AHF AIDS HEALTHCARE FOUNDATION

January 13, 2016

Dr. Stephen Ostroff, M.D., Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Ostroff:

I write on behalf of the AIDS Healthcare Foundation ("AHF") to register a formal complaint with the Food and Drug Administration ("FDA") against Gilead Health Sciences ("Gilead") for off-label promotion of its anti-retroviral drug Truvada® (emtricitabine/tenofovir disoproxil fumarate). AHF, a nonprofit, tax-exempt 501(c)(3) organization, is a global organization providing cutting-edge medicine and advocacy to more than 570,000 patients in 36 countries, and we are the largest provider of HIV/AIDS medical care in the U.S.

As you know, on July 16, 2012, FDA approved the antiretroviral drug Truvada to be taken by HIV-negative people to prevent HIV infection, a prevention strategy known as pre-exposure prophylaxis, or PrEP. As FDA said in its press release touting the approval, the agency approved the new use of Truvada to be taken as recommended "***and used in combination with safer sex practices***—to reduce the risk of sexually acquired HIV-1 infection in adults who do not have HIV but are at high risk of becoming infected." In addition, Truvada's FDA approved labeling clearly indicates how the drug is to be used:

> TRUVADA is indicated ***in combination with safer sex practices*** for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 in adults at high risk. This indication is based on clinical trials in men who have sex with men (MSM) at high risk for HIV-1 infection and in heterosexual serodiscordant couples. . . .
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> When prescribing TRUVADA for pre-exposure prophylaxis, healthcare providers must:
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> - prescribe TRUVADA as part of a comprehensive prevention strategy because TRUVADA is not always effective in preventing the acquisition of HIV-1 infection . . .
> - counsel all uninfected individuals ***to strictly adhere to the recommended TRUVADA dosing schedule*** because the effectiveness of TRUVADA in reducing the risk of acquiring HIV-1

was strongly correlated with adherence as demonstrated by measurable drug levels in clinical trials . . . . [and]

- screen for HIV-1 infection at least once every 3 months while taking TRUVADA for PrEP.

Despite the clear restrictions on how Truvada must be prescribed and used for PrEP, Gilead recently launched a brazen new ad campaign to promote situational use of the anti-retroviral as a "party drug." The television ads (also widely available and viewed on the internet) misleadingly imply that Truvada can be effectively used exclusively on a situational basis to prevent HIV infection on occasions when an individual decides to engage in sexual activity.[1] As the lead actor in one of the ads says, "I like to party," as the video shows him reaching for Truvada the morning ***after*** he presumably engaged in sex.

In no way is Truvada approved for use in this manner nor has it been shown to be effective at preventing HIV transmission if used in such a cavalier way. As FDA expressly recognizes, the drug has only been shown to work when taken as recommended ***and employed in combination with safe sex practices such a regular condom use***. Despite the clear indication that Truvada be used in conjunction with condoms, the ad is entirely and irresponsibly silent in this regard. The ad's makers know safer sex must accompany Truvada yet that requirement conflicts with their messaging about Truvada being a party drug so that critical element is completely excised from the ad. Moreover, people taking Truvada for PrEP must be screened regularly for HIV infection yet the ads completely ignore this critical requirement. In short, the Truvada usage pushed by the "I Like to Party" campaign entirely contradicts the scientific evidence for the drug's effectiveness and constitutes advertising for an unapproved and off-label use.

It is also worth noting that the ad goes even further than promoting off-label usage of Truvada and essentially promotes illicit drug use as part of an "I Like to Party" lifestyle. At one point, one of the ads clearly shows the primary actor reaching for recreational drugs as he leaves his home for an evening of "partying." It is precisely this cavalier attitude toward complying with the established PrEP regiment, consistent condom use, and regular testing that undermines the effectiveness of Truvada and expressly contradicts the approved usage of the drug.

The ads also exclude any references to the side effects associated with Truvada that are fully explained in the drugs labeling and which are typically included in direct-to-consumer marketing. While the ads subtly try to skirt this issue by refraining from mentioning Truvada by name, there is no doubt as to which drug the ads promote: there is only one drug approved for PrEP and that is Truvada. In addition, the actor in one of the ads is shown taking the distinctive blue, oval pill that is unmistakably Truvada. Finally, we note that the ads include a slate at the end reading, "Supported by funding from Gilead Sciences," thus clearly establishing a link between the manufacturer of Truvada and the inappropriate off-label promotion of the drug.

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[1]Videos available at http://www.hivbigdeal.org/HIVBIGDEAL2015/time2prep.html and https://www.youtube.com/watch?v=FXZcoBsoGBY. The ad has been viewed over 35,000 times on Youtube alone as of the date of this letter. [1] *See, e.g.*, sections, 505(a), 515 (a), 501(f)(1), and 301(a) and (d), of the FD&C Act (21 U.S.C. 355(a), 360e(a),

As you well know, the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations prohibit manufacturers from introducing new drugs into interstate commerce for any intended use that FDA has not determined to be safe and effective.[2] Further, under the FD&C Act, an approved new drug that is accompanied by written, printed, or graphic matter that suggests an unapproved use may be an unapproved new drug with respect to that use. An approved prescription drug that is intended for an unapproved use (whether referenced in labeling or not) would be considered misbranded, because the drug does not meet the regulatory exemptions from the requirement that its labeling bear "adequate directions for use."[3]

In contravention of statute and regulations, Gilead launched an ad campaign to mislead viewers into believing that Truvada is safe and effective for use on a situational basis despite knowing that the drug is not approved for such use. Consequently, the ad campaign constitutes impermissible off-label promotion, and we urge the FDA to take immediate action to (1) require Gilead to cease and desist all such off-label promotion; (2) require Gilead to publically correct the misinformation disseminated by the ad campaign; and (3) impose any sanctions permitted by law.

Thank you for your immediate attention to this urgent matter.

Sincerely,

Michael Weinstein
President

cc: U.S. Department of Health and Human Services Office of Inspector General

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351(f)(1)) and 331(a) and (d).

[3] *See* sections 201(m) and (p) of the FD&C Act, 21 U.S.C. 321 (m) and (p). Introducing an unapproved new drug into interstate commerce is prohibited. Sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).