Published in final edited form as:
AIDS Behav. 2014 February ; 18(2): 241–249. doi:10.1007/s10461-013-0498-9.

Could FDA approval of pre-exposure prophylaxis make a difference? A qualitative study of PrEP acceptability and FDA perceptions among men who have sex with men

Kristen Underhill[1], **Kathleen M. Morrow**[2], **Don Operario**[3], and **Kenneth H. Mayer**[4]

[1]Yale Law School/Yale Center for Interdisciplinary Research on AIDS, Yale University, New Haven, CT

[2]Centers for Behavioral & Preventive Medicine, the Miriam Hospital, Providence, RI

[3]Department of Community Health, Brown University, Providence, RI

[4]The Fenway Institute, Fenway Health, Boston, MA

Abstract

The FDA has approved tenofovir-emtricitabine for use as HIV pre-exposure prophylaxis, but it is unknown how approval may affect PrEP acceptability among US men who have sex with men. We conducted 8 focus groups among 38 Rhode Island MSM, including 3 groups among 16 male sex workers and 5 groups among 22 men in the general MSM community. Participants reported wide-ranging beliefs regarding consequences and meanings of FDA approval. Some participants would not use PrEP without approval, while others perceived approval as irrelevant or less significant than other sources of information. Our results suggest that FDA approval sends a signal that directly shapes PrEP acceptability among some MSM, while indirect influences of approval may affect uptake by others. Efforts to educate MSM about PrEP can increase acceptability by incorporating information about FDA approval, and outreach strategies should consider how this information may factor into personal decisions about PrEP use.

Keywords

Antiretroviral pre-exposure prophylaxis; HIV prevention; men who have sex with men; FDA; sex workers

INTRODUCTION

In July 2012, the US Food and Drug Administration approved tenofovir-emtricitabine (TDF-FTC) for use as pre-exposure prophylaxis for preventing HIV (1). The approved indication extends to all adults at high risk for HIV, and PrEP has been especially anticipated as a new strategy for men who have sex with men (MSM). MSM bear a large proportion of new US HIV infections (2), and prior research among US MSM reflects willingness to use oral PrEP (3-11). In-depth qualitative study is needed to understand factors that inform PrEP

Corresponding author and address for reprints, Kristen Underhill, D.Phil., J.D., Yale Law School / Yale Center for Interdisciplinary Research on AIDS, Yale University, PO Box 208215, New Haven, CT 06520, kristen.underhill@yale.edu, Tel. 401-484-8639, FAX 203-295-8182.

All authors contributed to the design of this study. KU and KMM collaborated on participant recruitment and implementation of study procedures. KU led focus group discussions. All authors contributed to data analyses and the preparation of this manuscript.

Conflicts of interest: No author has a conflict of interest to declare.

acceptability, and no study has yet investigated how FDA approval may affect willingness to use PrEP.

The views of MSM regarding the importance of FDA approval may differ from the views of the general population for several reasons. The MSM community has a decades-long history of activism and advocacy in HIV/AIDS-related issues, and many MSM may have been involved in prior efforts to influence FDA policy and practice regarding drugs for HIV treatment. These efforts were at times highly critical of the FDA (12, 13), particularly of the pace of drug approval decisions, and MSM today may still experience the legacy of these tensions. The views of MSM regarding the importance of FDA approval may also be shaped by the FDA's continued policy decision to bar MSM from donating blood. Some have criticized this policy as discriminatory toward MSM (14-16), and we wondered whether MSM who agree with this criticism may have more negative views of the FDA and the importance of drug approval.

Within the population of MSM, we were also interested in the views of men who engage in sex work. Male sex workers experience a high prevalence of substance use disorders (17-20), including the misuse of prescription drug products, and little is known regarding how the use of illegal substances or misuse of prescriptions may influence attitudes toward prescription drug oversight. Sex work is also illegal in most US jurisdictions, including Rhode Island, which recently closed a legal loophole that had permitted indoor prostitution (21, 22). Sex workers may have negative histories of legal involvement or experiences of violence (23-26), which may lead to mistrust of law enforcement and local governmental institutions. It is unknown, however, whether these experiences may influence attitudes toward other governmental entities such as the FDA.

We used a series of focus groups to understand attitudes among MSM regarding PrEP acceptability, including how FDA approval of TDF-FTC may influence willingness to use PrEP. Subsequent analyses of focus group data will focus on other factors influencing PrEP acceptability, attitudes toward risk compensation, and perceptions of PrEP efficacy. Given the potential influences of HIV activism history, perceived discrimination by the FDA, and experiences related to sex work, we expected that the MSM in our sample may have negative or conflicting views of the importance of FDA approval for using PrEP.

METHODS

We conducted 8 focus groups during February-June 2012 among MSM in Providence, RI. Each group enrolled 4-6 English-speaking males aged 18 and older, who self-reported negative or unknown HIV status and unprotected anal sex (receptive or insertive) within the last 6 months with a male partner of positive or unknown HIV status. Recruitment consisted of outreach and advertising in clubs, bars, entertainment venues, and sex work venues serving MSM, as well as advertisements in local media and websites. We also worked with community partners to recruit a subsample of MSM engaged in sex work; although several men in the sex work sample did not report engaging in transactional sex on our self-administered written questionnaire, all of these participants verbally self-disclosed having engaged in sex work during the focus group discussion.

All participants provided written informed consent before any data were collected. The focus group was preceded by a short written demographic questionnaire to obtain data on participant characteristics and key HIV risk behaviors. Two facilitators then led discussions following a semi-structured focus group agenda, which explored participants' prior knowledge of biomedical HIV prevention, willingness to use PrEP, attitudes regarding risk compensation behavior, and interpretations of messages about drug efficacy. Specific probe

questions included participants' knowledge, attitudes and beliefs regarding FDA approval of PrEP. One facilitator (KU) was the primary discussion leader, and the other prompted follow-up questions and took notes on group dynamics.

During group discussions, facilitators provided participants with a description of PrEP, including trial findings, side effects, adherence and HIV testing requirements, and the possibility of secondary resistance. Facilitators informed participants that the FDA had previously approved TDF-FTC for *treating* HIV, that the FDA was considering approving (but had not yet approved) TDF-FTC for *preventing* HIV, and that physicians could prescribe TDF-FTC off-label as PrEP without FDA approval. The final group took place several weeks before the FDA issued its approval of TDF-FTC for a PrEP indication. Groups separately discussed PrEP-related stigma and prior impressions of antiretroviral drug toxicity, but discussions did not specifically probe how these beliefs related to participants' FDA-related attitudes. Discussions were recorded and transcribed. We analyzed data using a framework matrix approach, which organizes themes for each focus group in a coding matrix (27). All procedures were approved by the Yale Human Subjects Committee and the Miriam Hospital IRB.

RESULTS

Participants were 38 MSM (Table 1); three groups (n=16) were designed to sample street-based male sex workers, and five (n=22) sampled the general MSM population. A comparison of group characteristics consistently demonstrates greater disadvantage and HIV risk among the sex work sample; men in the sex work groups had fewer years of education, greater unemployment, lower incomes, more homelessness, and less access to health insurance. Consistent with other analyses of male sex workers (18, 28), we found that this group was less likely than the general sample of MSM to identify as gay, and more likely to report having had both male and female sexual partners in the past 6 months. Men in the sex work sample also reported more sexual partners and anal sex partners of unknown HIV status, they were more likely to report "never" using condoms with anal sex partners of unknown HIV status, and they were more likely to report recent forced sex. Although all men in the sex work groups verbally disclosed having engaged in recent sex work, it is interesting to note that 23% of the men in the general MSM groups also reported having exchanged money, drugs, or other goods for sex. The high proportion of men in the general MSM sample reporting disability or unemployment may also reflect a particularly disadvantaged segment of the population, and the overall sample was more likely to identify as bisexual than gay. These characteristics may limit generalizability in other settings.

In both types of groups, participants reported limited prior knowledge and no prior use of PrEP; 2 participants in the general MSM groups reported prior use of antiretroviral post-exposure prophylaxis. Although participants reported a range of opinions and motivations influencing their willingness to use PrEP, a majority reported that they would be willing to use oral PrEP for preventing HIV. Principal barriers to PrEP use included cost and access to prescribing clinicians. We identified four thematic categories related to FDA approval (Table 2).

Consequences of FDA approval

Each group of participants reached the consensus that FDA decisions are highly consequential, with effects such as allowing drug manufacturers to advertise drug uses, encouraging insurance coverage, and requiring physicians to educate themselves about new drugs. Some participants in the general MSM sample believed that opposition groups could use FDA non-approval to deter PrEP use, implying that FDA approval status can serve as an advocacy tool. We noted, however, that these participants were most concerned that FDA

non-approval would be used by special interest groups who fear risk compensation behavior, MSM, or loss of profits from sales of products that may compete with PrEP; no participants identified advocacy opportunities to promote PrEP access given a favorable FDA decision. Men in both types of groups also emphasized the limitations of approval, stating that it cannot change drug affordability or informal market activity.

Direct influence of FDA approval on acceptability

Many participants in both types of groups stated that the lack of FDA approval made them unwilling or less willing to use TDF-FTC for PrEP. These men asserted that approval is necessary to trust drug safety and to avoid being an experimental subject. Several men in both types of groups emphasized that although TDF-FTC was approved for HIV treatment, a separate approval would be necessary to accept the drug for use as PrEP. These participants believed that a lack of FDA approval for a prevention indication conveyed that the government "isn't sure" of drug safety, signaling the need for consumer caution.

Other men in both types of groups asserted that FDA non-approval would not deter them from using PrEP. These men explained that TDF-FTC's prior approval for HIV treatment was sufficient, saying that drug approval for any purpose, particularly a related purpose, makes the drug "legitimate." Even without FDA approval, some men said that the chance of avoiding HIV is worth taking an unapproved drug, and that using an experimental product could benefit society. Several men in the general MSM groups emphasized that using experimental drugs could help future MSM, while participants in the sex work groups mentioned helping future generations of substance users. Some participants in both groups believed that the wait for approval would be long, making approval less of a prerequisite for drug use, and that the FDA should not interfere with individual PrEP choices if drug risks are known. Participants in both subsamples also commented that FDA approval is less meaningful than other sources of information, including prescribing clinicians or medical journals. Several participants in the general MSM sample noted the superior value of peer-reviewed journal publications in making decisions about PrEP, suggesting that off-label use may be more acceptable to sophisticated MSM who are comfortable using medical literature in their decision-making.

Participants who reported willingness to use PrEP without FDA approval were more likely to be younger than the median age (38.5) and more likely to report recent sex work, compared to participants who stated that FDA approval was necessary before use. Both positions, however, were represented in each subsample.

Meaning of FDA approval

Participants understood approval in several ways, interpreting it to mean that the FDA knows "everything" about a drug, that the drug is safe, that testing has demonstrated effectiveness, that labeling is accurate, or that side effects are non-lethal. Many believed that people who use medications off-label or prior to approval are "guinea pigs," but some men in both the sex work and general MSM groups viewed experimental or pre-approval use of PrEP as a public service to benefit future MSM. Some of the men from the sex work groups cautioned that FDA approval cannot reliably signify drug safety because of manufacturing errors, changes in scientific knowledge, or the possibility that the FDA approves dangerous drugs for the financial benefit of manufacturers. These opinions were less likely to arise in the general MSM groups.

FDA motivations and procedures

Some participants offered opinions regarding the FDA's motivations when approving new drugs, suggesting that the FDA has a profit motive influenced by drug manufacturers, and

that it is susceptible to lobbying. Although both samples mentioned these beliefs, they arose more frequently in the sex work groups. Several participants in the sex work sample also referred to mistrust of the government in general, and a few endorsed the belief that a governmental institution created HIV to eliminate "drug addicts." Although these participants did not specifically connect these beliefs to the FDA, one suggested that individuals who believe such theories "would be scared of [PrEP]."

Among the groups of general MSM, a number of participants believed that the FDA would be reluctant to approve PrEP because it fears increased sexual activity among MSM, making the approval of an HIV prevention drug more problematic than approval for an HIV treatment drug. Several participants from the general MSM groups also believed that the FDA had received prior applications for HIV prevention drugs, but had rejected them due to the fear that these drugs would lead to increases in risky behavior. Participants in one of the general MSM groups also characterized the FDA as paternalistic, believing that the agency had refused approval for a home-based HIV test due to the concern that individuals testing positive at home would commit suicide. Men in the general MSM groups often described FDA procedures as outdated, lengthy, and stricter than approvals in other countries, and at times reflected on the FDA's history of approving HIV treatment drugs as an example of lengthy drug approvals. These concerns arose less frequently in the sex work groups. Several participants also assumed that the FDA itself runs safety and efficacy trials.

DISCUSSION

The results of this study can contribute to the development of strategies for PrEP outreach and education among MSM in the US. When informing MSM about this new HIV prevention tool, it is important to understand the significance and meaning conveyed by FDA approval. The TDF-FTC approval decision may directly shape PrEP acceptability among target users, and our data indicate that FDA approval sends many MSM a credible signal that TDF-FTC is safe and effective for use as oral PrEP. Although no previous study has investigated the role of FDA approval in PrEP acceptability among US MSM, our findings add texture to prior research suggesting that PrEP may be acceptable to this community overall (3-11). Prior work has found that willingness to use PrEP may be related to cost (5, 10), perceived side effects (5, 10, 11), lower education (5), lower income (5), perceived efficacy (5, 7, 10, 11), race (6), number of high-risk sex acts (6), perceived HIV risk (10, 11), endorsement of sexual arousal as a barrier to condom use (6), the perceived opportunity to engage in sex with a non-condom prevention method with an HIV-positive partner (7), the perceived possibility of reduced anxiety during sex (7, 10), perceived ease of use (11), and prior experience with daily use of other medications (10). One study has also found that individuals lacking knowledge regarding PrEP may be more likely to express mistrust of medical systems and drug companies (10). Our findings examine attitudes toward FDA approval of PrEP drugs as another variable influencing the acceptability of PrEP for personal use. No participant told us that FDA approval would make him *less* willing to use PrEP; attitudes toward FDA approval were either favorable (approval increased PrEP acceptability), or neutral (approval had no effect on willingness to use PrEP). We conclude that communicating with MSM about FDA approval may help to encourage PrEP acceptability and uptake.

Beliefs about the relative importance of FDA approval, however, are complex. Many participants considered approval to be irrelevant or unnecessary in their decisions about PrEP, many weighed information from their physicians more heavily, and some questioned the FDA's procedures or motives. During our analyses, we were particularly attuned to the ways in which men's perceptions of the FDA may be informed by the MSM community's historical experience with HIV treatment drugs and current experience with the FDA's

blood donation policy. Some men in the general MSM sample drew on the FDA's history in approving HIV treatment drugs, citing these experiences as evidence that FDA processes are lengthy, outdated, and overly cautious to the detriment of the population. No participants commented on the FDA's blood donation policy; it is possible that the men were unaware of the policy altogether, or unaware of the FDA's role in this rule. But multiple participants in the general MSM sample commented that the FDA may be "afraid" of encouraging sexual activity among MSM, and that this fear would make drug approval less likely. These comments may reflect perceived discrimination or stigma against MSM, but they did not necessarily lead men to dismiss the importance of FDA approval. Instead, the focus groups yielded a diversity of opinions, with men in the general MSM sample approximately evenly split regarding whether FDA approval would be necessary before using a PrEP drug.

During analyses, we also considered the possibility that MSM who engage in sex work may differ from the general population of MSM in their perceptions of the FDA. We found a number of demographic and behavioral differences between the sex work and general MSM groups, including a higher likelihood of substance use and experiencing forced sex among sex workers. MSM in the sex work subsample were more likely to question the reliability of FDA approval, citing concerns such as improper financial motivations, poor controls over drug manufacturing, and the possibility for error. But these differences did not predictably affect participants' beliefs about the importance of FDA approval: none mentioned ways in which their experiences with prescriptions, illicit drugs, or other governmental institutions influenced specific opinions about the FDA. As with the general MSM sample, men in the sex work subsample fell along a spectrum regarding the perceived need for FDA approval before using PrEP. Like the general sample, sex work participants also discussed the value of other sources of information besides FDA approval, focusing particularly on the need to seek a clinician's advice.

This study has several strengths. We are the first to consider the potential influence of FDA approval on PrEP acceptability and demand among MSM. This work is timely in light of the FDA's recent approval of TDF-FTC for use as PrEP, and our use of qualitative methodology allowed a more complete exploration of the mechanisms by which men may draw conclusions about PrEP acceptability. The format of our focus group discussions allowed us to collect unprompted data about FDA perceptions; although we designed this study in part to understand the influence of FDA approval on PrEP acceptability, we did not originally plan to solicit men's perceptions of FDA motivations, procedures, and the consequences of approval. These comments arose spontaneously during group discussions, allowing facilitators to probe for more information. Our reliance on emergent data makes these results particularly robust. We also gained access to a hard-to-reach sample of street-based male sex workers, a population with key relevance for HIV prevention efforts in both MSM and heterosexual communities.

Our results also have limitations. Because this was a qualitative study, the sample size is relatively small and may not allow for generalizability to other MSM populations. Our sample was more socioeconomically disadvantaged and less gay-identified compared to other studies of PrEP acceptability (5-10), and a high proportion of men reported disability or unemployment. The design of this study does not allow us to demonstrate statistically significant differences between the sex work and non-sex work subsamples, nor does it allow for subgroup analyses by race, ethnicity, education, or other variables of interest. Finally, the study took place during the weeks before the FDA's decision to approve TDF-FTC, and it was not possible to gather data on the relationship between FDA perceptions and actual product use. Future research in this area can build on these results through the use of larger samples, quantitative methods that allow for rigorous subgroup analyses, comparisons of actual PrEP users compared to nonusers, and further investigation into the

relative importance of FDA approval compared to other considerations when deciding to use PrEP. Future research can also examine ways in which to incorporate facts about regulatory approval into outreach strategies to educate MSM about PrEP.

This study focused on the direct role of FDA approval in influencing PrEP acceptability. But it is useful to note that even among MSM unconcerned with approval, the TDF-FTC decision may indirectly shape PrEP uptake. For example, FDA approval of TDF-FTC may lead to expanded insurance coverage (29, 30), increased awareness and acceptability of PrEP among prescribing clinicians, and increased willingness to use PrEP among peers. As new PrEP candidate drugs are evaluated, FDA approval can play a significant signaling role in promoting PrEP's acceptability, uptake, and population-level impact.

Acknowledgments

We are grateful to the study participants, Project Weber, Miriam Immunology Clinic, the Yale Center for Interdisciplinary Research on AIDS, the Lifespan/Tufts/Brown Center for AIDS Research, Bobby Ducharme, Richard Holcomb, Michelle Lally, Caroline Kuo, and Miriam Community Access for their help. This study was supported by the National Institute of Mental Health, #5K01MH093273 (PI: Underhill).

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Table 1

Demographic and Behavioral Characteristics

	MSM in 5 non-sex worker (NSW) groups **n = 22**	**MSM in 3 sex worker (SW) groups** **n = 16**
Age	Range 21 – 61, mean = 43	Range 24 – 57, mean = 32.3
Ethnicity	9% Hispanic or Latino	13% Hispanic or Latino
Race	73% White 27% Black	75% White 19% Black 6% other
Education	5% did not finish high school 36% high school/GED 27% some college 32% finished college	38% did not finish high school 38% high school/GED 25% some college 0% finished college
Employment	36% disabled 32% unemployed 5% temporary/seasonal work 5% part-time work 23% full-time work	13% disabled 63% unemployed 6% temporary/seasonal work 6% part-time work 13% full-time work
Annual income*	14% less than $6,000 18% from $6,000 to $12,000 68% above $12,000	56% less than $6,000 13% from $6,000 to $12,000 31% above $12,000
Housing	5% homeless 5% staying with friends/family 91% rented or owned	19% homeless 38% staying with friends/family 44% rented or owned
Health Insurance	23% no health insurance 41% Medicare/Medicaid 27% private insurance	63% no health insurance 31% Medicare/Medicaid 6% private insurance
Sexual Orientation	45% bisexual 55% gay 0% straight 0% preferred not to say	63% bisexual 13% gay 13% straight 13% preferred not to say
Number of sex partners (oral, anal, vaginal) in past 6 months	Range 2-60, mean = 13.9	Range 2-150, mean = 27.5
Gender of sex partners (oral, anal, vaginal) in past 6 months	27% both men and women, 73% only men	56% both men and women, 44% only men
Number of male anal sex partners (insertive and/or receptive) of unknown HIV status in past 6 months	Range 1-42, mean = 6.9	Range 1-40, mean = 11.1

	MSM in 5 non-sex worker (NSW) groups **n = 22**	**MSM in 3 sex worker (SW) groups** **n = 16**
Condom use with male anal sex partners (insertive and/or receptive) of unknown HIV status in past 6 months	0% always 27% most of the time 9% about half the time 36% sometimes, but very rarely 27% never or almost never	0% always 13% most of the time 13% about half the time 31% sometimes, but very rarely 44% never or almost never
Reported sex (oral, anal, vaginal) under the influence of alcohol / drugs during the past 6 months	77% alcohol / 50% other drugs	50% alcohol / 88% other drugs
Reported exchanging sex (oral, anal, vaginal) for money, drugs, or other goods within the past 6 months**	23% yes 68% no 9% did not respond	69% yes 25% no 6% did not respond
Reported being physically forced to have sex (oral, anal, vaginal) against his will within the past 6 months	5% yes 86% no 9% did not respond	31% yes 69% no 0% did not respond

Percentages are rounded to the nearest whole percentage, so totals in some columns may not equal 1.

* Participants who reported making less than $12,000 per year were considered to fall below the poverty threshold set by the US Census Bureau, which was $11,945 in the year 2012 for a single individual younger than 65.

** All 16 of the men in the “sex worker” groups verbally disclosed recent experiences with sex work during the focus group. Some of the same men, however, may have been uncomfortable disclosing sex work in writing on our questionnaire. The questionnaire did not distinguish between purchasing sex and selling sex, but instead grouped both behaviors together as “exchanging sex.”

Table 2

Discussion Themes Related to FDA Approval

Theme	Participant Quotes
Consequences of FDA approval	
FDA decisions are extremely important in the US.	It's not like it's just like a scary, unapproved drug, which I'm sure like many people are gonna try and frame it, people that would strive to… keep others from accessing it… like, probably people who are just, like, uncomfortable with men having sex with men… or people… like medical professionals… who are afraid this is gonna… lead to decreased condom usage and more transmission of like, other types of STIs. (FG063, age 21, NSW*)
FDA approval is necessary to advertise a drug.	Maybe that's why they're not advertising it, because the FDA hasn't approved it… That's false advertisement, so there's no way they can put up flyers saying this drug prevents HIV because it's not been approved for that usage. (FG087, age 40, SW**)
FDA approval influences insurers' decisions about drug payment.	The street pharmacist doesn't wait for FDA approval. (FG052, age 47, NSW)
FDA approval requires physicians to educate themselves about new drugs.	Let's say they do pass that, the FDA approves it, it comes out tomorrow – not too many people are going to spend $700 a month for that.… If insurance don't cover it, there's no way. (FG047, age 39, NSW)
Lack of FDA approval can be used by critics of MSM, people who fear risk compensation, or market competitors to deter MSM from using PrEP.	
FDA approval is irrelevant in informal drug markets or when drugs are unaffordable.	
Direct influence of FDA approval on PrEP acceptability	
FDA approval is necessary before taking PrEP.	My personal opinion, I would wait 'till the FDA approved it just to be safe. It would make my mind more relieved knowing that the federal government approved it. (FG078, age 61, NSW)
Lack of FDA approval is a deterrent to using PrEP.	*Participant*: I take enough bad things without anything being approved. Why should I add something that the government's going to be telling me that they're not sure of? *Facilitator*: Even if they're okay with it for treatment? *Participant*: Yeah… I'd be, uh, skeptical of it, you know… I'd have to know more. (FG037, age 60, NSW)
FDA approval of TDF-FTC for HIV treatment is insufficient; approval for prevention is also necessary before taking PrEP.	The fact that [TDF-FTC has] been approved for a purpose and is being used for a related purpose, it would be fine by me. I would just want to, for my own curiosity, see more of the research. (FG036, age 48, NSW)
FDA approval of TDF-FTC for treatment is sufficient; approval for prevention is unnecessary.	I don't think [FDA approval makes a difference]… I mean, if it works, it works. … If the drug's already on the market and they've deemed it safe for people to ingest, I guess I mean if you want to use it for your own purposes, I don't see why not. (FG039, age 29, NSW)
Lack of FDA approval is not a deterrent to using PrEP.	A chance of it working is better than nothing, you know what I mean? (FG060, age 26, SW)
FDA approval is less meaningful than consulting with a physician or reading peer-reviewed journals.	I would rather see it in like – like peer-reviewed journals… I don't really care about the FDA approval. (FG046, age 28, NSW)
FDA approval is less relevant for individuals who are HIV-positive, or for whom approved medications are ineffective or toxic.	The non-FDA approval wouldn't deter me, but as far as discussing it with a medical professional, I would never be embarrassed about that. (FG055, age 33, SW)
Meaning of FDA approval	
The FDA has complete information about a drug.	The FDA and all that, they ain't gonna approve nothing unless they know everything about it. (FG004, age 47, NSW)
The drug is appropriate for human consumption.	If it gets FDA-approved, they would tell you all, like, the side effects and things of that nature… [I]f it's not approved, they'd just be giving it to us and not telling us anything… you get better information [when a drug is approved]. (FG081, age 44, NSW)
The side effects will not be immediately lethal.	I would definitely do it even though it was not FDA-approved… I don't mind donating my body to science… I don't mind being a guinea pig. (FG042, age 28, NSW)
The drug has been tested to prove effectiveness.	They move a lot of our pharmaceutical companies to other countries now… so there's been a lot of mistakes made… So don't take that, just because it says
The information provided to consumers is valid and complete.	

Theme	Participant Quotes
Using an unapproved or off-label drug is like participating in an experiment.	'FDA,' that everything's all right with that, 'cause it doesn't necessarily mean it is, you know? (FG087, age 40, SW)
FDA approval does not reliably signify safety because the FDA has a profit motive to approve dangerous drugs; science may eventually prove the drug is unsafe; and drug manufacturers make mistakes.	[FDA approval matters] because it hasn't been proven… isn't that what it means, that it's been tested enough times to where it scientifically proves that it's effective? … It's not hazardous. (FG090, age 28, SW)
FDA motivations and procedures	
The FDA has a profit motive and is susceptible to the lobbying of drug manufacturers and industry actors such as condom manufacturers.	[T]he FDA and the drug business is one of the most awful bad, bad, bad, bad, like industries in -- in our country, you know? It's mostly about money, period, point blank… Constantly the FDA approves medications that seriously harm people and mess them up for the rest of their life.… So of course, if they haven't approved [PrEP] yet, God knows what could happen to you. (FG066, age 29, SW)
The FDA fears risk compensation behavior among MSM, making approval less likely for HIV prevention drugs.	I think this government, the FDA or whatever you want to call it, is afraid of, if some pill came out like that, of how people are going to act… if they did approve something and people felt that well, you can't get HIV no more… people are gonna be havin' sex galore… So it's hard for them to approve that because then they think everybody's going to go crazy. (FG047, age 39, NSW)
Approval procedures are antiquated and lengthy, and the delay is harmful to the population.	I think they drag their feet. Like, you know, you look at like, England, and they'll have medications out two, three years before we even approve it. By that time, something new has come along that – that overrides what the FDA just approved for us, you know. (FG003, age 53, NSW)
The long duration of FDA processes means that drugs are outdated before they are approved.	I understand FDA approval, and I understand all of that, but I mean… do you know how many people's heads I held why they were dying with AIDS? … [W]e're ready for this, like let's do something, but it doesn't seem to be here. (FG052, age 47, NSW)
The US FDA is less likely to approve an HIV prevention drug than drug approval bodies in other countries.	*Participant A*: When it comes to every time that I've came across, in Brazil, they found a pill, or some scientist that prevents HIV, monkeys haven't even gotten it… FDA doesn't approve it… When it's for positive, they're very good at 'okay, sign off, approved' … but when it comes down to negative to prevent it … they're very hard to sign a paper… They're afraid. *Participant B*: Europe is a lot lenient – more lenient. (FG047, FG049, both age 39, NSW)
The FDA conducts safety and efficacy research itself.	

*NSW = Participant took part in a non-sex worker group.

**SW = Participant took part in a group designed to sample sex workers.