

2018

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Christopher DiSanto

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DiSanto, Christopher, "HIV Pre-Exposure Prophylaxis: Are we “PrEPing” for a new epidemic?" (2018). *Law School Student Scholarship*. 937.

http://scholarship.shu.edu/student_scholarship/937

Christopher DiSanto

AWR

Public Health

HIV Pre-Exposure Prophylaxis: Are we “PrEPing” for a new epidemic?

I. Introduction

On July 16, 2012, the FDA approved TRUVADA, the first drug approved to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection, such as those with an HIV-infected partner, or partners at high risk for HIV infection.¹ Truvada for HIV pre-exposure prophylaxis has been shown to prevent the spread of HIV.² However, significant risks exist if the drug recommendations are not properly adhered to which can lead to the spread of the HIV virus, as well as other diseases.³ This paper will first discuss a brief history of HIV medications and an introduction of how Pre-Exposure Prophylaxis (PrEP) was discovered, and what PrEP is. The paper will further discuss the TRUVADA Risk Evaluation and Mitigation Strategy (REMS) and the potential unintended consequences of the drug. The paper will then conclude with the best course of action that should be followed to address these consequences.

Each new generation of doctors and scientists is faced with the challenge of new and emerging diseases. These doctors and scientists join teams of established men and women who have spent their lives tirelessly looking for discoveries to put an end to diseases that have taken

¹Press Release, Gilead Sciences, Inc., U.S. Food and Drug Administration Approves Gilead’s Truvada for Reducing the Risk of Acquiring HIV (July 16, 2012) (on file with author).

² *Id.*

³ *Id.*

the lives of many people. When a new drug is approved by the FDA and is shown to stop the spread of the disease, prescribers and patients may jump at the chance to use the drug, especially when they have lost all hope. Often, these prescribers and patients may utilize the treatments before the full risks associated with the medication are appreciated.

II. Background

In 1981, doctors reported a new disease among homosexual men in the United States.⁴ It would take four years before an antibody test was available to diagnose infection.⁵ In 1983, the World Health Organization started Global HIV surveillance and held its first meeting on AIDS.⁶ It would be years before the government took any action to acknowledge the AIDS crisis.⁷ President Ronald Reagan did not mention AIDS publicly until 1986 and when he finally did utter the word, he provided very limited funding.⁸ The significance of President Reagan's delay in speaking about AIDS is that his delay may have led to the dearth of knowledge about the disease or what caused it, especially in groups at highest risk for infection, such as with men who have sex with men (MSM).⁹ Without society having the education or knowledge of HIV and its infectious potential, the disease spread and HIV infection rates soared. This remains relevant today because we continue to inadequately educate people on the dangers of unprotected sex.

Advancement in the use of HIV medications has come a long way since the discovery of the HIV virus. Azidothymidine, or AZT, was the first medication approved for the treatment of

⁴ *A Timeline of HIV/AIDS*, <http://www.AIDS.gov> (last visited Nov. 12,2016).

⁵ *Id.*

⁶ *Id.*

⁷ *Id.*

⁸ Philip Boffey, *Reagan Defends Financing For Aids*, N.Y. Times, Sept. 18, 1985.

⁹ *Id.*

HIV infection, in the 1980s.¹⁰ Care of HIV infected patients improved markedly when additional drugs were discovered, and the standard of care became use of several drugs in combination, a concept known as Highly Active Anti-Retroviral Therapy (HAART).¹¹ This concept remains the cornerstone of HIV treatment today.¹² In the subsequent years, physicians and scientists realized that HIV medications were effective in preventing HIV infection in patients who had been exposed to the virus.¹³ Post-Exposure Prophylaxis (PEP) for HIV was successful in preventing HIV infections in healthcare workers exposed to the virus through needle sticks.¹⁴ AZT is still the drug of choice for preventing perinatal HIV infection in the children of HIV-infected pregnant patients¹⁵. AZT is administered to the mother in several doses around the time of delivery, and is given to the newborn for the first 4-6 weeks of life.¹⁶ This is associated with an HIV transmission rate near zero, whereas HIV perinatal transmission occurs about in 25% of patients where there is no prophylaxis.¹⁷ In recent years, HIV prevention guidelines recommended the use of PEP in nonoccupational HIV exposures¹⁸. Nonoccupational PEP

¹⁰ Samuel Broder, *The Development of antiretroviral therapy and its impact on the HIV-1/AIDS pandemic*, 85 *Antiviral Research* 1 (Jan. 2010).

¹¹ Stefano M. Bertozzi, *The Evolving HIV/AIDS Response And The Urgent Tasks Ahead*, 28 *Health Affairs* 1578-1590 (Nov. /Dec. 2009).

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *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*, NIH.(Oct. 26, 2016).

http://www.aidsinfo.nih.gov/contentfiles/lvguidelines/peri_recommendations.pdf.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Updated Guideline for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV-United States, 2016*, CDC. (2016), <https://www.cdc.gov/hiv/pdf/programresources/cdc-hiv-npep-guidelines.pdf>.

(nPEP) is highly effective when a three drug regimen is started within 72 hours after a high risk exposure to the HIV virus, and continued for 28 days.¹⁹

Antiretroviral drugs are one of the most lifesaving discoveries in recent medicine, having saved millions of lives in patients infected with HIV, and have prevented countless potential infections in exposed patients²⁰. In 2012, a new frontier emerged in HIV prevention when an existing HIV treatment was approved for use in HIV negative patients for the prevention of HIV infection.²¹ Truvada is a brand-name medication containing two antiretroviral medications, tenofovir and emtricitabine.²² Truvada was initially approved for the treatment of HIV infection in 2004 in combination with other medications.²³ It is also a component of three drug regimens for HIV post exposure prophylaxis.²⁴ Approval of Truvada for a pre-exposure prophylaxis is indeed life changing, and in some cases lifesaving, but it is vitally important that a greater effort be made to ensure that the drug is used safely.²⁵ Modifications to how the drug is prescribed must be made to ensure that the drug is used safely and that patients are receiving the maximum benefit of the drug without the acquisition of unnecessary or unappreciated risk.²⁶

In 1987 the FDA approved the drug zidovudine (AZT).²⁷ AZT was the first drug available to treat HIV but it had significant obstacles in the treatment of the HIV infection.²⁸ The

¹⁹ *Id.*

²⁰ Antiretroviral drugs used in the treatment of HIV infection, FDA.gov. (Aug. 9, 2016), <http://www.fda.gov/ForPatients/Illness/HIVAIDS/Treatment/ucm118915.htm>

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *See supra* note 11.

²⁸ *Id.*

cost of the medication was extremely expensive and the medication had major toxicity.²⁹ Even with the high costs and burden of side effects, the drug did not have a long survival benefit that outweighed the obstacles.³⁰

Next, there was a development of a multi-drug therapy that was discovered to work better than AZT and this was considered one of the great success stories of modern medicine.³¹ It was discovered that the virus mutates and that a combination of drugs together would more effectively fight the disease.³² This combination of drugs (HAART) changed what was once a nearly universally fatal illness to a manageable chronic disease.³³

TRUVADA was first approved by the FDA in August of 2004 as a safe and effective treatment for HIV.³⁴ It was then discovered that individuals who take antiviral therapy shortly after exposure to HIV have a strong likelihood of avoiding infection.³⁵ This is known as PEP (post-exposure prophylaxis), and if taken within 72 hours of exposure is highly effective.³⁶

PrEP (Pre-exposure prophylaxis) was discovered based on the observation of monitoring how PEP worked.³⁷ PEP is prescribed when someone is or believes that they are exposed to the HIV virus.³⁸ The crucial aspect of the efficacy of PEP is the time from HIV exposure to the first dose of antiretroviral medication.³⁹ The time between when someone was exposed to HIV and

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ Takunda Matose, *The Problems With Pre-Exposure HIV Prevention*, Science Progress, Aug. 13, 2012.

³⁵ *Id.*

³⁶ *Id.*

³⁷ Raphael J. Landovitz, MD, *Preexposure Prophylaxis For HIV Prevention: What we Know and What We Still Need to Know for Implementation*, 23 *Top Antivir Med.* 85, (2015).

³⁸ *Id.*

³⁹ *Id.*

the time they took PEP was essential in getting the maximum benefit of the drug.⁴⁰ The closer the timeframe from exposure to medication approaches zero, the better chance the person has of not contracting the disease.⁴¹

PrEP is a means of using medications to prevent HIV infection in uninfected patients.⁴² On July 16, 2012, the FDA approved a new indication for TRUVADA.⁴³ It was now the first drug approved to reduce the risk of HIV infection in uninfected individuals who are at high risk of HIV infection and who may engage in sexual activity with HIV-infected partners.⁴⁴ The approval of TRUVADA was postponed a month because of pressing ethical concerns with the drug.⁴⁵ First, there was a concern that TRUVADA could encourage riskier behavior and potentially lead to higher rates of the HIV infection.⁴⁶ Second, non-adherence to the strict dosing rules can lead to more virulent strains of the virus.⁴⁷ Questions remain about whether the potential for non-adherence could cause more harm than the drug does good.⁴⁸

III. Truvada REMS

To address these serious ethical issues surrounding approval of TRUVADA for PrEP, the FDA required Gilead, the manufacturer of TRUVADA, to provide a risk evaluation and mitigation strategy (REMS).⁴⁹ REMS provides important information about adherence and the

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Truvada for PrEP Fact Sheet: Ensuring Safe and Proper Use. (2012), <http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM312279.pdf>.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ *See supra* note 34.

risk of developing drug resistance.⁵⁰ However, the REMS may not adequately address unrealistic expectations on the part of patients.⁵¹

The Food and Drug Administration Amendments Act (FDAAA) clarified FDA's authority to require enforceable risk management programs such as REMS.⁵² Section 505-1 of the FDAAA states when the FDA may require a REMS: "1) before approval: If the FDA determines a REMS is necessary to ensure that the benefits of the drug outweigh the risks. 2) Post approval: if the FDA becomes aware of new safety information and determining if REMS is necessary to ensure the benefits of the drug outweigh the risk."⁵³ An applicant is also permitted to voluntarily submit a proposed REMS if they believe it is necessary.⁵⁴ There are many factors that the FDA must consider when determining the need for a REMS. They must consider, "1) the size of the population that is likely to use the drug. 2) the seriousness of the disease; 3) the expected benefit of the drug; 4) the expected duration of the treatment; 5) the seriousness of known or potential adverse events and 6) whether the drug is a new molecular entity."⁵⁵

The FDA determined that a REMS is necessary to ensure that the benefits of TRUVADA outweigh whatever risks it may impose.⁵⁶ PrEP was approved with a risk evaluation and mitigation strategy (REMS) to minimize the risk to uninfected individuals of acquiring HIV

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² Lena Y. Choe, Risk Evaluation and Mitigation Strategies (REMS), <http://www.fda.gov/downloads/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/UCM276838.pdf>.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Truvada for PrEP Fact Sheet: Ensuring Safe and Proper Use. (2012), <http://www.fda.gov/downloads/NewsEvents/Newsroom/FactSheets/UCM312279.pdf>.

infection and to reduce the risk of development of resistant HIV-1 variants.⁵⁷ The core component of the TRUVADA REMS is a training and educational program to assist prescribers in counseling individuals who are taking or considering TRUVADA for PrEP.⁵⁸ The goals of the REMS for TRUVADA as a PrEP indication are:

To inform and educate prescribers and uninfected individuals at high risk for acquiring HIV-1 infection about: the importance of strict adherence to the recommended dosing regimen. The importance of regular monitoring of HIV-1 serostatus to avoid continuing to take TRUVADA for a PrEP indication, if seroconversion has occurred, to reduce the risk of development of resistant HIV-1 variants. The fact that TRUVADA for a PrEP indication must be considered as only a part of a comprehensive prevention strategy in order to reduce the risk of HIV-1 infection and that other preventive measures should also be used.⁵⁹

The first and most important goal of the REMS is to inform patients of the critical need for strict adherence to the recommended dosing regimen.⁶⁰ Patients must be instructed that daily dosing must be maintained or the patient will not receive the maximum benefits of the drug.⁶¹ The second goal is to ensure that patients are continuously being re-tested to make sure that they continue to test negative.

The importance of regular monitoring of HIV-1 serostatus to avoid continuing to take TRUVADA for a PrEP indication, if seroconversion has occurred, to reduce the risk of development of resistant HIV-1 variants. “A negative HIV-1 test must be confirmed immediately before starting TRUVADA for a PrEP indication and reconfirmed during treatment. Drug resistant HIV-1 variants have been identified with the use of TRUVADA for a PrEP indication following uninfected HIV-1 infection.⁶²

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ TRUVADA REMS. (last visited Dec. 1, 2016) www.gilead.com

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

It is important to note that monotherapy with TRUVADA is only adequate for pre-exposure prophylaxis in an HIV uninfected patient.⁶³ The two drugs in Truvada, when taken alone, are not effective for the treatment of HIV.⁶⁴ Current standards recommend a three-drug regimen for HIV treatment.⁶⁵ Using fewer than three drugs for the treatment of HIV has been shown to lead to inadequate suppression of the virus and has been associated with the development of drug-resistant strains of HIV.⁶⁶ Since the drugs contained in Truvada are also core components in many regimens for HIV treatment, drug resistance to one or both of these medications would significantly limit the treatment options available to a newly infected patient.⁶⁷ It is essential that a patient know their HIV status during the entire duration of treatment with PrEP for HIV prevention.⁶⁸ If the patient ever has a confirmed positive result, they must discontinue PrEP and begin treatment for the disease.⁶⁹

The REMS for Truvada consists of a training guide for healthcare providers which has prescribing considerations such as,

Only prescribe TRUVADA as a comprehensive prevention strategy...counsel all uninfected individuals to strictly adhere to their TRUVADA daily dosing schedule...confirm a negative HIV-1 test immediately prior to initiating TRUVADA for a PrEP indication...screen uninfected individuals for HIV-1 infection at least one every 3 months...do not prescribe TRUVADA for PrEP indication if signs or symptoms of acute HIV infection are present.⁷⁰

⁶³ *See supra* note 34.

⁶⁴ *Id.*

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ Training Guide for Healthcare Providers. (2016).

http://www.truvadapreprems.com/Content/pdf/Training_Guide_for_Healthcare_Providers.pdf

There is also a safety guide for patients.⁷¹ The guide informs patients that they should make sure that they are HIV negative and stay negative while on PrEP.⁷² One section of the guide reads “Just taking Truvada alone may not keep you from getting HIV-1 infection... You must continue using safer sex practices while you are taking TRUVADA to reduce your risk of getting HIV-1 infection.”⁷³ Interestingly, the word “condom” does not appear anywhere in this safety guide. It is making the assumption that 1) Patients will actually read this guide, and 2) That patients that do read the guide are capable to understand that condoms are being implied by the phrase “using safer sex practices.”⁷⁴

IV. Barriers to Access

There are barriers to accessing PrEP that can create obstacles to patients who may benefit from the drug.⁷⁵ The first major barrier is that people who can benefit from the drug are not receiving it because they may not even know that it exists.⁷⁶ Accessibility is a barrier to PrEP because it is a prescription only medication, and obtaining it requires a patient-provider discussion about patients’ sexual behaviors and level of risk.⁷⁷ Those who may know it exists may not feel comfortable discussing their sexual activity in front of doctors.⁷⁸ “In a recent survey

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ Joseph Schwartz and Josh Grimm, *PrEP on Twitter: Information, Barriers, and Stigma*, Health Communication. (Jun. 13, 2016)

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ James Wilton, *Pre-Exposure prophylaxis for sexually-acquired HIV risk management: a review* 7 HIV/AIDS- Research and Palliative Care 125 (April 28, 2015).

of over 9,000 MSM in the US, 16% did not have a primary care provider and only half of those with a provider felt comfortable talking to them about sex.”⁷⁹ If patients do not have a primary doctor that they see on a regular basis then they are less likely to feel comfortable to confide in a perfect stranger.⁸⁰ Patients in greatest need of PrEP may feel uncomfortable to discuss sexuality, let alone discuss their homosexuality and specific sexual behaviors which may place them at highest risk.⁸¹

Other patients may avoid getting PrEP because there is a stigma in regards to any type of HIV medication.⁸² PrEP may be associated with the stigma because people may believe that PrEP users are HIV infected.⁸³ There is a stigma that if someone is using PrEP they are promiscuous or irresponsible.⁸⁴ There are cultural and moral beliefs that someone that is using any type of HIV drug either has HIV or they are at high risk of being infected.⁸⁵ Furthermore, “Prep may have generated ‘moral panic’ in certain stakeholders concerned about a potential loss of sexual restraints, leading to so-called risk compensation (i.e. having riskier sex and thereby neutralizing the benefit of prep).⁸⁶ Even with the gay community, this concern has created a certain stigma affecting prep.”⁸⁷

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ *Id.*

⁸² Jeremy Sugarman, MD, *Ethics and Pre-Exposure Prophylaxis for HIV-infection* 63 J Acquir Immune Defic SSYndr. S135 (Jul. 2013).

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Carlos F. Caceres, *The Promises and challenges of pre-exposure prophylaxis as part of the emerging paradigm of combination HIV prevention*, 18 J Int. AIDS Soc. (July 20, 2015).

⁸⁷ *Id.*

Another issue of concern for MSM patients is the stigma of receptive sex.⁸⁸ There is a stigma that men who are the receptive partner are feminine and often these individuals may be reluctant to be honest about their sexual role out of shame or embarrassment.⁸⁹ This is critically relevant to HIV prevention, because the risk of being infected with HIV is substantially higher for the receptive partner in MSM relationships.⁹⁰ Being an insertive partner is ten times less risky than being a receptive partner.⁹¹ There is a 1 in 500 chance of becoming infected from one incident of unprotected anal sex with an HIV positive receptive partner, but there is a 1 in 50 chance of becoming infected from one incident of unprotected anal sex with an HIV positive insertive partner.⁹² Since men who engage in receptive sex are more at risk of contracting HIV, they should be the first to take advantage of PrEP.⁹³ Yet, this group of MSM may be less likely to ask their doctor about the drug for fear of being judged for their preferred sexual position.⁹⁴

About 14% of the more than 1.2 million Americans living with HIV are unaware of their status.⁹⁵ For young people the numbers are more troubling.⁹⁶ More than half of HIV-infected people age 13 to 24 are unaware of their status.⁹⁷ The large number of cases that are undiagnosed or diagnosed at, an advanced state, represent lost opportunity for prevention and

⁸⁸ B. Varghese, *Reducing the risk of sexual hiv transmission quantifying the per-act risk for HIV on the basis of choice of partner, sex act, and condom use*, 29 *Sexually Transmitted Diseases*. 38 (2002).

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ Lawrence O. Gostin and Lindsay F. Wilay, *Public Health Law: Power, Duty, Restraint* 369-370 (Univ. of Cali. Press, 3rd ed. 2016).

⁹⁶ *Id.*

⁹⁷ *Id.*

treatment.⁹⁸ Over time, however, it became clear that stigma and discrimination, which deter people from getting tested and seeking treatment were significant barriers to an effective public health response.⁹⁹ In 2001 the United Nations called on states to enact law to eliminate all forms of discrimination against, and to ensure the full enjoyment of all human rights and fundamental freedoms by people living with HIV/AIDS and members of vulnerable group.¹⁰⁰

Destigmatization has the dual purpose of safeguarding individual rights and protecting the public's health by reducing transmission.¹⁰¹

Provider-level barriers include a lack of PrEP awareness and knowledge.¹⁰² Often, patients go to their primary care doctor for advice on medical conditions or to seek treatment for an unknown illness.¹⁰³ Unfortunately, most generalists, even in urban areas with high HIV prevalence, are the least uninformed about the availability and use of PrEP.¹⁰⁴ HIV specialists have the most experience and knowledge about PrEP but often patients do not seek out an HIV specialist.¹⁰⁵ There may be a stigma that if an individual seeks out an HIV specialist that people will think that they have HIV.¹⁰⁶ They will avoid these specialists who have the most knowledge about the medication and who would be better educated at discussing the requirements of

⁹⁸ *Id.*

⁹⁹ *Id.* at 381.

¹⁰⁰ *Id.* at 383.

¹⁰¹ *Id.* at 383.

¹⁰² *See supra* note 71.

¹⁰³ *See supra* note 71.

¹⁰⁴ *See supra* note 71.

¹⁰⁵ *See supra* note 71.

¹⁰⁶ *See supra* note 71.

receiving the maximum benefit from the drug.¹⁰⁷ Furthermore, those patients who are unfamiliar with PrEP would not know to seek out a specialist, even if they were motivated to do so.¹⁰⁸

A survey was developed to evaluate the current practices and attitudes among infectious disease experts.¹⁰⁹ The main purpose of this survey was to assess provider opinions, readiness and current practices of PrEP in the United States and Canada.¹¹⁰ Questions included the physician's HIV practice, whom they provided or would provide PrEP to, how they assess eligibility, how they measure adherence, when they would discontinue PrEP, and what perceived barriers exist.¹¹¹ Nearly 75% of those physicians that responded supported the provision of PrEP but only 9% of those physicians actually provided PrEP to patients.¹¹² Most physicians stated that they did not provide PrEP because they were worried about adherence and the risk for future resistance.¹¹³ There was a concern from these doctors that there was a lack of resources and information and that they don't know enough to feel comfortable enough to prescribe the medication.¹¹⁴ When doctors were asked to rank the order of barriers to prescribing PrEP, many stated that it was too time consuming to counsel and access adherence.¹¹⁵

¹⁰⁷ *See supra* note 71.

¹⁰⁸ *See supra* note 71.

¹⁰⁹ Maile Y. Karris, *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 (Dec. 6, 2013).

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ *Id.*

Another barrier to access is financial coverage for the medication.¹¹⁶ The high cost of the medication can pose a significant hardship on the individual and some may even think the cost is not worthwhile.¹¹⁷ The issue with this barrier is, even when patients have prescription coverage for the medication, navigating the requirements to get approval for the medication is time consuming.¹¹⁸ It is often difficult to get approval and this can be very discouraging for many patients.¹¹⁹ There is a paradox where uninsured patients could access PrEP through patient assistance programs but patients who are insured do not have access to the program because only uninsured qualify.¹²⁰ Though these patients may have medical insurance, they cannot afford the medication because of the high cost of the deductible.¹²¹ There is also a concern that because follow-ups and monitoring are required they won't be able to afford the frequent co-pays for the doctor visits, testing and refills.¹²² Financial constraints could also be a barrier to implanting PrEP in government funded or subsidized health systems.¹²³

V. Adherence Concerns

Another issue is that some people who are receiving PrEP are not using it correctly.¹²⁴ There is a strong concern about adherence.¹²⁵ Adherence was strong among patients who

¹¹⁶ Sarah K. Calabrese, *Putting PrEP into Practice: Lessons learned from Early-Adopting U.S. Providers' Firsthand Experiences Providing HIV Pre-Exposure Prophylaxis and Associated Care* 11 PLOS one (June 15, 2016).

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ Douglas S. Krakower & Kenneth H. Mayer, *Pre-Exposure Prophylaxis to Prevent HIV Infection: Current Status, Future Opportunities and Challenges* 75 *Drugs* 243 (Feb. 2015).

¹²⁵ *Id.*

actively sought PrEP.¹²⁶ These patients researched what PrEP was and how it could change their lives or they knew of friends or family who told them about the drug and its benefits.¹²⁷ Many patients cite condom use as a barrier to physical intimacy and sexual pleasure.¹²⁸ Patients who sought out PrEP on their own initiative were more likely to diligently use condoms and were motivated to seek a suitable alternative were much more responsible in adhering to the requirements of treatment.¹²⁹ Alternatively, patients who started prophylaxis at the recommendation of their doctors tended to be less adherent.¹³⁰ In fact, some of these patients were overwhelmed by the follow-ups that were required and often did not return.¹³¹

Adherence among one of the target demographics for PrEP, young MSM, was most concerning.¹³² Most patients under the age of 25 have a limited degree of routine; they often do not do the same thing every day.¹³³ This particular demographic is specifically unfamiliar with a daily regimen of medications accompanied by relatively frequent doctor visits.¹³⁴

Another barrier is the anticipated behavior (risk compensation).

This concern is best explained by the prevailing theory about how individuals manage their personal risks. Risk “homeostasis” is defined as “a system in which individuals accept a certain level of subjectively estimated (or “perceived”) risk to their health in exchange for benefits they expect to receive from an activity” In accepting a particular level of risk for an adverse event, individuals maintain an approximate risk set point. However, introduction of an intervention that reduces the perceived risk of

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *See supra* note 109.

¹³³ *See supra* note 109.

¹³⁴ *See supra* note 109.

the behavior or activity may cause a person to increase risky behavior- this is called “risk compensation” so that the discrepancy between the level of risk he or she takes and the perceived risk increases.¹³⁵

In a study regarding ART (formally known as HAART), it was found that people who believed ART reduced the likelihood of HIV transmission or “lessened the likelihood of transmission were more likely to engage in unprotected sex.”¹³⁶ With this information it would seem plausible that people would have the same feelings about PrEP.¹³⁷ Prior to the FDA approval of PrEP, potential users were surveyed and reported that they believed taking PrEP could decrease their use of condoms.¹³⁸ But risk compensation after PrEP implementation has been examined in several trials and to date has not been associated with increased sexual risk behavior or sexually transmitted infections in the majority of these studies.¹³⁹ However, this may not be true in clinical practice; “all randomized and open-label trials of PrEP have provided and emphasized the use of condoms, as well as HIV testing: this model may not be fully implemented in clinical practice...sexual risk behaviors have been shown to increase following significant HIV biomedical breakthroughs.”¹⁴⁰

There is a misconception that PrEP is all that is needed to prevent the HIV virus when engaged in sexual activity.¹⁴¹ In a recent study on the use of PrEP, 30% of men reported that they would not use condoms or they would use condoms less often if they were on PrEP.¹⁴² One

¹³⁵ Jill Blumenthal & Richard Haubrect, *Risk compensation in PrEP: An old debate emerges yet again*. 16 *AMA Journal of Ethics* (Nov. 2014).

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ Colleen C. Hoff, PhD, *Attitudes Towards PrEP and Anticipated Condom Use Among Discordant Male Couples*, 29 *Aids Patient Care and STDs* 408 (June 9, 2015).

¹⁴² *Id.*

MSM in the study said, “If I were using it, I would assume I wouldn’t have to use a condom.”¹⁴³

The use of condoms is essential in combination with the drug to receive the highest level of the benefit of the medication.¹⁴⁴ Though PrEP may help decrease the spread of the HIV infection, it does not stop the spread of other sexually transmitted diseases The CDC reported,

Trend data shows the rate of syphilis are increasing at an alarming rate (15.1 percent in 2014). While rates have increased among both men and women, men account for more than 90 percent of all primary and secondary syphilis cases. Men who have sex with men (MSM) account for 83 percent of male cases where the sex of the partner is known. Primary and secondary syphilis are the most infections stages of the disease, and if not adequately treated, can lead to long-term infection which can cause visual impairment and stroke.¹⁴⁵

One reason that has been given to why sexually transmitted diseases is on the rise is because the change in behavior among gay and bisexual men and it correlates with the advent of HIV treatment.¹⁴⁶ PrEP has changed what people think of HIV. Individual outlooks on the disease have changed considerably, but maybe to their detriment.¹⁴⁷ Dr. Gail Bolan from the CDC was interviewed by NBC news and stated, “People are excited about it, and some have stopped using condoms so consistently, because they are no longer afraid of a deadly infection.¹⁴⁸ But, unfortunately, HIV treatment has no impact on prevention of other STDs. unless you are using condoms consistently and correctly, you are putting yourself at risk for

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ Centers for Disease Control and Prevention, Congenital Syphilis Fact Sheet (2014).

¹⁴⁶ Maggie Fox, *CDC Sees Alarming Increase in Sexually Transmitted Diseases*, NBC.Com (Nov. 17, 2015).

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

STDs.”¹⁴⁹ The 2015 CDC fact sheet shows that since 2014 Chlamydia is up 6%, Gonorrhea is up 13%, Syphilis (primary and secondary) is up 19% and congenital syphilis is up 6%.¹⁵⁰

Even though adherence to the strict dosing is essential, condom use must still be adhered to. The problem lies with patients who believe as long as they adhere to the dosing requirements they do not need to use condoms.

Initial data from demonstration studies in MSM show that people who choose to take PrEP may, in fact, be those who report episodes of unprotected anal intercourse, and their reported PrEP adherence is already high, with no subsequent risk compensation of change from their present condom use. Hence, at least among MSM, PrEP may become a choice among people at risk due to condomless anal sex, who feel that a daily pill may suit them better than condoms.¹⁵¹

The presumption that condoms are unnecessary while taking PrEP is critically flawed.¹⁵² Pre-exposure prophylaxis with TRUVADA alone does not confer 100% protection from HIV infection.¹⁵³ It is essential that condoms are used in combination with the medication. “PrEP was misunderstood as intended to replace condoms, while in fact it was meant to become one element (but never the sole element) of the emerging paradigm of combination prevention.”¹⁵⁴

David Knox, MD recently reported a case study at the 2016 Conference on Retroviruses and Opportunistic Infections (CROI) of a 43-year-old MSM with excellent adherence to the medication who tested positive for HIV after 2 years of treatment with PrEP.¹⁵⁵ The patient’s

¹⁴⁹ *Id.*

¹⁵⁰ Centers for Disease Control and Prevention, Congenital Syphilis Fact Sheet (2015).

¹⁵¹ *See supra* note 79.

¹⁵² *See supra* note 79.

¹⁵³ *See supra* note 79.

¹⁵⁴ *See supra* note 79.

¹⁵⁵ David C. Knox et al., *HIV-1 Infection With Multiclass Resistance Despite Preexposure Prophylaxis (PrEP)* <http://www.croiconference.org/sessions/hiv-1-infection-multiclass-resistance-despite-preexposure-prophylaxis-prep> (last visited Nov. 1, 2016).

adherence was confirmed with pharmacy dispensing records, as well as blood tests for levels of the medication.¹⁵⁶ Despite this excellent adherence and adequate drug levels in the body, he still contracted the HIV infection.¹⁵⁷ This was the first reported case of HIV infection with evidence of long-term adherence to PrEP, but it would not be only case.¹⁵⁸ In October of 2016, researchers at the 2016 HIV research for Prevention Conference made an announcement that a second man in the United States acquired HIV despite that he also was using PrEP.¹⁵⁹ Dr. Howard Grossman, a New York City Physician, says that the man is his patient and was adhering to the PrEP dosing requirements since 2015.¹⁶⁰ Dr. Grossman stated in an interview that “the man had required a rare strain of HIV that is resistant to both of the drugs found in TRUVADA.”¹⁶¹ Dr. Knox’s patient similarly acquired a strain of HIV resistant to both medications in TRUVADA.¹⁶²

Drug resistance is a particular concern if a patient is not consistently tested every three months.¹⁶³ There is a concern that if a person continues to take PrEP when they are already infected, resistance to the medication may develop, “the box warning for tenofovir-emtricitabine, includes cautionary language regarding the need to ensure that those using the product for prep are HIV-uninfected before initiating use and they are regularly tested.”¹⁶⁴ The current labeling for TRUVADA does not have a warning label in regards to adherence or using safer sex

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ Noel Gordon, *Man Contracts Rare Strain of HIV While on PrEP, Human Rights Campaign Blog* (Oct. 19, 2016) <http://www.hrc.org/blog/man-contracts-rare-strain-of-hiv-while-on-prep>

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² *Id.*

¹⁶³ *See supra* note 75.

¹⁶⁴ *See supra* note 75.

practices.¹⁶⁵ Without clear and simple instructions on how to take their medicines, these patients are subjected to medication errors that may lead to poor adherence and sub-therapeutic outcomes.¹⁶⁶ Complexity of written information hinders patients' understanding of their medications which then leads to misuse of prescribed medications.¹⁶⁷

One way to enhance patient understanding would be to develop patient warning labels. Prescription warning labels (PWLs) are small, colorful stickers adjacent to the prescription label on dispensing bottles that remind or highlight the most important instructions for patient's safe and effective use of medications.¹⁶⁸ For example, PWL's contain warning statements about specified medications such as "do not take with alcohol: or "take with food."¹⁶⁹ Including the word "WARNING" creates alertness. Patients expressed that the word "WARNING" drew their attention to the PWL and it made them think of the cautionary instruction.¹⁷⁰ Similar, pictorial warning labels were suggested on cigarette packs to convince people that smoking was bad for their health.¹⁷¹ Requiring pictorial warning labels on all cigarette packs would be appropriate for the protection of the public health because it would substantially reduce smoking prevalence and thereby reduce SADs and the morbidity and medical costs associated with adverse smoking-attributable birth outcomes.¹⁷² In 2009, the Family Smoking Prevention and Tobacco Control Act was signed into law, authorizing the FDA to regulate cigarettes and other tobacco products,

¹⁶⁵ CDC Fact Sheet For Truvada

https://www.cdc.gov/hiv/pdf/prep_gl_patient_factsheet_truvada_english.pdf

¹⁶⁶ *Id.*

¹⁶⁷ Olayinka O. Shiyabola et al., *Refining Prescription warning labels using Patient Feedback: A Qualitative Study* 11 PLOS one (June 2, 2016).

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¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ David T. Levy et al., *Public health benefits from pictorial health warnings on US cigarette packs: a SimSmoke simulation* Tobacco Control (Oct. 1, 2016).

¹⁷² *Id.*

including their packaging and labeling.¹⁷³ The D.C. Circuit Court of Appeals struck down the rule and hinged in part on a concern that the pictorial warning labels might not produce any significant reduction in smoking.¹⁷⁴ With recent studies on the effect of PWLS on prescription drugs there should be more of a warning on TRUVADA bottles and packaging.

Another barrier is that young people are engaging in sexual activity at a much younger age and are often not educated on proper safer practices.

According to the Center for Disease Control, almost half of U.S. high schoolers (46 percent) have had sexual intercourse, with approximately 6 percent having an age of sexual initiation as young as 13 years old. That means for the first few years a person is at the highest risk for acquiring HIV, they aren't eligible for Truvada Prep per the FDA approval...we see that these are also the groups with the greatest risk factors for non-adherence.¹⁷⁵

The most important risk of this medication is that some MSMs will continue to believe that PrEP is all that is needed to not get infected with HIV.¹⁷⁶ Numerous casual dating sites such as Manhunt, ADAM4ADAM and phone applications like GRINDR that make casual sex easier than ever.¹⁷⁷ Looking through these sites, one quickly finds an enormity of profiles that in search of condomless sex: "bareback only – HIV negative on PREP."¹⁷⁸ These profiles make the mistaken claim that bareback (unprotected) sex is safe, provided one party is on PrEP.¹⁷⁹ These

¹⁷³ *Id.*

¹⁷⁴ *Id.*

¹⁷⁵ *See supra* note 30.

¹⁷⁶ Sergio Nahuel Candido, *Community Healthcare Network Releases Report on Attitudes, Knowledge About HIV/AIDS Among Gay, Bisexual Men Who Use Social Networking Apps* (2013) <https://www.scribd.com/document/121689215/Zero-Feet-Away-Perspective-on-HIV-AIDS-and-Unprotected-Sex-in-Men-Who-Have-Sex-with-Men-Utilizing-Location-based-Mobile-Apps>

¹⁷⁷ *Id.*

¹⁷⁸ *Id.*

¹⁷⁹ *Id.*

individuals are mistakenly reassured in their immunity to HIV, not to mention their heightened risk for other sexually transmitted infections.¹⁸⁰ This is a problem that may see astronomical destruction, especially among the gay population.¹⁸¹

According to the study, *Zero feet away Perspective on HIV/AIDS and unprotected sex in men who have sex with men utilizing location based mobile Apps*, a total 727 participants were recruited through advertisements placed on large geo-social networking apps for MSM responded to questionnaires about unprotected sex¹⁸². Nearly 50 % of the men surveyed said they are afraid of getting infected or re-infected with the virus, yet they persist to participate in risky taking activities such as unprotected anal intercourse. An astounding 46 % admitted to never using condoms.¹⁸³

There are also concerns that the medication has some potential side effects which may cause patients to stop taking the medication as prescribed.¹⁸⁴ Toxicity is a problem associated with the medication.¹⁸⁵ The medication, in a small number of patients, has caused kidney and liver issues. “PrEP can cause decreases in kidney and liver function and bone mineral density, promisingly, renal function tended to return to normal after discontinuation of PrEP.”¹⁸⁶ The problem with this is that the medication has to be stopped in order for the renal function to normalize but PrEP has a strict dosing requirement; it is not meant to be discontinued.¹⁸⁷

¹⁸⁰ *Id.*

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *See supra* note 71.

¹⁸⁵ *See supra* note 71.

¹⁸⁶ *See supra* note 71.

¹⁸⁷ *See supra* note 71.

V. Possible Solutions

Education for both the provider, as well as the patient is key is to addressing some of the potential barriers. Provider-level barriers include a lack of PrEP awareness and knowledge, as well as negative opinions and attitudes toward PrEP.¹⁸⁸ The first step is to increase the awareness and knowledge of the benefits of PrEP among at risk populations and service providers.¹⁸⁹ Adherence is critical to reduce HIV infections.¹⁹⁰

If the public is not educated, there will be another epidemic that can sweep in. The Syphilis outbreak in the 1930's was a huge epidemic that was fueled by stigma surrounding testing and a concern that treatment would increase sexual risk behaviors.¹⁹¹ Practitioners need to make sure that patients seeking PrEP are not stigmatized in the same way that patients in the 1930's were stigmatized regarding syphilis.¹⁹²

There needs to be formal training and educational seminars so that prescribers are fully trained in effectively treating at risk patients about the use of PrEP. Currently, there is no formal training for prescribers or patients.¹⁹³ “Nearly all providers indicated that they were self-educated with respect to PrEP. Rather than participating in formal training, their knowledge about PrEP was obtained through a combination of reading relevant literature, attending professional talks and conferences, consulting with colleagues.”¹⁹⁴

¹⁸⁸ *See supra* note 71.

¹⁸⁹ *See supra* note 71.

¹⁹⁰ *See supra* note 71.

¹⁹¹ *See supra* note 88 at 381.

¹⁹² *See supra* note 88 at 381.

¹⁹³ *See supra* note 125.

¹⁹⁴ *See supra* note 125.

The New York State Department of Health Aids Institute produced a Guidance of Pre-Exposure Prophylaxis to Prevent HIV Transmission on what appropriate protocols should be followed to receive the maximum benefits of PrEP.¹⁹⁵ They suggest to first screen the patient to ensure they are a candidate for the medication¹⁹⁶. Next is to educate patient on how PrEP works, including its risks and benefits¹⁹⁷. They emphasize that strict adherence is needed to maintain protective drug levels.¹⁹⁸ Next, it is imperative that a negative test result is confirmed before PrEP is prescribed.¹⁹⁹ The guidelines then suggest that once PrEP is prescribed to have the patient follow up in two weeks to assess possible side effects²⁰⁰. Then the patient should visit every three months for another HIV test to make sure that the patient is still testing negative and also assess kidney function and screen for other STIs. It is very important that there is follow-up management and monitoring. Prescribers should not only test the patient every three months for HIV infection and other STIs, but should also discuss prevention services such as risk reduction counseling and access to condoms.²⁰¹

Before HIV was discovered, in the 1970's and 1980's gay men had a sexual freedom to do what they wanted, where they wanted and with whomever they wanted. Sex was happening in a variety of different places.

Establishments including certain bars, clubs and bathhouses which are used as places for engaging in high risk sexual activities contribute to the propagation and spread of such AIDS-associated retro-virus; Appropriate public health interventions to discontinue

¹⁹⁵ Guidance For the Use of Pre-Exposure (PrEP) to Prevent HIV Transmission, New York State Dept. of Health Aids Institute. (Last visited Dec. 1, 2016) www.hivguidelines.org

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ *Id.*

such exposure at such establishments is essential to interrupting the epidemic among the people of the State of New York.²⁰²

Bathhouses were closed down due to the public health concern of widespread HIV infection at these establishments.²⁰³ This led to the spread of the virus because men would meet up at these establishments and have unprotected sex because they were not aware of the consequences²⁰⁴. With PrEP, again MSM are not aware of the consequences.²⁰⁵ There is a new sexual liberation among gay men who believe that they can do what they want without protection and there are no consequences to having unprotected sex.²⁰⁶ In the 1970's no one knew what HIV was, what AIDS was.²⁰⁷ No one knew that there was this horrendous disease that would kill millions of people.²⁰⁸ In 2015 there were 17 million people living with HIV who were on antiretroviral therapy.²⁰⁹ There were 2.1 million new HIV infections. In 2014 there were 390,000 Tuberculosis-related AIDS deaths. In 2015 there were 36.7 million people worldwide living with HIV. there were 1.1million AIDS related deaths.²¹⁰ Since the beginning of the epidemic, 78 million people have contracted HIV and 35 million have died of AIDS-related causes.²¹¹ Without condom use there is a chance of individuals contracting HIV and any of the many other sexually transmitted diseases that can cause death.

Deaths from sexually transmitted diseases (STDs) often occur long after acute infection, making their incidence difficult to

²⁰² *New York v. New St. Mark's Baths*, 130 Misc. 2d 911, 497 N.Y.S.2d 979 (Sup.Ct. 1986).

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.*

²⁰⁷ AIDS By The Numbers, http://www.unaids.org/sites/default/files/media_asset/AIDS-by-the-numbers-2016_en.pdf (last visited Dec. 1, 2016).

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ *Id.*

²¹¹ *Id.*

estimate. Some infections, such as syphilis, may directly result in death. By contrast, human papilloma virus (HPV), HIV, and hepatitis more commonly cause death because of secondary sequelae. Genital herpes, gonorrheal infection, and chlamydial infection may cause death from primary infection.²¹²

The safety guidelines part of the REMS need to be modified.²¹³ There is not one place in the REMS guidelines where the word condom appears.²¹⁴ The guidelines should be clearer and say, “You must still use condoms while on this medication.” If people are fully aware that they must still use condoms with this medication, some might choose to forgo the medication and just use condoms.²¹⁵

The REMS are merely suggestions.²¹⁶ The REMS say “Uninfected individuals SHOULD be counseled about safer sex practices...SHOULD be tested to confirm they are HIV-1 negative...SHOULD be screened at least every 3 months for HIV-1 status.”²¹⁷ These guidelines only use the word “should,” it is a suggestion, meaning that they are able to deter from this guideline. These guidelines should be a “must.” If prescribers are able to deter from these guidelines, then patients and prescribers need to know what the consequences are if they do not adhere to these recommendations. HIV testing is mandatory in the United States for blood and organ donors, military applicants and sometimes federal and state prisons.²¹⁸

²¹² Kara A. McElligott, *Mortality From Sexually Transmitted Diseases in Reproductive-Aged Women: United States, 1999-2010* 104 *American Journal of Public Health* e101 (Aug. 2014).

²¹³ <http://www.truvadapreprems.com/truvadaprep-resources>

²¹⁴ *Id.*

²¹⁵ *Id.*

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ HIV Testing in the United States, The Henry J. Kaise Family Foundation. (last visited Dec. 1, 2016) <http://kff.org/hiv/aid/fact-sheet/hiv-testing-in-the-united-states>.

HIV- testing should be mandatory for anyone that is being prescribed PrEP. Testing should continue to be mandatory on a regular basis to make sure they are continuously being monitored to ensure they are not taking the medication while already have the virus. Perhaps there should be some type of mandatory computer system or registry to verify and confirm repeated testing results. New York State currently uses this type of system for prescription monitoring program for certain controlled substances.²¹⁹ Prescribers are required to consult the prescription monitoring program, known as I-Stop when prescribing controlled substances to determine whether prescription have been obtained elsewhere.²²⁰ Prescribers of PrEP could have a similar system where they must consult with a registry to make sure that when prescribing PrEP initial or as a refill, a patient is being retested for HIV.

Another possible solution is more research is needed to see why adherence is such a problem and how to decrease the stigma in associated with PrEP. Destigmatization is very important in order for patients to feel more comfortable is seeking out the drug. In 2001 the United Nations called on states to enact law to eliminate all forms of discrimination against, and to ensure the full enjoyment of all human rights and fundamental freedoms by people living with HIV/AIDS and members of vulnerable group.²²¹

In spite of being described as a miracle, employing the drug Truvada as PrEP remains a highly contested and often stigmatized solution for prevention.²²² Studying messages about PrEP on Twitter is valuable because it allows for a unique opportunity to explore how individuals

²¹⁹ https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/

²²⁰ *Id.*

²²¹ *See supra* note 88 at 383.

²²² Margaret L. McLaughlin, *Propagation of Information About Pre-Exposure Prophylaxis (PrEP) for HIV Prevention Through Twitter*. 31 Health Communication 998 (2016).

discussed PrEP.²²³ This is helpful to health professionals interested in understanding how to better address PrEP related stigma and how to reduce barriers to PrEP adoption.²²⁴ Stigmas and barriers to PrEP over the course of the history of AIDS in the US, significant portion of the American population reported feeling anger, disgust, fear, and blame toward people with AIDS.²²⁵ HIV-related stigmatization continues to occur because of the implication that PrEP will encourage people to abandon the safer sex practices, some MSM who take it report they were stigmatized by their medical provides, friends and sex partners.²²⁶ Huffington Post columnist David Duran referred to gay0 men on PrEP as “Truvada whores” because they might engage in condomless intercourse.²²⁷ In a widely cited Associated Press article, the President of the AIDS Healthcare foundation, Michael Weinstein described PrEP as a party drug.²²⁸

VI. Conclusion.

Randomized placebo-controlled studies have demonstrated that daily oral anti-retroviral pre-exposure chemoprophylaxis (PrEP) can significantly reduce HIV incidence among diverse at-risk populations.²²⁹ In these studies, the efficacy of PrEP was correlated with levels of adherence.²³⁰ These challenges include low awareness and utilization of PrEP by high risks persons, uncertainty about the drug. However, several potential barriers to implementing PrEP

²²³ *Id.*

²²⁴ *Id.*

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ *Id.*

²²⁸ *Id.*

²²⁹ *See supra* note 124.

²³⁰ *Id.*

remain. These include low awareness and utilization of PrEP by at-risk persons, uncertainty about adherence in real world settings, the majority of healthcare providers being untrained in PrEP provision, limited data about potential adverse effects from long-term use of tenofovir-emtricitabine, high costs of PrEP medication and stigma. ²³¹

PrEP has not been around long enough to fully appreciate the long term effects. There is not enough research to show that a person can use this drug for an extended period of time safely. There are concerns that PrEP may lead to more opportunities for drug resistant strains of HIV to develop. ²³² New diseases are discovered all the time. 50 years ago AIDS did not exist and when it was discovered, it would be years before testing could be done and even longer for treatment. If patients do not adhere to the recommendations to use PrEP properly with the combination of condoms, then we may face another public health epidemic with a new disease that may be transmitted sexually.

Not everyone is educated on the use of PrEP. Not only do the patients that are being prescribed need the education but also their sexual partners. If a person tells his partner that he is on PrEP, there is no indication or proof that he has been taking the recommended dose or that he is continuing to be tested for HIV as the guidelines recommend. The public needs to know what to ask and they need to be educated about the consequences of non-adherence.

Education was an important element in fighting the spread of AIDS. Today there is a lack of education, and media coverage is almost non-existent about HIV and AIDS. There needs to be

²³¹ *Id.*

²³² Dara A. Lehman et al., *Risk of Drug Resistance Among Persons Acquiring HIV Within Randomized Clinical Trial of Single- or Dual-Agent Preexposure Prophylaxis* 211 *The Journal of Infectious Diseases* 1211 (April 15, 2015).

constant training and education on AIDS and HIV and the use of treatment therapies and prevention.

If society continues to disregard the requirements to use PrEP with condoms, then society will face another epidemic when a new deadly disease is discovered and history will unfortunately repeat itself. PrEP is a miracle drug that has saved lives and changed how the world thinks about HIV. There needs to be modifications to how the medicine is prescribed and there needs to be better education and information about adherence to the drug.