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Intimate Innovation

Subjectivity, political economy, and a novel method to prevent HIV

by

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Abstract

Intimate Innovation:
Subjectivity, political economy, and a novel method to prevent HIV

Ryan Whitacre

In July 2012, the United States Food and Drug Administration (FDA) approved the commercial use of an antiretroviral pharmaceutical to prevent HIV. This method of preventing HIV is known as HIV pre-exposure prophylaxis (PrEP). The single pharmaceutical product approved for commercial use as PrEP is manufactured by Gilead Sciences, Inc (Foster City, CA) and sold under the brand name Truvada. This dissertation traces the development, commercialization, and implementation of Truvada as PrEP from an anthropological perspective, including by exploring several elements of the political economy of health, such as processes of innovation in drug development. The dissertation also displays how this novel method to prevent HIV emerges from a long history of HIV prevention in which the intimacy of 'at risk' individuals has been managed through techniques of discipline, including those that encourage individuals to engage only in 'safe' sex and to speak to physicians and investigators about their 'risky' practices. At the same time, this historical and ethnographic research marks an important shift in the value systems of antiretroviral markets, which once stitched together public interests (of the state and its citizen) and private interests (of the pharmaceutical industry) through the moral imperative to save life and are now strengthening public-private partnerships in order to secure health and manage sexual pleasure. By following the product life of Truvada from early moments in the antiretroviral market when Gilead obtained licenses for its pharmaceutical components into present day clinical care, where providers are prescribing Truvada as PrEP to augment sexual pleasure, this account brings together intimacy and innovation to show how they have become intertwined and inseparable. Thus, the dissertation argues PrEP is an *intimate innovation*.

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Introduction

In May of 2011 the AIDS Healthcare Foundation hosted a symposium about a novel method to prevent HIV known as HIV pre-exposure prophylaxis (PrEP). At the time results had been released from one clinical trial testing an antiretroviral pharmaceutical for PrEP, but the U.S. Food and Drug Administration had not yet approved its use. UC Berkeley anthropology professor, Lawrence Cohen, was invited to provide remarks. He tapped a doctoral student to join him. That student had expertise in the history of the virus and the politics of access to life-saving medications. He was also savvy enough to know the politics of the AIDS Healthcare Foundation, which had expressed polarizing opinions about PrEP. So, that student declined to join, and I went instead. We sat on a panel, which was comprised of public health providers, community advocates, and HIV care program directors.

Throughout the symposium presenters speculated about the potential impact of PrEP on the future of HIV prevention. Cohen contextualized PrEP within the discourse of HIV science that was persistently promising to "end" the epidemic and discussed a trend toward pharmaceutical prevention over behavior-based interventions and treatment. I noted how the rollout of PrEP would need to be supported by other care services, especially because the trial participants I had spoken with told me that they started having sex differently when they were taking that little blue pill. The other presenters cautioned the use of PrEP, noting toxicity and insubstantial evidence about efficacy as well as high cost and therefore likely struggles for access. Some of the presenters also emphasized the idea that taking a pill to prevent HIV might encourage risky sexual behavior. During much of the symposium, the future of PrEP looked

bleak.

However, the final speaker of the afternoon changed the tone of the conversation. He introduced himself as Dana Van Gorder, the executive director of Project Inform, an advocacy group for HIV care. He was there to represent Gilead. (The firm itself had opted out of the event.) Responding to the assertions of previous presenters, he was distraught after hearing little in support of what he considered to be the greatest sign of hope for HIV prevention in decades. His voice quivered. Seated among the table of panelists I surveyed the room. One man anxiously paced back and forth in the back of the room while most of the audience was transfixed — attentive to Dana's emotional plea. When Dana finished, he wiped tears from his cheeks. Meanwhile the man in the back of the room was granted his turn to speak. Like Dana, he was appalled by the lack of support for PrEP. He didn't care what we had to say about efficacy and economics. He was there to support "sex free of fear!"

PrEP is the first biomedical solution offered to help manage a decades-old problem: how to effectively prevent HIV. And as such PrEP is an "innovation" in the field. However the development and implementation of this new biomedical technology has also been shaped by several decades of interventions to secure the health of the population, including drug development and the management of sexual pleasure. Thus, to understand this innovation and what it means for the field of HIV prevention, I argue we must examine its development within a layered history of developing drugs and managing sexual pleasure.

This became clear throughout seven years of research on the topic, including during interviews with investigators that helped develop the intervention, participant observation in clinics that prescribe PrEP as well as interviews with providers who offer PrEP and patients who take it. And it was first evident when I participated in this symposium, where the effects of the

management of sexual pleasure on the intimate lives of these men were on display alongside concerns about safety, efficacy, and cost. We had all gathered that afternoon to have a collective conversation about how to best manage this new method to prevent HIV, including the science that supported its development and the resources that would be required for its implementation. In many ways, it was a typical moment in the history of HIV in which multiple stakeholders were granted space to articulate their shared interests in the pharmaceutical intervention. Thus, safety and efficacy were on the table, and cost was a concern. It was also a place where the relationships between public and private entities were on display. We convened in the public research university to discuss the implementation of a private product. A community advocate represented the pharmaceutical firm. However, as the symposium continued, it became a venue where these men who had lived their intimate lives in relation to a virus could express their inner desires. They reminded us that this was about more than science and economics. For decades they had managed their sexual pleasure in order to avoid infecting others and to not be infected themselves. They were ready to enjoy sex without fear, and they saw PrEP as a way forward – a way to ease anxieties about sex and open new opportunities in intimacy.

At the end of the day, I took away from this symposium a set of questions not only about science and economics, but also about intimacy. In this dissertation I trace the emergence of this novel pharmaceutical method to prevent HIV by detailing how several issues within the political economy of health become layered with the demands of intimate relationships, especially the way we manage our sexual pleasure. By bringing together issues in political economy and the techniques of discipline through which we manage our intimate lives, my goal is not only to describe how this 'innovation' has affected intimacy, but moreover to highlight ways intimacy preconfigures the very possibility of this innovation. Thus, I argue that PrEP is an *intimate*

innovation.

Background

To understand how PrEP has developed and is being implemented, one must also understand important aspects of the history of the AIDS epidemic, clinical research for anti-HIV drugs, and global concerns about access to these drugs. In this history, a few key themes emerge. The first is that diverse groups of actors, including activists, pharmaceutical firms, and regulatory agencies have played important roles in developing life-saving treatments for HIV, and most notably, antiretroviral drugs. For example, in the 1980s when AIDS incidence was at its height, there was urgent need to develop effective treatment but doing so required conducting clinical research studies that took years to complete. The prevailing standard protocol for studies required investigators to evaluate drug efficacy by measuring the difference between the number of people who died in the treatment group of the study and the control group. Recognizing how a public health emergency was being exacerbated by this sluggish statistical protocol, activists changed the protocol: removing observed death as a study end-point. Thereafter, investigators used discrete temporal periods, such as 24-week periods, and these temporal end points led to the approval of early treatments for HIV, such as AZT (Miller & Grant 2014). In 1992, activists again pressured the FDA to change research protocols. This time the activists urged the agency to adopt accelerated drug approval protocols that utilize biomarkers, such as HIV viral load measurements, as clinical end points (Miller & Grant 2014). With viral load biomarkers HIV drug development was once again made more efficient, and investigators developed more effective treatments, including antiretroviral drugs. These early examples show how diverse actors have played important roles in the history of the AIDS epidemic, and begin to reveal how the AIDS epidemic prefigured the

conditions of HIV treatment and prevention, especially through the development and distribution of drugs.

Second, antiretroviral drugs have played a vital role in HIV treatment for people around the globe, and providing access to these drugs has been a top priority for nearly two decades. Whereas previous drug regimens failed to significantly reduce the disease burden, antiretrovirals (ARVs) quickly reduced mortality rates and improved health outcomes for many people living with HIV. ARVs have been tremendously effective for people who can access treatment and maintain adherence to a regular drug regimen, and providing access to ARVs has been a priority for states and health organizations addressing the disease burden. Today in the United States, Australia and Europe, people living with HIV are entitled to free or subsidized access to ARVs at the point of care. However, in other regions of the world, including sub-Saharan Africa and Latin America, access remains a concern. While AIDS-related mortality has been significantly reduced across all geographies, the overall disease burden and incidence rates for new infections are still high among particular populations, including serodiscordant couples, transgender women, and men who have sex with men.

And third, biomedical solutions for HIV treatment have recently been joined by biomedical solutions for HIV prevention, which are now taking root in the contemporary market for health care in the United States, and in global health. As biomedical solutions to prevent HIV are implemented, one can see how the logics and practices for providing *access* to life-saving treatments are being extended through solutions that offer *value* to priority populations. In fact, collaborative global efforts have been constructed to provide better solutions for people within high-risk groups, which not only treat HIV, but also prevent it.

One solution began in 2003 when Gilead Sciences (Foster City, CA) first filed provisional patent applications for an antiretroviral tablet to be sold under the brand name Truvada (Nos. 60/440,246 and 60/440,308), claiming the invention provides combinations of antiviral compounds as well as methods to inhibit HIV. Specifically, Truvada combined two antiviral compounds, emtricitabine (FTC) and tenofovir disoproxil fumarate (TDF), which the firm had previously marketed under their own brand names: Emtriva TM (FTC) and Viread (TDF). The following year the firm claimed benefit of the provisional applications – particularly, identifying the benefit of combining chemically stable and structurally diverse anti-viral agents, and potential for greater patient compliance to one pill compared to two (PCT/US04/00832). In 2006 the firm filed a national stage entry patent application (Ser. No. 10/540,794), and through a subsequent application in 2008 (Ser. No. 12/204,174), was granted U.S. Patent No. 8716264 for Truvada.

While securing patent rights for Truvada based on intellectual property (IP) claims, Gilead was also investing in the research and development of its new drug product, sponsoring studies about its safety and effectiveness as HIV pre-exposure prophylaxis (PrEP), the first biomedical method to prevent HIV. In 2012 Gilead submitted an application to the U.S. Food and Drug Administration (FDA) for regulatory approval of Truvada-based PrEP. In the application Gilead presented the details of seven oral PrEP trials for review to evaluate safety and efficacy of the drug for this indication (US FDA 2012). Data from all trials confirmed safety. Efficacy was measured based on the reduction of risk for acquiring HIV compared to a placebo, and five trials (phase-III or IIb) offered efficacy results, though only two (iPrEx and Partners PrEP) were complete at the time of the application. Reviewing the results of these studies, the FDA concluded the benefits of Truvada for PrEP outweighed the risks, and expecting this new intervention would reduce the

epidemiological burden for specific demographic groups at risk for HIV acquisition, the agency approved the application for Truvada-based PrEP.

Currently, Truvada is the only drug approved for use as PrEP in the United States. In the six years since regulatory approval, Truvada has been prescribed to nearly two hundred thousand patients in clinics across the country. Concerns patients and providers have about Truvada-based PrEP, including its cost and toxicity, and potential to cause drug resistance (for those who acquire HIV while taking the drug) have been identified as significant obstacles to efficient implementation in primary care (Mayer et al., 2015). While toxicity and the potential for drug resistance have been shown to be minimal, the once-daily regimen costs roughly $14,000/year. However, costs for the drug to individual patients are contained by health insurance, and for those who are un- or underinsured, health care reform has opened new avenues for access and reinforced systems of value.

The Patient Protection and Affordable Care Act (ACA) intends to improve the delivery of care by introducing new managerial techniques, supported by new organizations, such as Accountable Care Organizations (ACOs). ACOs are designed around outcomes-based measures that are meant to increase the "value" of care. The Centers for Medicare & Medicaid Services (CMS) articulates the value gained from ACOs in a three-part aim: 1) better care for individuals; 2) better health for populations; 3) lower growth in Medicare expenditures. However, the Act contains no provisions to control the underlying costs of health care, and scholars have observed that by not threatening costs, the ACA found support from several stakeholders, including insurers, hospitals, pharmaceutical firms and providers, who recognized how the new legislation could bring them a massive new financing stream, as the previously uninsured and ineligible for insurance became insured (Morone 2009, 2010).

In this health care environment, Truvada-based PrEP will provide value to particular "priority populations" (Mayer et al., 2015). However, the overall cost-effectiveness of the intervention remains a concern. Recognizing that there are approximately 500,000 people in the United States that may benefit from PrEP (CDC 2014), there is great potential for growth in this market, but given the costs of the drug, hospitals and providers are confronted with a dilemma between providing value to "priority populations" and ensuring the economic sustainability of HIV prevention programs that utilize Truvada-based PrEP. In concentrated epidemics, such as the MSM-driven epidemic in the US, PrEP could have a substantial impact on incidence, but again, may not be affordable at current drug prices (Gomez et al., 2013). This dilemma is characteristic of health care in the United States as well as global health, which have "stuck in an access and volume mindset" (Porter 2009, 2010), but are moving toward the *delivery of value* for patients (Kim et al 2010; Dentzer 2009). As focus shifts from issues of access to the provision of value, careful attention is needed to understand what delivering value might mean for patients (Rosenbaum and Frankford 2012).

Amid these shifts, I argue anthropological inquiry must remain committed to understanding the systems of value-based care, and that following the path of Truvada-based PrEP as it moves from stages of clinical research and regulatory approval into primary care will be a productive form of inquiry about the delivery of value-based care, and what it means for patients. Following the development and implementation of a biomedical solution to prevent HIV is a helpful way to understand how health care reform reinforces and introduces new mechanisms to generate value, including by incentivizing the development and use of biomedical technologies, supporting methods for prevention, and opening new avenues to access care for populations that have long been considered to be at high-risk of acquiring HIV. Understanding how this intervention is

incorporated into care in diverse clinical settings, including private and public hospitals and public health clinics, some of which have been formed as model ACOs, will shed light on the way value is negotiated and determined in sites of care. Ethnography with patients in these clinics will also illuminate ways people experience care, both in clinical settings and when taking the drug in everyday life, such as by using a pharmaceutical tablet to mitigate risk and supplement health.

The Political Economy of Health

This dissertation adds to literature in the social sciences of medicine about the political economy of health, including scholarship concerning clinical research for drug development, the rise of evidence-based medicine, and the distribution of antiretroviral drugs. On the most fundamental level, it draws from the work of Karl Marx and Michel Foucault. For the social sciences of medicine, Marx provides theoretical and methodological tools to examine the ideological and material conditions through which medicine is produced and distributed. Meanwhile, Michel Foucault presents studies of state power and human subjectivity which offer philosophical and historical perspective about the ethics of sexuality, the development of the life sciences and other forms of governance intended to secure the health of the population.

Scholars who have worked across the writing of Marx and Foucault have explored various ways the political economy of health is significantly affected by pharmaceutical markets, which influence the way value is generated as well as how people experience care. Historical and social scientific literature about the political economy of health includes diverse inquiries about how pharmaceutical markets influence the value systems of health care (Dumit 2012), public health (Biehl 2008), and the life sciences (Sunder Rajan 2012). These value systems have been established in the United States through processes of reform, which have shifted over time through

association with different organizations of authority and the increasing use of statistical methods (Marks 2000), yet must be understood in the context of larger structural changes that affect many of the world's nations as well as the drug industry, such as structural adjustment programs (SAPs) (Peterson 2012). In these systems, legal mechanisms, such as intellectual property (IP) and patent rights, secure value by constructing boundaries between public and private rights (Jasanoff 2012), shaping market monopolies (Peterson 2014), and complicating the relationship between brand name and generic drug products (Hayden 2007; Greene 2014). Meanwhile, these value systems are reinforced as the methods to generate evidence in medicine – most notably, the randomized clinical trial (RCT) – tightly bind measures of efficacy to health outcomes and thus, determine how care is delivered through cost- effectiveness models (Adams 2012). Across this literature, we see that value is determined in several ways, ranging from abstraction in industrial production to speculative practices in innovative economies, as pharmaceutical firms exploit labor through processes of human subject participation in clinical research, investigators produce evidence about 'health' and firms produce, distribute and sell products, while generating surplus through the possibility of future productivity or profit (Sunder Rajan 2012).

Within these systems of value, the life sciences and capitalism continue to build and grow the biotechnology industry (Jasanoff 1999; Sunder Rajan 2006) while multinational pharmaceutical companies pick and choose which markets are worth investing in (Peterson 2014), and states as well as citizens fight to access drugs (Nguyen 2010, Biehl 2008). This opens opportunity for generic producers to compete for market share (Greene 2014), and for value to be generated through different formulations of health and risk (Dumit 2012). In some wealthy countries, such as the US, there is room for competition because drug markets are expanding as physicians are prescribing more medications for patient-consumers to treat and prevent conditions

with ever-lower risk thresholds, such as high-cholesterol, hypertension and anxiety (Greene 2009). Risk thresholds are lowered in ways that redefine health, grow market potential, and influence people to add drugs to their lives, which generates surplus (Dumit 2012). However, in countries that are burdened by decades of debt, where regulatory infrastructures are not as strong even the most savvy pharmacists struggle to manage the differences between brand name, generic, and fake drugs while entire populations are rendered "risky" and go without effective treatment for life-threatening conditions, such as HIV/AIDS (Peterson 2014). Yet, the economic values of drug development are paired with the ethical values, which are discursively and materially created in advertising, and rhetorical commitments to health, especially as corporations relinquish property rights for the common good (Sunder Rajan 2012). Backed by such values, the subjects of life sciences – in the sense of both, specific scientific fields and the practitioners of science – are constituted as moral subjects. And in these intersecting ways, value is at least a double-jointed concept that guides the ethics and economics of drug markets.

Scholars in medical anthropology, the history of medicine, and science studies have examined issues of access to medications, including for antiretroviral drugs. One prominent point of emphasis in this work is the relationship between public and private entities and how their contradictory interests limit access. These scholars show how the law, especially intellectual property (IP) and patent rights, determine ways resources are distributed among public and private entities and affect human health. Some scholars interrogate the history of IP law in global drug markets to show how property agreements are instituted in low-income countries through the dictates of multilateral organizations, such as the World Trade Organization (WTO) (Sunder Rajan 2015), reinforcing pharmaceutical monopolies, and linking the politics of valuation to the speculative practices of pharmaceutical markets, instead of the health needs of a population

(Peterson 2014). Others examine how property law, which is meant to strike a balance between material and nonmaterial value, functions through abstractions, including notions about "life" and "the public good" which introduce ambiguity and leave agreements open for interpretation (Jasanoff 2012), such that even "public" research need not identify any public beneficiary (Smith 2012). In this work, scholars tend to position public and private entities as opposing forces, allowing civil society groups and states to represent the public good, and therefore, the path to access while asserting pharmaceutical firms represent private interests and thus, limit access (Biehl 2008; Sunder Rajan 2012).

These scholars have also tracked issues related to the distribution of drugs for HIV treatment, highlighting how market dynamics affect the lives of people in need of care. For example, they highlight the role of global geopolitical measures, showing how Structural Adjustment Programs (SAPs) set the stage for the AIDS epidemic by dismantling national economies,[1] and how international responses to the epidemic — foremost, the US President's Emergency Plan for AIDS Relief (PEPFAR) — continued the politics and policies set forth by the SAPs.[2] These inquiries also display how the history of HIV has been affected by activism, including among community groups[3] and the actions of select state governments, who campaigned for access to treatment.[4]

Meanwhile, Cori Hayden and Jeremy Greene have presented ethnographic and historical accounts of pharmaceutical markets which offer further insights into the layered relations between public and private actors, especially as revealed by the production and distribution of generic drugs (Hayden 2007; Greene 2014). Cori Hayden (2007) tracks pharmaceutical politics in Mexico, where

1. Nguyen 2010
2. Pfeiffer 2013
3. Epstein 1996
4. Biehl 2004

tensions between public and private goods are being rearranged as one rapidly growing pharmaceutical chain develops and distributes generics in the name of populist nationalism, yet generic drugs circulate primarily in the private health care market. Drawing connections between pharmaceutical laboratories, political movements, and health clinics that each promote generics as "The Same But Cheaper" Hayden evaluates shifts in health care provision in Mexico, and asks: how does the generic drug influence political practice and discourse in the name of the public interest? Jeremy Greene (2014) writes a history of the American generic drug industry, describing how the industry was encouraged to develop as a private sector solution to a public health problem, and identifies a set of immensely ambiguous moral practices that have defined its growth. These ambiguous moral practices appear in the hope for rational prescribing versus the fear of rationing and the promise to spread innovation by making drugs more affordable versus the worry about impeding innovation by discouraging investment in R&D. Following how these tensions are produced by moral ambiguity, Greene argues the generic drug is a useful tool for understanding the value of the pharmaceutical brand.

Amid these many machinations, one helpful way to understand the value systems of drug markets is to follow specific drug products through stages of development into implementation. Historians of medicine have done this. Elizabeth Watkins (2001) documented the development and implementation of the contraceptive pill, and mapped the political spaces through which the pill was contested and given meaning when entering the medical market. Jeremy Greene (2008) showed how the development of particular pharmaceuticals transformed biological conditions into disease categories, which opened opportunities in markets and medicine. This work borrows an analytic orientation from Arjun Appadurai (1996) who displayed how commodities circulate in social life, and suggested that by following *things* and paying attention to their forms, uses and

trajectories, we can interpret human transactions and calculations that enliven things. This theoretical approach recognizes that people encode things with value, and as a matter of method, encourages scholars to follow things themselves to better understand the contexts in which they are given value. By tracking how commodities circulate in different contexts of exchange, Appadurai argued, we could understand the *social life of things*. While this analytic has been taken to understand the social lives of medicine and revealed insights about patients, prescribing physicians, pharmacists and health care strategy in several therapeutic areas (Whyte et al., 2001), no previous anthropological inquiry has tracked the product life of a single pharmaceutical for HIV prevention from development to implementation.

My ethnographic inquiry contributes to this literature by following a single antiretroviral drug product as it tested in clinical research trials, reviewed by patent offices and regulatory agencies, supported by health care policy, adopted in public and private formularies, prescribed in primary care settings, and ultimately added to the lives of individuals to prevent HIV. This inquiry is an opportunity to more adequately understand the ways antiretroviral drugs for HIV prevention move across systems of value in health care, and how recent health care reform policies reinforce established systems of value and introduce new mechanisms for generating value. This inquiry also presents opportunity to extend inquiry about how improving 'health' and mitigating 'risk" become goals for the patient-consumer under contemporary logics of pharmaceutical capital (Dumit 2012) by showing how the value of a pill to prevent HIV is always speculative – always determined through the potential of future productivity and profit – for both, the pharmaceutical firm that patents a drug and the patient-consumer that uses it.

To further extend this scholarship, I think most closely with research by Kaushik Sunder-Rajan and Vinh-Kim Nguyen. Sunder-Rajan borrows theoretical and methodological examples

from Michel Foucault and Karl Marx to explore the relationship between the pharmaceutical industry and biotechnology companies, track how post-genomic research shifted drug discovery and pharmaceutical production, and highlight the co-constitutive processes of biosciences and capitalisms. In so doing, Sunder Rajan reminds us that we can read Marx as a methodologist — not a dogmatic critic, but a scholar that offers analytics to better understand "rapidly emergent political economic and epistemic structures"[5] including the two capitalisms of drug development, which correspond to industrial capitalism and commercial capitalism[6]. However, he examines how the means of production in post-genomic markets rely on the "grammar of life" — an inventive rendering of Foucault's "life, labor and language" — that formation of human sciences, political economy, and philology through which biopolitics derives power — recast to show how *life itself* becomes a source of commodity production through the *language* of post-genomic science. This is where my analysis departs from that of Sunder Rajan.

I analyze how the means of production in antiretroviral markets to treat and prevent HIV

5. Thus, we need not dwell on the polemic tone of The Communist Manifesto (Marx and Engels 1986 [1848]) to sustain political economic critique, but rather, we may read closely The Eighteenth Brumaire of Louis Napoleon (Marx 1977 [1852]) in which Marx offers nuanced descriptions of capitalist processes and their tendencies. In particular, in this work, Marx offers an analysis of the presidency of Napoleon Bonaparte's nephew, Louis Bonaparte, describing how he rises to power amid the revolutionary and counterrevolutionary tensions of contemporary France to emerge as a leader with the support of both, the bourgeoisie and the peasantry. Through this history, Marx displays that even those, such as the peasantry, whose place in the structural relations of production would suggest they would support a revolutionary leader over Bonaparte, instead put their faith in this counterrevolutionary figure, and they do so precisely because they strive for political stability, which is necessarily conditioned by economic stability. Thus, there was no revolution, as the peasantry and the bourgeoise find shared political interests in a stable economy (Sunder Rajan 2006: 8).

6. For one, there is an economy that functions through the production, distribution and sale of commodities, like industrial capitalism. Second, there is an economy based on valuation, which is determined through financialization alone, like commercial capitalism. And these two economies function through the combined mechanics of innovation and speculation. The economy that produces, distributes and sells drugs is associated with innovation. Meanwhile, the economy based on valuation is speculative. And these two market mechanics are bound together in ways that reproduce themselves: as speculation aims to support innovation, innovation breeds a marketplace of speculation (Sunder Rajan 2006: 111). Thus, while commercial capital does not directly create surplus value, it reinforces the logics of commodity capital, and supports the circulation of capital itself, and in doing so, ensures commodities will continue to be produced, distributed, and sold. Sunder Rajan makes this distinction in a discussion of "the relationship between biocapital and systems of capitalism writ large" (Sunder Rajan 2006: 24)

operate through disciplinary techniques, including *confessional technologies*. Confessional technologies, Foucault explains, emerge from Christian techniques, which link the subject to truth and sex through analytical thought and verbalization. To think analytically and verbalize one's thoughts are exercises to renounce one's will and one's self by disclosing a hidden truth about one's self, and they are performed in obedience to someone else. Tracing the history of this ethical practice from its origins in Christianity and into the contemporary, Foucault observes how the human sciences shifted the circumstances of relation between subjectivity, truth and sexuality by no longer requiring one to renounce oneself, and instead, allowing one to constitute a new self through techniques of verbalization. To form a new positive self without renouncing one's self marks a new moment for subjectivity and truth, he asserts. And though the human sciences shifted the relations between subjectivity, sexuality and truth, the contemporary subject is still obligated to truth, and sex remains a central way to understand the self. Foucault further explains how the sciences, including economics, biology, psychiatry, medicine and penology organize "truths" which human beings use to understand themselves.[7]

Vinh-Kim Nguyen has adapted these Foucauldian *confessional technologies* within the history of antiretroviral markets by documenting their emergence and use before, during and after the AIDS epidemic in West Africa. Exploring the way subjectivity was constituted in the early treatment era, in particular, Nguyen shows how incitements to speak about the virus not only encouraged individuals to conjure their inner selves, such as in self-help groups, but also stitched together communities, and helped secure resources as people living with the virus spoke about their status and the effectiveness of treatment during prominent research conferences. In short, Nguyen shows how speaking about one's HIV status became a means to survive. Thus, I think

7. Foucault 1994 [1966]: 224

across the work of Sunder Rajan and Nguyen — who between them, adapt analytics from Foucault and Marx — in order to analyze the means of production and explore how subjectivity manifests in antiretroviral markets to produce therapeutic commodities that treat and prevent HIV.

A further contribution I make to the literature about the political economy of health involves highlighting the role of the management of sexual pleasure, as a moral practice for the human subject as well as a public health project intended to secure the health of the population. In Michel Foucault's historical studies of ancient sexual ethics, he discusses the constitution of subjectivity and care of the self by highlighting the intentional work of an individual on himself in order to align himself with a set of moral recommendations for conduct. Several scholars have adapted this observation in analytics of ethics, which determine a set of techniques one maintains in order to fashion one's self as a moral subject. However, in this work Foucault also discusses how the management of sexual pleasure offers key insights into the constitution of the human subject, and this discussion has been widely ignored in the contemporary social sciences of medicine. Thus, in my own extension of Foucauldian philosophy about the constitution of the moral subject and care of the self, I am most concerned with the techniques the subject uses to manage his own sexual pleasure, and how moderating sexual pleasure becomes a moral concern, which Foucault details at length in *The History of Sexuality, Vol. 2, The Use of Pleasure*.

Finally, my research contributes to this literature through its methodological orientation, which involves following a single drug product through its lifecycle. While historians of medicine have traced the development and implementation of other medications, such as the contraceptive pill, and have mapped the political spaces through which the pill was contested and given meaning (Watkins 2001), and have shown how the development of particular pharmaceuticals has transformed biological conditions into disease categories, which opened opportunities in markets

and medicine (Greene 2008), anthropologists have not traced the social life (Appadurai 1996) of a pill from development to implementation in order to better understand the lives of patients for whom that pill is prescribed. In following the social life of PrEP, my research will examine the way value is negotiated and determined across the life of this pharmaceutical intervention by analyzing the policies, structures, and practices of valuation that affect high costs of and access to care. This part of my research also intends to understand how the incorporation of PrEP in primary care and HIV prevention reflects elements of health care reform, especially those that reinforce established systems of value and introduce new mechanisms for generating value. In short, the introduction of a biomedical solution to prevent HIV reflects the way health care reform incentivizes the development and use of biomedical technologies, supports methods for prevention, and opens new avenues to access care for populations that have long been considered to be at high-risk of acquiring HIV.

On Method

I have conducted extensive research for this inquiry over the past six years, including interviews, participant observation, archival research, and literature review. My initial inquiry began in 2011 when I conducted interviews with clinical research staff, public health officials and HIV prevention researchers as well participants in clinical trials for PrEP. This study was conducted on the heels of the first clinical research trial to provide evidence PrEP could be a safe and efficacious method to prevent HIV. My inquiry concerned the social impact of the findings and their relationship to larger HIV treatment and prevention services. I mapped the controversy surrounding the findings, including claims about "medicalization" and PrEP – specifically, that PrEP was unnecessarily intensifying biomedical approaches to HIV care.

By the summer of 2013, additional study results had been published and I continued interviews with principal investigators, biostatisticians and bioethicists of PrEP clinical trials to better understand the relationship between the first PrEP trial to provide evidence of safety and efficacy and subsequent trials testing other drugs for PrEP among different populations in several countries. During this time, PrEP was being tested in demonstration projects as well. I shadowed clinical staff during patient visits for the demonstration projects and conducted participant observation among PrEP users, patient navigators, nurses, clinic directors and physicians, inquired about the ways adherence – "the Achilles heel of PrEP" – was being monitored and supported, and started tracking the various technologies emerging in support of the daily prevention regimen.

The following year I conducted a comprehensive review of news articles in major media outlets about PrEP and its target patient populations, particularly inquiring about how the news media represents sexual orientation, race, and gender in discussions of HIV risk and target populations for PrEP. This review was conducted under the guidance of Russell Robinson, Professor of Law, and Distinguished Haas Chair in LGBT Equity Professor of Law. We found that issues of diversity in race and gender were largely ignored in these representations, while white gay men were prominently represented as the likely and eligible consumers of PrEP.

Also in 2014 and continuing through 2015, as further study results were being disseminated and new trials were being developed, I collaborated with colleagues at the San Francisco Department of Public Health for a qualitative study about the implications of offering PrEP as the standard of care (or, "standard of prevention") in future biomedical trials for HIV prevention. For this study I conducted interviews with principal investigators, biostatisticians, bioethicists, community advocates, and representatives of funding agencies, all with experience working on clinical trials for HIV prevention. We found resounding consensus that PrEP should be included

in trials conducted in countries where regulatory agencies have approved its use, but very little consensus about what should be done to ensure access in countries where PrEP has not yet been approved. Many respondents were focused on the irony of "standards" of care, which unravel across national borders. Others were interested in providing PrEP as the standard of care in trials as a way to leverage local health officials and regulators to support PrEP. All were concerned about the way including PrEP in future studies would affect the development of additional biomedical methods to prevent HIV, including other PrEP applications and HIV vaccines.

In November 2015 I led visits to clinics that prescribe PrEP for a group of French journalists and scientists interested in PrEP implementation. Visiting San Francisco, the group was interested in lessons for other world cities, and most notably, Paris. At the time of the visit, French health authorities were making decisions about the future of PrEP for the country. Touring public sexual health clinics, private and public hospitals, meeting staff and PrEP users, we learned how PrEP programs have developed, what has worked well overall, and what remains to be done. While repeatedly baffled by US insurance policies and the cost of medications, reminded that AIDS and stigma have cast lasting shadows, and shown how vulnerable some communities in this city still are, we were also given insight into how people experience care on PrEP. While the PrEP users we spoke with were diverse in terms of age and ethnic background, and the settings where we have spoken have varied – ranging from sites of federally-funded demonstration projects to the executive suite of a private hospital – each PrEP user I have spoken with has identified as a gay or bisexual man, and every single man has reflected on the ways the AIDS epidemic had affected his decision to take PrEP. Whether 26 or 58, Black, White or Latino, in San Francisco at the time, or not yet alive, each has recalled stories of loved ones lost and how his sexual life had been haunted by HIV risk as well as how PrEP offered something new.

And from June 2016 through the present day I have continued my ethnographic study about PrEP focusing on how PrEP has developed and ways PrEP is being implemented, wherein systems of value and experiences of care may be examined. This research has involved participant-observation in PrEP clinics, interviews with PrEP users, providers and patient navigators, and analysis of research articles, health care policies, and regulatory documents pertaining to PrEP development and implementation. The main field sites for this research are sexual health clinics in San Francisco, the single city with the greatest number of PrEP users in the United States.

Archival Research and Document Analysis

The archival research and document analysis focused on health care policies, regulatory documents, and other media articles pertaining to PrEP development and implementation, including literature about the safety, efficacy, and cost-effectiveness of PrEP, the Patient Protection and Affordable Care Act (ACA) as well as applications submitted to the US Patent and Trademark Office (USPTO), Food and Drug Administration (FDA), and other national and international regulatory agencies for Truvada (FTC/TDF) as PrEP. This research traced multiple trajectories in the development and implementation of PrEP by: first, documenting how PrEP was tested in clinical research studies, ways this research produced evidence about the safety and efficacy, and how this evidence informed clinical prescriptions guidelines about its use; second, detailing how PrEP has been affected by the approval processes of national and international regulatory agencies, the strategic use of legal mechanisms, including IP and patent rights, and implementation of policy measures, such as the Affordable Care Act; and third, mapping ways PrEP gained institutional support, such as from the multinational pharmaceutical company that

funded clinical research for Truvada-based PrEP, health insurance companies that include coverage for the drug, as well as the private hospitals and public health departments that have included Truvada-based PrEP in their formularies. Following these key trajectories will reveal insights about the epistemological orientations that support PrEP and the political and economic levers that determine the value of PrEP.

More specifically, as PrEP has moved through different national and international processes of regulatory approval for pharmaceuticals, there have been opportunities to better understand several issues about the role of regulation, profit incentives and market size in pharmaceutical markets. These issues include ways the WTO-TRIPS agreement and US bilateral agreements place strictures on compulsory licensing (Oddi 1987), the national regulatory agencies responsible for approving drugs are notoriously slow (Eisenberg 2004), and firms are pursuing avenues to profit from existing products that avoid R&D costs (Bouchard et al., 2009). And as PrEP is incorporated in the formularies of public health departments and private hospitals, this inquiry has shown how PrEP flags changes in primary care and HIV prevention within the new era of health care reform, such as in ways "at-risk" populations are being reconceived in systems of value, which are supported by biomedical approaches to improving health. Thus, I intend to highlight the functions and consequences of this system that aims to provide *value* to individual patients through Truvada-based PrEP. This aspect of the inquiry also closely examines the way the ACA structures systems of value, and how PrEP fits within a value-based system for care.

Participant Observation and Semi-Structured Interviews

During participant-observation and interviews, I have tracked ways patients, patient navigators, and providers articulate the risk of acquiring HIV and notions of health, think about the value of PrEP and practice care. In interviews with PrEP users, I have asked about knowledge of PrEP, use of health insurance, and how PrEP has been incorporated into daily life. These interviews aimed to gather patient perspectives about PrEP safety, efficacy and value, and probed for insights about how the ACA has affected the ability to access and utilize PrEP. Most of all, these interviews have been key opportunities for understanding how PrEP users learn to think about health through logics of risk and value. In interviews with patient navigators I have asked about experiences with patients, avenues to accessing health insurance as well as the successes and ongoing obstacles to accessing PrEP. Patient navigators serve an important role in the current health care marketplace, where access to care and continuity of care are top priorities. Learning about the experiences of patient navigators in providing access and facilitating continuity for PrEP users has helped me better understand the implementation of PrEP within the new era of health care reform. In interviews with PrEP providers, I have asked about practices for prescribing PrEP and managing care for PrEP users. My questions concerned knowledge about PrEP safety, efficacy and use, experiences with patient evaluations that affect when and how PrEP should be prescribed as well as perceived successes and obstacles in the ongoing management of care for patients on PrEP.

A select group of physicians employed by the public health department within the city of San Francisco have also been educating patients and providers about the benefits of PrEP, effectively assuming the role of pharmaceutical representatives to support ongoing implementation efforts. Participant observation within these outreach programs presented opportunities to further understand how PrEP is being implemented within systems of value in health care, including how public resources are being used for a service that is usually associated with private industry.

Participant-observation has also be conducted during initial enrollment evaluations and ongoing appointments for PrEP that monitor patient safety and adherence and test for HIV as well as other sexually transmitted infections. In addition to observing conversations between providers and patients about health and risk, attending enrollment and monitoring evaluations has allowed me to observe particular techniques in the management of care, such as the administration of regular blood tests, and conversations about sexual practices and HIV risk.

My participant-observation has also included attending meetings among PrEP patient navigators as well as shadowing them during appointments with patients. My initial link to PrEP patient navigators was circumstantial. As I pestered providers to let me shadow for patient appointments, they often told me they were up to their armpits in medical residents angling for the same position, and suggested I should speak with the navigator in the clinic. After several email volleys with various providers, it became clear that my point of access for fieldwork in many clinical spaces was going to be through the navigators. Bearing in mind Judith Justice's insights about the benefits of following clinical workers lower on the clinical hierarchy, I was happy to connect with navigators. I also knew they would open more windows into the influence of health care reform on PrEP implementation.

One particularly rich ethnographic site, which I have returned to many times throughout my fieldwork, has been the presentation about PrEP. Being in rooms full of engaged professionals working to manage the development and implementation of PrEP has been incredibly productive to think with. This was first apparent to me during the conference at UCLA with which I began. In that moment, presenting alongside others thinking critically about this novel method to prevent HIV, I began to develop an appreciation for *thinking with* these professionals not only as informants but also as interlocutors. And throughout my fieldwork, I have found presentations to be

compelling venues for *thinking with* not only for the content offered during the presentation, but also for the conversations afterward.

After one grand rounds talk about how to implement PrEP in public health clinics, I approached the stage and introduced myself to the presenting physician. She said she knew what medical anthropology was because she had attended Harvard Medical School, and knew Paul Farmer. Pausing for a moment to clarify, she asked, "He's a medical anthropologist, right?" I provocatively replied, "Sort of." As we both laughed, I gathered myself and explained that he is absolutely a medical anthropologist, but I was interested in a different kind of anthropological project — one that started with political economic critique and did something more. But I was not yet sure what more that would include. At the time, no one knew what else to study. She said she would keep me in mind for future research opportunities.

A few months later, an investigator presented about emerging findings from subsequent data analysis of clinical trials, and after his talk, I moved through maze of chairs to introduce myself. When I told him that I was a PhD student in medical anthropology, he immediately asked if I was going to "do a discursive analysis of PrEP." I smiled at his knowledge of the theoretical tendencies of the field, and told him that I was interested in Foucault but was planning to doing something a little different. By this point, I had more developed ideas about my research. So I told him that I was interested in exploring the role of intimacy in the development and implementation of PrEP. He nodded and replied, "That's precisely what we need to understand. We need to know what people are doing in their bedrooms." He then pointed across the room to his research team, and welcomed me to engage with any of them to support my research.

The fact that one physician knew Paul Farmer and another investigator was familiar with discursive analysis struck me, but the fact that each presenter also invited me into their research

team stuck with me throughout my fieldwork. I have not only visited the clinics where these presenters work, I have also joined their research teams to think with them about the development and implementation of PrEP. Their influence on my ethnographic approach is clear. Through my engagement with them and in conversations about our shared interests, I have developed a greater appreciation for the history of their fields, including public health, HIV prevention, and clinical research for biomedical method to prevent HIV. And I have made significant effort to represent the history of these fields in this dissertation — not only for their empirical contribution but also for their theoretical insights — for the way they are good to think with. And to represent the centrality of the presentation about PrEP to my fieldwork, I begin each chapter in this dissertation with a scene from my research where I am not only entering a site to observe but also to participate.

In the first chapter I contextualize the commercialization of Truvada for PrEP within a larger cycle of innovation, and place the very concept of "innovation" under critical examination. In general, pharmaceutical development is said to produce an "innovation" through a three-phase cycle of clinical research which begins with safety testing on animals, continues through safety testing among a small ground of human subjects, and if successful, culminates in safety and efficacy evaluations involving large groups of human subjects. This is the form of innovation represented in the social scientific literature about the political economy of health in which many scholars argue that human subject participation in clinical trials serves as a form of labor for drug development and thus pharmaceutical firms and corporate research organizations generate value by exploiting the labor of clinical trial participants. Instead of echoing this argument about the role of the labor theory of value in drug development, through which scholars show that the capital-intensive activity of pharmaceutical R&D operates on material and abstract levels, in this chapter I discuss "innovation" as a process of articulating interests and visions, which generate value. I

also show how one innovation cycles into the next, as capital-intensive R&D processes justify high-price products, which generate significant revenue and that revenue is re-invested in another capital-intensive R&D process.

From this perspective I suggest we may more adequately analyze innovation for the many ways it operates through abstraction. This is especially helpful for understanding the specific case of Truvada for PrEP, which depended far less on the traditional mechanisms of "innovation" such as clinical research for drug development, and more on the practices of "speculation" including strategic decisions by a pharmaceutical firm to acquire biotechnology companies, secure licensing deals, and combine existing compounds to produce 'new' drugs. Also from this perspective we may more clearly see how the *private* pharmaceutical firm and the health of the *public* become intertwined — indeed, how they have shared interests, visions, and values. Most of all, I find it important to begin this ethnography about drug development by focusing on the iterative process of articulating visions, interests and values because increasingly this is how pharmaceutical "innovation" happens.

In the second chapter I situate clinical research about PrEP within the history of public health research about HIV prevention through which 'at-risk' individuals have been disciplined to manage their sexual pleasure through confessional technologies and other techniques of discipline. For example, I document ways the 'at risk' individual has been disciplined to get tested for HIV, talk with health care professional about their sexual practices, and disclose their HIV status to their intimate partners. Thus, this chapter extends inquiry about the disciplinary techniques that Michel Foucault describes, including *confessional technologies* through which the subject reveals hidden truths about the self. In particular, Foucault describes how confessing emerges in Christian ethics as a way of denouncing the self through verbalization, and extends this observation to the human

sciences, wherein the human subject no longer need denounce the self, but may now constitute a new self by confessing. Continuing this line of inquiry, I show how confessional technologies and further techniques of discipline have been integral to HIV prevention and the advent of PrEP especially through the clinical trials that led to its development wherein the very practice of confessing offered evidence about the safety and efficacy of the intervention. Whereas I bracketed questions of 'labor' to showcase other mechanics of drug development in the previous chapter, in this chapter I show how "experimental labor" is fundamentally a confessional practice — indeed, I identify how human subject research participation in clinical research for HIV prevention depends on *confessional labor.*

Lastly, I point to ways confessional forms begin to guide the implementation of PrEP as well. This is evident as care providers prescribe the drug and patients consume it. This is also clear at research conferences where PrEP users are encouraged to speak about their experiences with PrEP. In these spaces, PrEP users reveal how they manage pleasure and negotiate intimate relationships while also trying to prevent HIV. Thus, across this chapter, my intent is to underscore how the disciplinary techniques of testing for HIV and appropriate use of pleasure make possible the development and implementation of PrEP.

Advancing my arguments from the previous two chapters in the third and fourth chapters I continue to meld together analytics about the political economy of health and techniques of discipline as I examine explore the logics of public health in which pharmaceutical value takes root and grows. First, I trace how evidence from clinical research about PrEP is translated into prescription guidelines that inform the implementation of the pharmaceutical intervention in public health, including through calculations about the estimated number needed to treat (NNT) in order to prevent an infection. Here I work with Joe Dumit's insights about the ways the NNT determines

the prospective market size and value of pharmaceutical products. However whereas Dumit observes that value is determined by risk and the potential for illness, I argue risk is merely a starting point for setting prescription guidelines. Once prescriptive power enters the hands of the provider, the value of PrEP grows not only through the potential for illness but also the potential for pleasure.

As I develop my observations across several sites and scenes, I also point to the ways that implementation of a private product requires public infrastructure, and highlight the tensions between public and private entities that it reveals. This part of my research is closely related to the work of scholars in the social sciences of medicine who examine how public health infrastructure is disrupted by the provisions of policies and private interests, including in ways that disrupt the distribution of antiretroviral drugs. Thinking with this scholarship to understand the rollout of PrEP in the United States, I examine ways that funds are allocated in very specific ways to welcome new patients into care and support the consumption of a pharmaceutical to prevent HIV but not to support continuity of care, so public health workers must obtain additional support to manage PrEP care by applying for research grants, for example. Thus in this part of my research I draw from the work of scholars who document the rise of evidence-based medicine (EBM) in public health, where statistics, experiments and epidemiology are well supported because they provide the right kinds of evidence for cost-effectiveness models, which tightly bind measures of efficacy to health outcomes.[8] Due to the evidence-centric nature of EBM, health care is increasingly provided in experimental contexts, and through EBM, the public-sector activity of providing health care to the public is being transformed into a private-sector, profit-generating infrastructure.

Finally, to conclude I highlight obstacles and opportunities for the successful

8. Adams 2013

implementation of PrEP and the development of the next generation of PrEP technologies. First, I show how PrEP implementation digs into the history of antiretroviral drug markets, unearthing enduring dilemmas about how to provide life-changing medications to people who need them most, and showing how legacy issues in ARV markets continue to determine present day efforts to increase access to PrEP. At the same time, since Truvada, a patent-protected and relatively expensive medication, remains the only drug product approved by regulatory authorities for use as PrEP, its price and patent status as well as decisions about whether or not to include the drug in the formularies of national health systems have become central issues for PrEP implementation around the globe. Next, I suggest that these many processes of development and implementation, which have supported the rollout of Truvada for PrEP, will continue to drive the commercialization of the next generation of HIV prevention technologies, including rings, gels and microbicides, which are currently in development. In fact, many of these trials are being conducted in the same clinical spaces as Truvada was developed, supported by the same pharmaceutical firm, and utilizing the same confessional technologies to evaluate the efficacy of the experimental intervention. And therefore, I argue the future of PrEP will be determined through the very same processes of *intimate innovation*.

Chapter One

The Innovation Cycle: Visions, Interests and Values

In May 2017, John Milligan, the Chief Executive Officer (CEO) of Gilead Sciences emerged on a stage at the University of California, San Francisco (UCSF) for a public conversation with Barry Selick, the university's Vice Chancellor for Business Development, Innovation and Partnerships. Brook Byers, a member of the UCSF Board of Overseers as well as one of the Founding partners of a venture capital firm, began the event with a few introductory remarks. It seemed appropriate Byers should make the introductory statements since we were all sitting in an auditorium that carried his name.[9] As the conversation started, Milligan rehearsed important moments in Gilead's history, including the firm's early attempts to develop products, mainly for HIV treatment, then he moved to key shifts in commercial strategy, and later, updated the audience on Gilead's current priorities. Afterward, Milligan responded to questions from the audience. And amid this layered conversation about the history of Gilead, Milligan described the development of Truvada, first for HIV treatment, and second, for HIV prevention. Indeed, Milligan presented this single product as a centerpiece of the firm.

I begin with this on-stage conversation not only because it showcases the role of Truvada in Gilead's commercial history, but moreover, because it displays the intersections of the pharmaceutical industry, venture capital, and the public research university in the political economy of health, including the market for antiretroviral drugs, and begins to display how they

9. "A Conversation with John Milligan, CEO, Gilead Sciences." Thursday, May 11, 2017, Genentech Hall, Byers Auditorium.

are each stitched together in the process of drug development. Most clearly, the conversation showcases how public and private entities have forged collaborative relationships to develop pharmaceuticals in several therapeutic areas, including for HIV. This is evident as one leader of a pharmaceutical firm and one leader of a venture capital firm enter a public university auditorium to speak with a university leader whose very job it is to identify shared interests in business development. This is an important starting point from which to understand the conversation that follows, wherein public and private interests are persistently set in relation to one another, not only in the form of the conversation, but also in the commercial strategies of the pharmaceutical firm, which both depend on the research products of the university and become interwoven within health care infrastructures.

Moreover, as I will show, this conversation begins to display how developing a pharmaceutical compound into a new commercial therapy involves articulating several visions through which we can imagine futures wherein scientific knowledge and capital investment will support research, development and commercialization of a single drug product. This way of articulating "vision" allows us to see a path toward the future, which has not yet been realized, but may be manifested. Such "vision" must also be articulated in relation to multiple "interests" such as those of the pharmaceutical industry, academic medicine, and public health. In this process, the "value" of the new product gains multiple meanings, such as by representing commercial gains for the industry, prestige for the research university, and health for the public. Indeed, vision itself catalyzes this cycle of innovation, wherein visions are articulated, interests are reconciled, and multiple values are created. And at any point along this cycle of innovation, articulation mediates commercial activity.

To begin, Selick asks Milligan about the Gilead's history. Milligan, who was one of

Gilead's first employees and joined the firm as a young scientist, recalls early scientific limitations for developing its drug products, which were alleviated by a change of commercial strategy as well as a key licensing deal with a research university. Specifically, under the leadership of Michael Riordan, the founder and CEO, Gilead began its drug development program by trying to make anti-sense drugs, which used small nucleotides to knock out gene expression, however when John Martin became CEO (preceding Milligan), he shifted the company's focus to small molecule antiretroviral therapeutics. At this time, Gilead began licensing molecules and patents, beginning with deals with two research universities: the Katholieke Universiteit Leuven and the Academy of Sciences of the Czech Republic, where researchers had discovered a series of phosphate antivirals that would soon open pathways for Gilead to develop its first products. And with the knowledge and licenses to make these molecules into effective therapeutics, Gilead commercialized its first drug products, including sodofovir and adefovir. "These antivirals became the basis of Gilead," Milligan explains, "With these in hand, we were able to take the company public in 1990, and raise about $80 million. That gave us the capital to get our first drug approved … That drug was called Vistide, and it was approved for CMV retinitis, which affected AIDS patients with very low CD4 counts. However, related developments in the HIV treatment market affected the success of Vistide:

> That was also the year that triple combination therapy was first available, so it was also the first year the HIV death rates went down, and it was the first year in San Francisco that there were no new cases of CMV retinitis, which meant that our first product was a complete and utter bust. It peaked in 1997 at $11.3 million and declined precipitously after that. From 1997 to 2001, we continuously lost money. But we were able to get through it and establish ourselves … because the source of our failure also meant that there was a new path forward for our antiviral portfolio.

In the early drug development efforts at Gilead that Milligan describes vision, interest, and value are defined in relation to one another, and their articulation shapes innovation while also providing

a seemingly bottomless well of confidence and inspiration. First Riordan determined the initial vision for the firm to pursue anti-sense drugs. However, his vision did not garner interest nor create value. Though he made a claim to truth, he was not able to manifest the future he articulated. When Martin recognized the firm had not created value pursuing Riordan's future, he adjusted the vision, and in the process, aligned the firm's interests with those of two research universities. By reconciling the interests of multiple institutions within a set of singular products, value began to multiply. He moved the firm closer to the truth of the future he imagined, in which returns on investment would be realized. However, the value of his vision was soon limited because it did not keep pace with the interests of public health. The research university and the firm had combined interests too late. In the meantime, other firms had developed effective therapies, which undercut the therapeutic and commercial value of Gilead's first product, and thus, the product was a "complete and utter bust." Yet, in the process of setting a shared vision and reconciling multiple interests to create values with that one product, the firm had established a product portfolio, which could then be leveraged to pursue the next vision, and thus, Gilead restarted the cycle of innovation.

The way visions, values, and interests determine the cycle of innovation have been represented by scholars in the social sciences of medicine, including Kaushik Sunder Rajan, whose work guides my analysis in important ways. To extend this scholarship, as I examine the commercialization of drug products for HIV treatment and prevention, I trace how the vision of a new therapy is articulated through multiple values and interests. In this milieu, I aim to highlight how public and private interests become intertwined and inseparable, as a new product is given multiple values, and the interests of both public and private entities become encapsulated in a singular object. This observation is helpful for understanding cycles of innovation at large, and the

history of the market for HIV treatment in particular.

In short, in this chapter I discuss drug development as an iterative process of articulations, which define visions, and generate multiple values, while also reconciling potentially conflicting interest to ensure equity. I believe it is important to begin my ethnography here since it is within this complex milieu that pharmaceutical "innovation" happens. Indeed, to tell the story of how Truvada became PrEP, I must place Truvada within the cycle of innovation, and from this perspective, I may more comprehensively analyze innovation itself. Thus, in this chapter I move between Milligan's on-stage performance in which he recites the commercial history of Gilead, including and beyond the firm's role in the antiretroviral market, and larger trends in the history of this market, beginning with the commercialization of the first drug approved for commercial use to treat HIV.

The HIV Treatment Market, Part 1: From Innovation to Speculation

Innovation: The first drug to prevent HIV

On March 19, 1987, the HIV treatment market was established when the United States Food and Drug Administration (FDA) approved the first commercial drug product for HIV treatment, which utilized the pharmaceutical compound, azidothymidine. The product was developed and marketed by Burroughs Wellcome PLC, and sold under the brand name Retrovir, though it would become known more commonly as "AZT."

This early moment in the new market for HIV treatment can be explained, in part, through the standard model of pharmaceutical *innovation*, through which a pharmaceutical firm invests in and conducts extensive research, including to evaluate molecules that are likely to make good drug candidates, and tests them through multiple phases of research, vies for regulatory approval, then

manufactures, and sells their drug products, ideally in high-value markets.[10] Indeed, Burroughs Wellcome was able to develop a treatment for HIV much more quickly than other firms because the organization had been managing research about retroviruses for at least five years before the discovery of HIV.

Whereas many large pharmaceutical firms had filled their R&D pipelines with candidates for well-known medical needs, which were more likely to be lucrative, Burroughs dedicated resources to research for rare conditions. In the five years before the commercialization of Retrovir, Burroughs Wellcome and its parent company had spent $726 million on R&D in this therapeutic area.[11] And before that, the firm had attempted to develop anticancer drugs, and one of their unsuccessful attempts involved the pharmaceutical compound AZT. So the firm had both the clinical research infrastructure and a viable drug candidate ready to enter the pipeline. However, to explain the commercialization of AZT, one must also understand how vision, values and interests came together to affect the very form of the clinical trial testing the efficacy of AZT, and thus also, the means of production.

To realize their vision for Retrovir, Burroughs Wellcome would need to test its pharmaceutical compound across three phases of research. In the first phase, investigators evaluated how the drug interacted with the virus in the laboratory. After finding evidence it could be effective, they began a phase-two study, in which they introduced the drug to the human body, primarily to assess its safety. Though the drug had significant side effects, including severe intestinal problems, damage to the immune system, nausea, vomiting and headaches, for the public health emergency it was meant to address, it was deemed safe enough. Indeed, despite its toxicity,

10. More specifically, pharmaceutical firms work in a market that requires substantial capital investment to support research and development for new drug products, and are obligated to realize consistent returns on invested capital (ROICs, or "returns) that generate cash flow.
11. O'Reilly B and Field N 1990

moving the compound through the pipeline was also in the interest of public health. Next, the investigators would need to conduct a phase-three clinical trial to evaluate the efficacy of this potential medication. However, there was significant debate about how the trial should be conducted.

The debate about how AZT would be tested included not only representatives of industry, regulatory agencies, and scientific teams, but also those whose intimate lives depended on it, including those living with the virus as well as their friends, family and lovers. These people organized themselves as activist groups, such as ACTUP and Project Inform. They poured through clinical research literature in a desperate attempt to save the lives of those they loved. And when this promising molecule was identified, and clinical research protocols were being developed, they descended on the decision-making table to ensure their interests were being heard. As a reported in the May 1986 issue of *AIDS Treatment News* observed, "The companies who want their profits, the bureaucrats who want their turf, and the doctors who want to avoid making waves have all been at the table. The persons with AIDS who want their lives must be there, too."[12]

Once they found their seat at the table, they fought against the paternalism of the state. "[R]ather than endure the benevolent protection of the authorities," they demanded "the right to assume risks[13]." And their efforts were largely successful. They established consensus about how the efficacy trial for AZT would proceed. The trial would enroll nearly 300 participants. One half of the group of participants would receive AZT, the experimental medication, and hence, comprise the 'experimental' arm, meanwhile the other half of participants would receive a placebo, comprising the 'control' arm. In the first few months of the study, one participant taking AZT died. Meanwhile, over this same timeline in the placebo arm, a total of 19 participants had already died.

12. Epstein 1996: 195.
13. Epstein 1996: 190.

When investigators observed this clear difference, the study was quickly unblinded. Those still alive in the placebo arm were given AZT. And the drug was approved by the FDA.

Proving its value by saving lives and maintaining intimate relationships, Retrovir became the first effective treatment for HIV to be commercialized. Retrovir would also remain the only commercial product available for HIV treatment for the next four years, and thus, it would retain significant commercial value. And Burroughs Wellcome, as the first firm to commercialize an HIV treatment product, would maintain a *de facto* market monopoly during these years, so the firm had the opportunity to recover the costs of investment in R&D and create a new revenue stream, which would contribute to its future research budget. The firm justified the $6,300 annual (wholesale) price of the new product based on the high costs of R&D, production, and related expenses. In 1988, its first year in the US market, sales of AZT reached $113 million.[14] This number grew to $134 million in 1989 and $170 million in 1990.[15]

However, in these years following the commercialization of Retrovir, people living with HIV and their intimate others maintained a critical public discourse about the ways drugs to treat HIV should be produced and sold. For one, they observed that Burroughs Wellcome had leveraged government resources, including funding and regulatory approval mechanisms, to package an existing chemical compound into the only approved treatment available for their loved ones living with the deadly virus.[16] And they used this as evidence that Burroughs Wellcome should lower its price. After two years of ongoing debate over the price of Retrovir, the firm cited the ability to lower operational costs for ongoing production and distribution, and lowered the price by 20%. That year, sales plateaued, as Burroughs recorded only a $7 million gain in sales for fiscal year

14. Pink Sheet
15. Emmons W and Nmgade A 1993
16. Emmons W and Nmgade A 1993

1991.

They also demanded to continue participating in clinical research without the traditional ethical and statistical safeguards. This again involved representing their intimate interests by fighting against the paternalism of the state. They were aware of the risks, and knew participation might afford the opportunity to live. Eventually, they convinced the state to change the usual requirements for efficacy studies for HIV treatment, and thus, significantly decreased the time and resources needed to bring a drug to market. Responding to this pressure, in 1992 the U.S. Department of Health and Human Services announced initiatives "to provide earlier access to important new drugs" and "ease unnecessary regulatory burdens."[18] From this point on, "surrogate endpoints" would be used, which measured the effect of the experimental medicine within the body of all participants. In particular, surrogate end points would be used to evaluate how an experimental medicine changed the levels of detectable virus and T-cells in the blood of participants.

Changing the scientific inputs required for regulatory approval altered the means of production, reducing the long wait times for clinical evidence and regulatory approval to get life-saving drugs to the people that need them. Whereas it might have taken eight to ten years to bring a drug from phase one to the commercial market under the standard clinical research model, the new model reduced the timeline to as few as two years. This opened the door for the deregulation of drug development, which free-market economists had been striving toward for decades prior. Whereas previous reform efforts led by free-marketers had been dismissed as neoliberal speculation, when people affected by the virus themselves critiqued the government's paternalistic

18. "New Initiatives to Speed Access to New Drugs" AIDS Info, April 9th, 1992. https://aidsinfo.nih.gov/news/223/new-initiatives-to-speed-access-to-new-drugs

practices, they achieved reform.[19] In so doing, they crafted a new path forward wherein value could grow.

Speculation: How the Market Grew

By changing the means of production, activists created an important opportunity for firms to enter the market. Though few firms had active R&D programs for antiviral therapeutics in-house, those that did could now move their drug candidates through the development pipeline more quickly, and those that did not could more clearly predict the returns they would realize by investing in products in this market. And invest, they did.

To enter this new market, many large pharmaceutical firms pursued mergers and acquisitions[20] — or "M&A" for short — whereby they either merged with one other large firm or acquired a smaller biotechnology company. Through M&A a "bidding firm" seeks to own more commercial products, which they can produce, manufacture and sell. This often includes likely drug candidates, which the "target firm" has in the development pipeline. This allows firms to commercialize drugs more efficiently than they can develop them in-house.[21] Thus, in the terms of innovation, firms use M&A to both cut R&D costs, and increase the productivity of their product portfolios.[22] However, M&A also involves speculation, which is evident at the point of exchange,

19. As Cathy Gere explains, "The irony of the AIDS movement's antipaternalism was that activists who fought against profiteering in the pharmaceutical industry helped push through a deregulatory agenda that ultimately served the industry bottom line" (Gere 2017: 209).
20. This would continue to be a theme in the pharmaceutical industry, especially in the early 2000s, when several firms were flush with cash because they had recently marketed 'blockbuster drugs' which generated extremely high revenues. Pfizer, for example, commercialized both Lipitor and Celebrex in the 1990's, and generated record revenue from each.
21. M&A also allowed firms to create value in other ways, including by improving the performance of the target company, removing excess capacity from the industry, and creating opportunities for market access for products.
22. Through M&A, firms also cut costs such as by vertically integrating pharmacy benefit managers to counteract buyer power.

as the bidding firm makes an offer to the target firm based on market valuation — a calculation of potential productivity. This valuation is generally expressed in stock value, such as on Wall Street.

In a sense, M&A allows firms to maintain high valuations, which might otherwise be affected by poor productivity in their R&D pipelines. However, the cost of M&A also sets the target and pace for revenue growth. And since firms tend to acquire companies with multiple products across their development pipeline and product portfolio at relatively high prices, the price of all drug candidates and commercial products acquired determined the goals for revenue growth, and obligates median-high returns across the entire product portfolio.

The first major merger to affect the HIV treatment market was completed in 1989, as Bristol-Myers merged with Squibb, creating the world's second-largest pharmaceutical company at the time. And in less than two years operating as Bristol-Myers Squibb (BMS), the firm received FDA approval for Videx (didanosine, dideoxyinosine, ddI), which became just the second HIV treatment on the market. This rapid development was made possible for the newly merged company because Bristol-Myers had secured an exclusive license to produce and test dideoxyadenosine (DDA) and dideoxyinosine (DDI) two years before the merger completed. For Squibb, then, the merger represented an opportunity to capitalize on the licensing acquisition and R&D program Bristol-Myers had established. And with the time of trials dramatically expedited through the use of surrogate end points, the path for investment became clear.

Of course, investing in a HIV treatment product during this time was still a significant risk because the market was young and relatively untested. In fact, in an independent report about the newly restructured company, Videx was referred to as "the biggest wild card in the Bristol Myers Squibb pipeline."[23] Compared to Retrovir, Videx seemed to offer higher efficacy, lower toxicity,

23. Bernstein Research 1989: 145

and fewer side effects. However, the product still posed risk because the science was controversial, and the market forecast predicted growth in the market would be relatively slow, given that "fear, social stigma, and concerns about insurance coverage" would likely limit screening and diagnosis, "particularly in high-risk, asymptomatic populations." And further, as was made clear during the rollout of Retrovir, pricing would likely be affected by political pressure. Nevertheless, Videx had enormous potential. It was projected that by 1993, Videx would generate revenues between $250 and $300 million.

For Bristol Myers Squibb (BMS) to comprehend the projected growth of Videx, they needed vision. The vision they developed was constructed through a few key assumptions, including that the total number of new diagnoses would increase, even if slowly, and people on treatment would begin living longer, so the market would begin to expand, and Videx would assume an increasing portion of that growing market share.[24] Further, the firm needed to maintain this vision in the context of competition. In June of 1992, Roche commercialized its first competing product under the brand name Hivid (zalcitabine, dideoxycytidine, ddC). With Hivid, Roche threatened to steal market share from BMS. Facing competition, BMS launched its second HIV treatment product in 1994 under the brand name Zerit (stavudine, d4T). Despite whatever amount of market share might have been lost to Roche in the previous two years, with the commercialization of Hivid, BMS held two of only four available HIV medications within its product portfolio and regained market share.

Another significant merger began in 1995 when one firm, which was at the time known as GlaxoHoldings PLC, entered the market through a deal with Burroughs Wellcome. As a result of

24. For a snapshot of the market forecast for the "US anti-AIDS market" in 1989, see Bernstein 1989: pp. 147, Table 53.

this merger, GlaxoHoldings PLC and Burroughs Wellcome would become jointly known as GlaxoWellcome. GlaxoWellcome then continued a series of mergers and acquisitions through the end of the decade, by which time the firm boasted five products in its HIV treatment portfolio. And in the year 2000, the firm completed one more deal. This time with SmithKlineBercham. Emerging from this intense period of M&A with the name GlaxoSmithKline (GSK), the firm boasted six HIV treatment medications in its commercial portfolio.

Over the following decade, several other firms, including Genentech, Abbott, Merck, Boehringer Ingelheim, Agouron, and Abbvie each launched new HIV treatment products, many through M&A deals. Through the combination of an accelerated regulatory pathway made possible by patient advocacy and an efficient commercial strategy, many new HIV treatment products entered the market, as firms seized emerging opportunities. By the end of the year 2000 – just thirteen years after the first drug product entered the HIV treatment market – nineteen individual drug products had been commercialized, and these nineteen products were divided between the portfolios of nine different pharmaceutical firms. And into the new century, market productivity kept pace -- at least, the number of new products being introduced to the market per year stayed steady, meanwhile the number of new firms entering the market greatly declined. In fact, in the next decade, between 2001 and 2011, only Gilead Sciences and Janssen Pharmaceuticals would begin marketing HIV treatment products. However, those two firms would have enormous impact, and Gilead would become the biggest player in this evolving market.

While the surge of M&A activity in the previous years disrupted Gilead's vision to market a treatment for AIDS patients suffering from CMV, as Milligan mentioned, the firm emerged from that "complete and utter bust" and entered the HIV treatment market in 2001 by launching Viread, which utilizes *tenofovir disoproxil fumerate* (TDF). This product launch was also made possible

by a "fast-track" regulatory approval process as well as an acquisition of another company, which the firm had completed two years earlier.[25] For Gilead, the merger added proven products to the firm's commercial portfolio, strengthened the pipeline of products under investigation, and expanded the firm's reach in international markets.[26] And with Viread on the market, "The company finally became profitable," Milligan explains.

Less than two years later[27] in the summer of 2003 Gilead launched its second HIV treatment product, which utilizes *emtricitabine* (FTC), and would be marketed under the brand name Emtriva. Gilead was also able to bring this product to market by acquiring another company, Triangle Pharmaceuticals, Inc. At the time, Gilead's portfolio consisted of six commercially available products.[28] Meanwhile, Triangle had three antiviral candidates in the development pipeline[29] including emtricitabine, which had previously shown promising results for the treatment

25. In July of 1999 Gilead and NeXstar Pharmaceuticals, Inc. (Nasdaq: NXTR) stockholders approved the merger of the two companies in which Gilead acquired all of NeXstar's outstanding stock in a tax-free, stock-for-stock transaction. NeXstar stockholders received 0.3786 of a share of Gilead common stock for each share of NeXstar common stock. Valued at $550 million, the transaction was accounted for as a pooling of interests.
26. By adding two commercial products from the NeXstar portfolio, Gilead Sciences now had three products on the market: AmBisome® (liposomal amphotericin B), an injectable treatment for serious fungal infections; DaunoXome® (daunorubicin citrate liposome injection), an anticancer agent approved for the treatment of Kaposi's Sarcoma for people living with AIDS; and VISTIDE® (cidofovir injection), an antiviral agent used to treat cytomegalovirus (CMV) retinitis for people living with AIDS. As a result of the merger, Gilead's research pipeline now included five investigational compounds in various stages of clinical development: adefovir dipivoxil for hepatitis B virus infection (Phase III), tenofovir disoproxil fumerate (formerly known as PMPA) for the treatment of HIV (Phase II), MiKasome® (liposomal amikacin) for serious bacterial infections (Phase I/II), NX 1838 for age-related macular degeneration (Phase II) and NX 211 (liposomal lurtotecan) for ovarian and lung cancer (Phase I). Gilead also expanded its international development and commercialization team in Europe and Australia. Those teams would focus on the distribution, marketing and sales of AmBisome and DaunoXome, improve the firm's position to introduce future drug candidates to those markets, and add experience in cancer and HIV products, which would prove helpful in the launch of adefovir dipivoxil for HBV and Tamiflu (oseltamivir phosphate) to treat influenza. This acquisition was especially well timed because Gilead and its marketing partner, F. Hoffman-La Roche Ltd., had recently applied for regulatory approval of Hepsera (adefovir dipivoxil) for the treatment of HBV. In June 1999, Gilead filed a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for adefovir dipivoxil 60 mg to treat HIV.
27. F. Hoffmann-La Roche Ltd, Gilead's worldwide development and marketing partner for this potential product, had filed for marketing authorization of Tamiflu in the European Union.
28. Gilead's commercially available products included liposome injections (AmBisome and DaunoXome), one drug for the treatment and prevention of influenza (Tamiflu), one treatment for cytomegalovirus retinitis (AmBisome), one treatment for hepatitis B (Hepsera), and one treatment for HIV (Viread).]
29. Clevudine (L-FMAU) was in Phase I/II studies; amdoxovir (DAPD) was in Phase II; and Coviracil (FTC) was

of HIV and was being tested in a Phase III study for HBV.[30] Emtricitabine was the centerpiece of the acquisition. Three months before the deal began, Triangle had filed a New Drug Application with the U.S. Food and Drug Administration to market emtricitabine for HIV treatment under the brand name Coviracil. Triangle also expected to file a Marketing Authorization Application in Europe for the product before the end of the year.[31] The acquisition was valued at $464 million. Upon completion of the merger, Triangle became a wholly owned subsidiary of Gilead.[32] The deal held particular promise for Gilead because emtracitabine would allow the firm to further penetrate the antiviral market.[33]

In short, this early HIV treatment market was heavily influenced by political pressure from people living with HIV and their intimate others to ensure treatments would be commercialized more quickly, which involved adjusting the conditions of clinical research, and thus, allowed firms to bring new products to market more efficiently. This sparked competition in an emerging market. Firms began to enter the market as quickly as they could, including by acquiring and merging with other companies. Thus, the demand to save lives and get drugs into bodies invited a speculative

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in a Phase III. Clevudine and Coviracil were being tested for the treatment of chronic hepatitis B, and amdoxovir was being tested for the treatment of HIV.

30. At the time of the acquisition, Triangle's portfolio also included amdoxovir (DAPD), a nucleoside analogue in Phase-II clinical studies for the treatment of HIV, and clevudine (L-FMAU), a nucleoside analogue in Phase I/II studies for the treatment of chronic hepatitis B. Coviracil was also being tested in a Phase-III study for patients with chronic hepatitis B.

31. While acquiring the product because it was market-ready, Gilead also planned to co-formulate emtricitabine with Viread, as a potential fixed-dose combination treatment for patients with HIV. So by acquiring Triangle and emtricitabine, Gilead added value to its portfolio of potentially marketable products and to its development pipeline.

32. In connection with this transaction, Gilead also provided Triangle with $50 million in interim financing for working capital needs in exchange for a convertible note. In all, the deal was expected to be dilutive to Gilead's earnings in 2003, neutral in 2004, and accretive in 2005 and beyond. Goldman, Sachs & Co. served as financial advisor to Gilead. Banc of America Securities LLC represented Triangle.

33. Gilead turned to M&A as a mechanism for growth, including as a lever to enter the antiretroviral market. Though Gilead would soon build a 16-year M&A history during which the firm would acquire 13 companies for a total of $17.7 billion, and the target therapeutic areas the firm pursued would be vast, ranging from cystic fibrosis (CF) and pulmonary arterial hypertension (PAH) to human immunodeficiency virus (HIV) and hepatitis C (HCV), the firm's acquisitions that included antiviral products have proven most important for the company. These acquisitions began with NeXstar in 1999, continued with Triangle in 2003, and eventually, contributed to the development and implementation of Truvada for HIV pre-exposure prophylaxis (PrEP).

practice of pharmaceutical capital to take hold. As lives were saved, intimate relationships maintained, and young companies became profitable, the values of the market multiplied.

The HIV Treatment Market, Part 2: Combinations and Contracts

Whereas the earliest demands to gain political efficacy were rooted in the attachments of those affected by the virus, and their friends, family and lovers in the United States, and thus, took the form of critical public discourse that spoke back to the state, a second wave of demands had been circulating across the globe, based on the very same attachments — among people living with the virus, as well as their friends, family and lovers — in different geographies. While these intimate demands had not garnered political efficacy with the nearly the same prominence or urgency as those of white gay men who found a seat at the table among regulators and industry, many of the same demands had been circulating in other political spheres for just as long. Also, like the demands that made local and national news in the United States, these demands also asserted the 'right to live', and thus, aimed to extend this right to all. When these intimate demands finally rose to political prominence, they stitched together a global response that was less concerned with the means of production than with property itself.

Opening Property Regimes

This second wave of activism took aim at licenses, marking a new moment in the HIV treatment market, which would from then on be characterized through the politics of access. Whereas earlier efforts had some impact to lower prices, such as by pressuring firms to lower the price of their products, in this moment, advocate organizations and governments focused on designing patent laws in ways that favored access to medicine. By this time, the Agreement on Trade-Related

Aspects of Intellectual Property Rights (TRIPS) had been established between the member nations of the World Trade Organization (WTO). The agreement mandated that WTO member nations maintain minimum standards in intellectual property (IP) law. TRIPS offered an obstacle and an opportunity for expanding access. While member nations had more stringent IP protections in place, such could be used to shore up existing licenses, these protections could also be used as public health safeguards.

When several member nations convened at the United Nations agreed that products to treat HIV should be added to the World Health Organization's List of Essential Medicines, they essentially agreed governments would leverage public health safeguards, exercising their right to not grant nor enforce patents for drug products, and overriding patents in the interest of public health, such as by issuing compulsory licenses, and by maintaining "high standards for patentability to ensure only innovative products are rewarded with patent monopolies" and by upholding oppositions to patent applications.[34]

They also agreed to make the marketing licenses for these products available to generic firms. The effects of this new wave of advocacy were evident when several pharmaceutical firms and the UNAIDS Secretariat introduced the Accelerated Access Initiative through which they would offer ARVs at reduced prices to a range of countries where access was limited. The Initiative established the first differential pricing scheme for ARVs in developing countries. The Initiative also provided evidence that ARVs could be safely and effectively used in low-resource settings, where some had presumed there would be low adherence, which would lead to drug resistance and thus, exacerbate the impact of the epidemic, such as by limiting treatment options. In effect, activism that expanded access also created differentiated market segments: whereas previously

34. MSF 2012

only high-income countries could afford ARVs, there was now a low-income segment of the market where ARVs would be made available.

However, some firms held tightly to their patent rights. In these cases, advocacy groups and generic firms have contested patent applications and existing licenses. In related cases, firms have tried to flex patent laws, for example, by making small changes to existing drug products, which in some countries, affords significant patent extensions for as many as twenty years. Meanwhile, in countries where patent laws have been crafted to promote access, these firms have directly contested the law. So, governments, advocates and NGOs maintain a particular focus on patent laws in part because firms continue to test the boundaries of such laws. In short, advocates, governments and NGOs asserted the interests of the public health in order to affect product value. This opened patent regimes and facilitating the generic manufacturing and distribution of drugs. It also affected the vision of the pharmaceutical firms in the market.

Combining and Contracting Opportunities

This era of advocacy not only amended the commercial value of existing products, but also steered firms toward other opportunities. While far fewer brand name firms entered the market for HIV treatment at this time, Gilead and other firms that already had a foothold in the market began to shift their strategies for value creation, including how they would market existing commercial ARV products and add more products to their portfolios. While the M&A deals of the previous decade held great promise for the buying firms, the cost also set the target and pace for revenue growth. Since these firms had acquired multiple companies that had multiple products across their development pipeline and product portfolio at relatively high prices, the price of all drug candidates and commercial products acquired determined the goals for revenue growth, and

obligated median-high returns across the entire product portfolio. So, after firms decreased in-house R&D and could no longer justify M&A activity[35] they had to shift vision once again.

First, instead of continuing high-cost acquisitions, firms began to combine existing drug compounds, most of which were already used in commercial products, and market them in fixed-dose combination tablets under new brand names. For example, after Gilead acquired FTC and TDF from other companies, the firm also co-formulated the newly acquired products into a fixed-dose combination tablet, and brought it to market to treat HIV under the name Truvada. Truvada was backed by new clinical research findings, which emphasized the importance of adherence, such as through the assertion that a single pill would be easier to take than two separate pills. Truvada was also protected by new patents, and sold at a higher price. With its new higher-value co-formulated product, Gilead thus extended the original value of its capital-intensive M&A activity.

Explaining how Truvada added value to the market place, Milligan emphasizes that the product was a clear improvement on some existing medications available for treatment at the time. He shows a slide depicting a few large pills. "This is a representation of what a patient had to take in 1996. These pills were taken three times a day – some on an empty stomach, some after food. It was very difficult." Detailing the medication regimen and emphasizing the importance of

35. M&A also allowed the industry to streamline resources and add value to the marketplace by trimming excess capacity associated with redundant operations across firms, and by consolidating that capacity within fewer firms. Looking across the industry in the late 1990s, the management-consulting firm, McKinsey, estimated that a total of $60 to $90 billion in net present value could be cut from the U.S. pharmaceutical industry alone. Around the same time, David Ravenscraft and William Long (2000) tracked market reactions to the announcement of 65 pharmaceutical M&A deals in the previous decade and calculated returns to shareholders of target companies and bidding firms. Across the total 65 transactions, shareholders for target companies gained value while the shareholders of bidding firms lost value. Though the transactions were lopsided, value was created. In fact, these 65 deals, which merged individual firms – each valued over $500 million – created a total sum value of $18.76 billion for shareholders, and primarily, for those with shares in target companies. This kind of lopsided value-creation is well documented in pharmaceutical markets (Bradley, Desai, and Kim 1988; Jones 1996: 30).

adherence, Milligan continues:

> *The protease inhibitors actually had to be taken every eight hours. It was that precise. HIV patients would walk around with timers on their belts that would alert them when eight hours were up, so they could take their medication on time. If you missed your dosing window too frequently, you developed resistance. At this time, we saw massive amounts of resistance because this regimen was really hard to stick to.*

With the commercialization of Truvada, these concerns about adherence and resistance subsided because "we were able to simplify things by putting multiple medications in one pill to take once a day." In short, by combining existing products into a single product, Gilead added therapeutic value, improved patient experience, and extended commercial value.

Second, Gilead as well as other firms further leveraged licenses on existing commercial products, such as by offering their own products at discounted prices as well as by forming strategic partnerships with generic firms that would market their products in lower-value markets, or in some cases, by offering voluntary licenses. Though the value of individual ARV products had been reduced, with each of these strategies firms could still realize revenue from these products and extend the value of previous M&A activity without spending any significant capital. In short, by forming more strategic alliances with other companies, the firms could manage the low-value products already in their portfolios. By granting another company, such as a generic firm, the license to market a product, the originator firm could consolidate its sales force – moving personnel out of lower-value markets and into higher-value markets. When granting marketing licenses to generic firms, originator firms also collected a percentage of sales revenue from the generic firm.

The same year Gilead launched Truvada, Milligan explains, the firm also started its "global access program to try to make medicines available in sub-Saharan Africa and other areas."[36] More

36. It was no coincidence that the beginning of Gilead's program coincided with launch of the Global Fund for HIV, Tuberculosis and Malaria and PEPFAR, through which the United States dedicated a large amount of money to help countries in sub-Saharan African and other parts of the world access HIV treatment. Indeed,

specifically, Gilead launched its access program[37] in 2003 by offering Viread (TDF 300 mg) to 53 nations in Africa and 15 other developing countries (designated 'least developed' by the UN) at the discounted price of $475/year (or $1.30/unit). In 2005, following patent oppositions by civil society groups and increases in generic competition, the price of TDF fell significantly[38] and Gilead expanded its access program to include all nations in Africa, bringing the total number of eligible countries to receive Viread at a reduced price to 95. In 2006, the firm expanded access to three more countries, and began offering Truvada in the Access program as well.[39] However, access to Truvada and Viread remained limited because Gilead had not registered these products in several of the countries the firm deemed eligible. In 2006, for instance, Gilead's Viread was registered in only 13 of the 97 countries deemed eligible. Meanwhile, Truvada was available in only 4.

In 2006, however, 10 generic manufacturers[40] secured licensing deals from Gilead and through the terms of the contract, began offering generic versions of TDF (300 mg) tablets. Under the terms of the agreement, the generic firms were allowed to manufacture and export generic versions of TDF-based products to a limited pre-defined list of countries, against the payment of a 5% royalty.[41] While such licensing agreements could contribute to increased competition and improved access to affordable medicines, critics note these particular agreements limited competitive impact because they posed geographic market limitations. Manufacturers that signed

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both were direct responses to political pressure to increase access to ARVs around the world.
37. The program was designed and launched by Axios (http://axios-group.com/axiosinternational/services/market-access/).
38. MSF 2014 note 12
39. Today, Gilead's access program includes 110 low- income and 12 lower-middle income countries, each with high HIV-incidence (Appendix 1).
40. Since 2006, Gilead has signed license agreements with 11 companies, including
Aspen, Alkem, Cadila, Emcure, Hetero, Matrix (Mylan), McNeil & Argus, Medchem, Micro Labs; Ranbaxy, Sequent Scientific, Shasun, and Strides.
41. MSF 2010, 103.

the voluntary license agreements were prohibited, for example, from supplying countries such as Brazil and China. Consequently, in Brazil, even after negotiation with Gilead, the government has been required to pay between seven and ten times the best available generic price since 2006. However, one Indian generic firm, Cipla, did not accept the voluntary license and began manufacturing and selling its own versions of TDF and TDF/FTC. The firm was able to do this, in part, because neither TDF/FTC nor its the individual component parts are patented in India. These new licensing deals advanced the possibility that the generic market could make life-saving treatments available where the brand name market fell short, even with its 'access' initiative.

Tracking drug prices within this generic market, *Médecins Sans Frontières* compared prices between Gilead's TDF (300mg) tablets and generic TDF (300mg) tablets, as they fluctuated among generic manufacturers. Reviewing this data, there are a few apparent trends. First, between 2003, the year Gilead began offering a discounted price for TDF, and 2006, the year TDF was included on the WHO List of Prequalified Medicinal Products and Gilead issued licenses to generic manufacturers to produce TDF, the price of Gilead's TDF tablets decreased by 56%. Second, after 2006, Gilead's price for TDF remained constant for low-income countries. And third, through 2012, the generic price continues to drop. In fact, compared to the 2006 price, the 2012 price drops by 84%. Amid these pricing fluctuations, one overarching observation should be emphasized: in the period after 2006, as more generic tablets entered the market alongside Gilead's product, Gilead's price does not change, however the prices of generics continue to fall. What we observe in this moment then is not that generics drive down prices of originator products, but instead, how a competitive market for generics has emerged alongside the branded 'access' market. Therefore, the interests of the public, as represented by civil society, affected the vision of pharmaceutical firms and the values of their drug products differently in this stage of the market.

Whereas in the early treatment market, advocacy influenced changes in regulation, which allowed firms to more effectively realize their vision of bringing new products to market, when activism ensured firms had to work within the confines of their licenses, originator firms combined existing products, which extended licenses, and contracted with generic firms, which extended the value of their licenses. In each of these revenue-generating strategies, as in M&A, the key for the firm to create value was to hold the license for a product, or more commonly, several products. Licensing thus became a larger area of focus to drive value in drug markets. Whereas through M&A, firms with buying power could wait for other companies to develop high-value products, and place bets on specific products when the revenue prospects looked promising, with strategic alliances, when other products, such as those acquired through an earlier bet, turned less profitable, a firm would lean on another company to market that low-value product, and by charging a fee for use of the license, the originator firm could generate revenue.

The HIV Prevention Market, Part 1: Emergent Articulations

Innovation: The first drug to prevent HIV

In 2012, the HIV prevention market was established when the United States Food and Drug Administration approved Truvada for use as oral HIV pre-exposure prophylaxis (PrEP). As the first product to be commercialized for HIV prevention, in some ways the role of Truvada in this new market mirrors the role of Retrovir in the early market for HIV treatment. It is, for example, the only product in the market and so, represents a temporary monopoly for the originator firm. It is also a product of a shared vision, and hence, represents both commercial and non-commercial values. However, to understand the re-commercialization of Truvada for PrEP requires a closer examination of the vision that supports it, the interests the product reconciles, and the values it

encapsulates.

A New Vision

To understand the current vision supporting the re-commercialization of the drug, it is helpful to first recall how Truvada and its component parts were first commercialized with the support of iterative visions, which materialized a series of commercial strategies, including *speculation, innovation,* and *combination*. And through each of these commercial strategies, Gilead shifted its vision several times in ways that aligned with the public interest and created value on multiple levels. This included Gilead's acquisitions in 2001 and 2003, through which they obtained *tenofovir disoproxil fumerate* (TDF), and marketed under the brand name Viread, as well as *emtricitabine* (FTC), which they marketed under the brand name Emtriva. The firm then co-formulated this newly acquired products into a fixed-dose combination tablet, and brought it to market under the name Truvada, which was said to enhance the therapeutic benefit by offering two drugs in one tablet.

Now, the re-commercialization of Truvada is being supported by yet another vision, and again, to generate value, that vision must be articulated in relation to the public interest. This is evident as Milligan links the commercial history of the drug to its current use. "Now we also use Truvada for HIV prevention," he explains. And from his position on stage, he points toward the back of the auditorium, as if through the wall and across the street, to suggest that the clinical research the evaluated the safety and efficacy of Truvada for PrEP was "spearheaded" by "Bob Grant at Gladstone Institutes." Gladstone is an independent, nonprofit biomedical research organization located immediately across the street from the UCSF campus, where Dr. Robert Grant, a UCSF physician and professor, worked temporarily as he served as principal investigator

for the first trial to produce evidence Truvada could be safe and efficacious as PrEP. Hence, as Milligan articulates the "vision" that supported the development of PrEP, he attributes it to Dr. Grant, the figure conjured in this moment to represent the public university, and thus also the social good.

Milligan's attribution of the vision that supports PrEP operates on multiple rhetorical levels. On one level, it reconciles "values" within the research and development pipeline by intimating there is no "conflict of interest," which generally involves showing that the interest of the pharmaceutical firm that owns the product being tested does not disproportionately affect the scientific experimentation through which the safety and efficacy of that product is evaluated, such as by misrepresenting its therapeutic benefit. This articulation thus involves simultaneously acknowledging the possibility of untruth and overlaying that possibility with a further claim to truth. On another level, Milligan suggests the very *vision* for developing Truvada as PrEP was crafted by an investigator at a non-profit research institution. And thus, he also further distances himself from the truth claims about the efficacy of Truvada.

In detailing these articulations of vision, my aim is not to evaluate their veracity, but rather, to show that such articulations open a space for the private firm and the public institution to coexist and intermingle in the name of equitable interests. As Gilead donates drug for the trial, but offers no additional support, and Dr. Grant leads the investigation from his seat within a non-profit organization, the development of Truvada for PrEP can be articulated as an equitable relation between private and public interests. Thus, Truvada attains both novel therapeutic value as the first biomedical method to prevent HIV, as well as additional commercial value, as the first product on the market. And the value of this novel HIV prevention product extends further.

Market Conditions

Working with these renewed visions, shared interests and multiplying values, Gilead is clearly leading the new market for HIV prevention in the United States and around the world.[42] Though patient uptake was initially slower than some had imagined and hoped it would be, the consumer base has grown quickly in recent years. In 2012, the year the US FDA approved Truvada for PrEP, 8,768 prescriptions were written across the country. The following year, the number of active prescriptions grew slightly to a total of 12,540. However, in each of the next three years, growth significantly increased: in 2014, there were nearly 28,000 total prescriptions; in 2015, prescriptions nearly doubled, almost reaching 60,000; by the end of 2016, there were more than 77,00 active prescriptions for Truvada as PrEP in the United States. Based on a conservative estimate of $14,000 for the medication, revenues from the sale of Truvada for PrEP in the United States in 2016 alone amounted to more than one billion dollars.[43]

Gilead will continue to enjoy this temporary monopoly as the consumer base for Truvada expands. Gilead may also bring additional products to the HIV prevention market. The next opportunity for a new product to emerge in this market will be straight from the R&D pipeline, and this product is also wholly owned by Gilead.[44] Its brand name is Descovy, and it is currently being tested in a

42. In the global HIV prevention market, the rollout of Truvada began a few years later than it did in the United States, but since that time rollout has quickly increased as Gilead has obtained marketing approval for the new use of the medication in twenty seven countries in addition to the United States. The 28 countries where Truvada is approved for use as PrEP are: Australia, Brazil, Belgium, Botswana, Canada, England, France, Greece, Israel, Kenya, Lesotho, Malawi, Namibia, Netherlands, New Zealand, Nigeria, Peru, Scotland, South Africa, Slovenia, Swaziland, Sweden, Taiwan, Tanzania, Thailand, United States, Zambia, Zimbabwe.
43. $14,000 (conservative sale price for Truvada as PrEP) multiplied by 77,120 (number of total users) equals $1,079,680,000.
44. Another is TDF or "Viread." While Truvada proved slightly more efficacious than TDF in the single study in which both medications were included, in a separate study that tested TDF alone among people who inject drugs, TDF demonstrated significant efficacy. And no single study has proven the efficacy of Truvada among this population, so questions remain unanswered about why TDF has not been approved for use as PrEP among people who inject drugs. Choopanya et al., 2013

phase three study among men who have sex with men, primarily in the United States and European countries. Like Truvada, Descovy combines two known antiretroviral in a single tablet, and one of these antiretroviral drugs is emtracitabine. The other is *tenofovir alafenamide* (TAF), which is thought to have less toxicity and potentially greater efficacy than its predecessor, *tenofovir disoproxil fumurate* (TDF). So, it seems, Gilead will continue to command this new market for the foreseeable future.

The only other potential candidates that could be commercialized are developing with the support of foundations and government-sponsored trial networks. Some of these products offer a potentially advantageous delivery system – that is, whereas Gilead's products all come in the form of an oral tablet, other potential products include vaginal rings, gels, and films, rectal gels, and long-acting injectable solutions. The main challenge for moving these products through the development pipeline, however, is that Truvada already exists in the market, which places a greater burden on the new trials to establish efficacy. Unlike the trials testing Truvada, which functioned through a placebo-control, these new trials will not have that luxury. Since Truvada became the standard of care for the biomedical prevention of HIV, new products will be required to demonstrate greater efficacy than Truvada when tested head-to-head in a 'non-inferiority' study. In other words, the current regulatory standards may secure Gilead's monopoly.

The Innovation Cycle

When Selick shifts the conversation to the firm's current innovation pipeline, Milligan explains that he is crafting new visions for his company, which both include and reach far beyond the HIV market. First, he explains, "We continue to try to innovate for HIV patients." For example, "We recently launched our next generation HIV regimen, called Genvoya. That had four medications

in it. The main component, TAF, is far superior to Viread (TDF) in many ways. It is now the fastest growing HIV product in the US and countries where it has launched in Europe." At the same time, the Gilead has been pursuing other commercial paths, including in the new market for hepatitis C, which the firm entered by acquiring another company. As Milligan tells it:

> In 2011, we acquired a company called Pharmasset. They had a phase-2 drug that had been tested in about 45 people, showing very high cure rates of HCV. We spent $11 billion to acquire that company. Now, I don't know if you've ever spent $11 billion – maybe, I don't know – but it is a nerve-racking experience. We quickly turned that company, grabbed all their intellectual property, and went to work trying to make this into a real drug. The base of the drug, Sofosbuvir, is a kind of tertiary fluorine. It's very hard to make. We put 120 chemists on this to come up with a real, industrialized process. We were able to do that, get the product filed, and get the product approved in 2015, which was really remarkable.

The vision to develop hepatitis C products was supported by an existing capacity within the organization to develop antiviral products, which had been developed over years of producing antivirals for HIV treatment. This existing capacity to commercialize antivirals and the likeness between the therapies is also manifest as Milligan moves from talk of innovation and speculation to combination. In his words:

> *Sofosbuvir has become the backbone, if you will, of HCV therapy. We've added different medications to it, such as Ledipasvir, which is a NS5A inhibitor – another way to inhibit HCV that was invented at Gilead* [Harvoni]. *We've done another combination with velpatasvir* [Epclusa]. *And now we have a product that combines three drugs, including a protease inhibitor.*

"This kind of serial innovation is very hard to do," he tells the audience, and notes, "it doesn't happen very frequently in our industry." He also offers a few concrete examples of the firm's pipeline activities. Now, "We're pretty much done with HCV. We got to 99% in a lot of studies with our products." So the firm is pivoting to other areas, including liver diseases:

> *We're also now looking at things like Nonalcoholic Steatohepatitis, where we have some really compelling early stage data on three different compounds. We're trying to cure hepatitis B. That would be the ideal thing to do, but will be much more difficult. We're also working in inflammatory diseases. We have big, big programs in ulcerative colitis, Crohn's disease, and rheumatoid arthritis. We're partnering with Galapagos, a company in*

Belgium, to look at other inflammatory diseases.

As the event nears its conclusion, Selick returns to the idea of partnership, which he began the conversation with. After all, it was partnership that allowed Gilead to launch its very first product, Vistide. And it was partnership, Milligan explained, that was vital to the global response to HIV, of which Gilead had become an integral part. In this final moment, however, the two were interested in a very specific partnership — that is, their own. So, they conclude the conversation with an explanation about why it now makes sense for Gilead and UCSF to be partners. As Milligan elaborates:

> *I think we have a more common overlap with UCSF today than ever before, including in the case of immune-oncology, for example. There wasn't as natural an overlap when we were doing work on viruses. There were a lot of great models, but they were mostly elsewhere. We could do work with the NIAID because they had a great network of models. So there wasn't a real natural way for us to do the science together. However, we're moving into new areas, and much more difficult areas, where the biology of the disease is uncertain. Our industry is working with more un-validated targets than ever before, trying to determine if this, that, or the other pathway could cause NASH, diabetes, fibrotic diseases, and oncology. We are shifting our focus to different institutions than we've worked with in the past because the company has shifted. Frankly, we have something to at least control all the major viral diseases, so we have to explore other areas. I think that's the opportunity for a collaboration with UCSF.*

As the latter half of the conversation moves from Gilead's historical success with HIV treatment to ongoing efforts to 'innovate for HIV patients' then extends into related antiviral markets, and begins to extend into other therapeutic markets, we are offered insights about how the cycle of innovation will continue to churn. Here it becomes clear that the antivirals, which formed "the base of Gilead" and allowed the company to become profitable, also serve as a launchpad for the firm to move into higher value markets, where acquisitions far exceed the values of the HIV market, which ranged in the hundreds of millions of dollars, and allowed the firm to make acquisitions valued at several billions of dollars. And as Selick and Milligan publicly announce their vision for a partnership between the public research university and the private pharmaceutical

firm, they conclude with a joke about mergers and acquisitions in which the punch line is, “We’ll just buy them.”

Enduring Concerns

When the on-stage conversation between Milligan and Selick concludes, Selick welcomes members of the audience to ask questions. Almost immediately, a man to my left stands, and when he is handed a microphone, he introduces himself as “George Ayala, the executive director of “MSMGF, a small non-profit advocacy organization with headquarters in Oakland.” After explaining the mission of the organization is “to ensure equitable access to HIV services for gay and bisexual men worldwide while promoting their health and human rights,” he began his question for John Milligan:

> As you know, we’re doing a lot better in getting people access to treatment around the world. We’re at 17 million, but we have a long way to go. There are 34 million people living with HIV worldwide. So, access is an issue, particularly for vulnerable groups that shoulder a disproportionate HIV burden. I’m hoping you might share some of your thoughts about what it will take to get us to 100% access and easier access.

In reply, Milligan begins by highlighting several active partnerships Gilead has established with health departments, both in the United States and around the globe. He also demonstrates he is conversant in the priorities of HIV treatment and HIV prevention, citing for example, how testing services need to be linked to care.

> *We have a number of initiatives in the United States, and are continuing several others outside the US as well, to understand how we can better test and link to care. We have 165 partnerships that we’re sponsoring around the United States, both in rural and urban settings, trying to figure out how we can do a better job in different departments, including the emergency department and behavioral health department as well as sexual health organizations to figure out how we can better diagnose and link people to care. This is important because often times when a person is diagnosed, they go away, but continue to have HIV and unfortunately, may also continue to infect others. So we’re working on all these different ideas about how to link people from testing directly to care.*

More specifically, Milligan illustrates how Gilead employees have become integral to care.

> We have people called navigators, who get people from the point of diagnosis to their physician to try to make sure they get the counseling they need and access to the medication they need. We provide a coupon, so that person can get their first month's supply of drug right away, and then our people help them find access to some kind of ongoing health care provision, such as one of the plans through the Affordable Care Act, Medicare, the AIDS Drugs Assistance Program, possibly private insurance, so they can get continuity of care. These groups try to create a trusting environment, so people of all sorts of socioeconomic status feel comfortable coming into clinics. We hosted an event last night with these groups, and heard some great success stories about diagnosing and getting people into care. So these are some of the things we're piloting.

Perhaps most significantly, he identifies the challenges that lay ahead for the field, and displays how Gilead is an active part of the global response to HIV and a key player in addressing lasting health disparities, such as those that remain evident in the southern United States. In his words:

> In the United States, we have about 800,000 people in care, but over 1.2 million thought to be infected. There are about 400,000 people who probably don't know their status and are probably causing the 50,000 new infections that happen every year. We would love to figure out new ways to address this problem. But it's a big challenge. Even at 9,000 people, we're a pretty small organization, so we're using all these partnerships with community directors to try to get out there and figure out things that might work for them, particularly in the south."

Concluding this lengthy answer about Gilead's role in the global response to HIV, Milligan moves on to take questions from other members of the audience, who ask more about his thoughts on the regulatory standards at the U.S. Food and Drug Administration under the leadership of Scott Gottlieb — who he says he knows well and thinks is doing a great job, — and Gilead's current "innovation pipeline," including what the firm plans to do with its $3.2-3.5 billion research and development budget. To address this latter question, which he rephrases as "How do we bring innovation into Gilead?" he explains:

> We can't invent all the best things here, so we pick areas where we can become the experts on the biology, chemistry, or physiology of a disease, so we can then go out and find the opportunities that fit with what we want to do. So we often monitor different companies

> and different technologies, so we know what to bring in and how to bring it in. Over the years, we've set up lots of collaborations, and we've bought lots of companies.

In the innovation cycle, the visions, interests and values of one therapeutic market cartwheel into the next. This is evident as Gilead, the dominant player in the HIV treatment market, establishes a monopoly in the market to prevent HIV. This is also clear as the revenues from the commercial success in these markets allow the firm to move into higher-value markets through M&A. In the process, concerns are raised about how the lower-value market will continue to be served, as firms shift priorities.

Ayala's question demonstrates these concerns well. After sitting through the 90-minute conversation during which he heard Selick and Milligan craft a new vision for a public-private partnership that would dedicate resources away from the HIV market and into other therapeutic pursuits, he reminds everyone in the auditorium that half of the people living with HIV today still do not have access to treatment. He flags how much work is left to be done, which will not be solved by innovation, speculation or combination. Rather, to secure the health of the population will require a shared vision that represents the interests of those whose lives remain disproportionately affected by this virus. Ayala also reminds us these questions remain to be answered in the market where Gilead began, and as the firm shifts its priorities, these questions will endure. Meanwhile, Milligan's reply displays how Gilead has positioned itself in the market, not only as a developer of drugs to treat HIV, but also, as an organization committed to the provision of HIV care. This is clear, for example, as the firm establishes relationships with public health organizations to support the rollout of antiretroviral drugs, and employs its own benefit navigators to ensure patients can identify a path to access.

In sum, as Milligan and Ayala articulate enduring concerns about the innovation cycle, they remind us that the development and implementation of Truvada for PrEP must be understood amid

the tensions between visions, interests and values. They also define the context within which PrEP emerges, where public and private partnerships have become key to therapeutic and commercial success. In subsequent chapters, I explore how Truvada for PrEP must both articulate within this cycle of innovation, and reveals such enduring concerns.

Chapter Two

A Novel Method to Prevent HIV: The Product of Discipline

In 2010 a research team released promising results from one three-year study evaluating the safety and efficacy of using Truvada for PrEP. Soon thereafter community based organizations organized forums to discuss the results and potential implications with the public. I attended one of these forums in San Francisco, where study investigators, local physicians, city officials spoke about this new method to prevent HIV. First, they outlined the study design. Staging the trial across several countries, they had enrolled 2499 participants, all of whom were HIV-negative, reported sex with men, and self-identified as either men or transgender women. Participants were randomly assigned in approximately equal numbers to one of two study groups: one receiving Truvada, and the other receiving a placebo. Both groups were instructed to take the tablet once daily. While being monitored for the duration of the study, participants received HIV testing, risk-reduction counseling, condoms, and care for the management of sexually transmitted infections.

They also summarized the findings. At the conclusion of the study, 100 participants acquired HIV, but only 36 of them had received Truvada while 64 had received placebo. The results indicated a 44% reduction in HIV incidence, and suggested Truvada provided protection against acquisition of HIV (Grant et al. 2010). And given these promising findings from the study, city officials and local physicians suggested the novel method to prevent HIV would fit well within ongoing efforts to reduce HIV incidence, including by ramping up testing.

Next, a participant from the trial spoke. I will refer to him as Lance. Lance shared what it

was like to get tested and talk with the investigators. He said he liked getting tested for HIV regularly as part of the trial. There wasn't that persistent doubt in his mind, and he was more confident because he always knew his status. Lance also made light of the routine interrogations involved in the trial, especially those about his sex life. In front of the entire audience, he turned his head toward the investigators and joked, "It's like they want to put a video camera in my bedroom."

When the question and answer period concluded, I introduced myself to Lance. I was beginning my fieldwork about PrEP, and I wanted to interview someone who had participated in the trial. He agreed to schedule a time to talk to me. In the following weeks and years, we shared many conversations. In our first conversation, I learned that Lance started getting tested for HIV and talking to providers about his sex life during the early years of the HIV epidemic and the vast majority of people who were living with HIV did not know they had acquired the virus. At the time, many people who might be at risk for HIV were not submitting to HIV tests[45] and some who completed HIV tests were not returning to receive their results.[46] To mount an effective response to the growing epidemic, the state encouraged people to submit to HIV tests, and disclose their results to others.[47] The CDC and department of public health also released recommendations for how to have 'safe sex.' And as the state sought to secure the health of the population from this

45.CDC 1991

46.Attempting to better understand this phenomenon of not submitting to tests and not returning to receive results, one clinic that offered free and confidential HIV tests to over one hundred gay and bisexual men observed that only half of the men agreed to take the tests and only 35% of those who took the test returned to receive the results (Silvestre et al., 1993). These providers concluded that "gay men who are most aware of the potential psychosocial problems associated with HIV antibody testing" were "more likely to avoid testing."

47.The HIV status of health workers, for example, became subject to mandatory disclosure policies (Cruz 1991; Lenehan 1991; Pennsylvania Superior Court 1991; Keeney C 1992; Scheerhorn M 1995), and thus, it would be the responsibility of health care workers to reveal their status to their employer. So, as laws determined if and how health care workers should reveal their HIV status, hospitals became responsible for managing information about the HIV status of their care providers (Closen & Power, *AIDS In the Workplace,* COMPLEAT LAWYER, Summer 1988, at 14; Stephens BJ et al., 1995).

infectious disease, it disciplined the 'at risk' individual to get tested, talk about HIV status, and have 'safe sex'.

Thinking about my conversations with Lance, in this chapter I situate clinical research about PrEP within the history of public health research about HIV prevention through which 'at-risk' individuals have been disciplined to get tested for HIV, talk with health care professional about their sexual practices, and disclose their HIV status to their intimate partners. By exploring the links between the state and the individual subject through the theme of HIV prevention, this chapter continues inquiry about the disciplinary techniques that Michel Foucault describes, including *confessional technologies* through which the self reveals hidden truths (1990 [1976]). In particular, Foucault describes how confessing emerges in Christian ethics as a way of denouncing the self through verbalization, and extends this observation to the human sciences, wherein the human subject no longer need denounce the self, but may now constitute a new self by confessing. Whereas Vinh-Kim Nguyen shows how confessions became a means for the HIV-positive subject to survive, [48]especially during the rollout of antiretroviral drugs for HIV treatment, I show how confessional forms have been integral to HIV prevention as well.

In this sense I continue claims from the previous chapter wherein I detailed how the pharmaceutical is produced through claims to truth, including vision, interests and values. In this chapter I also show how drug development depends not only on claims to truth that circulate between the pharmaceutical firm, research university, and the public, but also how notions of truth emerge from within the individual clinical trial participant. Here I am referring first to biological truths that are detectable within human blood, and second, sexual truths that are latent within the individual subject. Both of these truths must be brought forth as a condition of participation in

48. Nguyen 2010

clinical trial research, and to evaluate the safety and efficacy of the experimental therapy. Indeed, they are vital to clinical research about the biomedical prevention of HIV. and have begun to guide the implementation of this novel method to prevent HIV.

Finally, I argue these techniques of discipline are central to PrEP implementation. This is evident as care providers prescribe the drug and other patients consume it. This is also clear at research conferences where PrEP users are encouraged to speak about their experiences with PrEP. In these spaces, PrEP users reveal how they manage pleasure and negotiate intimate relationships while also trying to prevent HIV. Thus, across this chapter, my intent is to underscore how the disciplinary techniques of testing for HIV and appropriate use of pleasure set the terms for the development and implementation of PrEP.

A History of Discipline

In 1987 Lance and his first male lover, Scott, heard an announcement on the radio encouraging gay men to get anonymously tested for HIV. They felt it was their civic duty to get tested. So they scheduled appointments and drove together to a clinic in San Francisco. "When we got to the clinic," Lance recalls, "my stomach felt like it was tied in knots." The other men in the room sat "with their heads down, trying to distract themselves by silently reading or closing their eyes." After waiting, they "moved into another room to watch a short video that explained how doctors thought the virus was transmitted and discussed ways of having 'safe sex.' The volunteers distributed free samples of condoms and lubricant and asked if anyone had any questions. The room was silent."[49]

Lance's anxiety was building. He "could see shadows behind the frosted glass of the exam

[49] Lance recounts this scene in his memoir. With his full permission, pieces of his memoir have been reproduced in this text. To maintain privacy and confidentiality, the title does of his work does not appear here.

room." When the test counselor opened the door and called his number, Lance glanced at Scott, stood up, and walked into the next room, where "the battery of questions about [his] sex life began."

> Condoms?
> Yes, starting about two years ago.
> Any broken ones?
> Once.
> How many partners in the past year?
> One.
> Positive partners in the past year?
> None, that I know of.
> Women?
> None.
> Sex under the influence of drugs or alcohol?
> No.

The counselor then sent him next door where a nurse prepared to take a vial of his blood. Lance recalls:

> I noticed the sweat from my palms discolored the preprinted sheet of labels I handed it to the attendant. I rolled up my sleeve. 'Place your arm on the table,' she instructed. 'Relax it. Now make a fist. Hold it while I put this tourniquet around your arm.' She paused for a moment, looking at my veins. 'Don't worry if you feel a small prick.' I quipped back, 'That's what potentially could have gotten me in this trouble.' She forced a smile. A piercing pain shot up my arm as I felt the needle penetrating my skin and going into my vein. I relaxed my fist as the tourniquet was removed. 'All done. Now don't lose your confidential number. You'll need it for your return appointment in two weeks,' she said while adhering my numbered label to the vial of blood.

When Lance walked out of the exam room, he waited for Scott and they walked together down the street to their parked car. Now they had to wait, and return to the clinic in two weeks to receive their results. Several days before Lance was scheduled to receive his results, he learned he had to travel to the East Coast for a few days on a business trip, so he had to postpose his return appointment for an additional week." However, while Lance when was out of town for work, Scott received his results. That evening Lance called Scott from his hotel:

> Well, did you get your results today?
> Umm, yes.

And … ?
They came back positive.
'Oh my God, no!'
< Silence >
'Honey, I'm so sorry.'
< Silence >

I didn't know what to say. I had just assumed that the test results would come back negative. I couldn't understand how he could be positive. The flight back home the next day seemed extraordinarily long, leaving me with way too much time to think on the airplane. The three-week gap between having blood drawn and receiving my results was harrowing. There were quite a few restless nights, but the delay helped me focus my mind and forced me to confront my fears and my past. I replayed my sex life on the video screen of my mind, pausing to examine certain moments in excruciating detail. I was driving myself nuts by concocting images of far-fetched but theoretically possible routes of infection.

Scott sat in his car while I walked into the clinic for my appointment. The same sterile smell filled the room as I approached the small wooden table acting as the receptionist desk.

'I'm here for my results. Here's my code.'
'Please be seated.'

My palms were sweaty again. My heart was beating hard. I could see my tight t-shirt pounding. 'Number 6125BL, please follow me.' I tried to force a smile as I followed the test counselor into a small room. I zeroed in on the folder, purposefully placed on the table, which contained my results. 'What have the last two weeks been like for you?' the counselor asked. Feeling irritated, I snapped back, then said, 'I'm sorry, but I would rather just get on with the results.' 'You are number 6125BL.' He covered up the results of the other individuals, so that only my number showed. He peeked at the result and covered it up again. My chest tightened. 'We're glad you came in to be tested. I want to let you know that your results are *negative*.

I thought I'd be positive. My lover was positive, so how come I'm not? Are you sure the test results are accurate? Can I get retested?

Yes, the results are accurate and there's really no reason to get retested immediately. But it wouldn't be a bad thing to do routinely every six months.

I stood up, thanked him, and left. The wave of relief helped to quell, at least for a while, the chattering in my brain, but I was still feeling sad and confused. I saw Scott's head peeking through the car window. As I began to open the car door he asked, 'Well?' I sat down, harnessed my guilt, looked him in the eyes, and said, 'I'm negative.'

In the story Lance tells, he describes several affective states, especially feelings of

obligation. This feeling is initially expressed as a 'civic duty' that compels him to go with his first lover to get tested. When he and Scott hear the announcement on the radio encouraging gay men to get tested for HIV, they feel a responsibility to comply. As that civic duty morphs into an overwhelming anxiety over what will be revealed, both her and his lover return to the clinic to hear that truth about themselves. And when they are told, they each then feel a responsibility to disclose their individual truths to each other. The way Lance and Scott feel compelled to disclose this truth about themselves is both a deeply private matter and a public concern. Indeed, by talking to each other about their HIV status, they are at once negotiating their intimate relationship and acting in the interest of public health.

Lance also details how obligation was paired with assurances to privacy and confidentiality. The announcement that he and Scott responded to encouraged gay men to get anonymously tested for HIV. In the clinic, they were called in by number. Their vials of blood were labeled according to a code. And they were asked to bring that code back when they returned to learn their results. At the same time as they were being asked to reveal truths about their inner selves, they were assured that information would be protected from public view. As liberal subjects, they were granted the right to privacy, and the privilege to disclose as they willed. Over the following years, however, the rights of the liberal subject would be called into question.

Beginning with this observation about how the 'at risk' individual comes to feel obligation to learn the truth about themselves and reveal that truth to an intimate other, in this section I briefly review the ethical and legal mechanisms through which the inner self of the liberal subject is constituted, such as through the right to privacy, and split open through the ethics of intimacy. In the following section, I discuss how this practice of disclosing truth about the self becomes useful to generate evidence in public health, especially through research about how to prevent HIV. Thus,

I read the story Lance tells to introduce several important themes in the history of HIV prevention, which I argue, is a history of discipline.

The Interior Self of the Liberal Subject

Beginning in the late 1980s, ethical and legal measures concerning the disclosure of HIV status simultaneously constitute the inner self of the subject as a private right and a public concern. The HIV status of health workers, for example, became subject to mandatory disclosure policies.[50] In some jurisdictions it was the responsibility of health care workers to reveal their status to their employer. In turn, hospitals were responsible for managing information about the HIV status of their care providers.[51] As laws determined if and how health care workers should reveal their HIV status, many workers developed fears their HIV status would be disclosed against their will,[52] and such requirements to reveal one's HIV status sparked controversy among nurses, physicians, psychologists, ethicists, and scholars of medical law.[53]

These controversies also extended to court hearings about the unlawful dissemination of test results, as plaintiffs alleged the disclosure of highly sensitive and personal information violated their rights to privacy.[54] In this case, the right to privacy would protect medical information identifying a person's HIV status from being shown or told to another person. Debates over the right to privacy also introduced further questions, including: Should patients be required to reveal

50. Cruz 1991; Lenehan 1991; Pennsylvania Superior Court 1991; Keeney C 1992; Scheerhorn M 1995
51. Closen & Power, *AIDS In the Workplace,* COMPLEAT LAWYER, Summer 1988, at 14; Stephens BJ et al., 1995;
52. Reid T 1994
53. Bocchino 1990; McDonald 1989, 1990; Doe 1990; Navran 1990; Christie 2002
54. See, for example, Harris v. Thigpen, 727 F. Supp. 1564 (M.D. Ala. 1990); McCune v. Neit- zel, 235 Neb. 754, 457 N.W. 2d 803 (1990); Closen, Connor, Kaufman & Wojcik, AIDS: Testing Democracy - Irrational Responses to the Public Health Crisis and the Need for Privacy in Serologic Testing, 19 J. MARSHALL L. Rev. 835 (1986).

their HIV status to dentists and physicians?[55] Do provisions within the Americans with Disabilities Act (ADA) protect patients from disclosing this information?[56] As these debates continued, departments of public health and professional medical associations began to take sides. The New York Health Department, for example, rejected mandatory disclosure laws in 1992,[57] thus upholding that revealing one's own HIV status was the right of the liberal subject. Though institutional policies were enacted early in the epidemic to compel the subject to reveal his or her HIV status, the right to privacy maintained that revealing personal information about the self, including one's HIV status, was a sovereign right of the liberal subject. Thus, in the context of HIV prevention, the self was initially constituted as that which the liberal subject has the right to reveal to another, if he or she wills to.

At the same time, there was debate about whether the subject that submits to an HIV test should be required to receive their own test results, or if such a mandate would disregard the choice to maintain individual privacy and liberty. This was a concern, the CDC observed, because people who might be at risk for HIV were not submitting to HIV tests,[58] and some who completed HIV tests were not returning to receive their results.[59] While many believed a patient would and should return for the result, others contended, "The tested individual [would be] afforded no choice in the matter."[60] These critics highlighted that not being afforded choice in the matter was particularly concerning because the subject would be confronted with the obligation to disclose in association

55. Perry SW et al., 1993
56. Goldberg I and Sprotzer I 1998
57. Becker 1992
58. CDC 1991
59. Attempting to better understand this phenomenon of not submitting to tests and not returning to receive results, one clinic that offered free and confidential HIV tests to over one hundred gay and bisexual men observed that only half of the men agreed to take the tests and only 35% of those who took the test returned to receive the results (Silvestre et al., 1993). These providers concluded that "gay men who are most aware of the potential psychosocial problems associated with HIV antibody testing" were "more likely to avoid testing."
60. Closen 1990: 447

with a litany of activities, including when he or she applies for life or health insurance, volunteers to donate blood, semen or organs, is imprisoned, or otherwise agrees to medical or mental health services, and moreover, that disclosure in these contexts could lead to significant legal, economic and social hardship. The "constitutional rights of liberty and privacy," the argued, "mandate that citizens be permitted to decline forced disclosure of this information." "Each individual," therefore, "should have the right to decide in advance whether he or she will be told of the HIV test result."[61] Here again, the rights of the liberal subject triumphed, as it was decided that one cannot be told a truth about one's self against one's will.

While the right to privacy ensured the subject maintained sovereignty over the inner self, the doctor-patient relationship introduced further questions that moved beyond privacy to primarily concern confidentiality, such as: In what ways does knowing a patient's HIV status introduce ethical conflicts for a physician?[62] Under what conditions is a health care provider required to maintain confidentiality or disclose personal information?[63] If a patient refuses to disclose his or her HIV status to an intimate partner, do these rights and responsibilities change?[64] This latter set of questions concerning the obligation of a health care provider to maintain confidentiality of a patient's HIV status in the case that individual was not disclosing to an intimate partner was taken up by Elliot D. Cohen, who constructed an ethical framework to guide how psychologists should respond.[65] In his article entitled, "Lethal Sex," Cohen recognized that confidentiality is generally required in situations where patients "feel comfortable in revealing their darkest secrets" but he also acknowledged that this "bond of trust has its moral limits." He

61. Closen 1990: 448
62. Pochard F et al., 1998
63. Cohen ED 2003
64. Chiodo GT and Tolle SW 1992
65. Cohen ED 2003

asserted such limits are crossed "in some cases in which HIV positive clients are sexually active with unsuspecting third parties."[66] Advancing these assertions, Cohen drafted "a model rule for the American Counseling Association's Code of Ethics that permits, and sometimes morally requires disclosure." Cohen's model rule about the limits of confidentiality disrupts the will of the individual subject, who would otherwise maintain the right to privacy over the truth of one's self. The rule also seeks to protect the intimate other from harm. So, despite the sovereignty of the subject — to know what one wills to know, and to reveal what one wills to reveal — by withholding that truth from an intimate other, the sovereignty of the individual is split open, and the subject becomes answerable to another set of ethics, which concern the encounter with the intimate Other. I will refer to these as intimate ethics.

Whereas the right to privacy reinforces the sovereignty of the liberal subject over the self, intimate ethics introduce an obligation for the subject to disclose. In the United States, these intimate ethics are written into law as "disclosure laws," which discipline the HIV-positive subject to reveal one's own HIV status to the Other. And under the terms of the law, the HIV-positive subject that does not reveal this truth about one's self to the Other becomes legally culpable.[67] Each year, there are numerous cases in which disclosure laws are used to prosecute the HIV-positive subject.[68] Under the terms of the law, people are prosecuted for charges such as "sexual intercourse without disclosure of HIV." James Fyffe, for example, was "accused of intentionally

66. Cohen ED 2003
67. While advocates have championed laws that protect the subject from legal prosecution (Holmes D and O'Byrne P 2006), and have promoted a public health approach to disclosure over and above criminal law (Batteridge G 2005), and most pointedly, arguing criminal law undermines public health efforts (Galletly CL and Pinkerton SD 2006).
68. The Center for HIV Law and Policy has published a list of arrests and prosecutions for HIV exposure in the United States for years 2008 through 2017, and though the list is only illustrative and non-exhaustive, each year cases number in the dozens.

hiding the fact that he had HIV when he had sex with a woman."[69] According to court records, several people told Fyffe to disclose his HIV-positive status to the woman, but he refused. Fyffe was charged with felonious assault. In a similar case, the defendant was ordered to register as a sex offender by a "judge who said he worried the defendant could have had other sex partners whom he did not tell about having HIV."[70] By not disclosing this truth, these men had violated a basic tenet of intimate ethics, and therefore were punished.

In short, law and ethics concerning the disclosure of HIV status have both secured the sovereignty of the subject over the self and imposed an obligation on the subject to reveal one's self to the intimate other. This latter imposition opens the subject to medical scrutiny and legal culpability. It also obligates the subject to the ethics of intimacy. Thus, at the nexus of the obligation to disclose and the right not to, the inner self of the subject is constituted simultaneously as a public concern and a private right; that which ought to be brought forth, and should be protected; and as an element of the self that is known to exist, but also allowed to remain hidden.

Disclosure Practices

Though the state could not forcibly compel the subject to disclose truth about self, the state could trace how the subject voluntarily disclosed, and to whom — that is, to monitor how the subject aligns the self with the ethics of intimacy. Thus, public health research about HIV prevention began tracing disclosure practices. Though initial inquiry about whether or not people were talking about

69. Ferrise 2017
70. Lynch 2017

their HIV status with intimate others produced contradictory findings[71][72] the field soon moved beyond questions about the fact of disclosure to ask: To whom is one most likely to disclose HIV status? How is disclosure affected by other social factors, like social support and stigma? What role do race, gender, and sexual orientation play? And further, how does disclosure relate to health outcomes? Is disclosing associated with HIV prevention interventions, like testing, condoms and behavior change? Also, could there be a relationship between effective treatment and disclosure practices? By tracing this intimate practice in these various ways, the state began to compile a body of evidence about techniques of discipline.

For one, public health research about HIV prevention evaluated how the subject disclosed to sexual and romantic partners or family members[73] and monitored differences in disclosure practices among subjects according to race, sex, gender, and sexual orientation.[74] This research found, for example, that heterosexual African-American women almost always disclose to their mothers and sisters in a relatively short period after receiving a positive result.[75] Meanwhile, men who have sex with men disclose to both 'intimate lovers' and family members[76] however it would likely take more time to talk to family, and when they did, the way they told family about their status varied significantly by ethnicity.[77]

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71. Some research found that most people "spoke about it" (Levy A et al., 1999) and this research was reaffirmed by assessments of disclosure at "high-rates" and associated with positive health outcomes (Maman D et al., 2003). Meanwhile, other research found that a significant number were not disclosing (Stein MD and Samet JH 1999). With contradictory evidence about the practice HIV status disclosure and estimates of its prevalence, how people made decisions to disclose and other factors related to disclosure became key areas of interest for the field.

72. Given these mixed findings, public health programs also reinforced interventions, like 'safe sex' and social support, as appropriate second-order interventions because disclosure itself seemed to not have enough influence. In the words of one research group, "Rather than focusing primarily on the promotion of serostatus disclosure, behavioral interventions should emphasize the practice of safer sex" (Geary MK et al., 1996).

73.Marks G, Richardson JL and Maldando N 1991; Marks G et al., 1992, 1993; Schnell et al., 1992

74.Serovich JM, Esbensen AK and Mason TL 2007

75.Serovich JM, Craft SM and Yoon HJ 2007

76.Mansergh G, Marks G, Simoni JM 1995

77.Fekete EM et al., 2009

This research also observed different practices in how people living with HIV disclose to partners, friends, family members, and religious leaders or clergy.[78] People disclose to family and partners motivated by 'a sense of duty' as well as to seek material support. People disclose to religious leaders when seeking advice. However, people hesitate to disclose to friends because of a lack of trust, and specifically, a fear that friends might tell others. Men are more likely to disclose directly to partners, while women use less direct communication methods. And overall, roughly one third of participants rely on a third-party to disclose to an intimate partner.[79] Thus, the state had reason to typify at-risk populations, and characterize their intimate relations.

These findings suggest that social support and stigma affect disclosure practices, corroborating evidence, so the state also dedicated resources to understanding how disclosure practices were affected by different social institutions. The motivating concern behind these questions is that people living with HIV fear disclosure because HIV is stigmatized. In 2001, the United States Centers for Disease Control and Prevention (CDC) had found that 1 in 5 people stigmatize HIV. Moreover, stigma had been shown to contribute to bad outcomes, and such effects were particularly concerning among minority communities for whom social stresses were intersectional,[80] such as for African-American women.[81] In fact, even for people who had not personally experienced stigma, but who lived in a social environment where popular stigma against HIV persisted, the perception of stigma inhibited disclosure.[82]

Conversely, social support[83] was positively associated with disclosure practices[84]. So, when

78.Miller AN and Rubin DL 2007
79.Miller AN and Rubin DL 2007
80.Körner H 2007
81.Clark HJ et al., 2003
82.Derlega VJ et al., 2002
83.Rier DA 2007
84.Kalichman SC et al., 2003

Earvin "Magic" Johnson disclosed his HIV status in the early 1990's, researchers tracked the impact on the public perception of HIV as well as disclosure practices. On a national scale, public health researchers saw an uptick in HIV counseling[85] and noted an increased readiness to reduce risk after he announced his diagnosis.[86] And his disclosure affected subpopulations differently[87] including by more significantly affecting perceptions of AIDS among African-American men.[88] Noting the links between disclosure practices and social support, HIV prevention also sought to promote social support and thus, improve health outcomes. Disclosure practices were associated with behavioral and mental health correlates.[89] Linked to psychological wellbeing and quality of life[90] disclosure was conceptualized as a strategy for coping.[91] Practices of disclosure and techniques for managing emotional distress were said to be associated with self-efficacy.[92] People were also more likely to disclose their status after counseling.[93]

Another set of questions concerned the relationship between practices of disclosure and interventions for HIV prevention, including HIV testing, counseling, condom use, and behavior change. Some of these studies focused on provider-patient communication about 'safer sex' and disclosure[94] or evaluated behavioral interventions, such as the links between disclosure, 'high-risk' sex, and condom use.[95] Others tracked the relationship between patterns of testing and disclosure.[96]

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85. Cohn DL et al., 1992
86. Kalichman SC and Hunter TL 1992
87.Ehde DM, Holm JE, Robbins GM 1995
88.Kalichman SC et al., 1993
89.Ostrow et al., 1989
90.Chandra PS et al., 2003; Golub SA, Tomassilli JC and Parsons JT 2009; Menon A et al., 2007; Zea MC et al., 2005
91.Holt R et al., 1998; Vance D 2006; Medley AM et al., 2009
92. Kalichman SC and Nachimson D et al., 1999
93. Perry et al., 1993
94. Marks G et al., 2002
95. Kangwende RA, Chirenda J and Mudyiradima RF 2009; Pinkerton SD and Galletly CL 2007a
96. Dafatry A, Padayatchi N, Padilla M 2007

Finding, for example, that disclosure of status increases with post-test counseling[97] this work aimed to reduce transmission by increasing disclosure.[98] This research also found several related benefits to disclosure. One study observed that the "positive outcomes" of disclosure "included risk reduction behavior, partner testing, increased care-seeking behavior, anxiety relief, increased sexual communication, and motivation to plan for the future.[99]

Research about the relationship between disclosure practices and interventions for HIV prevention were supported by similar research about the links between disclosure and effective treatment. For a body of research that began shortly after the emergence of the epidemic when no treatment was available and had continued through an era of effective treatment, important questions about the impact of treatment were coupled with social and behavioral factors associated with treatment adherence and effectiveness. By comparing outcomes before and after the introduction of highly active antiretroviral treatment (HAART), this research was able to isolate the role of treatment within studies about predictors and patterns of disclosure[100] and show the results for a variety of affected populations.[101]

This research also evaluated the relationship between disclosure and adherence to treatment.[102] Aiming to understand "how highly active antiretroviral treatment (HAART) affects views and patterns of disclosure and how disclosure interacts with treatment decisions," one study recruited 152 adults living with HIV, including roughly equivalent numbers of women and men who have sex with men, and people who inject drugs from four cities in the United States.[103] The study found that treatment "interacts with and shapes HIV disclosure issues in several ways,"

97. De Rosa CJ and Marks G 1998
98. Pinkerton SD, Galletly CL 2007b
99. King R et al., 2008
100. Batterham P and Rice E et al., 2005
101. Siegel K, Lekas HM, Schrimshaw EW 2005
102. Stirrat MJ et al., 2006
103. Klitzman RL et al., 2004

highlighting a dynamic relationship between the drugs, their effects, and disclosure. This dynamic was apparent, for example, as having the medications would "'out' people living with HIV," signaling their HIV-positive status. So, some people hid their medications. Of course, hiding medications or modifying dosing schedules was not a helpful solution because it interfered with adherence. Meanwhile, the "observable side effects of medications" both contributed to 'outing' such as by causing lipodystrophy (fat redistribution, which contributes to symptoms such as facial wasting and "buffalo hump") and conversely, could also play a role in delaying disclosure, such as by improving one's physical appearance, so they did not look 'sick.' Indeed, some people would wait until they were on treatment and looked 'well' before disclosing. Just as treatment seemed to influence disclosure, disclosure affected treatment. If, for example, disclosure was met with antagonism and discrimination, treatment adherence could be negatively affected. However, disclosure can also "lead to support that facilitates initiation of, and adherence to, treatment." In these critical ways, "HIV disclosure and adherence can shape one another."

Global health research about HIV prevention also focused intently on the matter of disclosing HIV status, especially to children who had acquired the virus, such as through mother-to-child transmission. This was a prominent concern because studies had found the likelihood a mother would disclose her status to her own children was less than 50% and among some subpopulations lower than 35%.[104] The 'best practices' for disclosure to children thus became a key topic,[105] especially for research teams in low- and middle-income countries, where mother-to-child transmission has historically been high, including Ethiopia,[106] Kenya,[107] South Africa,[108] and

104.Simoni JM et al., 2000; Murphy DA, Steers WN, Dello Stritto ME 2001
105.Lester P et al., 2002; Moodley K et al., 2006
106.Mengistu 2013
107.Gachanja G, Burkholder GJ, and Ferraro A 2014
108.Madiba S 2016

Thailand.[109] Across these studies, researchers described the process of disclosing to youth,[110] compared approaches to disclosure with illness experience models,[111] evaluated the extent of disclosure, such as by recording what children have been told about their status[112] documented issues that arise when parents disclose to their own children[113] as well as when health care workers disclose to children[114] and evaluated prevalence and correlates of disclosure in different countries.[115] Even after decades of research on the topic, medical journals continued to publish articles on the topic of disclosing HIV status to children. Representing the ongoing challenges of talking to children about their HIV status, a title for one research article published in 2013 read, "Disclosure of HIV Diagnosis to Children: A Poorly Addressed Issue in Pediatric HIV Care."[116] Another research article published in 2016 identified a lack of skills among caregivers for disclosing to children in resource-limited communities,[117] and a related study in Kenya summarized a prominent feeling among children about delays in disclosure with the question, "Why did you not tell me?"[118]

Maintaining this intent focus on the disclosure practices of the HIV-positive subject over more than three decades, the state determined which subjects were fashioning themselves in accordance with the ethics of intimacy. Further, as individuals of various demographic markers disclose to family, friends, and lovers, the state began to differentiate between various 'at-risk' sub-populations. And through this project of monitoring disclosure practices, the state generated

109.Oberdorfer P et al., 2006
110.Vaz L et al., 2008
111.Abadía-Barrero C, Larusso MD 2006
112.Murnane PM et al., 2017
113.Qiao S, Li X, and Stanton B 2014; Gachanja G, Burkholder GJ, and Ferraro A 2014
114.Madiba S and Mokgatle M 2015
115.Britto C et al., 2016; Odiachi A and Abegunde D 2016; Gyamfi E et al., 2017
116.Mengistu AD 2013
117.Madiba S 2016
118.Vreeman RC et al., 2015

evidence, both about the differences between sub-populations, and about how to improve the health of the population. Indeed, after disciplining the subject to align one's self with the ethics of intimacy, the state typifies the subject through his or her ethical practices, which are shown to be vital to improve health and secure life.

Manage Pleasure

After Scott learned he was HIV-positive, he and Lance maintained "sexual intimacy that was very fun and enjoyable." Their sex simply did not include "any penetration." They "learned it can be fun and enjoyable without having to 'fuck'. It was romantic and passionate." However, when Scott "started getting sicker and started on medication, his sexual drive went down." And when "his health started to decline," Lance tells me, the "intimacy that we had been accustomed to changed."

> That transition was extremely challenging for me. It was a shock for me to realize it wouldn't get better. His health was only going to decline. And that close physical intimacy we had was never going to be there again. But the tenderness and closeness we had shared was always there. I felt so close to him, and he felt close to me.

For Lance, intimacy has long been linked to HIV risk, including the ways he manages loving relationships, and has sex amid and despite the virus. Intimacy is a context in which he has to manage HIV risk, but he is not willing to let HIV risk determine who he will be intimate with. His second relationship was with a man named Dan.

> I was instantly attracted to him. He just had this, this glow about him. It was infectious and inviting. I could see people around him were happy and engaging and wanted to be near him. He was living in LA at the time, and wanted to move up to San Francisco. After going back and forth between the two, he moved in with me. He was also HIV-positive.

When Lance began his relationship with Dan, people asked him, "How can you be in a relationship with someone who is positive again?"

> It was 1997. AIDS was becoming less common, but still, people were dying left and right. I told them, 'You love a person for who they are; not what they have." Even if Dino did die, I knew I would be willing – emotionally, and physically – to go through that again because he was such a wonderful person.

As he explains, "I'll fall in love with whoever I fall in love with. I don't care if they're negative or positive because you love a person for who they are, not for what they have." There is only one caveat. "When you are in a relationship with an HIV-positive man, you just have to be safe."

> I don't think he ever … He never penetrated me. But we had a very active, fun, intimate, wonderful sexual relationship, and I was always safe when having sex. Or, at least, I was as safe as I was willing to be.

Continuing to think with Lance in this section I describe how intimate relationships are a key site for interventions to prevent HIV.[119] To begin, I show how the field of HIV prevention has examined several ways intimate relations, including romantic and marital relationships, might contribute to the risk of acquiring HIV. Next, I detail how public health constructs ideals for being intimate in ways that improve health, such as by pursuing pleasure through a limited set of sexual acts. And through such interventions, I argue, the intimacy of the "at risk" subject is given form. Intimacy thus becomes integral to the ethics of the subject whose life has been affected by HIV and to the research that aims to improve how we treat and prevent the illness.

Assess Risk

Over the course of the epidemic, the field of HIV prevention has examined several ways intimate relations, including romantic and marital relationships, might contribute to the risk of acquiring HIV. In these studies, HIV risk is measured primarily through the frequency of condom use during sex as well as the likelihood a person will use a condom. The participants recruited for this research include heterosexual couples and gay male couples, couples comprised of young people (18-25),

119 Watney 1987

and partners with mixed HIV status. Across age, sexual orientation, and HIV status, the research aims to better understand intimacy among people managing significant relationships. To gather data, researchers ask participants about the kinds of sex they are having, with whom, and whether or not they use condoms when they do. In these studies, participants are also asked about motivations for using or not using condoms.

Across several studies, researchers observe intimacy is a key reason for having sex without a condom, and seek to identify which relational elements influence people to have sex in this way. The authors of one study articulate the urge to have sex without a condom as "the desire to achieve emotional intimacy[120]." Several additional studies[121] observe that people do not use condoms because condoms pose barriers to intimacy, reporting for example that participants "describe nonuse of condoms as a strategy to find and maintain a primary relationship." Further, the corollary seems to be true: people consider using condoms to be a violation of intimacy.[122] Studies about why people do not use condoms also identify related interpersonal elements that condoms impede, including trust,[123] spontaneity,[124] commitment,[125] and pleasure.[126]

This research further develops the notion that the intimacy of long-term partnership and feelings of trust constitute risk factors for HIV transmission. This conclusion is established in studies conducted among diverse study populations, including: men who have sex with men in Beirut, Lebanon and New York City, New York; men who work in informal economies in Thika,

120. Greene GJ et al., 2014
121. Bernstein E et al., 2013; Corbett AM et al., 2009; Blais M 2006; Elam et al., 2008; Ferguson A et al., 2004; Fernet et al., 2011; Golub SA et al., 2012; Middelthon 2001; Ramanaik S et al., 2014; Wagner GJ et al., 2012; Zabrocki C et al., 2015
122. Pivnick 1993
123. Elam et al., 2008; Middelthon 2001
124. Elam et al., 2008
125. Wagner GJ et al., 2012
126. Golub SA et al., 2012; Middelthon 2001

Kenya; Tajik male migrants and their regular female partners in Moscow, Russia: people who use cocaine and heroin in Boston, Massachusetts; young injection drug users (IDUs) of mixed-HIV status in Kohtla-Järve, Estonia; and female sex workers in Karnataka, India as well as in areas of The Dominican Republic. Across these various study cohorts, researchers observe that when people felt "increased intimacy" their "intentions to use condoms diminished[127]" and conversely, when people feel reduced intimacy, condom use increases significantly[128]. As one study among female sex workers asserts and another confirms, "the intimacy [the women] shared with regular paying partners played a significant role in the use of condoms. In fact, the more intimate the relationship, the less likely it was that they would use a condom[129] because people value "the relationship above health risks.[130]

As public health researchers continue to probe the couple form, they point to inequities in risk across gender roles, sexual and racial identities, and fertility desires, all of which "hinder condom use."[131] One of the most prominent findings in this research is that female gender roles put women at greater risk for acquiring HIV. The "emotional strength and caretaking" associated with strong female gender ideologies, study findings suggest, "may be linked to a heightened desire for male intimacy and tolerance of male sexual risk behavior."[132] Observing that women had sex with men without condoms even when the women distrust the men and know what they are doing involves the risk of acquiring HIV, women try to "maintain hope, sensuality, intimacy" and "stability with a male partner," meanwhile others feel they need to "satisfy a man" and accept

127. Zabrocki C et al., 2015
128. Ferguson A et al., 2004
129. Kerrigan D et al., 2003; Murray L et al., 2007
130. Uusküla A et al., 2012
131. Sarna A et al., 2009
132. Kerrigan D et al., 2007

infidelity and the risks it poses to health.[133] Moreover, for each type of relationship, "different levels of intimacy" have "a bearing on practicing safer sex."[134] For participants that seroconvert explain their reason for acquiring HIV as the result of "love and intimacy."[135] As evidence about the risks of intimacy accumulates, researchers refer to intimacy as one of the "classic" factors influencing condom use[136] and not only identify intimacy as a risk factor[137] but also measure "sexual intimacy" through 'incidence' rates.[138]

Reviewing these findings, researchers conceptualize nonuse of condoms as "an attempt to stabilize intimate relationships and a strategy to reaffirm mutual trust, desire and intimacy" among regular partners[139]. They find that many people have "unprotected intercourse while recognizing their risk of HIV and other STDs, placing their love for their partner and other emotional needs over concerns about their health."[140] They also find associations between the nonuse of condoms and "perceived faithfulness," "length of involvement" and whether or not one wants to become pregnant.[141] Importantly, these studies do not imply people ignore risk. Rather, they emphasize that condom use reminds people of HIV infection, and it is that very reminder that people want to live and love without.[142]

Harm Reduction

Throughout the 1990s and into the new millennium, public health also aims to more adequately

133. Jones R and Oliver M 2007
134. Mugweni E, Pearson S, Omar M 2016
135. Kippax S et al., 2003
136. Sarna A et al., 2009
137. Lear 1995
138. Meyer JC, Le Roux JA 1994
139. Blais M 2006
140. Corbett AM et al., 2009
141. Bernstein E et al., 2013
142. Fernet M et al., 2011

incorporate sexual pleasure into HIV prevention interventions, such as through "harm reduction" strategies, which loosen the reins on normative sex, and help the intimate subject "weigh the relative value of the activity and the costs of taking the risks."[143] In these moments, HIV prevention has to manage a messaging dilemma, which involves bringing together what is pleasurable with what is safe, including by pursuing answers to question such as: "Is oral sex safer?"[144]

In efforts to balance pleasure and safety, the use of condoms remains a central point of focus for HIV prevention alongside 'alternative' practices through which the subject might maintain intimacy and find sexual pleasure. For example, in one article published in the late 1990s, researchers introduce their findings with clear statements about the effectiveness of condoms to "stem the spread of HIV" and instructions about the "proper storage and use of condoms" and review the use of "similar devices, such as dental dams and female condoms," but amid this tutorial on condom use, the authors also list "alternative forms of intimacy that promote an environment of safer sex."[145] Reporting on a similar study, the authors identify "the practice of non-coital forms of sexual intimacy" as deserving "wider promotion among women." These authors reason, "Since no one safer sex strategy is likely to be acceptable to all heterosexual women, public health campaigns should emphasize as many choices as possible."[146]

Meanwhile, advocates of sexual health education develop behavioral interventions for intimacy, such as "The Sexual Health Model," and direct its "application to long-term HIV prevention through comprehensive, culturally specific, sexuality education." Derived from a "sexological" approach to education, the model defines ten key components posited to be essential aspects of healthy human sexuality, including: "talking about sex, culture and sexual

143. Odets 1996
144. *AIDS Alert* 1995
145. Whitfield L 1998
146. Gavey N, McPhillips K 1997

identity, sexual anatomy and functioning, sexual health care and safer sex, challenges to sexual health, body image, masturbation and fantasy, positive sexuality, intimacy and relationships, and spirituality."[147] By not discouraging the subject away from sex, but rather, directing the subject to seek pleasure through specific sexual acts, public health contends people can harness intimacy and protect themselves from acquiring or transmitting this communicable disease. Sexual pleasure thus become another important site for intimate intervention. Yet, certain forms of sexual pleasure seem to defy disciplining techniques.

"Bareback sex" is a way of having sex "generally understood" to be "intentional unprotected anal intercourse between men where HIV transmission is a possibility."[148] Lance says this is the kind of sex his second partner was pursuing when he acquired HIV. In his words, Dean "actually became positive on purpose. It was the early nineties. All of his friends were becoming HIV-positive and … he started having unprotected sex with positive people, being a bottom." For Dean, intimacy and HIV had been linked together, and "there was something going on in his mind that made him want to."

While the field had worked to understand how intimacy affected HIV prevention in several ways, the research about bareback sex indicated there was something more than intimacy underlying motivations to intentionally have sex without a condom. In particular, researchers contended bareback sex might reveal additional social and psychological factors affecting how people have sex. This contention was supported by study findings that men who have anal intercourse with non-primary partners and do not use condoms score high on loneliness tests, and their self-esteem is 'unstable'. Similarly, men that have anal intercourse with primary partners and do not use condoms also score low on loneliness tests. Not using a condom is thus interpreted as

147. Robinson BB et al., 2002
148. Berg RC 2009

an avoidance strategy "to help participants cope with loneliness or other negative affect" and said to be an indicator of emotional instability[149]. Thus, this particular way of pursuing sexual pleasure is associated with psychosocial pathology.

Developing an emphasis on psychological determinants motivating bareback sex, this research persistently pursues underlying factors for having sex in this way. One such study recruited "an ethnically diverse sample of men who bareback (n = 120)" and stratified the sample to include a larger proportion of men that reported both unprotected receptive anal intercourse (URAI) and being HIV-negative. For the psychological component of the study, the research team used the "Decisional Balance to Bareback (DBB) scale," and tested the association between DBB and risky sexual behaviors. The study reported several significant findings. First, "HIV-positive MSM (n = 31) reported higher costs/losses associated with condom use than HIV-negative men (n = 89)." Second, there were two underlying factors in the DBB scale: "a Coping with Social Vulnerabilities subscale; and a Pleasure and Emotional Connection subscale." Moreover, there was a "positive association between DBB (i.e. greater gains associated with bareback sex) and URAI occasions, number of partners, and having one or more sero-discordant partners in the past 3 months." Reviewing these findings, the authors conclude, "MSM may avoid using condoms in order to cope with psychosocial vulnerabilities and create intimacy with other MSM."[150]

This research reaffirms the "pivotal role that sexual pleasure and intimacy have in this population and how drives for sexual satisfaction, adventure, intimacy, and love overpower health concerns and condom use recommendations," yet also consistently points to psychological responses associated with this behavior. For example, the research findings consistently assert,

149 Martin JI and Knox J 1997a, b
150 Bauermeister JA 2009

"Men interested in bareback sex use a variety of defense mechanisms to account for, justify, and exonerate their behavior."[151] The assertion across this literature is not only that intimacy affects decisions to bareback, but also that intimacy converges with a variety of other factors, including negative feelings about homosexuality, community norms, and drug use, and together, these many factors influence this new form of intentionally 'risky sex'.[152]

As research on the topic matures however some investigators push back against the tendency to find psychological determinants to this practice, and instead, emphasize how bareback sex is a practice that explicitly prioritizes "pleasure, freedom, choice, and intimacy over HIV prevention."[153] A related set of studies shows how young gay men exhibit "a diverse range of knowledge, values, and functions of semen, especially in relation to its exchange."[154] The authors continue, "Beliefs about semen appeared to differ by HIV-status and were linked with intimacy, identity and pleasure, particularly among … HIV-positive men." This study is significant because it provides evidence counter to the "dominant representations," which frame the relation between HIV and semen through description of "loss, anxiety and infertility."[155]

Over these decades of research, HIV prevention recognizes that intimate relationships are an important context for better understanding HIV transmission and effectively intervening in risky sexual behavior. Through techniques aimed to evaluate and ensure subjects are seeking romantic love and sexual pleasure in specific ways, intimacy becomes an integral component of the public health response to HIV. Further, by working through a public health apparatus that conceptualizes intimacy as key to HIV prevention, public health shapes intimate subjectivity. For the majority of

151 Carballo-Diéguez A et al., 2011
152 Berg RC 2009
153 Carballo-Diéguez A et al., 2006
154 Schilder AJ et al., 2008
155 Schilder AJ et al., 2008

the history of HIV prevention however the field has relied on a narrow set of techniques for intervention, and thus, also a limited set of techniques for working with intimacy.

While taking aim at the very "nature of sexual relationships" in order to better understand how to prevent HIV, public health research encounters the excesses of intimacy, including romantic love and sexual pleasure. Thus, public health constructs a secondary aim to manage these excesses through disciplining techniques. One technique of discipline involves evaluating and instilling normative ideals of romantic love, such as the heterosexual dyadic 'couple' for which honesty and monogamy are said to buttress romance and contain sexual pleasure. A second technique involves tracking sexual pleasures that fall outside of this normative frame, like having sex without a condom and outside of the 'couple'. This line of public health intervention then either diagnoses such practices as pathologies or incorporates them into interventions, such as through 'harm reduction'. In either case, both of these disciplining techniques target intimacy as a site for intervention and a medium for discipline.

Cultivate Health

Since intimate relationships are sites for HIV risk, they are also sites for interventions to prevent HIV and thus, cultivate health. Realizing the potential of intimacy for intervention, public health efforts to prevent HIV suggest one should direct sexual pleasure into 'safe' activities. This section highlights how the field of public health seeks to develop a specific kind of intimacy to improve health by reducing HIV incidence – indeed, how public health seeks to foster a 'healthy intimacy.'

The couple-form is one key site to increase testing and counseling as well as promote behavior change.[156] Research about the couple probes "the relationship context itself … to

156. El-Bassel et al., 2014a; El-Bassel et al., 2014b; Jiwatram-Negron and El-Bassel, 2014; Simmons and

understand sexual risk behavior."[157] This research also recognizes that 'safe sex' is limited by its "dependence on a certain level of interpersonal honesty and fidelity."[158] This is true, for example, for couples trying to practice "negotiated safety," which involves using condoms until both members of the couple verify their HIV status, and talk to each other about personal histories with sex or injecting drugs.[159] Through this disciplining technique, normative forms of relations, such as monogamy and fidelity, are linked to healthy behavior.

Leading with these normative ideals, one set of public health studies points to the epidemiological concerns associated with having sex outside of the monogamous couple. One such study about HIV testing among heterosexual couples offers both members of a couple HIV tests and facilitates an opportunity to share the results between the partners.[160] For members of couples in which one receives a positive test result, the diagnosis serves to confirm suspicions about infidelity. For other couples, negative results remind the individuals "of the importance of fidelity." Further, negative results present an opportunity for behavior change. In each case, the authors show fidelity is associated with better health outcomes, meanwhile infidelity, they claim, poses risk.

Reporting on a related study, researchers observe, "Concurrent sexual partnerships play a key role in sustaining the HIV epidemic."[161] This research team observes the determining factor for sex outside of a couple is 'relationship dissatisfaction' and further, extrapolates there are as many as four possible types of sexual relationships that could form outside of the couple, including relations involving a sex worker, casual partner, regular girlfriend or informal polygyny. Thus, the authors not only instill the notion that sex outside of a monogamous relationship is risky, they also

McMahon, 2012; Remien RH et al., 1995
157. Darbes L et al., 2014
158. Gavey N and McPhillips K 1997
159. Corbett AM et al., 2009
160. Tabana H et al., 2013
161. Mugweni E, Pearson S, Omar M 2016

place responsibility for HIV risk on the failures of intimacy – termed 'relationship dissatisfaction' – and give shape to four central figures of sexual risk which haunt monogamy and 'sustain the epidemic.'

In another study about how couples test for and talk about HIV, researchers observe that marital relations determine the appropriateness of testing and talking about the virus.[162] Specifically, testing before marriage is acceptable because it confers "trustworthiness and commitment to the relationship. Conversely, "during marriage, a spontaneous discussion of HIV testing signifies a breach of fidelity or that a partner could not be trusted." While examining fidelity as an intimate concern that influences HIV testing, this study acknowledges how the tribulations of intimacy, such as maintaining trust throughout different stages of one's marriage, becomes the context in which members of couples must make decisions to be tested. Finding that perceptions of infidelity are likely to inhibit testing, the study also reaffirms the challenges intimacy poses to effectively managing the epidemic. A related study that examines the relationship between HIV risk and gender norms in rural villages of Cabo Delgado, Mozambique finds, "Men and women who actively take measures to decrease their risk of HIV infection associate a partner's acceptance of condom use and an HIV test as confirmation of emotional intimacy in the relationship."[163]

One significant body of this research also examines how normative ideals of the family relate to HIV incidence. Across these studies research observes that heterosexual men and women are more willing to broach challenging conversations about HIV risk with their partners if the conversation is focused on ideas about children and "the future of the family."[164] Another study

162. Conroy AA 2015
163. Bandali S 2013
164. Mindry D et al., 2011

concludes that HIV diagnosis demands self-inquiry about how heterosexual men with children "performed their role as fathers."[165]

Across more than three decades of studies, this research establishes that several elements of intimacy, including love, trust, and emotional stability are leading risk factors for acquiring HIV. Over this same timeline, the field recognizes that intimate relationships are an important context for better understanding HIV transmission and effectively intervening in risky sexual behavior. Through techniques aimed to evaluate and ensure subjects are seeking romantic love and sexual pleasure in specific ways, intimacy becomes an integral component of the public health response to HIV. Further, by working through a public health apparatus that conceptualizes intimacy as key to HIV prevention, public health shapes the discipline of the 'at risk' subject through the management of pleasure.

A Product of Discipline

By tying intimate relationships to public health research about HIV prevention, thus far I have displayed how intimacy became inextricably linked to interventions to prevent the virus, and thus also how the intimacy of the "at risk" subject has been shaped through HIV prevention. This is evident in my conversations with Lance, who was motivated to participate in clinical research for PrEP because he first lover died of AIDS. Over the next three decades, he lived his intimate life in relation to a virus. Thus, his intimate relationships were sites for intervention, and understanding himself and his sexuality meant getting tested for HIV. In the next section, I show how the development and implementation of PrEP builds on this history of discipline.

As Lance tells me about his sense of obligation to participate in the trial, like in his early

165. Okoror TA et al., 2016

story of getting tested with Scott, here too he leads with his sense of responsibility to the community. "When I found out about this study," he explains, "I knew it had potential to benefit a community larger than my own." And further, "I was willing to kind of put myself at risk in the hope of helping others. Lance is referring to the possibility of taking a drug that is known to raise creatinine levels and reduce bone mineral density. And given these safety concerns, as part of his participation in the trial, investigators monitor the toxicity of the drug. "Every quarter I go to the clinic," he tells me, "and they do a bone scan. They're looking to see if the medication is deteriorating your bones." "I'm willing to be a guinea pig and take a risk. A lot of people aren't and that's fine. They don't join the study. But those people that are willing to be a little more risky to advance science come forward. Those are the people that are in the study."

In addition to building on this sense of obligation, PrEP trials also build on specific techniques of discipline, including the management of sexual pleasure. While the subject has been disciplined over three decades to manage sexual pleasure, and cultivate a "healthy intimacy", including by limiting 'risky' sexual practices, the subject who did not submit to such forms of discipline become the ideal participant in PrEP trials. This is reflected in the inclusion criteria for enrollment. In fact, to qualify to participate in clinical research about PrEP, one must tell investigators he or she is "at risk" for acquiring HIV. This risk is measured through the number of sexual partners one has — the higher the number, the higher the risk — and specific sexual practices, which vary depending on the risk group. For gay men, risk is most closely associated with receptive anal intercourse. Meanwhile, for heterosexual women, risk is defined in terms of vaginal sex. And for each of these groups, having sex without a condom constitutes higher risk. Some inclusion criteria also specify that a potential participant must have acquired a sexually transmitted infection or have had sex with someone who is living HIV. And these risk criteria are

evaluated within specific timeframes, such as the past six months. Thus, the enrollment criteria for PrEP trials are defined in terms of how an individual manages sexual pleasure.

Under these inclusion criteria, Lance qualified to participate in a PrEP clinical trial because he was "having a lot of sex." In particular, he was having sex with multiple men, sometimes as the receptive partner, and occasionally without a condom. Also, some of the men he had sex with knew they were living with HIV. He was, for the purposes of the study, 'at risk' and thus, also an ideal participant. While HIV prevention had tirelessly cultivated a 'healthy' intimacy through disciplinary techniques, and thus, crafted the sexual ethics of the 'at risk' subject, the subject who defied discipline and was only "as safe as he was willing to be" became the ideal participant in clinical research for PrEP.

Second, the way the subject reveals truth about him or herself, which had for three decades been vital for understanding the path of transmission and the spread of the virus, became integral to the production of evidence within PrEP trials wherein the main clinical end point is HIV incidence. In other words, participating in clinical research for PrEP involves getting tested for HIV on a regular basis. As Lance reflects on his participation, he thinks about this history of discipline through which his sense of self has been tied to sex and the risk of acquiring the virus. "As a gay man," he explains, "I get tested once or twice a year. But the study tests me on a monthly basis. And that's wonderful. Because you always kind of wonder. Every time you go to get tested, even though you feel relatively confident you're going to come back negative, there's always still that little bit of doubt in your mind." More than two decades after Scott received his 'positive' result, and Lance was surprised by his own 'negative' result, Lance continues to be tested, and to doubt the results.

Yet, in this conversation, his tone is different. While he acknowledges some doubt about

his status, he has new energy and confidence about getting tested regularly within the trial. "Getting tested on a monthly basis helps," he says, "because you're not thinking, 'Oh, in the last six months, or the last year, who have I had sex with?'" Now, there "is a very short window, and they quickly come back, and tell you, 'You're HIV-negative,' like ten minutes after you give them blood because they use rapid testing. It was also just nice knowing that every month I'll be tested. That angst wasn't there. I wasn't wondering is there that possibility." He qualifies his statement slightly, "I mean, even getting tested every month, there is that possibility. But I never even thought about it. When I would go in annually, the night before I get my results, it's on my mind, wondering which way it's going to come back. When I get tested monthly, there's not that concern on my mind."

Lance was one of nearly 2500 participants in this single trial, and this was one of five active trials at the time. As a combined total, there were approximately 15,000 people participating in trials for PrEP. All participants were asked to report to a local clinic regularly for testing and to talk about themselves and their sex. In other words, by submitting to HIV tests, Lance and other participants constituted the evidence base for PrEP trials, which allowed investigators to measure drug efficacy. In particular, investigators evaluated efficacy by observing the difference between the number of people who acquire HIV in the control group and treatment group. If HIV incidence in the treatment group was significantly lower than in the placebo group, the treatment could be considered efficacious. This model formed the basis for all safety and efficacy trials for PrEP.[166]

166. To understand whether PrEP could prevent HIV acquisition in heterosexual populations as well, a team of researchers for "Partners PrEP" conducted a randomized trial in Kenya and Uganda with serodiscordant couples. The HIV-negative partner in each couple was randomly assigned to one of three arms of the study. Participants in each study arm received a once-daily tablet, and all were monitored monthly for up to 36 months. The study arms with HIV-negative study subjects were differentiated only by the type of tablet the participant received, which was either 1) tenofovir (TDF); 2) a combination of tenofovir and emtricitabine (TDF–FTC, "Truvada"), or 3) a placebo. Researchers followed the 4747 couples for the duration of the study. Three other trials (FEM-PrEP, VOICE and CDC TDF2) tested PrEP among women in African countries. The

By participating in this trial evaluating the safety and efficacy of Truvada for PrEP, Lance and others contributed to the commercialization of the drug through a kind of *confessional labor*. Indeed, I suggest labor in trials to prevent HIV is confessional — in the sense that it involves revealing a hidden truth about one's self. While roughly half the participants receive a placebo and the other half receive Truvada, all participants are asked to return to the clinical research site for regular visits during which they talk to investigators about their sexual practices and submit to tests, which both, monitor the levels of drug in their blood and detect HIV antibodies. These *confessional technologies* link the subject to truth and sex as well as constitute evidence about whether the drug is efficacious or not. Indeed, through confessional technologies, evidence about efficacy of the drug is established, which is then submitted to regulators for commercial approval.

In the trial Lance participated in, 100 participants acquired HIV, but only 36 of them had received the medication while 64 had received placebo. The results indicated a 44% reduction in HIV incidence. Similarly, in another PrEP trial, 82 participants acquired HIV, but only 13 of those received Truvada while 52 had received a placebo. In this study, a third cohort had received a similar medication, tenofovir. These participants accounted for the other 17 who acquired HIV during the trial. With these results, the study team for each trial began to release their findings, which suggested that oral Truvada provided protection against acquisition of HIV (Grant et al. 2010; Baeten et al. 2012). And based on the evidence produced through confessional labor, the FDA approved Truvada for PrEP. Truvada thus became the first commercial drug product for HIV prevention. Thus, I argue that the development of PrEP depended on the very same practices that

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FEM-PrEP trial enrolled more than 2,000 high-risk women in Kenya, South Africa, and Tanzania. This trial tested Truvada against a placebo. The VOICE trial enrolled approximately 5,000 women in South Africa, Zimbabwe and Uganda. This trial included five study arms, wherein participants received either: 1) oral TDF; 2) oral Truvada; 3) oral placebo; 4) tenofovir gel; or 5) placebo gel. TDF2 was conducted in Botswana with women as well as men. This trial compared Truvada to placebo. Each of these trials, like iPrEx and Partners PrEP, provided a comprehensive prevention package, including counseling and condoms.

HIV prevention and its subjects had relied on from the beginning: tracing how people manage their own sexual pleasure and reveal truths about themselves, especially through tests for HIV..

After Truvada was approved by the FDA for use as PrEP, providers began to write prescriptions for their patients to use the pharmaceutical in this novel way. A year after PrEP implementation began, I attended day-long forum on the topic that convened health care workers from across the nation in one room in a hotel in San Francisco. Though much of the day involved listening to investigators, physicians and directors of community-based organizations speak about the state of the science, and best practices for incorporating PrEP in clinical care, in the afternoon we all convened in the central conference hall for a panel entitled, "PrEP Experiences from the Community." The panel included four people: two women, Marcel and Christine, and two men, David and George. Black, Latino, gay, trans – these are the typified subjects that were identified through research about confessional technologies, and in this moment, they were on stage to talk.

The two women spoke first. Marcel told us she recruits for HIV prevention research studies. She works with "trans-women, 18-29, who are hetero-identified and high-risk." In her clinic, she explained, "No one knows what PrEP is." Many are familiar with PEP (post-exposure prophylaxis), but not PrEP. When she tells them about PrEP, some are interested because they are not sure what their partners are doing when they're not around, and PrEP would be extra protection. Immediately, Marcel asserts the women she works with are interested in PrEP because it augments trust.

Similarly, Christine explained she does outreach work at a women's health clinic, where she talks to a lot of women about PrEP. She relays one conversation she recently had with a friend who goes to her clinic and does commercial sex work. That friend saw PrEP as a way to stop using condoms, and was very excited about that prospect. Christine tried to temper her friend's initial

reaction by explaining that PrEP does not protect against other STIs. Still, the idea of not using condoms anymore made her friend giddy. Christine also tells us that PrEP is a personal matter for her. Her husband is HIV-positive, and she had a baby with him. When they were considering conceiving the child, PrEP was presented as an option. And she considered it. However, she also knew her husband had an undetectable viral load. Therefore, it was unlikely she would contract HIV and there was a low risk of infection for the fetus. She compared the risks and benefits, and decided it wasn't right for her. But, she tells the audience, "Just because it wasn't right for me, doesn't mean it's not right for you."

David spoke next. He began his story by talking about someone dear to him, who he calls M. David met M around 2012. "We got involved and quickly it became sexual," he explains. "Three weeks in, M was diagnosed with HIV." David had never been intimate with someone who was HIV-positive. He started taking a class about sexual health to make sure he was protecting himself. That eased his mind. He also talked to his doctor about the relationship, and his doctor suggested he might want to take PrEP. But access was difficult. David went to a neighborhood clinic, then was referred to another clinic downtown, where he discovered it would take three months for him to get PrEP because he had to wait for a demonstration project to begin. In the meantime, he explains, "Being intimate was awkward. I was constantly Other-ing him." His internal dialogue was: "People like me are negative; people like you are positive." David was optimistic PrEP would change that. "PrEP would ease the anxiety," he hoped. "But," David says, "I got it a week too late. We're no longer together." The anxiety he felt had him worrying constantly, so the relationship didn't work. And though their relationship ended, David reflects, "I still felt me being on PrEP was the best thing I could do to prevent HIV." So, he continues to take PrEP.

The last speaker on the panel was George. He introduced himself as a member of the Ballroom community, and a gay man on PrEP. When he first heard about PrEP, George recalls, "My theory was I'll take it when I'm going to Miami, when I'm going to Detroit — for party weekends." He also told us he had gathered a lot of information about PrEP on his own, which he felt was necessary because his doctor did not know much about it. And as he gathered more information, his perspective changed: "Now I think of it as the birth control pill for HIV, and I don't want a baby."

These "experiences from the community" are staged as perspectives about what is happening in the "real world" following the introduction of an antiretroviral for HIV prevention. They resemble the confessions during the rollout of ARVs for HIV treatment, which helped secure resources by speaking to the effectiveness of treatment during research conferences, however they function differently. Instead of 'putting a face on the epidemic', they give a voice to issues of intimacy, and thus, echo the findings of decades of research about intimacy as a leading risk factor for HIV acquisition. The trans-women Marcel works with are interested in taking PrEP because "they are not sure what their partners are doing when they're not around." For them, "PrEP would be extra protection." David seeks out PrEP to maintain a relationship. He expresses hope for the future, and embeds that hope in this novel method to prevent HIV. Christine's friend saw PrEP as a way to have sex without condoms — a new way to manage pleasure. That was the first thought George had, too. Each of the speakers address? Talk about? how intimacy is risky, and PrEP offers a new way to prevent HIV. They tell us PrEP holds potential because it offers a new way to secure relationships, and manage pleasure.

These experiences from the community also function differently than those confessions of the early treatment era because they do not display treatment success, and instead, acknowledged

challenges and shortfalls in PrEP implementation. Marcel tells us recruitment is challenging because there is little knowledge about PrEP among at-risk communities. Christine explains she didn't take PrEP because the benefits of PrEP don't outweigh the risks. David and George struggled to access PrEP. Moreover, for the individual negotiating intimate issues, the panelists emphasize that PrEP should be a choice. In Christine's words, "Just because it wasn't right for me, doesn't mean it's not right for you." Speaking to you — that hypothetical figure of a choosing subject granted the choice to secure a relationship and to pursue pleasure — Christine recommends weighing the risks and benefits, and deciding if PrEP is 'right for you.' Some of the women Marcel works with were considering that choice. David had already decided for himself it was right for him. And George not only decided for himself, he wants to educate people about it. By emphasizing choice in a room full of public health administrators, policy makers, and clinicians, these panelists did not demand public health leaders get drugs into bodies, but instead, asked them to make PrEP available as an option to at-risk communities.

As the panelists talk about PrEP, they echo the messages of "harm reduction," a guiding ethic of HIV prevention, which emerged in the 1990s and continues in the present day, to help the 'at risk' subject "weigh the relative value of the activity and the costs of taking the risks."[167] This approach attempts to strike a balance among sexual pleasure, safe sex, and choice. Harm reduction has, for example, promoted 'alternative' practices through which the subject might maintain intimacy and find sexual pleasure, such as through non-coital sex.[168] The logic is that, "Since no one safer sex strategy is likely to be acceptable to all … public health campaigns should emphasize as many choices as possible."[169] And by not discouraging the subject away from sex, but rather,

167. Odets 1996
168. Whitfield L 1998
169. Gavey N, McPhillips K 1997

directing the subject to seek pleasure through specific sexual acts those pose less harm, public health researchers contend people can harness intimacy and protect themselves from acquiring or transmitting this communicable disease. Indeed, PrEP continues a history of harm reduction through which sexual pleasure has become a substrate for intimate intervention. Therefore, I suggest PrEP implementation is best understood as an extension of interventions in intimate relationships through which the 'at risk' subject has been disciplined to manage pleasure in order to cultivate health. And thus, I also assert that access to PrEP is best conceptualized as another choice made available to the liberal subject.

Chapter Three

Public Health Priorities and Pharmaceutical Values: Populations, Persons and Pleasures

The United States Food and Drug Administration (FDA) approved Truvada for use as PrEP in July of 2012. In the previous year there were nearly 50,000 new HIV infections in the country and 2.5 million new infections in the world despite existing efforts to prevent HIV. In the city of San Francisco there was a rise in new HIV cases among young men who have sex with men (ages 13 to 24), meanwhile African-American individuals of all ages and genders remained disproportionately affected by the virus. There was also evidence that "risk behavior" was relatively stable "though possibly rising" among several at-risk groups. These are the facts that a physician at the San Francisco Department of Public Health presented to introduce her grand rounds talk about PrEP at San Francisco General Hospital shortly after the FDA approved the intervention.

She was speaking to a room full of physicians and her central message was that PrEP offers new opportunities to address the enduring epidemic. Not only does PrEP hold the potential to reduce HIV incidence across the population, she suggested, it also holds the potential to address health disparities among specific groups, such as higher incidence rates among young MSM and African-American individuals. According to the statistics, the existing prevention options were not working for many, so PrEP might be a better option for them. In particular PrEP might be a better option because it gives the individual the ability to prevent HIV before "the sexual encounter."

Indeed, PrEP represented a promising new direction for the field that did not involve managing sexual pleasure.[170]

Of course, she also acknowledged the challenges involved in implementing PrEP. While the FDA deemed Truvada safe and efficacious for use in HIV prevention, the science behind the intervention would need to be refined.[171] And given what was known about the efficacy of PrEP, it seemed patients would need to take a pill once a day, which is often a hurdle to engagement in care, especially for the most vulnerable populations. PrEP was also intended for primary care, where most providers were not accustomed to prescribing antiretroviral drugs. And ensuring access could be difficult because the medication comes with a high price tag. Throughout her talk, she made it clear that these many challenges would need to be addressed in the process of implementation in order for the promise of PrEP to be realized.

Fortunately, these challenges were surmountable, she contended. That is, there were potential solutions for each. To refine the science behind the intervention, public health could conduct demonstration projects. To train providers to properly prescribe the medication, and encourage patients to adhere to the pharmaceutical regimen, public health would launch education campaigns for patients and providers. And since the Patient Protection and Affordable Care Act (ACA) had recently been approved by Congress, it would be easier to ensure access to the high-cost pharmaceutical to 'at risk' populations. Indeed public health could pay for the medication, or guide patients toward the best insurance options for covering the cost.

I lead with this grand rounds talk about the potential of PrEP for several reasons. Most

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170. This is a key difference between PrEP and other biomedical prevention options. Whereas post-exposure prophylaxis is used after exposure to prevent transmission, and antiretroviral therapy is necessarily used after transmission, PrEP offers a method to prepare to prevent the virus before exposure.

171. Truvada has known toxicities. These toxicities were observed in clinical research for PrEP. They were also known from long-term monitoring of people living with HIV who used the medication for treatment. Meanwhile, the clinical evidence produced a range of findings about efficacy, so exactly which numbers to use was unclear.

clearly it displays how the logics of public health are focused on securing the health of the population, including by reducing the risk of acquiring HIV. At the same time it begins to show public health priorities present opportunities for pharmaceutical value to take root. And in this case, the pharmaceutical introduces a novel opportunity for public health — it shifts the field away from the management of sexual pleasure and toward prescribing pills. Therefore, this grand rounds talk also begins to show how PrEP prescription blends the logics of public health with those of pharmaceutical capital, so that the risk of acquiring an illness is transformed into a source of value.[172] The imperative to secure the health of the population reinforces the call 'to get drugs into bodies' through a process scholars in the social sciences of medicine have referred to as *pharmaceuticalization*.[173] In this process, governments and industries jointly shape pharmaceutical prescription and consumption. This is evident as both public and private entities support the production of clinical knowledge, pave pathways for access to medicine, and make patient populations available for new interventions.[174]

The fact that PrEP implementation is a form of pharmaceuticalization is clear. My observations in this chapter stem from this fact and I focus most on how the processes of pharmaceuticalization through which the priorities of public health allow pharmaceutical value to take root and grow. We see this for example as the physician giving the grand rounds talk acknowledges that managing PrEP prescription will involve overcoming the challenges of implementing a high-cost brand name medication that has known toxicities and only demonstrated partial efficacy. Here there is no question that public health would be responsible for crafting solutions to such challenges, and thus would also support the rollout of this private product. In this

172. Dumit 2012
173. Biehl 2007
174. Whitmarsh 2008

way this chapter continues an observation from the first chapter in which I showed how public and private interests have been stitched together over the history of the antiretroviral market.

We also see this as the physician introduces PrEP by referencing its potential to reduce new infections, including the 50,000 new HIV infections in the country and 2.5 million in the world in the prior year. Her suggestion is that if PrEP can avert new infections, especially among "high risk" groups, its value to public health would be realized. And given clinical research findings about the efficacy of Truvada for PrEP it was clear that PrEP would have public health impact, however since efficacy numbers varied significantly — both between and within studies — the overall value of PrEP was speculative.

Working within this speculative space, the speaker asserts that PrEP holds the potential to reduce health disparities among those groups that have been most affected by the virus, including African-American individuals in the United States. This claim about the potential "value" has little basis in the empirical world. It is more of a fabrication than a fact. Such potential is certainly not demonstrated in clinical research about PrEP. Yet, this claim about the potential impact of PrEP defines its potential.

In the following sections I explore the logics of public health in which pharmaceutical value takes root and grows. First, I examine how evidence from clinical research about PrEP is used to guide its implementation, especially through calculations about the estimated number needed to treat (NNT) in order to prevent a single infection. To develop this point, I work with Joe Dumit's research about the "prevention paradox" in which "many people must take precautions in order to prevent illness in only a few"[175] as well as his research about the ways the NNT determines the market size and value of pharmaceutical products. However where Dumit shows that

175. G. A. Rose 1992, 12

pharmaceutical firms design trials in ways that grow markets and value, I point to the ways the provision of care, even within public health departments, supports this process.

Building from these initial observations I also trace how clinical research evidence is translated into actionable prescription guidelines that inform the implementation of pharmaceutical interventions in public health, including how information from clinical research disseminates into patient education materials, and how patients as well as providers take up the information and take on the responsibility of understanding this novel method to prevent HIV. And as I do, I pay particular attention to the fact that PrEP is used "before the sexual encounter" because it does not require he or she manage sexual pleasure to prevent HIV and thus marks a clear departure from other prevention options, which have shaped the sexual practices of the 'at risk' subject. As I continue this observation in the latter part of this chapter, I will show how this pharmaceutical method to prevent HIV is prescribed by providers and used by patients through the logics of risk and also for the pursuit of pleasure.

From Evidence to Implementation

Like all experimental medications PrEP was evaluated through clinical research studies, which recruited large participant groups in order to simulate population effects and to more easily observe the effects of an experimental medicine, which are essentially magnified by the number of people in the study. Thus, the results of these clinical trials were expressed as facts about the health of the population, which can then be extrapolated within cost-effectiveness studies for public health or projections of value within the accounting ledgers of pharmaceutical firms.

The FDA approved Truvada for clinical use as PrEP based on the results of two clinical trials that provided evidence the intervention could be effective. One was known as "iPrEx" and

the other "Partners PrEP." iPrEx recruited nearly 2500 participants, all of whom identified as men or transgender women who have sex with men (MSM or TWSM). In this trial each participant was randomly assigned to one of two study arms: one arm was offered Truvada, and the other received a placebo. Partners enrolled nearly 4800 couples, each comprising a mixed-status relationship — meaning that one partner is HIV-positive and one is HIV-negative. In the Partners trial there were three study arms: in one arm, HIV-negative partners received a placebo, meanwhile in the other two, the HIV-negative partner received PrEP either as the combination tablet of tenofovir and emtracitabine, which we know as Truvada, or as tenofovir alone, one of the components of Truvada. trial ran for approximately three years and produced promising results. At the conclusion of the iPrEx trial, investigators observed HIV incidence was reduced by 42% in the experimental arm receiving Truvada relative to the control arm receiving placebo. In the Partners PrEP trial, HIV incidence was reduced by 75% for those receiving Truvada, and 67% for the participants receiving tenofovir.

Following FDA approval public health departments began to adapt this evidence from clinical research in order to effectively guide PrEP implementation, including by assessing the "number needed to treat" — a statistical observation that identifies the quantity of people who would need to be treated by a specific medication over a period of time (usually between one and five years) in order for a single negative outcome to be prevented. In this case, public health physicians assessed how many people would need to take a medication proven to have a protective effect against HIV acquisition in order to prevent a single infection. According to iPrEx data, the number needed to treat (NNT) to prevent a single infection with Truvada would be 62. This means that for every one person that would prevent an HIV infection by using Truvada for PrEP, another 61 would use PrEP without realizing any direct clinical benefit. Meanwhile in the Partners trial the

NNT with Truvada was 68, meaning that 67 additional people would need to take Truvada in order to prevent a single infection.

These calculations produce what Joe Dumit would call "surplus health" because they indicate that a significant number of patients should be taking "unnecessary treatment" and thus the value of the medication will grow far beyond its clinical effectiveness. Indeed, according to these calculations, PrEP should be prescribed to far more people than need it to prevent HIV. In this section I take Dumit's concept of "surplus health" as a starting point for understanding how the market size for PrEP and its value were first estimated. And to build from Dumit's observations, I examine how NNT calculations for PrEP vary according to assumptions not only about efficacy but also about the management of sexual pleasure. Indeed, I suggest that the market size and value of PrEP is determined by a combination of demonstrated efficacy of the pharmaceutical intervention as well as the ways people who consume the pharmaceutical pursue sexual pleasure, and this is reflected in calculations about the number needed to treat.

Pairing Efficacy and Pleasure

After the completion of the clinical trials, investigators continued to generate evidence about the safety and efficacy of PrEP. First of all, investigators dug deeper into the data produced in the clinical trials, sifting through the statistics to identify differences between participants who had adhered closely to the daily regimen for taking the medication and those who had taken the medication less frequently. The study teams also ran open-label extension studies. These studies offered PrEP to trial participants for upwards of a year after the main study had completed. These studies were un-blinded, meaning investigators knew which participants were receiving medications, and participants themselves knew they were being offered a medication that had been

shown to be safe and efficacious in the previous trial. While all trial participants were invited to participate, none were required to, nor accept PrEP as part of the extension study.

As these extension studies concluded, the research teams produced additional evidence about the efficacy of PrEP. By controlling for medication adherence in the data from the main trials, the study teams showed the efficacy of Truvada for PrEP was much higher among those who took the pill regularly. These findings were produced by testing drug concentrations in participants' blood. In the iPrEx open-label extension study dried blood spot tests were used to monitor for drug levels, and researchers compared concentrations of drug levels between all people who acquired HIV during the study and a random sample of those who did not. Through this analysis of HIV incidence and drug concentrations it became clearer that regular adherence to the regimen was positively associated with efficacy.

In fact, the 42% risk reduction which had been shown in the main iPrEx trial now appeared to be associated with taking just two or even fewer tablets of Truvada per week. Risk reduction was far greater when people took 2-3 tablets per week. And further, according to this analysis, taking more than 4 pills per week equated to nearly 100% risk reduction -- that is, no one in the open-label study who took Truvada for PrEP four or more times per week acquired HIV. While clinical research findings from phase-three randomized placebo-controlled trials involving human subjects, such as iPrEx and Partners, are considered the 'gold standard' in evidence-based medicine, the findings of these subsequent studies also informed the evidence base and are now guiding how PrEP should be prescribed and consumed.

For example, in 2014 a team of investigators from several research universities and public health departments across San Francisco, Seattle, and Boston conducted a secondary analysis of the iPrEx study data to determine how the NNT varies according to the assumed efficacy of the

intervention. Whereas the intervention had demonstrated a 42% risk reduction across the entire cohort, and the NNT based on this data would be 62, these investigators observed that for every single risk behavior and measure of relative risk reduction (based on adherence to the pharmaceutical regimen), the NNT varied. Through secondary data analysis in which investigators isolated a highly-adherent segment of the experimental cohort, they identified a 92% relative risk reduction for the intervention, and thus effectively reduced the NNT to 30. In this scenario, there would only be 29 patients who would use PrEP (without realizing any direct clinical benefit) for every 1 individual who would be protected from acquiring the virus. This lower NNT would make it easier for public health departments to justify implementing a high-cost medication to prevent HIV.

This same study team also characterized individuals by their reported risk behaviors in order to further specify the NNT. This was possible because upon enrollment in the initial study participants were asked to report if they had, in the past three months, engaged in any of several risk behaviors, including cocaine use, anal sex with an HIV-positive partner, 'bottoming' without a condom with a partner who is HIV-negative, HIV-positive, or did not know his HIV-status. Participants were also asked to report how many partners they had in the past three months (1, between 2 and 5, or more than 5), and whether or not they had been diagnosed with a sexually transmitted infection in the past 6 months. And for every single risk behavior, the investigators found that the NNT varied. Whereas the overall NNT for the study cohort was 62 with an assumed 42% efficacy, when investigators isolated participants with a single sexual partner in the past three months, a relatively "low risk" activity and assumed a slightly lower efficacy the NNT reached as high as 100. Meanwhile, when investigators zoomed in on a subgroup of participants engaged in a more "high risk" sexual activity, like not using condoms while 'bottoming' with a partner with

an unknown HIV status, the NNT was lowered to 41. Indeed, in this part of the study, the investigators' analysis showed that PrEP implementation would be guided not only by assumed efficacy, but also by the pursuit of sexual pleasure. And further, the investigators began calibrating measures of efficacy based on different means of pursuing pleasure – whether sex was 'low' or 'high' risk mattered, and not only for the subject, but also for the science.

Also in 2014 two investigators from John's Hopkins University conducted a subsequent analysis, which was based on the iPrEx data and adapted to estimate clinical effectiveness and cost-effectiveness of oral PrEP among men who have sex with men (MSM) in the United States across a variety of 'risk' scenarios. In this study, as in the previous, efficacy is shown to fluctuate with prospective adherence of men who will take PrEP in the real world, and hence, the investigators offer similar NNT figures: 64 if men in the 'real world' adhere to the pharmaceutical regimen at the same rate as the participants in the trial, and 30 if they adhere to the regimen similarly to those who demonstrated highest adherence in the trial.

Additionally, the investigators chart ways efficacy will fluctuate with risk behavior. For one, they show that if a man who takes PrEP exhibits "behavioral disinhibition" which they define as a 15% decrease in condom use, an increase in sexually transmitted infection prevalence, or an increase in sexual frequency, the NNT will rise to 97. This is counter-intuitive. It seems that if a participant demonstrated more 'risk behavior' the NNT should decrease. However, in this analysis efficacy is paired with 'risk behavior.' That is, these investigators contend the two must be analyzed together because participants who demonstrated more "behavioral disinhibition" also demonstrated less adherence to the pharmaceutical regimen, and therefore, the efficacy of PrEP was much lower for these participants — indeed, given lower adherence, the relative risk reduction was just 28% and thus, the NNT was quite high.

Conversely, the investigators showed there were some participants who maintained very high risk throughout the duration of the study and demonstrated high adherence. One key difference among these participants was that their risk was not linked to their own behavior rather they lived in places where HIV prevalence was extremely high (above 35%) and therefore, their assumed risk for acquiring HIV was also very high. For participants in these settings who demonstrated high adherence, the NNT dropped to 17.

And lastly, these investigators showed there was one subgroup for whom the NNT would rise far above all others. While this subgroup maintained moderate adherence and thus, demonstrated the same rate of adherence as the entire cohort — reducing their risk by 44% — this subgroup also substantially lowered their risk by always using condoms. In fact, they reported 100% condom use. This raised the NNT to 212. And thus, the highest projected NNT in either analysis was produced by a subgroup of participants that managed their sexual pleasure the most rigidly.

This series of calculations work within and reorient the observations Dumit has made about the mechanics of "surplus health." For one, where Dumit argues that surplus health is determined by pharmaceutical firms which seek to grow value and markets by designing trials in ways that produce larger NNTs, this example about the way the NNT for PrEP is estimated shows there is a certain inevitability to market size and value, which is not necessarily shaped by pharmaceutical companies, but is built within the process of translation between clinical research and public health. Furthermore, these calculations show how the pursuit of sexual pleasure ultimately moderates value in the market to prevent HIV. Though assumptions about efficacy and incidence rates tend to be the primary factors that affect NNTs and therefore also value in markets for prevention, this case shows us that the management of pleasure drives value and grows markets,

too.

From the Population to the Personal

Of course, something is lost within population-based estimates. By relying on evidence from clinical trials that test experimental medications on larger patient populations and making efficacy estimates based on their prospective impact in public health, it becomes difficult to understand how taking the pill will affect the health of the individual. The prospective patient-consumer is left with a series of abstract facts based on a variety of hypothetical scenarios, which he now has the responsibility to think through in order to understand efficacy and what taking the pill will mean for one's self. Joe Dumit discusses this phenomenon of seeing one's self using the pharmaceutical or being a good candidate for doing so, as "pharmaceutical witnessing." Here again he focuses on the role of pharmaceutical firms, suggesting that through various marketing campaigns, firms convince prospective patients they need to take a medication in order to assume responsibility for their lives, and thus translate clinical research evidence about the impact of treatment on the population to the potential benefit of using the product for the individual person.

Continuing to think with Dumit in this section, I point to ways that the field of public health plays an active role in articulating the value of the pharmaceutical, including by translating facts about the population, so that they may be more readily taken up by the person, and I trace how the person begins to think of himself as a potential PrEP patient. To develop these observations I think across multiple materials and moments from my fieldwork. First, I return to a conversation with Lance, who I first spoke to while he was participating in the iPrEx study. By this time, he is participating in the iPrEx open-label extension study in which he is receiving Truvada for free, and he is beginning to question whether or not he will take the medication after the study concludes

– that is, if he sees himself as a potential PrEP patient. Next, I offer a presentation by Dr. Robert Grant, the principal investigator of the iPrEx trial and the iPrEx open-label extension study, in which he expresses concerns about the ways population-level data are being communicated, and begins to offer providers a better way of presenting PrEP to potential patients.

Is PrEP right for me?

When I sat down for this conversation with Lance, I approached it with "pharmaceutical witnessing" in mind. I was most interested to know if he would continue taking the medication after the demonstration project concludes — that is, whether or not he sees himself as a potential PrEP patient. And in our conversation, Lance expressed interest in taking PrEP after the study, but he also mentioned he has concerns about it. His first concern was the high cost of the medication. As he explained, "I'll keep taking PrEP if I can get it for free. It's expensive. That's one of the main controversies, right? It's about $35 per pill. So, if my insurance isn't covering it, that's a lot of money." His second concern was about the limited efficacy of the intervention. He knew that Truvada was approved by the FDA based on clinical research findings about its efficacy, and how the investigators had adjusted the efficacy estimates to account for adherence, however he also understood that the research findings showed PrEP is not 100% effective. So, "It's hard to justify spending hundreds and hundreds and hundreds of dollars a month for something that is not even 100% effective – something that is only going to reduce my risk – even if I take it every day." His third concern was less about the pharmaceutical itself, and more about himself, including the ways he manages his sex. He continues, "I guess if I was in a high-risk category, I might evaluate it. If I was a bottom having a lot of anonymous sex, and not using condoms, and I knew this pill was out there, if I could afford it, I would do it."

I begin this section with my conversation with Lance to extend inquiry from the previous two chapters. In the first, I showed how public and private interests have been stitched together over the history of the ARV market. In the second, I displayed how the liberal subject has been shaped by techniques of discipline, including through the management of pleasure. Thus, I have laid a foundation for examining the constitution of the liberal subject within the political economy of health. Here I observe that the way Lance thinks through his decision to take PrEP is characteristic of the subject who has been granted the freedom to choose. This is evident as he asserts his own personal responsibility to maintain health, demonstrates savvy in calculations of value, and manages his own sexual pleasure. In these ways, Lance begins to show us how the sensibilities of the liberal subject shape pharmaceutical consumption, such as through "witnessing."

However, I hear something more in his answer. As Lance details his careful calculations, I hear a tension between his interest in consuming the pharmaceutical and his concern about it. His interest drives him to consider taking the pill, and he understands the specific terms with which to evaluate whether or not PrEP is right for him. He asks himself: Will my insurance cover the cost of the medication? How well will PrEP work? And his interest generates concern. He wants to take PrEP because it would reduce his HIV risk, but it is expensive, so he is not sure he can. He also knows PrEP only reduces HIV risk, so even if he takes it every day, he would still be worried about the possibility of acquiring the virus. Thus, he relates to the pharmaceutical as that which he is simultaneously interested in and concerned about.

As I follow this tension in Lance's words, I recognize that his liberal sensibilities do not directly translate to pharmaceutical use. Rather, in one moment, he critiques the high cost of drugs, and the science behind the pharmaceutical intervention, especially the efficacy of the medication.

From this critical perspective, he expresses concerns about PrEP in terms of cost, science, and sex. However, in the next moment, his concerns are alleviated as he envisions a scenario in which it would make sense for him to take PrEP. As Lance navigates between his interests in PrEP and his concerns about it, then envisions how it would be *right for him*, he offers a glimpse into the intimacy of pharmaceutical use — what I will refer to as "pharmaceutical intimacy."

Pharmaceutical intimacy refers to the practices and logics through which the subject becomes interested in and conflicted about consuming a medication. It also describes the way the subject comes to relate to the medication through knowledge about one's self, especially one's own sexuality. That is, pharmaceutical intimacy first highlights the productive tension between interest in pharmaceutical consumption and concern about it, then shows how truth about the self is able to slice through such tension.

Though Lance expressed initial concerns about the cost of the drug and its limited efficacy, which seemed to lead to a dead end, when he shifted to knowledge about himself, including whether he would have "safe" or "risky" sex in the future, he found a path forward. If he was able to afford the drug and knew he would likely have risky sex, he concluded, it would make sense for him take it. So, just as he scrutinized his own interest in using Truvada in terms of its cost and efficacy, he also imagined how it would be *right for him*. His knowledge of himself, including how he has managed his own sexual practices in the past, and how he would likely continue to manage his sex in the future, cut through the tension between interest and concern. And ultimately, this knowledge of himself guides his decision to take PrEP.

Throughout our conversations, pharmaceutical intimacy manifests in several ways, including as moral reflection about pharmaceutical profit, distrust of doctors, and skepticism about the science supporting the use of drugs, especially in the context of 'risky sex'. For example, Lance

suggests that Gilead, the pharmaceutical firm that markets Truvada, might not be managing the rollout of PrEP responsibly. "There's an ethical thing," he says. "Gilead is trying to make more money by saying, 'It helps. We don't know for sure how much, but try it. Sign here, sign here.' Corporate America is trying to get more money, meanwhile we don't have conclusive results yet." Here Lance expresses suspicion that the firm may be prioritizing profit over and above the health of the public.

Lance also critiques the physicians that have begun prescribing PrEP. "There's a risk in what they're doing," he asserts. "They don't have all the knowledge yet to really share with people a clear recommendation." Yet, they are "putting it out there, and saying, 'start it if you want to.'" In each of these claims, Lance focuses on his concerns about cost and science, and his interest in PrEP layered with his concerns about it. In particular, he is concerned that the pharmaceutical firm that manufactures Truvada and providers who are prescribing it may not be managing implementation responsibly. He sees how the freedom to choose opens the individual subject to potential risks, meanwhile it also displaces responsibility on the individual.

Next, he re-emphasizes his concerns about the limited efficacy of the intervention, as he tells me, "People need to understand it's not 100% effective." He is particularly concerned about limited efficacy because he thinks it might lead to risky sexual practices. In his words:

> *I hope people reading the news don't think 'I can just take this pill once, and be okay.' It requires every day adherence.' What was it, like 70% effective for those people that truly took it every day?' It's not fool proof. You still need to be smart about it. I'm scared people will think, 'Oh, I just take the pill, and I'm not going to become HIV-positive.' This will require a lot of education, so that people understand it reduces your risk, but the potential is still there. So, don't go out and start getting fucked by HIV-positive guys, and let them cum inside you. That's not wise."*

In the beginning of our conversation, Lance had said that if he was in a high-risk category, he would consider PrEP, and if he could afford it, he would take it. In that moment, his anxieties

about risk could be addressed through pharmaceutical use. But here, his anxieties endure. This is clear as he communicates a message of caution for anyone that might start PrEP. He hopes they will be responsible. And he hopes their responsibility will carry through in their everyday practices, as patients who maintain daily adherence to the drug, and as men who have sexual lives that might put them at risk for acquiring HIV. Lance shows us how risk and responsibility play several roles for the liberal subject, twisting and turning into one another in confusing and contradictory ways.

As he steps back into his own careful calculus, he once again shows us how 'the personal' cuts through the confusion. He explains:

> *Wouldn't you rather take one pill in advance to keep you negative, potentially, than become HIV-positive and take a whole set of toxic pills for the rest of your life? If you are choosing the lesser of two evils, I would rather take the one. Or, you could not take the pill, and be celibate, or have 100% safe sex: put a condom on when you're giving a blowjob. I don't do that. Never have. Never will. There's always a risk. So, why not reduce that risk?*

By positioning himself as the potential PrEP user, he acknowledges that he has sex in some ways that might introduce a very small risk of acquiring HIV. His sexual practices, like the efficacy of the pharmaceutical, are not 100% safe. "So, why not reduce that risk?" he asks. Here again, by envisioning himself as a PrEP candidate, he constructs a scenario in which PrEP would be *right for him*.

Through my conversation with Lance I present the concept of *pharmaceutical intimacy* to explore how liberal ethics spark and alleviate anxieties about pharmaceutical consumption, which tend to coalesce around concerns about the high costs of the medication as well as uncertainties about its toxicity and efficacy. In the case of PrEP, these anxieties also concern the management of sexual pleasure. And given that *pharmaceutical intimacy* plays on the minds of potential PrEP users, it poses significant obstacles for implementation. If someone is a good candidate for PrEP,

but they are concerned about the high price of the drug, or they are concerned about the safety and efficacy of the intervention, for example, they might not take it. Recognizing this, investigators and patient advocacy groups have constructed several education initiatives for patients and providers in an effort to alleviate these concerns. These efforts have gained momentum over several years of PrEP implementation but they began shortly after the FDA approved Truvada for PrEP.

What happens when "you" take PrEP?

The year after FDA approval Dr. Robert Grant, the principal investigator for the "iPrEx trial — one of the clinical trials that produced evidence PrEP could be safe and efficacious — presented an update about emerging research findings in which he translated facts about the population for the prospective PrEP consumer. The presentation was hosted by the Center for AIDS Prevention Studies (CAPS), a research arm of the University of California, San Francisco (UCSF), and titled, "Emerging Interpretations of PrEP: What do we know about efficacy from the trials and the demonstration projects?" Dr. Grant was concerned that messaging about PrEP, especially its efficacy, had been poorly construed, so he revisited the data from the PrEP trials and subsequent analyses of demonstration projects to assert "a much clearer, simpler, and far more user-friendly interpretation of PrEP efficacy." The basic message that Dr. Grant wanted to convey was that "If you take PrEP, you don't get infected."

The talk began with an observation from a survey about PrEP awareness among men who have sex within men across the United States, which found that "barely more than 1 in 5 had previously heard of PrEP." This held true, he contended, "even after the results of the iPrEx trial made front-page news from the San Francisco Chronicle to the New York Times." Dr. Grant

reasoned there were likely several reasons news about the innovation had not resonated. These reasons included "attention to the $13K/year retail cost of the drug in the US (instead of the ~$120.00/year manufacturing cost)," the "focus on the intent-to-treat results that appeared lackluster," and "distorted messages … that imply that the benefit of PrEP can only be achieved when condoms and lubricant are also consistently used." Indeed, he observed that concerns about cost, science and sex were stifling implementation.

He observed how these many concerns had "apparently coalesced to make an utter muddle of the science underlying PrEP efficacy, at least in the minds of potential PrEP users." And a key way the messaging went wrong, he suggested, was by including "the interpretive frame used in trials," which presents "the analysis from the investigators' perspective" and "really entirely ignores what people are actually doing in these studies." Whether or not a participant took the study medication is not considered in this analysis, he explains:

> We included everyone that was offered PrEP, including those who did not take any of it, those who took some then gave up after a few days, those who left the study then came back later because they knew they'd become HIV-infected ... They became included in this. This analysis includes everyone, and doesn't consider any information about how people actually use this technology. It is the effect of offering PrEP. It doesn't consider anything about what people are thinking about PrEP and how they are using it.

"This is critically important for everyone to understand," he contended because it greatly influences the efficacy numbers. "We think efficacy tracks nearly one to one with actual use." What the "intention-to-treat" analysis reveals is not the true efficacy of the intervention, but rather the rate of adherence. In his words, the "efficacy measured on an intention-to-treat basis, tracks extremely well with the percentage of the cohort that is actually using the intervention." This was true across several trials:

> In Partners PrEP, 81% of the cohort had drug detected; efficacy on an intention-to-treat basis was 75%. In ASANA, 79% using the drug, 62% was the intention-to-treat estimate. In iPrEx, 51% had detectable levels of drug in their blood, and efficacy was 44%. In FEM-

PREP, 26%, the lowest drug exposure by far, and the lowest efficacy.

Indeed, adherence to the study medication determined the efficacy findings in each trial. Thus, whether or not participants took the drug was extremely significant for the reported findings. And by focusing on "what people are actually doing," we see greater evidence of efficacy. Given these results, he reminds the audience that the intention-to-treat interpretation is useful for regulatory decisions, but as-taken interpretation frames are better suited for informing potential users. "It is therefore wrong to tell someone there is a 42% reduction in HIV risk if PrEP is taken." And unfortunately, this is on most of the information sheets available.

Dr. Grant shows how pharmaceutical intimacy complicates messaging about PrEP to potential users. Those who might have been interested in the intervention, he suggested, likely developed concerns about the cost of the medication and the science behind the intervention. To cut through these concerns, he wanted show what happens when *you take the drug.* He wants them to envision themselves taking the pill every day. He believes that a better message is: "If you take PrEP, you don't get infected.

Prescription and Pleasure

In the following years, as the Centers for Disease Control and Prevention (CDC) continued to update guidelines for PrEP prescription, and community based organizations around the nation began to write more user-friendly patient education materials based on the CDC recommendations. For one, Project Inform, the patient advocacy organization for HIV care, started to author educational materials about PrEP that adapted the CDC guidelines into a series of 'yes' or 'no' answers for the potential PrEP consumer. These adapted guidelines ask the potential PrEP consumer questions including "Have you been the receptive partner for condom-less anal or

vaginal sex?" and "Is your main sexual partner HIV-positive?" Whereas for the previous three decades a 'yes' answer to one of these questions would have indicated that one's intimacy is risky and therefore one should work to cultivate a healthy intimacy, including by strictly managing sexual pleasure, in this information packet about PrEP a 'yes' answer to these same questions suggests that "PrEP might be a good thing to discuss with your provider." Therefore, the 'good' and 'bad' ways of being intimate, which defined the pleasures of the at-risk subject for decades, began to be redefined for the PrEP consumer. By being a responsible patient, these guidelines suggested, the PrEP consumer could manage pleasure in new ways.

Amid this prospective shift in the management of sexual pleasure, I became interested in understanding how people obtained PrEP prescriptions, including by answering these questions for themselves, or through conversations with their providers. One man who decided to take PrEP explained his decision by telling me about his experience going to a provider. I will refer to him as Hank. When Hank entered the clinic, the receptionist handed him a questionnaire and asked him to indicate the services he was there for, enter demographic information, and answer a few questions about HIV risk. He checked a few boxes, which he felt indicated a relatively low risk. And when Hank spoke with the provider he was asked more questions about how he managed his sexual practices in relation to HIV risk. In response, he told his provider about his history with HIV risk.

He said, "I have always been extremely cautious with sex. I have never done anything without a condom. That would include oral." Hank explains that he has been practicing 'safe sex' for his entire sexual life, and he traces the origin of his practices to the AIDS epidemic. "After AIDS, I realized that whenever you're having sex with someone, you are having sex with everyone they've ever had sex with." So he relentlessly questioned his partners about their sexual histories.

"I would really grill people before I have sex with them. I would try to find out how active they were. The more active someone was, the less willing I'd be. If they were out there every night, I was not interested." He also tells the provider that he gets tested regularly. "I get tested every year and I'm never worried about HIV." "Well," he clarifies, "I have always figured I could pick up an STD, though that's never happened, so I don't have any anxiety waiting for test results, thinking they'll come back positive."

As Hank explains how he always uses condoms, including for oral sex, 'grills' people about their sexual histories, and gets tested for HIV annually, even though he is never concerned he might have been exposed to the virus, it is evident that his intimate life has been shaped by HIV risk. By sustaining each of these techniques, especially in combination with the others, Hank is reducing his risk as best he can, while still having sex. And as a result of his combined practices, he believes he has eliminated his HIV risk. This is why he is not nervous about receiving results from HIV tests. In fact, he is confident he has never done anything "risky." Therefore Hank is not sure that he wants to start PrEP, but he wants information about it. He expects the provider to say, "Okay, I've given you information about it, think about it, and come back if you're interested." But his provider is more direct, as Hank explains. "It couldn't have been more than 10 minutes in when he said, 'I think we should put you on PrEP.'"

Hank is surprised when this provider recommends he start PrEP so quickly. "When he told me that I should go on it, it almost felt too soon. I thought he'd ask me a lot more questions before even considering that. But no, he was like, 'We should put you on PrEP.'" Hank was not only surprised at how quickly his provider recommended PrEP, but also the reason he recommended it, which in Hank's words was, "You'll just enjoy sex a lot more." He reflects, "That was not what I was expecting to hear from a doctor. But I think he heard what I was saying about being safe, and

he knew I probably had been holding back sexually, and hadn't experienced a lot because of that." "And well, he was right! I do enjoy sex a lot more now." Since Hank started taking PrEP, the ways he manages sexual pleasure have changed. As he explains:

> *I am much more relaxed. I don't think I've become wild or anything. But it's so much easier to meet up with guys, or be willing to meet up with guys, and try things. I used to have concerns, like: Did I floss my teeth last night? Well, then I could've gotten a cut, so I won't put a cock in my mouth the next day, or for the next two days. Today, I'm probably not as discriminate about who fucks me. I'm just more open to it. But I still ask questions to try to find out how many sex partners that they have. If it sounds like they're out there every night, I still avoid them. Overall, I think my sex life is better.*

Hank's case shows us that risk is merely a baseline for value in the pharmaceutical prevention of HIV. Hank has always been low risk. He has never acquired an STD. He has always used condoms, even when having oral sex. So if he had read the questions about whether or not he is a good PrEP candidate, he would have answered "no." If Hank's provider had screened him according to prescription guidelines, he might have noted that prescribing for Hank would likely constitute "unnecessary treatment." Reporting 100% condom use, Hank fits in that risk category in which over 200 people would need to take PrEP in order to prevent a single infection. Interestingly, Hank's provider did not recommend PrEP because he fit within any risk criteria at all. Rather he prescribed PrEP so that Hank could pursue more pleasure. Once prescriptive power enters the hands of the provider, value of PrEP grows not only through the potential for illness but also the potential for pleasure.

Chapter Four

Building Infrastructure: Welcoming New Patients, Constructing the Continuum of Care

On the first day of open enrollment for "Covered California" in 2016 staff from the San Francisco Department of Public Health hosted a meeting for patient navigators who have been hired specifically to help people access PrEP. In fact their professional role, "PrEP patient navigator" developed in response to the implementation of PrEP and the number of navigator positions quickly ballooned in the San Francisco Bay Area because city officials, community based organizations, and public health workers recognized the need to help people navigate the complex terrain of insurance markets in order to more effectively support PrEP care. Essentially, the role of the PrEP navigator is translating insurance benefits for patients, and showing them how high cost medications can be accessible within complex health care systems. The email I received about the meeting indicated the presenters would offer a cost analysis of PrEP within the Covered CA plans available in the new enrollment period, and detail factors involved in ensuring that people who want to take PrEP can access it. I knew the updates to the new insurance plans could play an important role in ongoing PrEP care and I was interested in the conversation among navigators about the new plans, so I attended.

The meeting was held in a building I knew well from interviews with providers. When you enter the building the walls rise several stories overhead, leading your eye to archways above. The floor is all marble, and the entire space is dimly lit. As I proceed through the lobby I notice a white

a-frame sign propped up in front of the elevator bay. The sign clearly signals ongoing maintenance in large bold font. Since I have just a few minutes before the meeting begins, I decide to scurry up the stairs. On the landing for the second floor the stairs end and marble quickly turns into compacted carpet. The hallway meanders slightly left then turns right and eventually sharply left again before ending with a clear right angle. I see no stairs, no open doors, and no way up. Feeling defeated, I turn and walk back through the hall, scanning for a second staircase or elevator somewhere, but find only more misshapen corridors. So I run back down the stairs, now less interested in the marble and more convinced the city had chopped up an old religious building and awkwardly inserted public health offices throughout.

In the lobby again standing in front of the elevator bay I read the maintenance sign. It promises the broken elevator will be operational again in two months. I enter the single operational elevator and ascend to the third floor. And I arrive just in time for the meeting. The hosts of the meeting, both on staff at the public health department, quickly acknowledges the meeting is "convening the most experienced individuals in benefit navigation for PrEP anywhere in the country." Most work in departments of public health or for local community based organizations (CBOs), which have supported care for HIV-positive patients for decades.

I begin this chapter with this scene to show how the implementation of an innovation depends on *building infrastructure*. And I use the term infrastructure to refer to physical structures, such as the elevators, stairs and entryways of office buildings, as well as knowledge, resources, and personnel that support PrEP care. Some of this infrastructure is already in place, though its parts need to be reconfigured and made to work. The public health department relies on the space of an old religious building, chops it up and inserts offices throughout. HIV prevention gathers together what it can from HIV care, including personnel and expertise, and retrains them each year

to keep pace with policy. However, other parts of the infrastructure remain non-operational, and the divide between the two reveals important insights, including about the ways funding is allocated as public and private interests mix. In this case, it is not merely that the elevator to the public health offices need to be fixed, but rather that it will take two months to repair. Meanwhile, three floors above "the most experienced individuals in benefit navigation for PrEP anywhere in the country" are convening to ensure they can efficiently leverage public resources to pay for a private product. As I develop my observations across this chapter across several sites and scenes, I point to the ways that *building infrastructure* happens, how it supports the implementation and uptake of PrEP, and the tensions between public and private entities that it reveals.

The research reflected in this chapter is closely related to the work of scholars in the social sciences of medicine who examine how public health infrastructure is disrupted by the provisions of policies and private interests, including in ways that disrupt the distribution of antiretroviral drugs. These scholars have shown how outside the US Structural Adjustment Programs, for example, set the stage for the AIDS epidemic by dismantling national economies[176] and how international responses to the epidemic, foremost the US President's Emergency Plan for AIDS Relief (PEPFAR) continued the politics and policies set forth by Structural Adjustment.[177]

By not supporting the public sector, Pfeiffer argues PEPFAR created a fractured health care landscape where state-of-the-art HIV/AIDS testing and treatment facilities are paired with crumbling state hospitals and wealthy donors showcase clinics in some regions while neighboring regions atrophy. PEPFAR also structured a focus on the clinic, where interventions could be followed and their results could be measured, but offered no resources for understanding the impact on a national level where myriad social factors contribute to outcomes, and provided no

176. Nguyen 2010
177. Pfeiffer 2013

incentive for health workers to stay in public positions while NGOs began paying them more to provide specialized services. So, as pregnant women, for example, were presented with several obstacles to care, like hunger, side effects of medication, and the stigma of AIDS, they became at highest risk for being "lost to follow up" and the Plan made no adjustments to remedy this situation.

Thinking with Pfeiffer's claims to understand the rollout of PrEP in the United States, I examine ways that funds are earmarked in specific ways to welcome new patients into care and support the consumption of a pharmaceutical to prevent HIV but not to support continuity of care, so public health workers must obtain additional support, including by applying for and obtaining research grants, which they then conduct in order to support PrEP care. Thus, this chapter also adds to scholarship about the relation between research and care, such as inquiry about the rise of evidence-based medicine (EBM) in public health[178] and the fact that health care is increasingly provided in experimental contexts. As a result, the public-sector activity of providing health care to the public is being transformed into a private-sector, profit-generating infrastructure.

How the Public and Private Mix

Once the meeting is underway a senior health program planner for the department of public health begins her presentation. She outlines the insurance landscape across the state and in the city, identifying the twelve state-wide insurance companies, and the six health insurers working specifically in San Francisco.[179] She also details how one can calculate the costs of a PrEP prescription by accounting for a variety of variables, including the costs of health insurance itself and the costs of medication as well as associated costs, such as clinic visits, lab tests, and pharmacy

178. Adams 2013
179. The insurance companies in San Francisco are Anthem, Health Net, CCHP, Kaiser, Blue Shield of California, and Oscar.

fees. Considering both the cost of the plan and the cost of PrEP helps map out potential costs to the patient, she explains, because there is the premium cost for the insurance itself and the out-of-pocket cost for care services including the medication.

Two staff members from a local community-based organization presented next. They began their presentation with a brief dialogue they often have with new PrEP patients. The patient says, "How much is this going to cost me?" They reply, "Well, if we do our jobs as navigators well, the cost to you should be zero." And the patient asks, "Really, how?" They answer this question by outlining the main public and private insurance options available. MediCal covers the cost of Truvada in full, if the patient earns less than $16,832 annually. For those who can afford a private plan available through Covered CA, they steer them toward the Silver plan, which on average covers 70% of costs of the medication. And to cover the rest, they can use the Gilead co-pay card. Indeed, they can say that "the cost to you should be zero" in part because several public and private insurance options can be supplemented by a private offer from Gilead Sciences, the pharmaceutical company that manufactures and markets Truvada.

After outlining these three options for accessing PrEP, including the option Gilead offers, the presenters admit, "People want to forgo insurance because they are in the advancing access program." However, the presenters also remind the audience that under the terms of the ACA there is a penalty for not having insurance, which is generally assessed at 3.5% of an individual's annual income. So, they conclude, "if you are using PrEP, you want to choose a plan, and it should be one you can afford to pay on a monthly basis." In brief, "You want to choose a plan with the lowest deductible that is affordable to you." And by choosing a plan that offers a modest deductible, they indicate, you can supplement any remaining costs to cover the deductible with the Gilead co-pay card. With these options displayed on the screen, the presenters offer an example of how they

would cover the cost of the medication for a prospective PrEP patient. They call him Martin. He is 35 years-old and makes $24,000. For Martin, the Silver would run just over $100 per month. And on the Silver plan, Martin would have a $2,200 deductible and a $250 pharmacy deductible, meaning he would have to meet the $250 deductible before the cost of PrEP begins to be covered. This is where the Gilead co-pay card comes in. By using it, "we would be able to meet the deductible."

Across these presentations it is apparent that the work of a PrEP navigator involves tracking many moving parts, including the benefits of insurance plans as they change by the year and company as well as by monitoring how these changes affect the out-of-pocket costs for the individual consumer. By following these many moving parts as they work to ensure patients can access PrEP, the navigators play an essential role in building the infrastructure for PrEP implementation. And in the second presentation, the navigators highlight a surprising dynamic between public and private interests. For those that would have to pay significant out-of-pocket costs to access this high-cost medication because the nation's health care policy forces them into a private insurance market, where individual plans can be expensive and deductibles remain high, Gilead picks up most or all of the remainder of the bill. The company does this through its "advancing access program" which originated amid licensing pressure in the 1990's and expanded in the 2000's to ensure access to antiretroviral drugs for treatment including Truvada around the globe. Here again, the pharmaceutical firm inserts itself within the public infrastructure, and in this moment to support the market for HIV prevention, over which it holds a monopoly.

After the meeting I walk straight to the elevator bay where the doors are open and the up-arrow is lit. I stand aside, waiting for the single elevator to come back down. A woman wearing a staff badge approaches. I push the down-button. Then I push it again and again, expecting it will

light up. But it doesn't. The woman behind me comments, "It's broken, like the system." These moments happen every day in the public health facilities across the city. They are not extraordinary moments. In fact, they are all too ordinary. I have come to understand these moments as part of the daily life of public health care, where a broken button, a single operational elevator, and a floor to nowhere, can stand as signs of a poorly functioning system. The button, the elevator, the architecture, they're all "broken, like the system." Thus, the need for infrastructure and the evidence of its absence are not merely my observations. These are the observations that public health staff make as well. And I find it important to represent my claims alongside their observations because after all it is they who are responsible for making the system work. They are *building infrastructure*, including by connecting the pieces.

Connecting Pieces

On the train home that night, I step onto the same train car as one of the PrEP providers I know. He has just finished a shift at one of the city's public health clinics. As we start to talk, he asks how my research is going, and I tell him that I had recently shifted from studying the "innovation" side of PrEP to studying how the Affordable Care Act is affecting the implementation of PrEP. He replies, "Without the Affordable Care Act, PrEP implementation would look very different." His comment struck me. I knew it was true. I had spent the past few months attending these meetings among PrEP patient navigators — whose very job is to guide patients through the new insurance landscape that the health care bill left in its wake in order to access PrEP. So I knew he was right but I wanted to know exactly what he meant. He explained, "Many patients who have never been in care before, and many who have never had insurance previously are now taking PrEP." With his answer, Dr. B reminded me the ACA had opened a new avenue for the previously uninsured to

access insurance and thus also represented a huge milestone for securing the health of the population.

Historically, many people in the United States have been un- or underinsured due to the high costs of coverage, employer-dominated markets, and relatively low incomes. These limitations in health care access have been produced over the past century during which the U.S. health insurance market has lacked oversight. While other nations moved toward universal systems of health care coverage in the 1920s, in the U.S. physicians and hospitals sought to prevent government oversight of health care financing, and instilled a libertarian ethic. As a result, employers emerged as a source of insurance instead of the government, linking the 'benefit' of being employed to access to health care.

Through the Depression, as the number of people unable to pay out of pocket for services grew, states sanctioned the formal creation of non-profit, community based plans, Blue Cross and Blue Shield. However, these organizations offered coverage only in support of the entities they were controlled by, hospitals and physicians – the very same entities states were trying to regulate. In the 1940s and 1950s, the system of employer-based coverage found further support through federal exemptions to fringe benefits, sparked by an Internal Revenue Service (IRS) ruling that determined such compensation to be tax exempt as well as an amendment that codified these decisions in the tax code, which further incentivized an already burgeoning commercial insurance market for employer-sponsored plans. Even as this market grew over the next two decades, the central issue remained: coverage was not available to all, even those who were employed.[180]

Building from this history, the Patient Protection and Affordable Care Act shifts a few significant conditions of access to care. Most significantly the ACA establishes a viable individual

180. Rosenbaum et al. 2012, Access under the Common Law: 2-10, 21-31, 33-35

market for people to access coverage without an employer-sponsored plan or public insurance. The ACA also strengthens Medicare and Medicaid, and expands Medicaid to extend coverage to low-income nonelderly adults who are pregnant, disabled or parents. In addition, the Act makes significant changes to public insurance, including major revisions to Medicare that improve coverage for preventive care and prescription drugs.[181] However, the Act did not control for the underlying costs of health care in any significant way. [182] Critics argue that a much more meaningful strategy would apply to all payers, and give government the power and means to control high health care spending and unsustainable cost increases.[183] Thus, they contend the ACA stirs up commotion, but does not follow through with much movement.[184] [185] Yet, the shortcomings

181. The Act also provides new opportunities for people younger than 65 years of age to obtain insurance.
182. Instead of directly controlling costs, the Act offered a grab bag of politically acceptable mechanisms for market reform that may eventually affect costs (Orzag 2011). These market-based mechanisms for reform include competitive bidding by insurers and value-based purchasing strategies aimed at incentivizing patients and physicians to make the right choices. Tom Baker observes, "The Affordable Care Act embodies a social contract of health care solidarity through private ownership, markets, choice, and individual responsibility. While some might regard this contract as the unnatural union of opposites – solidarity on the one hand and markets, choice, and individual responsibility on the other – those familiar with insurance history will recognize in the Act an effort to realize the dream of America's insurance evangelists: a 'society united on the basis of mutual insurance.' Public ownership and pure, tax-based financing are technically easier and almost certainly cheaper routs to health care solidarity, but they come at a cost to the status quo that Congress was not prepared to pay."
183. Critics also contend the ACA provides only "technical fixes" for the high costs of care, such as the creation and adoption of a National Quality Strategy, comparative research of competing treatments, pilot and demonstration projects to improve the quality and efficiency of care, and new service delivery models, known as "medical homes" and "Accountable Care Organizations."
184. The Act also fails to create a national risk pool, or even large regional pools, that would spread risk across the population. Instead, the Act retains a state-based approach to health insurance markets and market regulation, as well as employment-based coverage. The Act continues to pay providers low rates for Medicaid beneficiaries. This is a notable problem because providers have refused to see Medicaid beneficiaries based on these rates. The Act also encourages state insurance Exchanges to act as high-risk pools for individuals with the lowest levels of income and the poorest health. While the Act protects newly established Exchanges from adverse selection, it leaves leeway that encourages high-risk pooling, and retains non-Exchange markets for healthier and wealthier populations.
185. The Act also provides no significant support to graduate medical education in primary care specialties. Of the billions of dollars in federal Medicare funding spent annually on graduate medical education, there is only one modest new program to train primary care physicians at "teaching health centers" and a new National Health Service Corpse investment, while there are no provisions for training for family practice, general internal medicine, pediatrics, obstetrics and gynecology, dentistry, nursing, physician assistants or public health. Further, the Act excludes coverage for individuals not legally present in the US. These individuals are barred from participating in state exchanges and Medicaid (Rosenbaum et al., 2012: 218-240).

of the Act may have been key to its passage. By not threatening costs, the ACA found support from several stakeholders, including insurers, hospitals, pharmaceutical firms and providers, who recognized how the new legislation could bring them a massive new financing stream, as the previously uninsured and ineligible for insurance became insured.[186] Given the many provisions within the Act, there would be many ways to trace its influence on PrEP implementation. For my fieldwork, I followed how the Act strengthened Medicare, including by improving coverage for preventive care and prescription drugs, and welcoming new patients into care.

Welcoming New Patients into Care

At the next meeting of PrEP navigators, I recognized there was only one African-American navigator at the table. I will call him Jay. After the meeting I introduced myself and asked him to tell me more about his clinic. He explained that the clinic is in The Tenderloin, a historically low-income but also rapidly gentrifying neighborhood near downtown San Francisco. The people who receive care at his clinic have sex for work, and live on the street. Many are also African-American. And they have never heard of PrEP.

He also told me that he needed to get back there for work after the meeting for another shift that evening. So we walked down Market Street together and as we walked, Jay explained that his work always begins on the train in the morning. Either on the train car or as soon as he makes it up to the street level, where he starts seeing his clients. There was an edge of exhaustion in his voice, but he admitted there are benefits of connecting for a conversation on the street, including

186. Through several compromises in Congress, the Act passed, bringing together two unlikely companions as key policy elements. On the one hand, it expanded the right to access health care on the basis of "risk-solidarity" and thus, introduced an idea akin to "We're all in this together." However, on the other hand, the Act was designed with a market-based approach to risk-solidarity, which emphasizes individual responsibility (Morone 2011).

opportunities to bring clients into the clinic. On the street he can get their friends and family to apply pressure. He explained, “Say Michael hasn’t been into the clinic in a while. I can tell his mom, or his auntie. I can catch them all together and let them know. Then I bet he’ll show up.”

As we continued our conversation, I realized Jay was playing an important role in supporting PrEP uptake, including by bringing patients into care, telling them about PrEP and ensuring they have access — usually through Medi-Cal, the state’s public insurance option. In fact, to bring people into the clinic and get them on PrEP, Jay tells me, “I walk the block.” He walks up to people, asks if they have Medi-Cal, and since most of them do he confidently tells them, “I can get you PrEP.”

A few weeks later Jay told me he was hosting an information session about PrEP at his clinic, so I attended. To get to the clinic door, I weave my way between open luggage bags full of watches, mobile phones and tangled electric cords. Men in sun glasses stand nearby. Drop-in hours for the clinic are officially closed, but Jay and a few other staff members hold the clinic open for the information session. When I enter the clinic lobby is beginning to fill. Most of the chairs are already taken. So I find a place in the hall, as people keep pushing in through the door. A little after 6 o’clock Jay enters the lobby to make an announcement. He acknowledges that there were in fact two events scheduled for that evening: the PrEP information session as well as an anger management seminar. He then tells everyone the anger management session has been cancelled because the facilitator could not make it, and encourages them to attend the information session about PrEP which “is a pill that allows you to prevent HIV.” Hearing this, some of the people in the lobby filter back out in the street, but the majority stay and on Jay’s instruction walk down the hall into the community room.

The community room is furnished with two couches, a dozen folding chairs, and a folding

table. As we all settled in, I find a seat next to a woman who I will call Robin. She was maybe 40 years old. She told me she heard about PrEP a few times a couple of years ago, but she assumed it would be too expensive for her to access. Jay handed out pink brochures about PrEP which the San Francisco AIDS Foundation constructed three years prior and I had seen around clinics for just as long. These brochures had been assembled to educate both prospective patients and providers about PrEP and were released alongside several public ad campaigns around the city – posted in municipal rail stations, across the sides of city buses, and on billboards. The Foundation also launched a website about "PrEP facts" which was designed with racially-conscious aesthetics, organized by 'risk group' and populated with the same information as the brochure. Yet, these messages had not reached Robin, or rather, she had seen some of the messages but knew PrEP was too expensive for her. "It was for rich white gay men," she had thought. However, that night when Jay assured her she would be able to access PrEP, the message resonated. She stayed for the two-hour long informational session to learn more.

From this first moment when Jay talked about walking the block to get people on PrEP, and Robin reflected about PrEP being for 'white gay men' we see that Truvada is racialized and knowing it is expensive deters people from trying to access it. For most any individual to understand the price he or she will have to pay to access PrEP involves far less knowledge about the product's price itself and much more about insurance plans, including how to interpret the stated benefits of the plan, and translate these benefits into pathways through which they themselves can access PrEP. These interpretations are intimidating, especially for those who are not accustomed to the 'joys of bureaucracy'.[187] And given this is the context in which one must access care, we can see how the use of an expensive medication may not be an effective way to

187.David Graeber details the 'joys of bureaucracy' in his work, *The Utopia of Rules.*

decrease health disparities. Certainly, in the United States, where health disparities are most closely associated with race and class, this claim has credence. As white gay men take up Truvada for PrEP in far greater numbers and at a more rapid pace than other "high risk" groups with higher HIV incidence rates, the truth of this claim is becoming more pronounced.

Shared Interests

Jay's information session involves PrEP education, HIV testing, and pizza. He starts to talk about how well PrEP works and answer questions about it. He gives everyone in the room a number. When their number was called they were told to follow him or a test counselor down the hall where they would talk about how they had been managing their sexual pleasure and take a test for HIV. In the meantime, they are offered educational materials about PrEP and pizza. As Robin continues reading the pink brochure to learn more "PrEP facts," she occasionally glances up at me, starting to form questions. "Do you know anything about this stuff?" she asks. I nod and smile. Jay has not introduced me yet. He was moving in and out of the room and I was there to observe, not educate. But she was onto me. As people shuffle around the room, returning from testing or to get another slice of pizza, another man hurries in. He stands out because he is white, and towing a rolling bag. He is maybe 50 years old. He sits on a large couch, next to a couple who had just returned from testing. On his arrival, Jay introduces this man and myself. "This is Ryan. He is from UCSF and he works on PrEP. And this is Kevin. He is from Gilead. He is here to talk to you about PrEP."

Kevin begins by saying he works for the company that makes Truvada, but he used to be a case manager in a local public health clinic. Kevin also explains what PrEP is, how it relates to post-exposure prophylaxis, and how each PrEP and PEP relate to treatment as prevention. He mentions some side effects from Truvada and how well it works as PrEP. He uses two percentages:

42% and 75%. 42% he says is the protective effect for "people with penises and people who had penises at birth" and 72% is the protective effect "for straight couples where one is HIV-positive."[188] Robin opens the brochure and flips to the page about how well PrEP works, cross-referencing the numbers on another information card Kevin has handed around, then she asks about the numbers. To answer her question, Kevin tells us all to pretend we were in one of the trials. Some of us received Truvada, and the other half received a little sugar pill. Among those who received Truvada, far fewer acquired HIV. Robin nods and replies, "Okay, so it works pretty well."

As others in the room began to ask questions, including about what else is involved in taking PrEP, like how often you need to see a doctor, and get tested for HIV, or how long you need to take PrEP for it to work, Robin searched for facts about side effects. She whispers questions to me and others near her before announcing, "I'm most worried about the side effects." Kevin responds by explaining that he was most concerned about side effects at first, too. He has seen a lot of the consequences of toxic HIV drugs throughout his career and in his personal life. So, he was skeptical about using one of these drugs for HIV prevention at first. But then he learned that Truvada has a relatively short half-life, meaning that when you stop taking the drug, the side effects go away. Indeed, the iPrEx and Partners trials offered favorable safety results, showing only minor bone mineral density loss, and some heightened creatinine levels, which could affect kidney

188. Kevin was referring to the results of two clinical trials that provided evidence Truvada could be efficacious for PrEP. One was known as "iPrEx" and the other, "Partners PrEP." iPrEx recruited nearly 2500 participants, all identifying as men or transgender women who have sex with men (MSM or TWSM). Each participant was randomly assigned to one of two study arms: one arm was offered Truvada, and the other received a placebo. Partners enrolled nearly 4800 couples, each comprising a mixed-status relationship, meaning one partner is HIV-positive and one is HIV-negative. In the Partners trial, there were three study arms: in one arm, HIV-negative partners received a placebo, meanwhile in the other two, the HIV-negative partner received PrEP, either as the combination tablet of tenofovir and emtracitabine, which we know as Truvada, or as tenofovir alone, one of the components of Truvada. Each trial ran for approximately three years. At the conclusion of the iPrEx trial, investigators observed HIV incidence was reduced by 44% in the experimental arm receiving Truvada relative to the control arm receiving placebo. In the Partners PrEP trial, HIV incidence was reduced by 75% for those receiving Truvada, and 67% for the participants receiving tenofovir.

function. The findings also built on previous evidence that Truvada has a relatively short half-life. "That's what sold me on PrEP," he explains, and notes, "this was long before I worked for Gilead – when I was still working in public health."

Examining this scene a diligent social scientist might read this encounter skeptically, as a typical pharmaceutical sales pitch wherein patient education is little more than a marketing ploy, especially as a representative of the pharmaceutical firm explains the science of PrEP to patients in the public health clinic, who are the potential consumers, and repeatedly establishes credibility through appeals to past work for the public interest. However, I suggest this scene offers additional insight about public-private relations, and I want to mark this moment as exceptional. Never before had I seen a Gilead representative enter a public clinic during my fieldwork. In the previous few years of PrEP implementation, local physicians and public health staff had taken on the responsibility of spreading the word about Truvada for PrEP around the city. The department of public health sponsored ad campaigns. The San Francisco AIDS Foundation wrote the PrEP facts brochure. In short, the public health department and a community-based organization had been translating knowledge about PrEP to people who might benefit from it for years. The PrEP navigator position itself developed through a public response to a lack of Gilead representatives selling the drug to potential consumers. However, Jay invited Kevin to the clinic that day. Indeed, the public called for the private interest to show up — to support PrEP uptake.

In this case Gilead's role in supporting PrEP uptake involves helping patients in a public sexual health clinic understand themselves as potential consumers. Though Jay had been promoting PrEP to client in his clinics for the past few years, Robin had never considered herself a potential consumer before. PrEP was for white gay men, she had thought. She needed assurance

that PrEP was for her too, which Kevin, a representative from Gilead was able to provide.

Invoking the Personal

When Kevin finished speaking, two newcomers to the session introduce themselves. One explains he came to the clinic to learn about PrEP. The other says, "I was excited to see you were having an information session about PrEP. I'm already on it. I just came here to spread the word." He says he wants to shout about it from the rooftops, so everyone in the Tenderloin knows what PrEP is. Robin stirs in her seat. Her attention is split between her brochure and this man, reflecting about his experience on PrEP. She interjects, "Can I ask you a personal question?" He indicates he is more than open to personal questions. Building slowly toward saying something, Robin turns to the next page of her PrEP facts brochure and says, "Now we're getting to the good stuff." She then asks, "Do I have to use a condom if I take this?" The man that takes PrEP defers to Kevin. Kevin explains, "Truvada protects you against HIV, but not other diseases – that's what condoms are for." And the man who takes PrEP follows by reflecting, "I'm asked this all the time. Some people assume I'm a total whore now because I take this little blue pill. I tell them it doesn't replace condoms. It's for extra protection. But let's be honest, who really likes condoms anyway?"

Unprompted, he continues, "I'm not even having sex right now, but I'm taking PrEP." As he speaks a man next to him offers quiet words of encouragement: "You might meet someone!" Robin smirks and adds, "You never know." He laughs, and quickly justifies his use of the drug even when he is not having sex. "You can't give me a logical reason not to," he says, almost challenging us to find one. Finally, he explains, "I have Medi-Cal. That pays for it. So, I'm just going to keep taking PrEP." As this man volunteers his experience with using PrEP, he embodies the tension between public and private interest, which ran through the information session. He

reads like a pharmaceutical sales representative who came to the clinic to educate others about this drug, but he says he voluntarily showed up to educate others in support of a public good. At least, he wanted others to know about PrEP, and understand they could leverage their public insurance to access it.

However, what strikes me most about this exchange between Robin and the man on PrEP is the way they invoke the personal, and how the personal concludes the conversation. Throughout the two-hour information session, no one had talked about sex except at this final point when Robin asked about condom use and the man on PrEP said he is not even having any sex. In the meantime they talked around sex. They intimated about it. They built up to it. They knew it was there, waiting to be talked about. This is the way they gave it meaning. Sex was made into something hidden that needed to be built up to. I contend that the way they built up to it and gave it meaning is an intimate process, which is key to bringing new patients into care.

Constructing the Continuum of Care

Before the next meeting one patient navigator who I will refer to as Molly invited me to her clinic to shadow during an appointment to start a new patient on PrEP — "a new PrEP start." Her clinic is in the middle of the campus of a large public hospital where rows of identical brick-clad wards line an asphalt lot, however her particular ward is surrounded by memorial gardens from the AIDS epidemic, which lead to the entryway. As I walk into the lobby and edge past a jumbled line of people waiting for same-day appointments I first find an elevator covered in an 'X' of caution tape. As I begin to look toward the one operable elevator, Molly greets me. We ascend to the clinic level together, and talk about the multiple research grant applications we are both juggling. Amid our rants and grumbles, she tells me the patient we are planning to see today, named Ron, has

rescheduled previous appointments to start PrEP six times. She raises her eye brows and tells me that he seems to lose his phone a lot.

Once in the clinic we move from the reception desk down the hallway to Molly's office. When she opens the door I am surprised to see a new computer and a second desk. Sitting at her new computer, Molly launches a medical record system, which displays information about all patients on PrEP in the clinics. The updated system utilizes *Qualitrics* software and populates in-take data to the *Salesforce* database displayed on the screen. Looking over the screen, she also explains, "We started a few research projects recently, including about an app for patient adherence, and another about online panel management, which includes several metrics, including for risk-assessment, adherence, and appointments, and allows you to track each over time."

Glancing over to the second desk where I am now sitting, Molly explains that the social workers and panel managers in the clinic have far too many patients, so the department made a few new hires recently, and one of them moved into her office. Though it is a small space, she assures me there would be room for herself, myself, and the patient. Plus, she had texted her new officemate earlier that morning to notify her she would have a patient in the office, and asked her to find another space to work that morning. Then Molly's phone rings and she begins negotiating a hiring process for a new PrEP navigator position. When she hangs up, she sighs and explains the pains of this hiring process which always includes a five-week delay because they want to hire an external person. She also emphasizes this is just one of several bureaucratic hurdles the clinic is managing to support PrEP care, and she concludes the physician she works with is "going to cry."

To build infrastructure in public health clinics, clinical staff work to bring patients into care

and provide PrEP. Simultaneously, they work to secure enough resources to accommodate as many patients as they can. This includes securing research grants, which make available funds to support the implementation of new technologies and allows the clinic to hire new personnel. However, once such grants are obtained, accommodating new technologies and personnel becomes its own kind of work, which includes finding them physical space in the clinic.

As Molly speaks, Ron walks past to the office door, comes back, stops, smiles and waves. Molly waves back and just as Ron walks toward the waiting room, the panel manager enters the office. Molly greets the panel manager, and the two talk through their new system for sharing the office.

> M: "Hi. Are you here today? Did you get my text?"
> Panel Manager: "No, I only have my personal phone with me today."
> M: "I have a patient this morning."
> Panel Manager: "I don't know where I would go. Could you use an exam room?"
> M: "I have to be online to work in the patient portal. I would have to move a lot of stuff.
> Panel Manger: "I don't know where I would go."
> M: I got moved out of here countless times when it was just me in here. I had to sit on the floor and work on my laptop."

As the panel manager retreats out of the office into the hall, Molly follows her. After fifteen minutes of searching for an open exam room, she returns to her office and explains to me that she threw a fit with the panel manager, so we can stay in the office for the appointment. Molly then returns to the waiting room and hands Ron an iPad. She asks him to read the questions on the screen and answer them honestly. She assures him she will return in a few minutes to collect the iPad.

While searching for Ron's record in the database, Molly explains how she met Ron.

> I met him in the waiting room one day. He usually comes with a female partner, who has been in care here for over ten years. They come during the women's drop-in clinic. I assumed he was positive and here for care, too. But a few months ago, we started some small talk and I discovered he has been accompanying his female partner, but not receiving care himself. I didn't know if he was negative or positive, but in our conversation, we

> started talking about PrEP, and he expressed interest. So, I invited him to come into the clinic sometime to learn more.

After reviewing his medical record, Molly moves to the waiting room, retrieves the iPad from Ron and tries to review the results, so she can begin the in-take appointment. But when she looks over the responses, she sees he has only responded to the first question about gender. He never clicked through to advance to the next question. So, she returns to the waiting room with the iPad in hand and encourages him to continue filling in the in-take survey. Ron explains a message popped up about a server error, then he was asked to give his labs, so he forgot. Molly hands Ron the iPad again.

The patient entering the clinical for PrEP, like the 'at risk' subject of the past three decades of HIV prevention, is expected to reveal significant information about his intimate life through confessional technologies. However, in clinical spaces that prescribe PrEP confessions are increasingly performed by interfacing with new digital technologies and software systems that record and track information about the subject. These technologies make possible the contiguous management of clinical data and thus reinforce the ideal of a 'continuum' for care. Yet, the actual use of these digital technologies contributes to discontinuities in the everyday provision of care.

Sitting back in her seat, Molly picks up the in-take form on her desk, writes the start time, and notes, "We're only 56 minutes late." She tells me she was assured Ron was next in-line for labs, "so he should be in here soon." Seconds later, a medical assistant stops by and clarifies, "There are actually two patients ahead of him for labs," implying it might take a little longer.

While Ron waits to complete his labs, Molly refreshes Ron's medical record in the Salesforce database, which receives results directly from the *Qualitrics* survey. Molly explains this data is automatically compared to the CDC guidelines that assess HIV risk and the appropriateness of prescribing PrEP and populates to his *Salesforce* profile. After a few refresh attempts, Ron's

results populate, and Molly begins interpreting the answers out loud to me:

> So, in the last six months, he's had three female partners that are positive, and four male partners that are negative, and six male partners with unknown HIV status. He uses condoms with some. Okay, he doesn't always use condoms. Wait, alright, overall, it looks like he's had more than 30 partners in the last six months, one quarter of them are positive, half don't know their status, and he often uses condoms for anal sex, but almost never for vaginal sex, and he has sex with some trans-women. In terms of substance use, he reported 25-35 alcoholic beverages per week, and cocaine use.

The practice of revealing hidden truths about the self, such as by talking about how one manages sexual pleasure and submitting to HIV tests, is essential to prescriptive practices — beginning with the initial visit for a PrEP prescription and continuing on a regular basis throughout one's PrEP care. And through the increasing use of digital technologies, the way such truth is interpreted has become at least partially automated.

Dr. B walks in. He happens to be on rounds today. We say hi. Molly summarizes Ron's risk profile. Dr. B concludes, "He sounds perfect for PrEP." So, Molly asks, "Do you have all you need to talk to him about PrEP?" Dr. B replies, "Yes, just remind me of the URL. And is he currently in care here?" Molly provides the URL and explains, "He goes to another public clinic, but he's not really in care there. He hops in and out."

When Ron returns, Molly starts the conversation with questions about coming to this clinic for care: "It looks like you go to another clinic now for care. Would you be okay to come here for PrEP?" When Ron answers, "Yes," she continues, "So would it also make sense for you to start coming here for your primary care? Would you be okay with that change?" Knowingly, Ron replies, "When things change, you have to change with them."

She continues, "Do you have a phone now?" Ron smiles, "No, I haven't had a phone for two weeks. But I contacted them about my number, and I'm going to change to get a new one." Molly clarifies, "You're going to get a new phone?"

R: No.
M: Will your phone number change?
R: No.
M: Okay, so I will be able to contact you on your new phone soon?
R: Yes.

Given that Molly had to reschedule Ron's appointment six times, now that he has presented in the clinic, Molly and Dr. B want to ensure he will stay in care. And since lapses in communication were one of the problems that led to rescheduling the current appointment so many times, Molly is very interested to know how she will be able to contact him. Molly is also interested in ensuring Rob will be able to adhere to the pharmaceutical regimen, which involves taking a pill every day.

M: Have you taken a daily medication before?
R: Yeah, antibiotics. I take two antibiotics every day.
M: Okay. How do you remember?
R: There are pills shaking in my pocket.
M: Would it be helpful if I told you about some of the ways other people remember to take PrEP every day? Some people keep them by their keys, or by their phone, and before they leave in the morning, they see the pills, and know they should take them.
R: That won't be the case for me. It wouldn't work. They'd get swiped.

Ron clarifies that he is living with a friend right now, sleeping on the couch, and sometimes other people are there, who might 'swipe' his pills. Molly opens a file drawer, pulls out a bag of egg-shaped pillboxes on key chains, and explains that these are helpful for storing pills. Ron smiles again, agrees to take one, and says, "I'll take them in the morning with breakfast. I'm always hungry in the morning. I always eat breakfast. And I always take my antibiotics. I'll just take this at the same time."

"Great," Molly replies, "And knowing when you're going to take it is really important because you need to take the pill consistently for it to reach protective levels." Molly also tells Ron that establishing protective levels varies depending on the body parts he is using for sex, and she lays out the different timelines: "For bottoming – that is, if a man is using his penis to penetrate

your anus – it takes one week to reach protective levels. For topping – if you're using your penis to penetrate a vagina or anus – it takes three weeks." And she continues, "In the meantime, using condoms is a good idea, and even after those three weeks, condoms can still be really great because PrEP doesn't prevent STIs or pregnancy." Pointing to the corner of her desk, where there is a large plastic jar full of condoms, Molly asks, "Do you want some condoms?" Ron looks down at his coat, clutches the pocket, and shakes it. Molly confirms, "They're in there? Okay!"

"So, how long should I take it?" Ron asks. "Great question," Molly replies. "So, if you're having sex with people that are positive, or if you don't know their status, it's a good idea to take PrEP. If you start having sex only with people who are negative, you might consider not taking PrEP." Ron nods and confirms, "So I should tell you guys where I'm at with sex." And Molly replies, "That would be great, but ultimately, it's your body, and your choice."

As Molly moves down the list of standard in-take questions for a new PrEP start, Ron replies to affirm each of the ways he is prepared to be a good PrEP patient as a new way of managing his sexual pleasure. He knows how to take pills because he is accustomed to taking antibiotics to treat sexually transmitted infections. He knows where to find condoms. He already has some in his pocket. And he knows that he will be expected to reveal truth about his sex to clinic staff.

As Ron speaks, we hear a knock on the office door. Molly maintains eye contact with Ron as she rises from her seat, and when she opens the door, the panel manager asserts, "I need to get my food." She makes her way past Ron and toward her desk where I am sitting, picks up her Subway sandwich, turns and leaves. Molly closes the door and continues the appointment.

As the appointment approaches its end, Molly explains there are some side effects and common symptoms, including upset stomach and Ron asks, "So, can I take it with food?" Molly

replies, “Yes, and it sounds like you have a good system for remembering how you will take PrEP every morning with breakfast.” Ron nods and explains, “Yes, and if I skip breakfast, I can take them with lunch. My first meal of the day – I’ll take it with my first meal of the day.” And after a brief pause, he probes, “Speaking of food, can I get a voucher?” Molly opens her desk drawer again, and glances into it. She doesn’t have any vouchers for food. But she is hoping she can offer him something. “Unfortunately, we’re not as well supplied as the other program. We just have candy and condoms.”

Ron persists, “Could you ask someone else? Maybe Dr. B has some.” Molly agrees, “I promise I’ll ask and try to find you a voucher.” Still disappointed, but holding onto the hope that Molly might find a voucher for him, Ron follows Molly to the waiting room, where Dr. B will soon greet him. Molly returns to her office, looks at me, and explains, “Our funding works differently here. We don’t have as many bells and whistles as the programs for positive people. So this comes up a lot, especially for people who have positive partners.” When Dr. B returns to the office, he echoes Ron’s desire for a food voucher.

In the process of building infrastructure to manage pleasure, candy and condoms supplement care, and it is easier to write a prescription for a high-cost medication than it is to find a voucher for food. So, sometimes providing care involves leveraging the resources of other programs. After searching clinic rooms for a few minutes, Molly returns to report, “I got one!” Relieved, Dr. B thanks Molly, and concludes, “He is going to be thrilled. Thank you.”

Responsibility

After attending several regular meetings with PrEP benefit navigators, I was invited to one of their ‘meet ups’ at a local restaurant. When I walked in I found a bar full of them – some who were

familiar from our meetings, some less so. And as I joined the small swarm of navigators huddling together in line for drinks, I was quickly greeted by a woman I had not met before. She introduced herself as Michelle, and I asked her how she is connected to the group. She explained that she is involved in PrEP implementation efforts around the west coast, mostly in large cities in California and Washington, but also some smaller cities, such as in Hawai'i. She travels to places where PrEP is being incorporated in health departments to conduct trainings and host forums with local experts about best practices for PrEP implementation. Fascinated with the scope of responsibilities, I ask her who she was working for, and I learned Michelle is a community research specialist for Gilead.

After we all had drinks in hand we were invited to the private dining room downstairs, where we sat around a long communal table, so we could all see the screen where presentations would be projected. Michelle led the conversation, instructing each navigator to introduce the clinic they are representing by describing the patient volume and demographic makeup as well as the current challenges to PrEP care. As they proceeded, two topics were repeated. One was about the high costs of PrEP, including the cost of the medication and additional associated costs for managing PrEP care, such as the necessary lab work for ongoing monitoring of side effects and testing for sexually transmitted infections, including HIV. To address the topic of high costs, Michelle ensured all navigators knew how to link patients to Gilead's advancing access program. The program could not cover additional associated costs, such as for necessary lab work and clinical staff, but the program would cover the costs of the drug.

The second was about the need for new prescription guidelines, both for women and people who inject drugs. Amid frenzied conversation about facts from ongoing research studies, Michelle noted the CDC had no budget to update the guidelines for prescribing PrEP to women. In reply, the navigator I was sitting next to suggested we should "Make Gilead pay for it." Michelle

wrote the suggestion in her notebook. I added, "It's always puzzled me why the CDC guidelines have not included recommendations for people who inject drugs. The Bangkok tenofovir study showed efficacy, yet the results are not represented in the guidelines." Following on the previous suggestion to "Make Gilead pay for it" I asked Michelle why Gilead had not applied for commercialization based on the Bangkok study data. The table full of navigators nodded their heads. In response, Michelle contended it was not Gilead's responsibility. Since the trial had been conducted using generics, which Gilead supplied to the state, the state was in turn responsible for making the drug available, she contended. Troubled by her logic, I replied, "That's not how that works." What did donating drugs have to do with it? Gilead did not sponsor any of the PrEP trials that led to commercial approval in the US. They were sponsored by the National Institutes of Health and the Gates Foundation. Gilead was not responsible for managing the trials either. Investigators at public universities around the world ran the trials. Gilead only provided the drug, one that the company had been manufacturing for another use for nearly a decade. Visibly annoyed, she moved on.

Here was Michelle, representing the pharmaceutical firm, and ushering public health employees through presentations about implementation while buying us all drinks and dinner and yet dismissing the idea that Gilead might have a role to play in implementation. It struck me as strange. It struck others as irresponsible. So we were interested in continuing the conversation about the responsibility of the pharmaceutical firm to support PrEP implementation. Of course, this conversation among two dozen PrEP navigators, one Gilead representative and myself in a restaurant in San Francisco was not going to influence the firm's policy or strategy. But it was a moment when we were enacting what one might call the "micro-politics" which define the dynamics between the staff of the department of public health and the pharmaceutical firm.

Indeed, these are micro-politics in the sense that they represent larger tensions in the relationship between the public organization and the private interest. And these micro-politics are a part of the everyday work that public health staff do, especially while interfacing with the private interest. This is not the work that will bring a new drug to market, nor the conversation that will open access to Truvada for decades to come, but it is a moment between those events in which public heath employees call for the private interest to take responsibility for building infrastructure.

In this sense, this scene continues to show how public and private interests become interwoven and interdependent in the political economy of health. Echoing the earliest moments in the HIV treatment market, it continues to display how private interests are called in to provide public goods. Drawing from a long history in which the public and private have mixed, it displays how public health has become dependent on the private interest, especially in a health system where resources are scarce. It is indicative of a public health infrastructure that has been left to function in repurposed buildings, where broken elevators impede access, and public health personnel work to support the rollout of private products. The suggestion to "make Gilead pay for it" comes from the very same public health personnel who apply for national research grants to keep pace with patient volume, who are given the resources to hand a prospective PrEP patient an iPad, write a prescription for a high-cost medication, and track patient outcomes in a Salesforce database, but must beg and steal to secure a food voucher for the same patient. These are the same benefit navigators that invite Gilead employees into public health clinics. These are the ways public health employees have become accustomed to inviting the private interest to show up.

Conclusion

In this dissertation I have explored several elements of innovation within the political economy of health by tracing the development, commercialization and implementation of the first commercial drug product for HIV prevention. I have also documented the rise of an increasingly neoliberal form of governance through which public and private interests have become intertwined and inseparable, especially in the market for antiretroviral drugs. In the first chapter I showed how public interests (of the state and its citizen) and private interests (of the pharmaceutical industry) began to be stitched together through the moral imperative to save life, as AIDS activists demanded regulators expedite the commercialization of effective treatments during the early years of the epidemic, including by loosening regulations on clinical research for drug development. Whereas previous reform efforts led by free-marketers had been dismissed as neoliberal speculation, when people affected by the virus themselves as well as their friends, family and lovers critiqued the government's paternalistic practices, they achieved reform, and thus, realized the neoliberal dream. As a result, the size and value of the HIV treatment market expanded rapidly as pharmaceutical companies, venture capital firms, and public research universities rushed in, capitalizing on their shared interests in developing antiretroviral drugs. However over the following years, as activist groups and civil society continued to work to ensure all people living with HIV could access treatment, they amended the value of ARV products. Most significant commercial activity soon declined. Yet one pharmaceutical firm continued investing in the market, and began to assert its role within public health infrastructures around the world. Today, that same firm, Gilead Sciences,

owns more than half of the global market for HIV treatment and holds a monopoly in the market for HIV prevention, and continues to strengthen its relationships with public health — no longer only developing drugs, but also increasingly taking responsibility for clinical care.

In the second chapter I detailed the ways intimacy was made into a site of research and intervention to prevent HIV. Taking aim at the intimate lives of people 'at risk' for HIV, the field of HIV prevention focused on the management of sexual pleasure to prevent viral acquisition, including by encouraging 'at risk' subjects to discipline themselves to have 'safe' sex. At the same time, investigators in the field collected intimate information about the 'at risk' individual and filled research journals with findings about who is having sex with who, and how. Indeed, for decades the field has disciplined the individual subject to reveal hidden truths about the self, as a kind of confessional practice, in ways that supported research and interventions for HIV prevention. In more recent years investigators also utilized these confessional technologies within clinical research about biomedical prevention methods, including to establish evidence that Truvada could be effectively used to prevent HIV. Reviewing this history of discipline, especially in clinical research for PrEP, I have argued that the intimate life of the 'at risk' subject made PrEP possible. Indeed, the very practices that constitute the 'inner' self of the human subject, especially the confession of hidden truths about the self, were rendered into key resources for the field of HIV prevention and clinical research for drug development.

Thus, I have also shown how intimacy is integral to innovation. For any diligent social scientist, this observation might set the stage for several further claims about the ways subjectivity is crafted within the political economy of health, however I have intentionally resisted extending this analysis in some predictable directions. For example, I make no claims about exploitation nor commodification, which could extend from the argument I have presented, and would suggest the

subject is shaped by the machinery of the market. Several scholars have made such claims about exploitation within human subject participation in clinical research, which I do not echo here. Rather I emphasize how our relation with ourselves and others makes innovation possible — not only through the processes of experimental labor, but also through the practices of intimacy itself. Yet, I cannot avoid the fact that capitalism is the dominant social form of our contemporary moment and thus overdetermines all other strata of social life, as Louis Althusser has asserted. So I work within Althusser's formulation of capitalism as a context, and show how subjectivity plays a role within political economy — or, more specifically, how intimacy is integral to innovation. Thus, I argue for the productive power of the intimate. From this perspective, my intention is to highlight how we get caught up within dialectical materialism because the very practices through which we come to understand our selves, and manage our pleasures also provide the raw material necessary for pharmaceutical innovation.

In the third chapter I extended these observations to show how the goal of managing sexual pleasure at the population level has been embedded within the scientific and economic calculi of public health research and clinical care, including in ways that allow pharmaceutical value to take root. These calculations produce what Joe Dumit would call "surplus health" because they indicate that a significant number of patients should be taking "unnecessary treatment" and thus the value of the medication will grow far beyond its clinical effectiveness. Indeed, according to these calculations, PrEP should be prescribed to far more people than need it to prevent HIV. Thus I use Dumit's analytic as a starting point for understanding how the market size for PrEP and its value were first estimated, and to build from Dumit's observations, I examine how calculations about the number needed to treat (NNT) vary according to assumptions about the management of sexual pleasure. In particular, I review studies about PrEP implementation wherein investigators calibrate

measures of efficacy based on different means of pursuing pleasure in which the NNT for PrEP and therefore also the value of the product are determined according to risky sex — be it 'high' or 'low'. So, whereas Dumit argues that surplus health is determined by pharmaceutical firms that seek to grow value and markets by designing trials in ways that produce larger NNTs, research about PrEP implementation shows market size and value are also built into the process of translation between clinical research and public health, and determined through estimates about intimacy. Thus, the value of PrEP grows not only through the potential for illness but also the potential for pleasure.

In the fourth chapter, I entered public clinics and hospitals managing PrEP implementation, wherein techniques for managing sexual pleasure center on prescription and consumption, and continued teasing out the tensions between public and private entities that support the delivery of PrEP care. For example, I pointed to the many ways that the rollout of a private product requires public health infrastructure, and conversely, how private entities have been assuming increasingly prominent roles in the practice of public health. In contrast to the first chapter in which I showed how the interests of public and private entities have been stitched together through the shared visions of a social good, especially the moral imperative to save life, in this chapter I traced ways resources are increasingly concentrated to support solutions with measurable outcomes, such that the prescription of a pharmaceutical to prevent HIV is paired with the use of digital tracking technologies. In these clinical spaces, as digital economies are leveraged to track the prescription of pharmaceutical technologies, confessions are solicited on iPads that populate to electronic medical records. In this process, truths about sex and sexuality that were once thought to be specific to the relation between the physician and the patient, or the investigator and the participant, have begun to accumulate as clinical data to be distributed across research networks.

In all four chapters, I have aimed to display how intimacy has affected the antiretroviral market, and supported the development and implementation of this innovation. Along the way I traced the rise of a neoliberal form of governance, wherein public and private interests have become inseparable, each creating value by saving life and securing health as well as offering new techniques and tools with which to manage sexual pleasure. Thus, I attempted to offer an ethnographic account of a pharmaceutical market that is equal parts political economic critique and exploration of subjectivity. By embedding techniques of discipline within systems for managing the health of the population and developing pharmaceutical interventions, I intend to show how subjective formations fuel political economy – how intimacy is key to innovation.

Though this ethnography is particular to the product life of Truvada it is also indicative of a larger relation between intimacy and innovation — between pleasure and political economy. The arguments I have presented here may be extended to explore several further ways that intimacy drives industry, including in economies that reach far beyond medicine. Social media could be said to run on intimacy as well. I open Facebook to say something to those I know, to see what my friends are doing — to like, to love, to make a sad face. Every expression, every interaction feeds the algorithm. In this sense social media is not so different from clinical trial participation, which makes drug development possible. They are both contexts in which our intimate information becomes material that the market depends on. However, I maintain that the drive to keep people alive through biomedical interventions is a more fundamental expression of our attachments, and so as I continue this research, I will continue inquiry about intimacy and biomedical innovation.

Certainly, there are also opportunities to bring this research into closer conversation with other scholarly work about biomedical technologies, which enliven common questions about prevention and sex. For example, this work could extend other scholarly work about the birth

control pill, including through a discussion about the ways that PrEP opens a new space for dialogue between gay men and physicians about sexual health, much like the pill did for women around contraception. This dissertation could also point to more similarities with social science research concerning breast cancer and cervical cancer, wherein subjectivities take form through discipline, and altruistic ideals drive clinical trial participation. The specific history of PrEP also shares much common ground with treatments for Hepatitis C, including the same pharmaceutical manufacturer and similar notions of 'safe' and 'risky' sex. So, while my claims are specific to the social and historical trajectory of a single biomedical technology for the prevention of HIV, they may carry significance well beyond the domains I have detailed.

This research also opens several opportunities for the social sciences of medicine to explore additional theoretical trajectories in economic sociology about the way demand drives industry, such as represented by the work of Werner Sombart (1967) in which he argues the demand for luxury goods motivates the circulation of valuables and influences long-term shifts in commodity production.[189] During the nexus of early capitalism in Europe – a period between the early 14th century and the late 18th century – trade, industry and finance greatly expands, and the principal cause of this expansion, according to Sombart, was the demand for luxury goods, primarily on the part of the nouveaux riches, the courts, and the aristocracy. To meet this demand required a manufacturing infrastructure with multi-level production processes, wherein primary processes produce goods, and those goods are used in secondary and tertiary processes that produce finer goods. For example, "the manufacture of silk looms supports silk-weaving centers, which in turn

[189] Though Sombart has been criticized for methodological deficiencies and controversial claims, this set of points about demand and its effects are considered generalizable, form the foundation of his arguments about the origins of occidental capitalism, which offer an alternative to the Marxian and Weberian arguments, and have been taken up by others, such as Arjun Appadurai in his influential work, The Social Life of Things.

support the creation of luxury furnishings and clothing" and "the sawmill produces wood that is critical to the production of fine cabinets" (Sombart 1967: 165).[190] In the work, there is a clear argument about the demand-side of economics, which may best be coupled with supply-side analytics that scholars in the social sciences of medicine have more commonly used in ethnographies of the pharmaceutical industry. Indeed, I contend we need inquiry that examines both the exploitative practices of labor *and* the intimate desires that drive demand, so that we can show how each depends on the other. From this perspective, we can better understand how we create the conditions for our own exploitation.

I also have an aspiration to extend inquiry by William Pietz, who outlines an analytic tendency within social science scholarship to rely on theories of fetishism, which position the human body in relation to material objects, and further, claim the body is subjugated by material entities. For example, Marxist theorists claim personal activity is directed by the impersonal logic of abstracted institutional relations, an approach found in the very order of the argumentation, which positions the market as the determining structure in social production, and therefore, also orders personal relations, and determines consciousness about the 'natural value' of social objects. In these theories, the material fetish is shown to have "power over the desires, actions, health, and self-identity of individuals whose personhood is conceived as inseparable from their bodies" (10).

Pietz takes issue with the analytic tendency toward fetishism in social science scholarship and aims to reverse the order of relations between the self and the material object. In particular, he examines how this object "evokes an intensely personal response from individuals" (11), which

190. Of course, such goods rely on particular resources, and when those resources are exhausted, the demand for other resources increases. For instance, "when timber is exhausted, coal comes to be in great demand for the glass industry" (*ibid* 165). And as demand shifts, economic strategies produce unexpected outcomes. Though iron foundries may have been created to meet the demands of industry, iron foundries also "provide the pipes critical for the fountains of Versailles" (*ibid* 166).

he terms “the crisis moment,” and he emphasizes how this crisis moment is experienced in a movement that begins ‘inside’ one’s impassioned body and moves ‘out’ into a material object. In the process, the crisis moment fixes the life of the self and that of the outside world, instills it in personal memory, and mounts “a peculiar power to move one profoundly” (12). With this move, it may seem Pietz is attempting to liberate the subject – to show that it is the self that bestows the power of the fetish within the object, and thus, like the organic intellectual Marx describes, the subject has the capacity to overcome the illusion of fetishism. However, he also explains that the crisis moment lacks coherence, and therefore, has no formal code to be translated for any means of communication or applied to any established register of value. And “because of this degradation from any recognizable value code,” a crisis moment garners “infinite value” as it expresses “the sheer incommensurable togetherness” (12) of the personal self and the material world. That is, he does not offer a way to liberate the subject, but he suggests the subject and the object are on the same plane of relations. He argues materialism and subjectivity have become inextricably linked.

These arguments by Pietz resonate with my own. For example, as I have argued that intimacy makes PrEP possible through the economics of supply and demand, I have attempted to enliven the human elements of political economy. I have argued that clinical research for drug development functions not only through labor, but also intimacy. I have also shown how pleasure motivates consumption. From each side of the political economy machine, I have shown how the intimate drives innovation. Yet, I recognize that intimacy also depends on innovation. After decades of managing sexual pleasure, the pharmaceutical object liberated the subject from a disciplined sexuality. Thus, the technological also opened new horizons for the human. So, the two influence each other.

In this sense my arguments about the relation between intimacy and innovation also

resemble those offered by Chandra Mukerji, who observes that taste, demand and fashion are at the heart of capital, and to best understand modern Western thought and practice, we must recognize the role of materialism, and specifically, the role of the object.[191] Indeed, "The heart of capitalism and materialism alike lies in the shape of objects – in pens, books, chairs, and tables, cities and fields, warships and satellites" in which we have embedded our greatest theories and dreams, and with which we pursue "today's pleasures."[192] Furthermore, Mukerji observes, it is the proliferation of objects of all kinds, many of them startlingly novel, that sets the context for the establishment of new and elaborate systems of thought. Thus, material culture functions through the ever-accumulating output of objects, and this form of accumulation has generated a dialectic in which material things alter consciousness and physical reality, meanwhile consciousness results in further transformations of material culture.[193]

These scholars offer rich observations that may guide future ethnographic inquiry about the biomedical prevention of HIV. Following Sombart, we might ask what ties the sensual sensibilities of the 'at risk' subject to the demand for increasingly finer pharmaceutical goods? Following Mukerji, how does pharmaceutical production, like capitalism more generally, function through the ever-accumulating output of objects? Following Pietz, how might the 'crisis' moment generate "infinite value" and expresses "the sheer incommensurable togetherness" (12) of the personal self and the material world?

In addition to exploring these theoretical directions, there are also several emergent opportunities trace how PrEP is moving through different spaces, including across national

191. While Baudrillard observed the object emerged with the theoretical formulation of the Bauhaus (Baudrillard 1981: 185), Mukerji (1983) traces the emergence of the object to the Renaissance.
192. Mukerji 1983: 261
193. Mukerji presents this argument through a discussion of the calico connection between England and India in the 17th century, Mukerji further provides a case study of the complex links between trade, fashion, sumptuary law, and technology (Mukerji 1983: 166-209).

borders, in different bodies, and emerging online, while also taking new forms, as new PrEP products move through the research and development pipeline. First by continuing to follow the implementation of Truvada for PrEP around the globe will provide important perspective for this research because access looks very different in other countries. Though the FDA approved Truvada for PrEP in the United States in 2012, the European Medicines Association waited until 2016 to approve the intervention, and even two years after approval, most European countries have yet to make the drug available. Meanwhile, implementation is further fragmented throughout Asia, Africa, and Latin America. Behind this imbalance in implementation is a simple fact: the U.S. FDA does not account for drug costs. The FDA approves drug application based on evidence of safety and efficacy alone. Meanwhile, other agencies responsible for the regulation of commercial pharmaceuticals, such as the EMA, include cost within their regulatory calculus. However, momentum is mounting in many spaces. For example, after considerable pressure from local activists in the UK, the National Health System recently approved the first PrEP demonstration project. Meanwhile, with the support of state governments and American research universities, additional demonstration projects are beginning around the globe. And in many geographic spaces where implementation is still lacking, many consumers are turning to the Internet to access PrEP. To support global access to PrEP, grass-roots movements modeled after Project Inform and ACTUP have moved online, where they have made generic versions of Truvada available for anyone to purchase. As Truvada and its generic equivalents move across borders and into bodies, there will be rich opportunities to examine how the history of the antiretroviral market, including the licensing deals Gilead made with generic manufacturers and the moral imperative to get drugs into bodies, continue to influence PrEP implementation today.

At the same time as I monitor new developments in global implementation of and access

to PrEP, I will also evaluate how several more HIV prevention methods and technologies are being developed and implemented. One such method utilizes Truvada for 'event-based dosing.' While the FDA approved Truvada for PrEP based on a regimen of daily adherence, subsequent studies offered evidence that an "on-demand" or "event-based" dosing regimen is also safe and efficacious method to prevent HIV. This dosing regimen is focused on the "event" of the sexual encounter and instructs that a patient take 2 tablets between 2 and 24 hours before the sexual encounter and another two in the 48 hours after. On-demand dosing thus involves a greater level of prediction than the daily regimen, which prepares the patient for sex at any time. The patient who takes PrEP on-demand must envision the event before it happens. In this process one's intimate future must be predicted.

There are also several new technologies that utilize many different pharmaceutical compounds and rely on diverse delivery systems to get the drug into the body. These new technologies are being developed following findings that one of the active pharmaceutical ingredients in Truvada establishes a reservoir in the rectum, so it has the most direct prophylactic effect for the receptive partner during anal sex, meanwhile it does not work as well for vaginal, urethral or blood-to-blood exposure. Indeed, the efficacy of PrEP depends on the specific biology of the consumer and the kind of sex one has. Recognizing how such a specific biological aspect of sex is affecting the efficacy of the pharmaceutical intervention, current clinical research trials are evaluating potential PrEP products that utilize a wide array of pharmaceutical compounds[194] and new delivery systems to get drugs into bodies, including vaginal gels, rings, and films, rectal gels, nano-fiber, and long-acting injectable solutions. Indeed, this next generation of PrEP technologies accounts specifically for the timing and biology of intimacy, and thus opens additional

194. These pharmaceutical compounds include a new formulation of tenofovir (TFV), dapivirine (DAP), darunavir (DAR), maraviroc (MVA), griffithsin (GRF), ripilvirine, and vicriviroc.

opportunities to examine the role of intimacy in innovation.

Meanwhile, trials testing these potential new PrEP products are sponsored by several global health organizations[195] as well as pharmaceutical and medical devices firms[196] and therefore will be important sites to examine the ongoing role of public and private entities in the market for antiretroviral drugs. For example, the International Partnership for Micobicides (IPM) is sponsoring 11 trials, the greatest number among any sponsor in this space. Meanwhile, CONRAD (a partnership funded primarily by the CDC and USAID), and the Population Council, which is backed by numerous governments, governmental agencies, multi-lateral organizations, and non-governmental organizations, are each sponsoring 5 trials.[197] And though strategic partnerships sponsor the greatest number of all trials for future PrEP products, the largest pharmaceutical firms vying for space in this market, namely Janssen, GSK and ViiV, sponsor half of the phase-2 trials. Thus, the market, in which Gilead has enjoyed a temporary monopoly, is turning competitive, as public and private organizations race to develop new PrEP products.

In short, the market for HIV prevention is transforming from monopolized to competitive. The single product I have studied will soon be one of many. Taking one pill per day is being augmented by predictive dosing. And oral tablets are being supplemented with more intimate applications. For these many reasons, this market will be a productive site to examine the ever-accumulating output of material objects, as the demands of intimacy continue to fuel industry. Thus, I suggest the future of PrEP will be determined through processes of *intimate innovation*.

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195. The global health organizations sponsoring ongoing PrEP trials include the Albert Einstein Foundation, Amsterdam Institute for Global Health and Development, Gates Foundation, International Partnership for Microbicides (IPM), Mintaka Foundation RTI International, Population Council, USAID and the U.S. Centers for Disease Control and Prevention (CDC),

196. These pharmaceutical and medical devices firms are TaiMed Biologics, ImQuest Biosciences, Janssen Pharmaceutica, GlaoxoSmithKline (GSK), and ViiV Healthcare.

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