The Honorable Eric T. Schneiderman
New York State Attorney General
120 Broadway
New York, NY 10271-0332

Via Electronic Mail and United States Mail

August 4, 2017

RE: Antitrust Concerns Regarding Generic Truvada Paragraph IV Litigation

Dear Mr. Attorney General:

We write this letter to bring to your attention a series of potentially anticompetitive settlements between Gilead Sciences and various generic drug manufacturers concerning the generic production of Truvada. Truvada is a blockbuster drug used in the treatment and prevention of HIV infection. Importantly, Truvada is the only drug currently approved by the Food and Drug Administration (FDA) to be used for preexposure prophylaxis (PrEP), the most effective method of preventing HIV infection in HIV negative individuals.

Over the last nine years, at least seven generic manufacturers have filed Abbreviated New Drug Applications (ANDAs) with the FDA seeking approval for generic Truvada. Although Truvada is hypothetically patent protected until 2024,[1] the generic manufacturers have asserted in their ANDAs that these patents are invalid.[2] Gilead, the manufacturer of Truvada filed patent infringement lawsuits against each generic drug manufacturer who filed an ANDA for generic Truvada. The suits focused on emtricitabine, one of the two active ingredients in Truvada. (The other component goes generic in 2018.) All of these cases were settled before the court could issue a ruling on the validity of the patents in question, in some cases after the district court had conducted a bench trial. Further details about these cases are contained in the enclosed table.

Although the settlement agreements are confidential, we believe that this pattern is consistent with reverse payment settlements, also known as "pay for delay" settlements. Our suspicion was partially confirmed when it was revealed in a Gilead analyst call last month that although Teva Pharmaceutical Industries Ltd.'s ANDA for generic Truvada was approved by the FDA in June,[3] it will not be marketed until at least 2021, pursuant to the settlement agreement between Teva

[1] This can be seen by searching the Food and Drug Administration's "Orange Book" listing for N021752.
[2] These assertions were made pursuant to "Paragraph IV" of the Hatch-Waxman Act. 21 U.S.C. §355(j)(2)(A)(vii)(IV).
[3] Food and Drug Administration. Approval Letter for ANDA No. 090894. URL: https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2017/090894Orig1s000ltr.pdf (Accessed July 28, 2017)

and Gilead.[4] This date is very close to the expiration of the patents challenged in Teva's lawsuit with Gilead.

Truvada is an extraordinarily expensive drug — a thirty-day supply costs, on average, over $1,500,[5] despite costing less than $9 to produce.[6] This artificially high price poses a significant burden for payers and patients alike. Indeed, because Gilead's copay assistance program only covers a maximum of $3,600 in out of pocket expenses[7] — well below the out of pocket maximum established by the Patient Protection and Affordable Care Act (ACA) of $7,150 for individual plans and $13,700 for family plans[8] — even insured patients are often forced to pay significant amounts of money or rely on third party support mechanisms in order to access the drug.

Allowing generic versions of Truvada to be marketed would dramatically reduce the price of the drug.

We are aware of your leadership on patient access to affordable generic drugs. Your landmark challenge to "product hopping" in the Namenda matter, and your office's advocacy before the Supreme Court in the *FTC v. Actavis* reverse payment case, have brought important relief to New Yorkers. We believe that the Truvada settlements might represent an equally important instance of anticompetitive conduct.

Due to the confidential nature of the Truvada settlements, and what we believe to be the parties' studied efforts to avoid even basic disclosure of the settlements, it is impossible for us to evaluate whether Gilead in fact paid for delay. We urge you to open an investigation of these settlements. As a first step, we suggest that your office gain access to and review the settlements in question, to determine whether they violate the Sherman or Donnelly Acts.

We look forward to discussing this issue with you or your team at your earliest convenience.

Please do not hesitate to contact us with any questions or concerns.

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[4]Seeking Alpha. "Gilead Sciences (GILD) Q2 2017 Results - Earnings Call Transcript". URL: https://seekingalpha.com/article/4091021-gilead-sciences-gild-q2-2017-results-earnings-call-transcript?page=8 (Accessed on July 28, 2017)

[5] Centers for Medicare & Medicaid Services. National Average Drug Acquisition Cost Database. URL: https://data.medicaid.gov/Drug-Pricing-and-Payment/NADAC-as-of-2017-07-26/yv6n-8hzz (Accessed on July 28, 2017)

[6] Hill AM, Pozniak AL. "How can we achieve universal access to low-cost treatment for HIV?" *Journal of Virus Eradication*. 2016;2(4):193-197. Full Text: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5075345/

[7] POZ Magazine. "'Significant Victory' as Gilead Expands Co-Pay Assistance for Truvada as PrEP". URL: https://www.poz.com/article/truvada-prep-copays-27981-3779

[8] Centers for Medicare and Medicaid Services. "Out-of-pocket maximum/limits". URL: https://www.healthcare.gov/glossary/out-of-pocket-maximum-limit/

Thank you.

Sincerely,

James Krellenstein
Peter Staley
Tim Horn
Jeremiah Johnson

CC: Beau Buffier (Chief, Antitrust Bureau), Brain Mahanna (Chief of Staff for the Attorney General)

Truvada Paragraph IV Litigation Cases:

Case No. (Venue)	**Case Name**	**ANDA No.**	**Drug**	**Outcome**
17-02335 (NJD)	Gilead Sciences and Emory University v. Amneal	209-721	Truvada	Filed: Apr 6, 2017 **Dismissed w/o Prejudice by Gilead and Emory:** Apr 18, 2017
16-04938 (NJD)	Gilead Sciences and Emory University v. Hetero Drugs Ltd.	201-086	Truvada	Filed: Apr 11, 2016 **Dismissed with Prejudice by Gilead and Emory:** Aug 26, 2016
16-04178 (NJD)	Gilead Sciences and Emory University v. Aurobindo Pharma LTD	90-513	Truvada	Filed: July 8, 2016 **Stipulated Order Dismissing Case**: Sept 16, 2016
14-00099 (NDWV)	Gilead Sciences and Emory University v. Mylan	20-6436	Truvada	Filed: June, 9 2014 **Dismissed with Prejudice by all parties:** November, 2, 2015
14-03928 (SDNY)	Gilead Sciences and Emory University v. Mylan	20-6436	Truvada	Filed: June 2, 2014 **Voluntary Dismissal by Gilead and Emory:** June 30, 2014
12-06350 (SDNY)	Gilead Sciences and Emory	91-168	Truvada	Filed: August 20, 2012

	University v. Cipla			**Dismissed with Prejudice by all parties:** July 29, 2014
12-06293 (SDNY)	Gilead Sciences and Emory University v. Lupin	20-4131	Truvada	Filed: Aug 16, 2012 **Dismissed with Prejudice by all parties:** Sept 17, 2014
08-10838 (SDNY)	Gilead Sciences and Emory University v. Teva	09-0894	Truvada	Filed: Dec 12, 2008 See settlement stip