents. "Project PrEPARE" is a national clinical trial conducted by the Adolescent Trials Network and funded by the National Institutes of Health. Gilead Sciences, the company that makes Truvada, has donated the medication.

The study follows two groups of young gay and bisexual men and transgender women: The first includes 79 teens between the ages of 15 and 17, and the second is composed of 200 young adults between the ages of 18 and 22 (although members of this age group can already legally take PrEP, researchers have little data on their adherence rates for the medication). Researchers hope the results of the trial, which also includes quarterly screenings for HIV and other sexually transmitted infections, will persuade the Food and Drug Administration to lower its age requirements for preventative Truvada.

The researchers behind the study hope it will also counter the racial disparities often present in clinical trials, said Sybil Hosek, the lead investigator and a clinical psychologist at the John H. Stroger Jr. Hospital in Chicago. The 2010 study on Truvada's effectiveness as PrEP used "an overwhelmingly white [and older] sample," she said. "That's not who is getting infected in this country." In Project PrEPARE, by contrast, around half of participants in the younger group are Latino (another group disproportionately affected by HIV) and one-third are black; in the older group, around half are black and just over a quarter are Latino.

Project PrEPARE has been met with resistance by some institutional review boards that raised bioethical concerns about the younger age group. The study is being conducted in 12 different cities, and six of the research sites did not approve the younger group. That undermines the purpose of the research, Hosek says, and doesn't reflect the real-life conditions faced by many teens at risk of HIV. Young gay men "may face harm or violence if they come out [and] tell their parents they are having sex with men," she said. "We felt strongly that they should be able to access this medication through the trial without having to come out to their parents. We wanted them to consent for themselves much like a young woman requesting birth control or Plan B."

Officials at the NIH agree. "There are important precedents for adolescents to receive care without obtaining parental consent," said George Siberry, a physician and medical officer at the NIH's Maternal and Pediatric Infectious Disease Branch. "The ability for adolescents to seek HIV treatment and preventive care represents a similar situation."

After Project PrEPARE wraps up in September and the researchers submit their final report to the FDA, either NIH or Gilead will need to submit a formal request to the FDA before the minimum age for Truvada as PrEP can be lowered. The researchers say they don't plan to lobby for any particular age, but believe that "it should be indicated for youth that are sexually active," Hosek said. "Going down to 15 years old may capture the youth who are particularly at risk. But it's not for us to say."

Public-health experts still aren't sure why new infections are increasing among younger black gay and bisexual men in particular. Research has shown that among men in relationships with partners of the same race, black gay couples are actually more likely to use condoms than their white counterparts, but many researchers believe that several different social and economic factors—including poverty, limited access to healthcare and insurance, high incarceration rates, homophobia, and racism—play a role in keeping the infection rate high.

Even if the FDA were to lower its age restrictions for Truvada, many young people would likely still have a hard time accessing the drug, which can cost up to $1,500 monthly. PrEP is covered by most insurance programs (Medicaid coverage varies by state), but black and Latino youth, in particular, are less likely to have insurance than their white counterparts. And even teens with health insurance may

be deterred from using it for Truvada, for fear that their parents will find out when they receive the medical bills.

In July, Washington became the first state to offer financial assistance for PrEP, and a handful of other states, including Illinois and New York, are considering following suit; Gilead has a financial-assistance program as well. PrEP advocates argue that if the age is lowered, some funding should be directed toward similar programs for adolescents that allow them to access Truvada without parental knowledge. “We need to challenge insurance notification for young men—over and under 18—who are still on their parent’s insurance and want to access PrEP,” said Steven-Emmanuel Martinez, a graduate student in public health at Brown University who is writing his thesis on the effectiveness of PrEP counseling among young gay and bisexual men.

Equally important, Martinez said, is educating doctors and patients alike on how Truvada could help the groups at highest risk for HIV. “The research community and PrEP advocates—myself included—have done a mediocre job of reaching medical providers and primary-care physicians,” he said. “We’ve also done a poor job at translating research on PrEP for communities that aren’t particularly scientifically literate.”

Still, he added, knowledge of Truvada’s potential is catching on among young people: “My friends are discussing it,” he said. “Conversations around PrEP are happening.”

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State Adolescent Consent Laws and Implications for HIV Pre-Exposure Prophylaxis

Lindsay Culp, JD, MPH, Lisa Caucci, JD, MA

Background: Recent large clinical trials have found that pre-exposure prophylaxis (PrEP) reduced HIV infection among men who have sex with men (MSM), but efforts to provide clinical care to minors, including young MSM, may be complicated by a lack of clarity regarding parental consent requirements with respect to medical services.

Purpose: The goal of this paper was to analyze law related to a minor's ability to consent to medical care, including HIV diagnostic testing and treatment, and its implications for PrEP.

Methods: Analysis was performed in 2012 on laws current as of December 31, 2011. Public Health Law Program staff collected all statutes and regulations pertaining to an adolescent's ability to consent to HIV diagnostic testing and treatment and sexually transmitted infection (STI) diagnostic testing, treatment, and prevention.

Results: No state expressly prohibits minors' access to PrEP or other HIV prevention methods. All jurisdictions expressly allow some minors to consent to medical care for the diagnosis or treatment of STIs, but only eight jurisdictions allow consent to preventive or prophylactic services. Thirty-four states either expressly allow minors to consent to HIV services or allow consent to STI or communicable disease services and classify HIV as an STI or communicable disease. Seventeen jurisdictions allow minors to consent to STI testing and treatment, but they do not have an express HIV provision nor classify HIV as an STI or communicable disease.

Conclusions: Minors' access to PrEP without parental consent is unclear, and further analysis is needed to evaluate how state law may relate to the provision of clinical interventions for the prevention of HIV infection.

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Background

Pre-exposure prophylaxis (PrEP) is an HIV prevention approach in which people who are at high risk for acquiring HIV take daily oral doses of antiretroviral medication in an effort to lower their risk of becoming infected with HIV. The antiretroviral medication used for PrEP is a fixed-dose combination of tenofovir disoproxil fumarate and emtricitabine (Truvada®). It currently has a U.S. Food and Drug Administration (FDA) labeling indication for the treatment of HIV infection, and a decision about a labeling indication for prevention of sexual acquisition of HIV infection is pending. Recent large clinical trials have found that PrEP reduced HIV infection among men who have sex with men (MSM) as well as heterosexual men and women.[1,2]

Although the annual number of new HIV infections in the U.S. was stable overall from 2006 through 2009, there was an estimated 21% increase in HIV incidence in people aged 13–29 years. This increase in HIV incidence was driven by a 34% increase in HIV incidence in young MSM (the only group to experience a significant increase in incidence in this age range).[3] The increasing number of new HIV infections among young gay and bisexual men underscores the importance of reaching young MSM with effective HIV prevention programs.

However, efforts to provide clinical care to minors, including young MSM, may be complicated by a lack of clarity regarding parental consent requirements with respect to medical services. Young MSM may be reluctant or unwilling to disclose their sexual orientation or sexual activities to their parents and may be deterred from seeking medical services, such as PrEP, if parental consent is required. Minor consent for medical care raises complicated

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issues with several competing interests, including parental rights to make medical decisions for minor children, confidentiality between physician and patient, and privacy rights of minors with respect to certain types of health care, particularly sexual and reproductive health care.

Although the U.S. Supreme Court has affirmed the right of parents to make decisions regarding the care of their children, the rights of parenthood are not without limitation.[4–6] In the past few decades, the Supreme Court has recognized that minors themselves have constitutional rights. In particular, the court has established that minors have a constitutionally protected right to privacy, including decisions regarding procreation.[7] The Supreme Court rejected a district court's suggestion that parental consent requirements were necessary to safeguard the family unit and parental authority, holding that allowing a parent to overrule a reproductive healthcare decision made by a minor child and her physician was unlikely to either strengthen the family unit or enhance parental control.[8]

Further, although parents in most instances must consent for medical services provided to their minor children, case law and legislation have evolved in recent decades to allow minors to consent for themselves in many circumstances. (See Figure 1 for age of majority by state.) These include minors who legally have been emancipated by a court. Criteria for emancipation vary from state to state but often include minors who are married, pregnant, parents, in the military, high-school graduates, or self-supporting and living apart from parents.[9]

In some states, courts also have established through case law the right of "mature minors" to consent to certain types of health care; court decisions generally define "mature minors" as minors who are found to possess the intelligence and maturity to make a healthcare decision. When emergency treatment is required, parental consent is assumed and, therefore, explicit parental consent is not required to treat a minor.[10,11] Further, the state is authorized to act to guard "the general interest in youth's well being" and take action to protect the public's health.[12]

States have recognized that requiring parental involvement in certain sensitive health decisions may deter minors from seeking timely care and that the need to ensure access on the part of the minor outweighs the importance of parental involvement in the decision. Therefore, many states have enacted statutes expressly allowing minors to consent to certain types of care, including sexually transmitted infection (STI) testing and treatment, HIV testing and treatment, prenatal care, and contraceptive services.[10,11]

A minor's ability to consent to medical services may affect the success of a pharmacologic prevention measure for HIV, such as PrEP. Therefore, the current paper analyzed state laws associated with minor consent for medical care in order to explore whether state law would affect adolescent access to PrEP and related HIV prevention methods without parental consent. For this article, the CDC, Office for State, Tribal, Local and Territorial Support (OSTLTS), Public Health Law Program (PHLP) surveyed laws affecting consent to general medical care, consent to STI prevention and testing, and consent to HIV testing and treatment.

Because the use of a pharmacologic intervention to prevent HIV infection is a new concept that has not been addressed expressly by state law, for the purposes of this legal survey, PHLP analogized PrEP to prevention measures for STIs. By analyzing minors' access to STI prevention measures, this article contemplates how state law might treat minors' access to PrEP. Additionally, because few jurisdictions allow minors to consent to preventive or prophylactic treatment for STIs, this article also explores what medical services states do allow minors to consent to, which is typically only the care covering the diagnosis and treatment of STIs.

Methods

The CDCs Division of HIV/AIDS Prevention requested a 50-state analysis of minor consent law and its implications for PrEP. PHLP staff used WestlawNext, a subscription-only online legal research service (www.westlaw.com), to systematically collect all statutes and regulations pertaining to mature minor doctrines and an adolescent's ability to consent to HIV diagnostic testing and treatment and STI diagnostic testing, treatment, and prevention. Staff first searched the statutory code and administrative regulations of each state individually using the search string "consent & (treat! prescribe diagnos! health medical counseling)" and then narrowed the results using "minor or adolescent."

Statutes and regulations from all states, as well as municipal regulations from the District of Columbia, were reviewed and relevant laws entered into a database organized by state. PHLP relied on state HIV, STI, and communicable (although some states use the alternate descriptions "contagious," "infectious," "dangerous," and "reportable") disease statutes to determine whether adolescents potentially could access PrEP without parental consent. Analysis was performed in 2012 on laws current as of December 31, 2011.

Public Health Law Program staff then compared the results to those described in *The Center for Adolescent Health & the Law's State Minor Consent Laws: A Summary*, an extensive compilation of legal research on this topic that provided an excellent cross-check to ensure that all relevant statutes and regulations had been captured by PHLP's original research.[13] Staff analyzed statutes and regulations for each state and ascertained an adolescent's ability to consent to medical care using generally accepted rules and conventions of statutory interpretation.[14]

Results

No state expressly prohibits minors' access to PrEP or other HIV prevention methods. Forty-six states and the District of Columbia explicitly allow minors with certain status exceptions to consent to medical care for them-

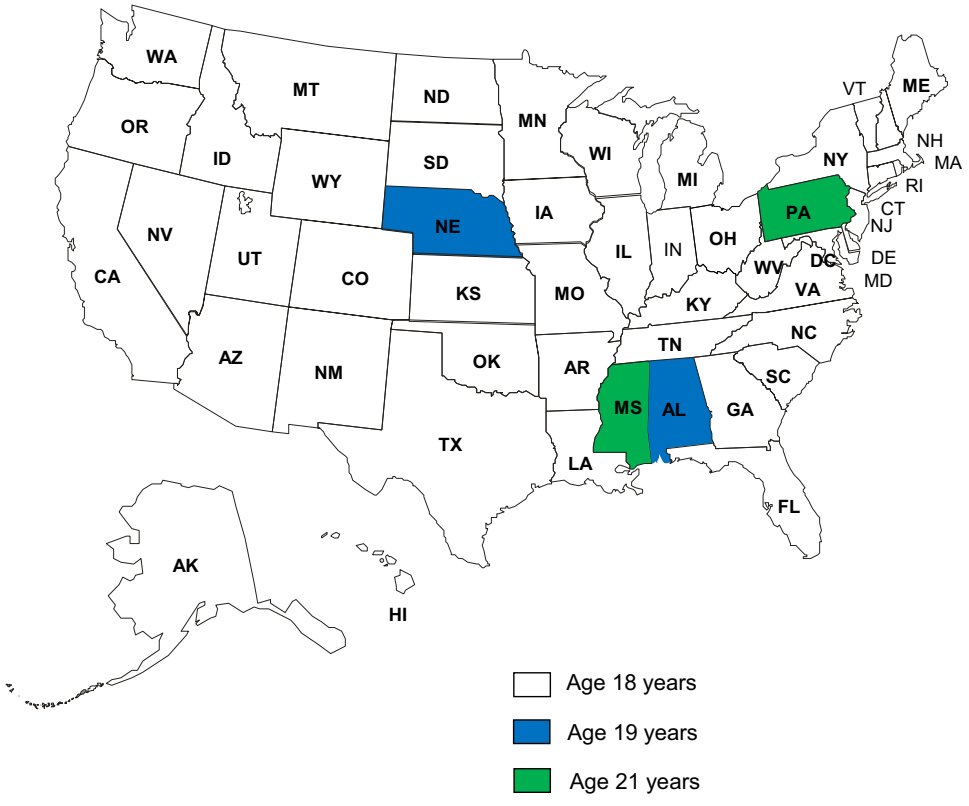

Figure 1. Age of majority in years, by state

selves. These exceptions vary by state, but the most common exceptions are for a minor who is emancipated by court order, serving on active duty in the military, married, a parent, or a high-school graduate. (In order to be emancipated by court order, states generally require minors to fulfill other specific conditions, such as living separate and apart from their parents and being financially self-sufficient.) Only New Hampshire, Rhode Island, Tennessee, and Wisconsin do not have statutes or regulations allowing certain minors to consent to medical care based on their status.

All jurisdictions expressly allow some minors to consent to medical care for the diagnosis or treatment of STIs. However, the criteria under which minors may consent vary (Figure 2). Twenty-one states and the District of Columbia allow all minors to consent for diagnosis or treatment of STIs, while another 21 states either impose age restrictions or allow only those who may have been exposed to an STI to consent.

Only seven states (California, Iowa, Kansas, Montana, Nebraska, North Carolina, and South Dakota) and the District of Columbia expressly allow minors to consent to preventive or prophylactic services for STI. Preventive services may include counseling, male and female condoms, diaphragms, vaccination, and other methods, but what is allowable may vary from state to state. Of these seven states, four (Kansas, Montana, Nebraska, and South Dakota) allow prophylactic treatment only if a minor is suspected of coming into contact with an STI. Additionally, one state—California—adds an age restriction, allowing only minors who are at aged ≥12 years to consent to preventive care for an STI. Two other states (Iowa and North Carolina) and the District of Columbia do not place any conditions on a minor's access to STI preventive care, whereas South Carolina allows a minor who is aged ≥16 years to consent to medical services that a provider deems necessary.

Public Health Law Program grouped laws regarding minor consent to HIV testing and treatment into three categories: (1) jurisdictions that expressly allow minors to consent to HIV diagnostic testing or treatment; (2) jurisdictions that expressly allow minors to consent to STI or communicable disease diagnostic testing or treatment and further specify that HIV is a communicable disease or STI; and (3) jurisdictions that expressly allow minors to consent to STI diagnostic testing or treatment but are silent as to whether HIV is a communicable disease or STI, and have no express provisions for minor consent to HIV diagnostic testing or treatment (Figure 3).

Twelve states (Arizona, Colorado, Connecticut, Delaware, Florida, Iowa, Michigan, Mississippi, New Jersey, New Mexico, New York, and Ohio) expressly allow minors to consent to HIV testing or treatment. Of these, five states (Arizona, Mississippi, New Mexico, New York, and Ohio) allow minors to consent to HIV testing, but not treatment. Two additional states (Delaware and Florida) have an express provision only for HIV testing, but minors can consent to HIV treatment under broader communicable disease provisions.

Twenty-two states (Alabama, California, Idaho, Illinois, Kentucky, Massachusetts, Montana, Nevada, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, Tennessee, Texas, Utah, Vermont, Vir-

ginia, Washington, West Virginia, and Wyoming) allow minors to consent to testing or treatment for STIs or communicable diseases and classify HIV as either an STI or communicable disease. Consequently, minors in these states may consent to HIV testing or treatment under those STI or communicable disease provisions. Sixteen states and the District of Columbia allow minors to consent to STI testing and treatment, but they neither have an express HIV provision nor classify HIV as an STI or communicable disease. Among these states, South Carolina allows minors aged ≥16 years to consent to any care a provider deems necessary, and Arkansas allows minors of sufficient intelligence to consent to any medical treatment or procedure.

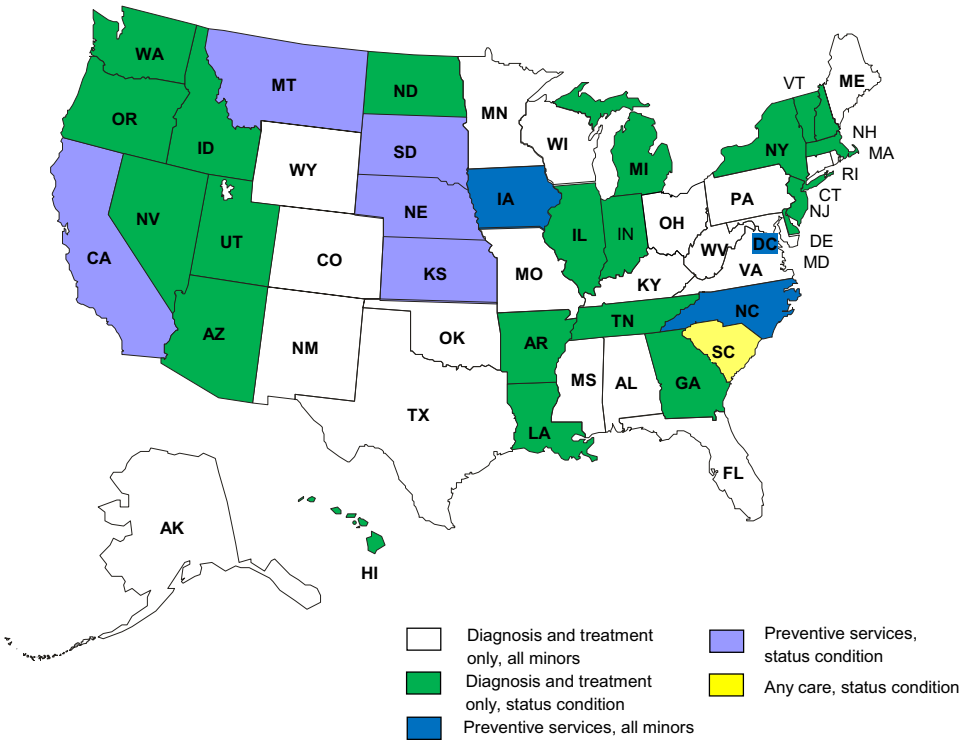

Figure 2. Minor's capacity to consent to sexually transmitted infection services, by type of service and minor status

Discussion

A state may allow minors to consent for themselves to a particular medical service if there is a substantial interest in ensuring access to that service. Preventing HIV infection is an important public policy goal of states and sufficiently compelling that state courts have ruled that minors may access prevention methods such as condoms without parental consent.[15] However, allowing minors access to condoms without parental consent is arguably distinguishable from allowing minors to receive PrEP without parental consent because condoms are a substantially less invasive method of prevention than antiretroviral medication. (Case law on minors' access to condoms without parental consent merits further exploration as it pertains to PrEP.) Additionally, taking antiretroviral medication carries a small risk of side effects or toxicities, whereas this risk is rare for condoms. Even so, given the serious consequences of HIV infection, the state has a strong interest in preventing new infections among minors as well as adults.

Another factor affecting adolescent access to PrEP is the issue of prophylaxis itself. Many state statutes and regulations make a substantial distinction between allowing minors to consent to preventive medical services and allowing minors to consent to medical treatment. At least one district court has held that condoms are a preventive measure, rather than a medical treatment, because they "are non-invasive, are not used to diagnose or cure disease, and do not require medical training or supervision for their use."[16] However, such a holding may not extend to PrEP, as the medication must be ingested and does require prescription and medical supervision for safe use. Therefore, states will find it arguably more difficult to draw an analogy between PrEP and condom distribution.

Even though the use of antiretrovirals in PrEP is by definition preventive medical care, these same antiretrovirals are standard treatment for individuals who already have HIV infection. Although most states allow minors to consent to medical treatment for STIs other than HIV infection, this exception is typically for adolescents who actually have been diagnosed with an STI. Indeed, in many states, only adolescents who have reason to believe they have been exposed to an STI are allowed to request STI testing without parental consent. This distinction between medical treatment for a diagnosed health condition and a clinical preventive measure is crucial, and a provider's ability to prescribe PrEP to adolescents under current law may hinge on whether PrEP is determined to be more analogous to a preventive or a treatment measure.

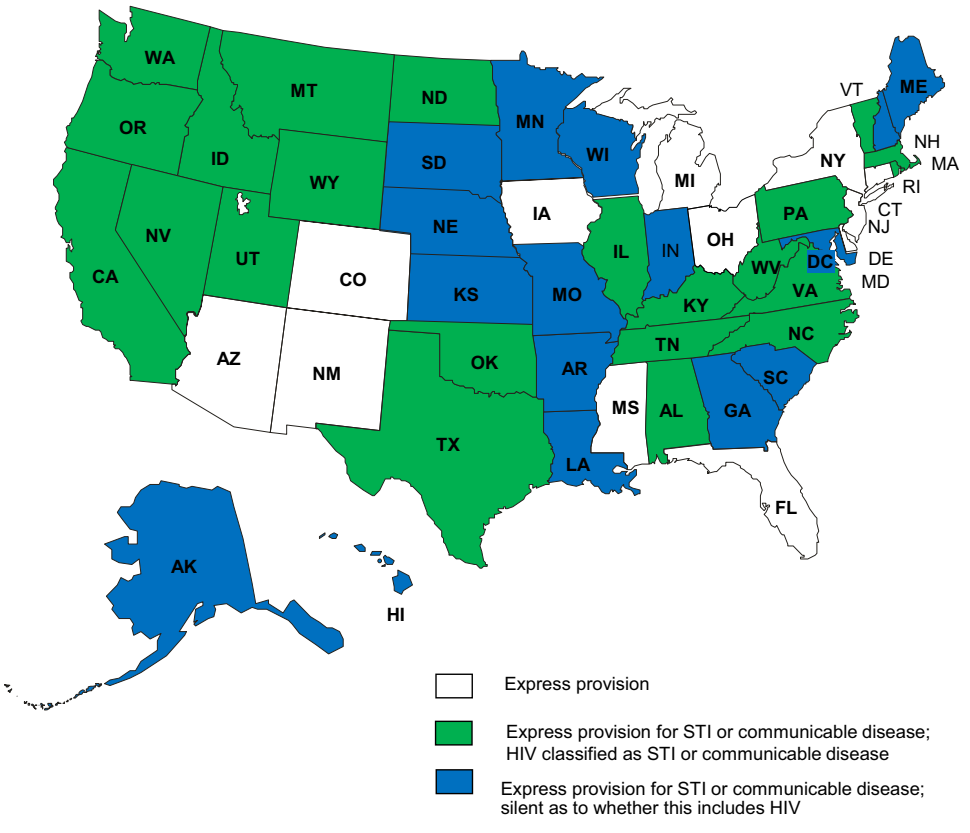

Figure 3. Minor's capacity to consent to HIV services, by type of service
STI, sexually transmitted infection

Although no law expressly prohibits the use of PrEP in any jurisdiction, it may be permitted by implication for adolescents in the eight jurisdictions that allow minors to consent to STI preventive care, because HIV can be considered an STI. In the remaining 43 jurisdictions, minors' access to PrEP may rest on whether "treatment" is defined broadly or narrowly. For example, Mosby's Medical Dictionary defines treatment broadly as "the care and management of a patient to combat, ameliorate, or prevent a disease, disorder, or injury," encompassing both preventive and therapeutic care.[17] Conversely, Stedman's Medical Dictionary defines treatment as the "medical or surgical management of a patient," seeming to limit treatment to only therapeutic care.[18]

State statutes and regulations do not provide a uniform legal definition of treatment. Therefore, whether a healthcare practitioner prescribes PrEP to a minor at risk for HIV infection may depend on each state's interpretation of the term *treatment*. If a state seeks to amend its laws to provide PrEP to minors without requiring parental consent, the new language should explicitly permit access to STI preventive care instead of merely authorizing minors to consent to STI diagnostic and treatment care. For example, California amended the minor consent provision of its Family Code in the 2011 legislative session to allow minors aged ≥12 years to "consent to medical care related to the prevention of a sexually transmitted disease."[19]

Another avenue through which minors may be able to access PrEP is the Title X Family Planning Program. Title X is a federal grant program created for the express purpose of "providing individuals with comprehensive family planning and related preventive health services."[20] Under federal regulations, family planning clinics receiving Title X funds must provide services to anyone, male or female, regardless of age and must maintain confidentiality. Although the federal regulations encourage minor patients to involve parents in their family planning decisions, a federal court held that parental notification cannot be required and, following this line of reasoning, clinics receiving Title X funds cannot require parental consent.[21] (The Medicaid program also requires that family planning services be kept confidential.)

In addition to family planning services, Title X–funded clinics provide many other preventive health services, including pregnancy diagnosis and counseling, breast and cervical cancer screenings, and STI education, counseling, testing, and referral (www.hhs.gov/opa/title-x-family-planning/). Title X–funded clinics also must provide "at a minimum, education about HIV infection and AIDS, information on risks and infection prevention, and referral services" (www.hhs.gov/opa/title-x-family-planning/). Moreover, Title X–funded clinics have the option to "provide HIV risk assessment, counseling and testing by specially trained staff." If a clinic does not offer these optional services, it must provide clients "with a list of health care providers who can provide these services."[22] Because these family planning clinics are bound by federal regulations regarding a minor's ability to consent, some adolescents could access PrEP at Title X–supported clinics, in theory. However, limited funding means that many Title X clinics are

unable to provide HIV services beyond the required minimum.[23]

Limitations

This review has two key limitations. First, for clarity and efficiency, PHLP staff narrowed analysis to state statutes and regulations and did not comprehensively review case law, professional licensing board opinions or rules, and other enforcement guidance, such as attorney general opinions, that could affect the provision of PrEP to minors in many states. Second, this analysis examines the law on its face only and does not examine how the law is applied. Because the laws of most states are silent on the issue of preventive treatment of STI, a physician may exercise her discretion to treat an at-risk adolescent minor by prescribing PrEP. This discretionary prescription could alter significantly the availability of PrEP to minors from what state law, or gaps in the law, suggest.

Conclusion

Clinical trials have demonstrated that PrEP is a potentially useful public health prevention measure for HIV, but the findings from this study indicate that minors' access to PrEP without parental consent is unclear. Further work is needed to evaluate case law and enforcement guidance, and to establish each state's definition of the term *treatment* as it may relate to the provision of clinical interventions for the prevention of HIV infection.

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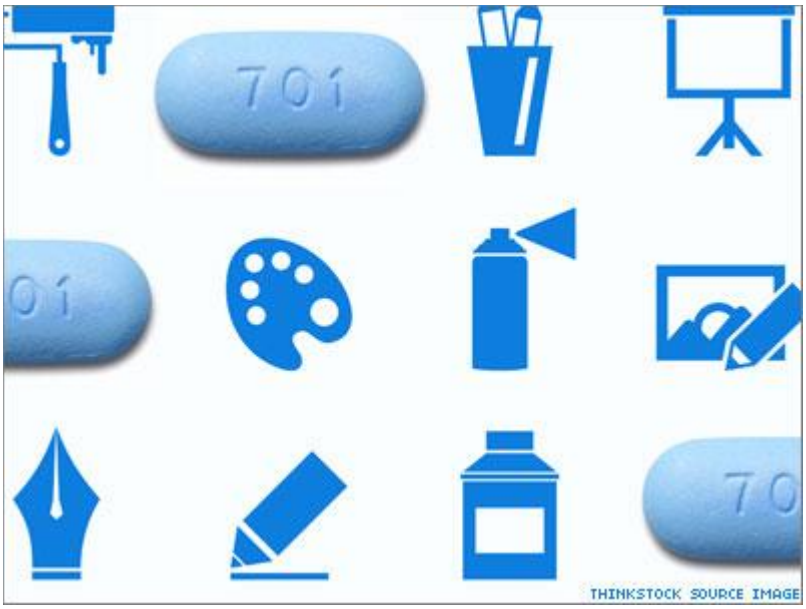

Does Hobby Lobby Have to Pay for My PrEP?

By Matt Baume

Originally published on Advocate.com October 27 2014 8:00 AM ET

Last June the Supreme Court ruled that religious-minded business owners could essentially line-item veto some forms of birth control out of their employees' health care plans. Does that mean that antigay bosses can target queer employees by doing the same with HIV prevention pills?

The *Hobby Lobby* decision was a major victory for religious conservatives, who in recent years have increasingly sought exemptions from laws designed to protect LGBT people. And while the case focused on birth control, the decision could have significant implications when it comes to health care for workers who are at elevated risk of acquiring HIV, such as sexually active gay men.

PrEP is a daily regimen of the drug Truvada, which when taken daily as prescribed can reduce the risk of transmission by 99 percent, according to studies. Although Truvada has been approved as HIV treatment for more than a decade, it's only relatively recently that it's been adapted as a preventive measure. And the number of prescriptions is still small.

Because it's so new, there haven't been any publicized incidents of PrEP-related discrimination, says Iván Espinoza-Madrigal, legal director for the Center for HIV Law and Policy. But, he adds, "that doesn't mean it's not happening."

While the Americans With Disabilities Act bars most workplaces from discriminating against employees with HIV, Espinosa-Midrial says HIV-positive workers have been discriminated against when it was discovered they were taking Truvada. "I wouldn't be surprised if people are suffering the same impact if they're on PrEP," he says.

But HIV-negative people taking preventive measures are a bit different from HIV-positive individuals, says Scott Schoettes, HIV Project director and senior attorney at Lambda Legal.

"We're not dealing with people who are living with HIV," Schoettes says. "They don't have a qualifying disability."

But, he points out, "this is medically necessary care. We have guidelines now from the [Centers for Disease Control and Prevention], talking about PrEP and when it's appropriate to prescribe PrEP."

And although the Affordable Care Act contains provisions about providing preventive care, Schoettes says, "there have been problems in some places with HIV medications being placed on specialty tiers and made expensive or unavailable altogether. ... We are looking at ways to prevent all of those practices."

The good news is that insurance companies are prohibited from designing benefit programs specifically to discourage disabled or at-risk people from enrolling. And existing laws do provide some level of protection.

"When it comes to nondiscrimination protection, they apply to people who are living with HIV ... or association with people who are living with HIV," says Espinosa-Madrigal. "For instance, if I work at a restaurant and people find out that my partner is HIV-positive, they might not know my status, and I haven't disclosed my status, but the fact that they are associating me with somebody who is HIV-positive is enough to cover me with legal protection."

Although both the use of Truvada as PrEP and the *Hobby Lobby* decision are recent developments, LGBT nonprofits are prepared to defend access to health care.

"We've heard about some doctors who are reluctant to prescribe PrEP," says Schoettes. "I think that's problematic and something that will need to be addressed," potentially through litigation. "A person's health care should not be dependent on their doctor's viewpoints on their sex lives."

And of course, a refusal to cover treatment or preventive measures would have significant public health consequences.

"Any type of barrier to treatment runs counter to very sound public health policies," says Espinosa-Madrigal. "If an employer is using moral or religious beliefs to deny people access to health care ... it would contribute to the epidemic."

Fortunately, there have been, so far, no documented cases of antigay employers trying to use the *Hobby Lobby* decision as a weapon against queer health care. But the possibility still exists.

"The decision could mean that religious interests now trump other interests in many circumstances, with religious believers entitled to impose their views at others' expense in ways systematically rejected in the past," Lambda Legal's Law and Policy Project national director, Jennifer Pizer, wrote after the decision.

"Right now we're still trying to assess the impact of *Hobby Lobby* in the workplace and minimizing the harm," says Espinosa-Madrigal.

LGBT employees often have unique health care needs, he says, such as reproductive services, transgender care, and HIV-related treatments. "Post-*Hobby Lobby,* it is important to revisit insurance policies to make sure that the policies cover all of these important segments."

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