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Christopher Morten, Supervising Attorney

VIA OVERNIGHT UPS DELIVERY AND FACSIMILE

ATTN: USPTO OFFICE OF PETITIONS

To: The Honorable Andrei Iancu

Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office 600 Dulany Street Alexandria, VA 22314

c/o United States Patent and Trademark Office Customer Service Window Mail Stop Petitions Randolph Building 401 Dulany Street Alexandria, VA 22314

USPTO Central Fax No: 571-273-8300

CC: The Honorable Admiral Brett Giroir

Acting Commissioner, U.S. Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PETITION UNDER 37 C.F.R. § 1.181(a)(3)

Dear Director Iancu,

I submit this petition under 37 C.F.R. § 1.181(a)(3)¹ on behalf of my client, the PrEP4All Collaboration ("PrEP4All"), concerning the petition we filed under 37 C.F.R. § 1.183 on December 4, 2019. Our December 4 petition seeks review from the U.S. Patent and Trademark

¹ In the event that a fee is required, PrEP4All submits a Credit Card Payment Form (PTO-2038) and authorizes the U.S. Patent and Trademark Office to charge the requisite fee, up to \$1,000.

Office ("the Office") of the applications for patent term extension ("PTE") on U.S. Patent Nos. 7,390,791 and 7,803,788, assigned to Gilead Sciences, Inc ("Gilead").

I submit this petition, respectfully, to invoke the supervisory authority of the Director. I write to raise concerns and seek clarification regarding a series of seemingly inappropriate communications made by Mary C. Till, Senior Legal Advisor with the Office, to my client on the legality and merits of its petition via the social networking service Twitter. Specifically, I seek to clarify (1) whether Ms. Till was authorized by the Office to contact my client directly, without seeking first to contact myself as counsel of record; (2) whether the allegations and opinions expressed by Ms. Till are official Office positions and represent the Office's official response to our petition; and (3) whether, given the inappropriate nature of the comments, the Office intends to allow Ms. Till to continue to participate or represent the Office in connection with my client's petition and the PTE applications it references. In light of Ms. Till's comments, taken together with other comments that reveal bias on the part of Ms. Till, I respectfully request that she be reassigned and removed from any of the Office's action responding to our petition and the related PTE applications.

Relevant Facts of Our December 4, 2019 Petition and Ms. Till's Conduct

Our petition was filed on the afternoon of December 4, 2019 by hand delivery (courier) to the Office's customer service window and separately by fax. The Office confirmed receipt on the same day. We delivered additional copies of the petition to the Office by overnight UPS service on December 5, 2019. On the morning of December 6, 2019, the Office twice charged my client's credit card a petition fee of \$400, indicating it had accepted our petitions.

According to a published biography,² Ms. Till has been an employee of the Office since 2005. Ms. Till appears to have served as Senior Legal Advisor with the Office since at least 2012.³ She also appears to be the Office's designated representative on questions of PTE under 35 U.S.C. § 156. She is identified as such on the USPTO's website⁴ and on the Food and Drug Administration's (FDA).⁵ Ms. Till appears to be the Office official overseeing the specific PTE applications at issue in our petition, concerning U.S. Patent Nos. 7,390,791 and 7,803,788.⁶

² Biography for Mary C. Till, https://www.americanconference.com/pharmaceutical-and-biotechnology-patent-life-cycles-and-portfolio-strategies-801114-nyc/speakers/mary-c-till/ (last visited Dec. 7, 2019).

³ See, e.g., Changes and Examination Guidelines To Implement the First-Inventor-to-File Provisions of the Leahy-Smith America Invents Act; Reopening of the Period for Comments, 77 Fed. Reg. 61,735 (Oct. 11, 2012) ("Mary C. Till, Senior Legal Advisor").

⁴ Patent Terms Extended Under 35 USC §156, https://www.uspto.gov/patent/laws-and-regulations/patent-terms-extended-under-35-usc-156 (last visited Dec. 7, 2019).

⁵ Small Business Assistance: Frequently Asked Questions on the Patent Term Restoration Program, https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/small-business-assistance-frequently-asked-questions-patent-term-restoration-program (last visited Dec. 7, 2019).

⁶ See, e.g., Letter of Mary C. Till to FDA dated January 31, 2017 concerning the application for patent term extension of U.S. Patent No. 7,390,791, in the file of U.S. Patent No. 7,390,791; Letter of Mary C. Till to FDA dated January 31, 2017 concerning the application for patent term extension of U.S. Patent No. 7,803,788, in the file of U.S. Patent No. 7,803,788.

A now-deleted Twitter account with the name "Mary C Till" and handle "@mary_c_till" is Ms. Till's account. We recovered a cached version of the account and its tweets from Google, which is attached to this letter as Exhibit A. Among other things, the account's most recently cached tweet references the Hatch-Waxman Act and the hashtag "#Bottleoflies," indicating an interest in pharmaceutical patent law and corroborating its being Ms. Till's. In addition, a screenshot of a now-deleted tweet dated October 15, 2019 from the account states, "Just another day in the world of administration of 35 USC 156. Yeah, that is 18 submissions. Various companies." See Exhibit B. Another now-deleted tweet dated September 19, 2019 states, "I work st [sic] USPTO and deal with pharma issues." See id. These tweets confirm that this account is Ms. Till's.

On December 5 and 6, 2019, Ms. Till tweeted at least 7 times about our petition, the anti-HIV compound tenofovir alafenamide ("TAF") described in our petition, and the PTE process, and she directed some of her tweets directly to my client, PrEP4All.⁸ Screenshots of these tweets, recovered via web cache or obtained by Twitter users before Ms. Till's account was deleted, are attached to this letter as Exhibit B.

- 1. On December 5, Ms. Till tweeted, directly to my client, "Where is the proof they stopped developing TAF. Truvada used a different pro-drug of tenofovir, it used tenofovir disoproxil fumarate, whereas descovy [sic] isn't tenofovir alafenamide [sic]. Do facts even matter to you?" Her tweet responded to a tweet by my client concerning Gilead's decision to stop clinical development of TAF in 2004 and resume development in 2010.
- 2. Also on December 5, 2019, Ms. Till tweeted, directly to my client, "No, you can't, by law no third party participation." Her tweet responded to a tweet by my client concerning the Office's acceptance of our petition.
- 3. Also on December 5, 2019, Ms. Till tweeted, "So you don't believe the data on decreased renal toxicity and less effective t [sic] on bone density??? The multiple clinical studies are all lies??? Proof please." Her tweet responded to a thread of tweets discussing the safety of TAF compared to another anti-HIV compound, tenofovir disoproxil fumarate ("TDF") in connection with a Washington Post story⁹ on our petition.
- 4. Also on December 5, 2019, Ms. Till tweeted, "No expertise, no sales force, no manufacturing facilities, etc. you think drugs are expensive now. . . The companies with experience get this job done spending millions sometimes just to see a drug product fail in clinical trials. Keep your comments to something you know!" Her tweet responded to a thread of tweets discussing the Washington Post story on our petition.

⁷ The hashtag "#Bottleoflies" appears to refer to a recent book, "Bottle of Lies," investigating the generic pharmaceutical industry. Katherine Eban, *Bottle of Lies: The Inside Story of the Generic Drug Boom* (2019).

⁸ PrEP4All's Twitter handle is "@PrEP4AllNow." https://twitter.com/PrEP4AllNow (last visited Dec. 8, 2019).

⁹ Christopher Rowland, *Gilead delayed safer HIV drug to extend monopoly profits, advocates allege*, Washington Post (Dec. 5, 2019), https://www.washingtonpost.com/business/economy/gilead-delayed-safer-hiv-drug-to-extend-monopoly-profits-advocates-allege/2019/12/05/71d4d6ae-1538-11ea-8406-df3c54b3253e_story.html (last visited Dec. 8, 2019).

- 5. Also on December 5, 2019, Ms. Till tweeted, "I think other studies that compare TDF to TAF are also highly relevant." Her tweet responded to a thread of tweets discussing the Washington Post story on our petition.
- 6. Also on December 5, 2019, Ms. Till tweeted, "What proof???" in response to a post from U.S. Senator Bernie Sanders's official Senate Twitter account ("@SenSanders"), 10 linking to the Washington Post story on our petition.
- 7. On the morning of December 6, 2019, Ms. Till tweeted, "My comment was about the proof of the allegation, not a comment on the merits of anything pending at USPTO." Her tweet responded to a thread of tweets discussing the Washington Post story on our petition.

Although our December 4 petition clearly identified my client as being represented by me and provided my contact information, Ms. Till did not contact me, through Twitter or otherwise. I learned about Ms. Till's tweets only because my client brought them to my attention. Neither I nor my client responded to any of Ms. Till's tweets.

Ms. Till deleted her Twitter account at some point on the morning of December 6, 2019. Twitter now states that "[t]his account doesn't exist." 11

This series of communications from Ms. Till via Twitter constitutes direct communication with my client PrEP4All concerning our petition. Ms. Till's tweets addressed substantive questions, both factual and legal, raised in the petition, and they revealed her view on these questions. For example, her 1st tweet quoted above indicates her disagreement with the proposition that Gilead stopped and then restarted development of TAF, a critical adjudicative fact in our petition. (Ms. Till's position is puzzling, as Gilead itself admitted that it stopped and then restarted development of TAF in the very PTE applications under her review. Her 2nd tweet quoted above indicates she has concluded the Office cannot or will not, as a matter of law, accept our petition under 37 C.F.R. § 1.183, despite the extraordinary circumstances described in the petition. Her 3rd tweet quoted above indicates her view that TAF is safer than TDF (at least in some patients), another critical fact in our petition.

Question #1 for Clarification: Was Ms. Till authorized by the Office to contact my client, via Twitter, regarding our Petition?

Please clarify whether Ms. Till was authorized to contact my client, via Twitter, regarding our petition. I note that contacting clients who are known to be represented by counsel

¹⁰ https://twitter.com/SenSanders (last visited Dec. 8, 2019).

¹¹ https://twitter.com/mary c till (last visited Dec. 8, 2019).

¹² See, e.g., Application for Patent Term Extension in the file of U.S. Patent No. 7,390,791, 7, filed Dec. 14, 2015.

without counsel's knowledge or consent is generally considered inappropriate and, under some professional rules of conduct, unethical. *See* ABA Model Rule 4.2. 13

<u>Ouestion #2 for Clarification</u>: Were the allegations and opinions expressed by Ms. Till official Office positions, and do they represent the Office's official response to our petition?

Please clarify whether Ms. Till's tweets represent the official positions of the Office. If so, please clarify whether tweets from Ms. Till's Twitter account are "permanent records" registered with the National Archives and Records Administration and whether deletion of her account and tweets is compliant with the Federal Records Act.

Question #3 for Clarification: Given the inappropriate nature of the comments, does the Office intend to allow Ms. Till to continue to participate or represent the Office in connection with my client's petition and the PTE applications it references?

The tweets from Ms. Till's quoted above reveal bias. That she tweeted on December 5, just one day after our petition was submitted, suggests that she somehow formed an opinion on the merits of the petition without thorough consideration and may have prejudged the outcome. That she wrote, directly to my client, "Do facts even matter to you?" and "No, you can't, by law," indicates she may be fundamentally biased against our arguments and does not intend to give them fair consideration.

Moreover, earlier tweets from Ms. Till reveal a general bias against scrutiny of brand pharmaceutical companies:

- 1. On June 5, 2019, Ms. Till tweeted a response to "@Angie_Harmon," the Twitter account of the actress Angie Harmon, ¹⁴ calling for a petition to the brand-name pharmaceutical company Pfizer calling on Pfizer to release information on a potential Alzheimer's drug to scientists. Ms. Till responded, "Their data is proprietary to the company. They generated it, it is their property." This tweet suggests Ms. Till does not believe Pfizer or other pharmaceutical companies that generate data have an obligation to share it.
- 2. On October 26, 2019, Ms. Till tweeted a response to "@KatherineEban," the Twitter account of Katherine Eban, author of the book *Bottle of Lies*, and other Twitter users. ¹⁵ Ms. Till wrote, "Clearly Congress should be scrutinizing brand companies and attempting to curtail this innovation so we can have more generics in the US. It is all about cheaper, efficacy does not matter. This is sarcasm in case you didn't catch that." Ms. Till thus publicly expressed a view that, in general, scrutiny of brand pharmaceutical companies is

¹³ Her tweets also placed me and my client in a difficult position vis-à-vis the Office's Rules of Professional Conduct: Under 37 CFR § 11.305, I may not "[s]eek to influence" an "employee or officer of the Office" and may not "[c]ommunicate ex parte with such a person during the proceeding unless authorized to do so by law, rule or court order." We did not respond to her tweets and did not undertake ex parte communication, despite her invitation to do so.

¹⁴ https://twitter.com/Angie Harmon (last visited Dec. 8, 2019).

¹⁵ https://twitter.com/KatherineEban (last visited Dec. 8, 2019).

undesirable because scrutiny curtails innovation.

Screenshots of these tweets are included in Exhibit B.

Perhaps even more troubling, an earlier tweet from Ms. Till reveals *specific* bias in favor of Gilead. On November 11, 2019, Ms. Till tweeted a response to a New York Times story, "Who Owns H.I.V.-Prevention Drugs? The Taxpayers, U.S. Says." That story describes a lawsuit for patent infringement brought by the U.S. Department of Justice and U.S. Department of Health and Human Services (HHS) against Gilead. This patent suit implicates one of the same drugs, Descovy, at issue in our December 4, 2019, petition. The New York Times article opens, "[a]fter years of prodding by patient advocates, federal officials on Wednesday sued the drug maker Gilead Sciences, charging that it had infringed government patents on the idea of preventing H.I.V. with a daily pill." After a first commenter asked, "Who paid for the safety trials?," Ms. Till tweeted in response, "I think we know it was not the government." Ms. Till thus publicly expressed a view on this pending litigation, a view favorable to Gilead's litigation position and unfavorable the government's, indicating her specific bias in favor of Gilead and against the United States. A screenshot of this Tweet is included in Exhibit B.

Taken together, Ms. Till's tweets and the bias they reveal suggest that Ms. Till is not a neutral decisionmaker, and they could undermine the credibility of the Office's decision on our petition. "With regard to judicial decisionmaking, whether by court or agency, the appearance of bias or pressure may be no less objectionable than the reality." D.C. Fed'n of Civic Associations v. Volpe, 459 F.2d 1231, 1246–47 (D.C. Cir. 1971); see also Texaco, Inc. v. Fed. Trade Comm'n, 336 F.2d 754, 760 (D.C. Cir. 1964) (participation in an agency's decision-making process by an individual who "had in some measure decided in advance" the outcome "amounted in the circumstances to a denial of due process which invalidated the order under review").

For these reasons, I ask, respectfully, whether the Office intends to allow Ms. Till to continue to participate or represent the Office in connection with my client's petition and the PTE applications it references, concerning on U.S. Patent Nos. 7,390,791 and 7,803,788. I ask that the Office clarify who within the Office will consider and act upon our petition. In light of Ms. Till's comments, I respectfully request that she be reassigned and removed from any of the Office's action responding to our petition and the related PTE applications.

¹⁶ Donald G. McNeill Jr. & Apoorva Mandavilli, Who Owns H.I.V.-Prevention Drugs? The Taxpayers, U.S. Says, N.Y. Times (Nov. 8, 2019), https://www.nytimes.com/2019/11/08/health/hiv-prevention-truvada-patents.html (last visited Dec. 8, 2019).

¹⁷ Ms. Till's statement is incorrect. In fact, the U.S. government paid for clinical trials documenting the safety of Truvada as PrEP. For example, the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) paid for Phase II, Ilb, and III clinical trials of Truvada as PrEP. *See, e.g.*, a document from the FDA's approval of Truvada (emtricitabine/TDF) as PrEP, "021752Orig1s030 Summary Review," at p. 7, https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/021752Orig1s030SumR.pdf (last visited Dec. 8, 2019).

I make these requests while recognizing that a third party petitioner has few enumerated rights under existing Office regulations. I ask simply that the Office treat my client fairly, as it does other stakeholders.¹⁸

My client and I filed our petition to bring to the Office's attention evidence that Gilead breached the duty of disclosure it owed the Office, a breach that could threaten the integrity of the PTE system. As the Secretary of HHS, Alex M. Azar II, stated last month when announcing HHS's patent infringement lawsuit against Gilead, "Gilead must respect the U.S. patent system." Our petition presents evidence of Gilead's disrespect, and it deserves thorough and fair consideration.

We thank you for your consideration.

Dated: December 9, 2019

Respectfully submitted,

Christopher Morten (Registration No. 69,974)

Teaching Fellow and Supervising Attorney

Technology Law & Policy Clinic

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Counsel for PrEP4All

¹⁸ For example, the Office has created a Patents Ombudsman to help patent applicants through the patent application process when issues arise between an applicant and the patent examiner and/or supervisory patent examiner. See Keeping the Road Clear: The Patents Ombudsman Program, https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/keeping-road-clear-patents-ombudsman-program (last visited Dec. 6, 2019).

¹⁹ United States Files Patent Infringement Lawsuit Against Gilead Related to Truvada® and Descovy® for Pre-exposure Prophylaxis of HIV, HHS.gov (Nov. 6, 2019), https://www.hhs.gov/about/news/2019/11/06/us-files-patent-infringement-lawsuit-against-gilead-pre-exposure-prophylaxis-hiv.html (last visited Dec. 8, 2019).

Index of Exhibits

Exhibit A: Twitter account for "Mary C. Till" ("@mary_c_till") recovered from Google

Cache.

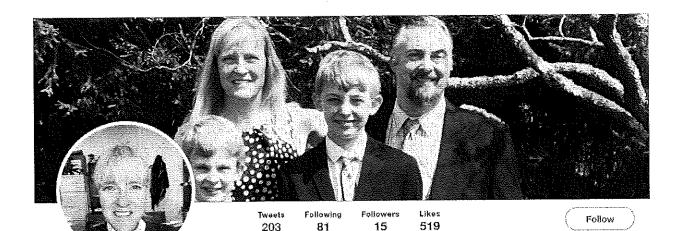
Exhibit B: Screenshots from the now-deleted "Mary C. Till" ("@mary_c_till") Twitter

account, arranged in roughly chronological order.

EXHIBIT A

Mary C Till (@mary_c_till) | Twitter

Q Have an account? Log in * **5** Moments Search Twitter Home View source Text-only version Full version Tip: To quickly find your search term on this page, press CfrI+F or %-F (Mac) and use the find bar.



Mary C Till

@mary_c_till

Mom, wife, self-described nerd. Into fitness, cooking and friendships.

Fort Hunt, VA

Joined August 2017

Tweets & replies Media **Tweets**



Mary C Till @mary_c_till · Sep 25

Missed it by a day, but yesterday was the 35th anniversary of the Hatch-Waxman Act signing into law. How appropriate reading #Bottleofiles.

Q

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Mary C Till @mary_c_till - May 30 Shame on you @AmericanAirtil

T @Torasorus

@AmericanAir just robbed me of a day with my husband right before his deployment. Wouldn't let him on the plane after multiple gate changes and delays. Doors were open, my husband pleaded, told them I was pregnant, he was

Show this thread

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Mary C Till @mary_c_till - 23 Aug 2018 Never mind, I see it is September 26.

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Show this thread

t) Mary C Till Retweeted

Bridges Coffey @bridgescoffey3 - 14 Aug 2018 Help me out...

📶 U.S. Cellular 🗢

9:43 PM

LSU 🌼 **@LSU**

Mary C Till (@mary_e_till) | Twitter

Q Have an account? Log In * Search Twitter Moments Home 9:44 PM 500k 9:46 PM 9:46 PM = Q t٦ Show this thread Mary C Till @mary_c_till - 10 Apr 2018 Oh yes, Wegmans. Been out of town last 2 weekends and missed going. Planning a trip FridayIII Thanks for the lovel! @romper 8 Signs You're A Wegmans Mom remper.com/p/8-signs-your... Q T] 1.) Mary C Till Retweeted ABC News @ @ABC ⋅ 13 Mar 2018 March of the Penguins: Fans of all ages watched and waved as the Pittsburgh Zoo's penguins waddled around and strutted their stuff at the zoo's "Penguins on Parade" event. abon.wa/2FxM0v9

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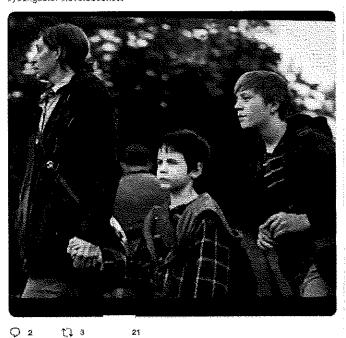
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11 Mary C Till Retweeted



Xavier Wolf @ActorXavierWolf - 5 Mar 2018 Did you catch all the action on #Homeland last night? Oh and me ##actorslife #youngactor #lovetobeonset



Mary C Till @mary_c_till - 23 Feb 2018 Well hello @LastBottleWines who arrived today. Can't wait to try some this weekend.

Q

t↓ Mary C THI @mary c till - 17 Jan 2018

Search Twitter Have an account? Log in ▼ Home & Moments Eurapei Au. nan. su uraca di du linda "If the Steelers ain't gonna win the Super Bowl, what have we been going to church for?" Dad reacts to Steelers vs Jaguars playoff game! youtu.be/YHv1Ld2P23Q Mary C Ti[] @mary_c_tiil - 13 Jan 2018 The Verizon spokesperson is super annoying, t.] Mary C Till @mary_c_till - 2 Jan 2018 Great interview @JoeMoravsky. Ninja Warrior Nation @ @anwhation Learn more about how much dedication and focus went into @JoeMoravsky's second year as the last Ninja standing. americanninjawarriornation.com/2017/9/19/1633... Mary C Till @mary_c_till + 27 Dec 2017 Awesome! Hasn't earned the J. yet, hahaha. Pittsburgh Dad @Pittsburgh_Dad NEW episode: Dad reacts to Steelers vo Texans! youtu.be/el300n0vNHc Show this thread Q tī Mary C Till @mary_c_till + 26 Dec 2017 My tweat from 3 days ago said letting him go was worst decision ever, didn't you see this coming Steelers? #HereWeGo Steelers Pittsburgh Dad @Pittsburgh_Dad This is my nightmare twitter.com/adamschefter/s... Q Mary C Till @mary_c_till + 28 Dec 2017 What is wrong with you, Steelers!?! He is still a beast. Grm. NFL @ @NFL Steelers release James Harrison: on.nfl.com/mCOLEG





Q Ü



Mary C Till @mary_c_till - 22 Dec 2017

Wrapped a bunch of presents for everyone today, for me, let's see a Steeler win on Monday. 🦃

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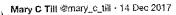
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 Search Twitter

Q : Have an account? Log in -





Why oh why did we switch to #sprint? Huge mistake, why can't our billing dispute be resolved in over 2 months. @marceloclaure-how awesome is sprint?

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ta Mary C Till Retweeted

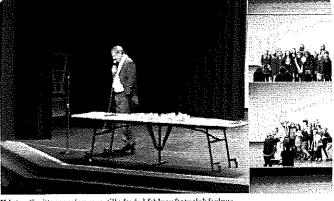
fan Rapoport 🏶 @RapSheet - 5 Dec 2017

#Steelers LB Ryan Shazier has shown promising signs this morning. I'm told he has some movement in his lower extremities after last night's back injury, but the next 24-48 hours are key for increased improvement.

t

13 Mary C Till Retweeted

West Potomac HS @theWPboard · 8 Nov 2017 Marching Band Awards #westpoband #bestintheland



| /6/2019 | | Mary C Till (@mary_c_till) Twitter | | | | | | |
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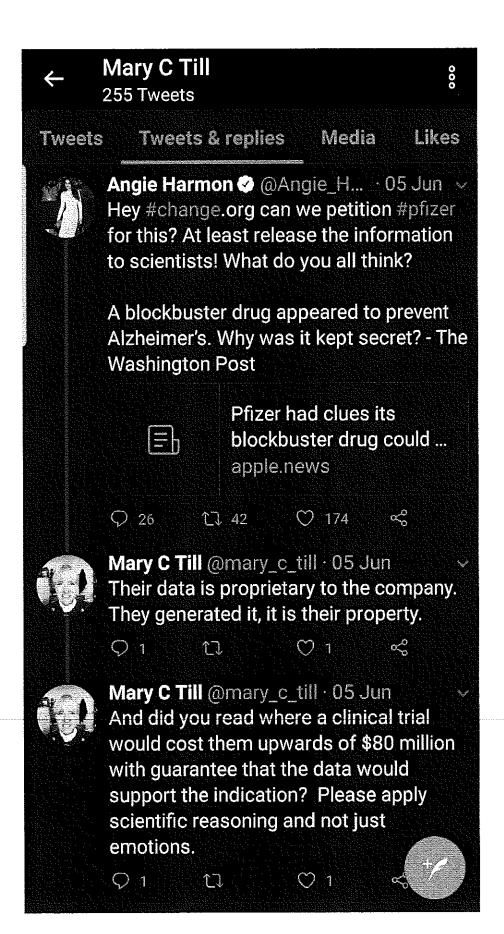
Sign up now to get your own personalized

timeline!

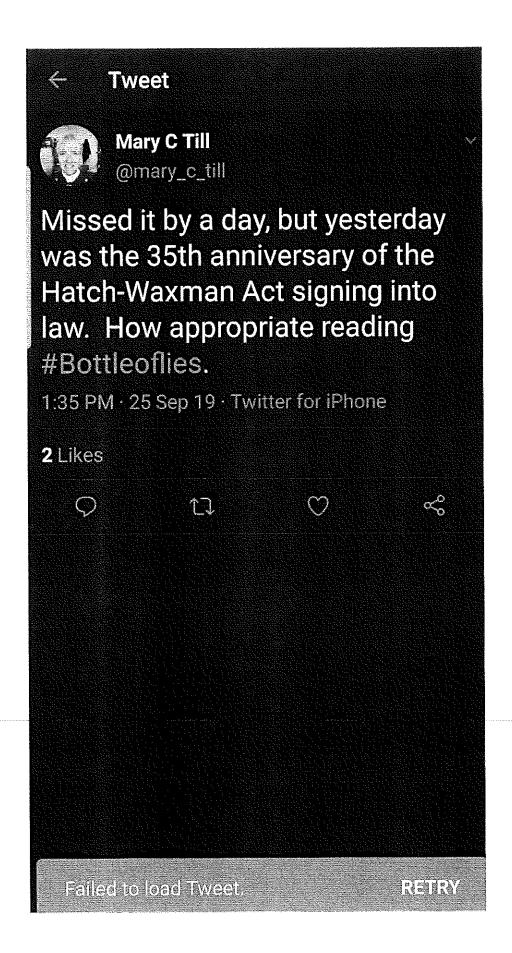
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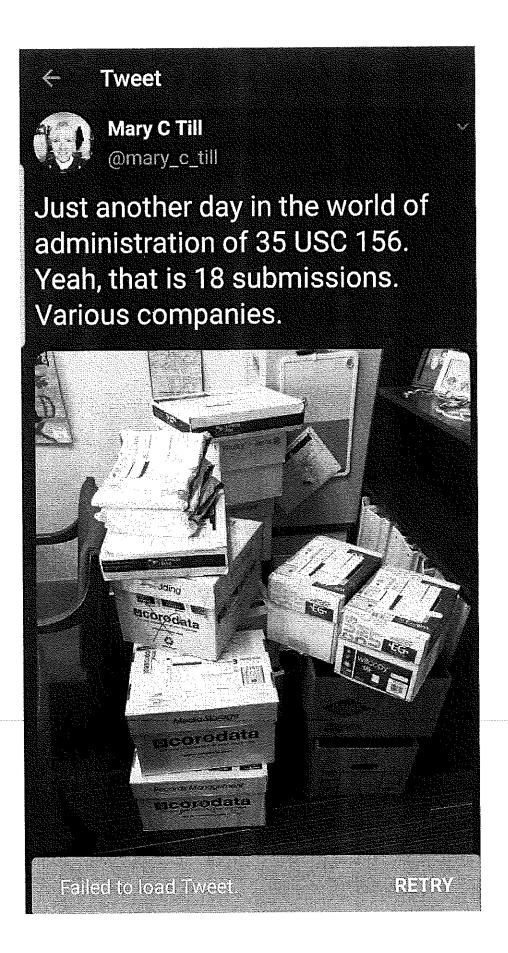
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EXHIBIT B

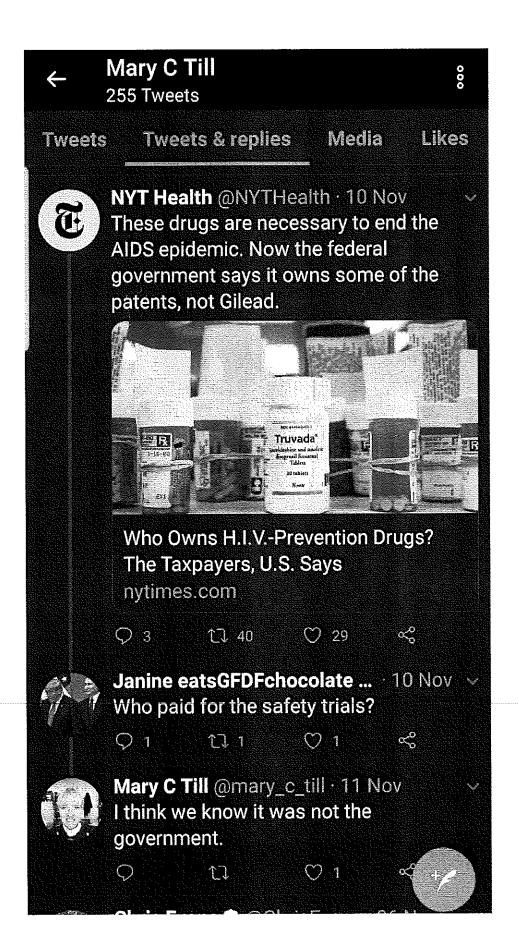


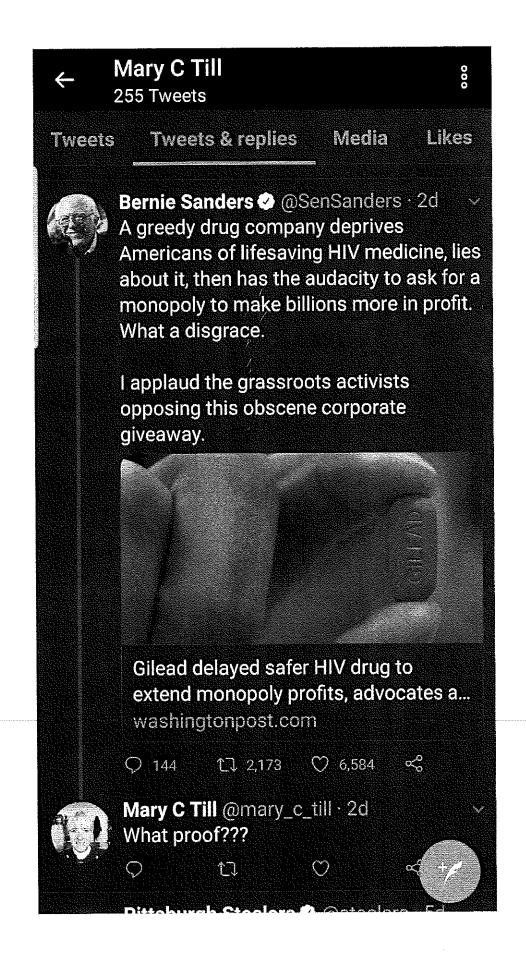






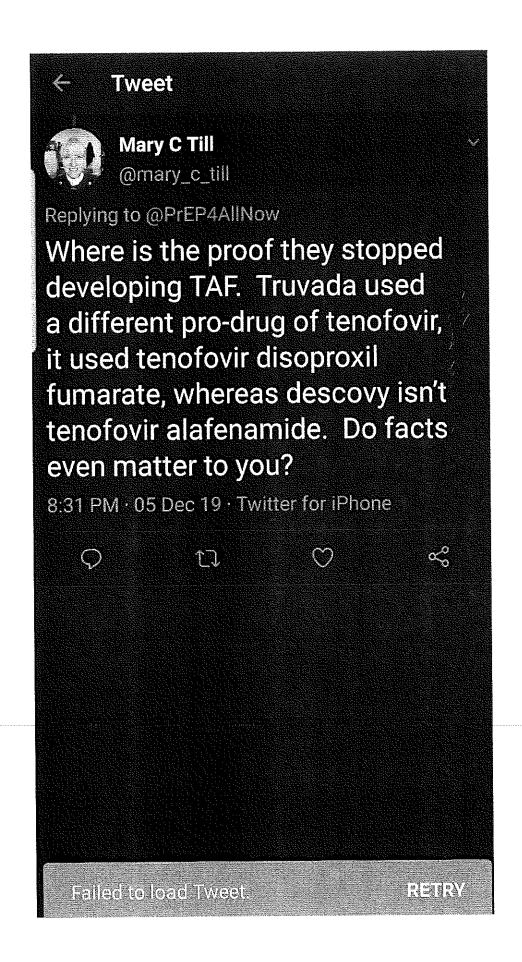


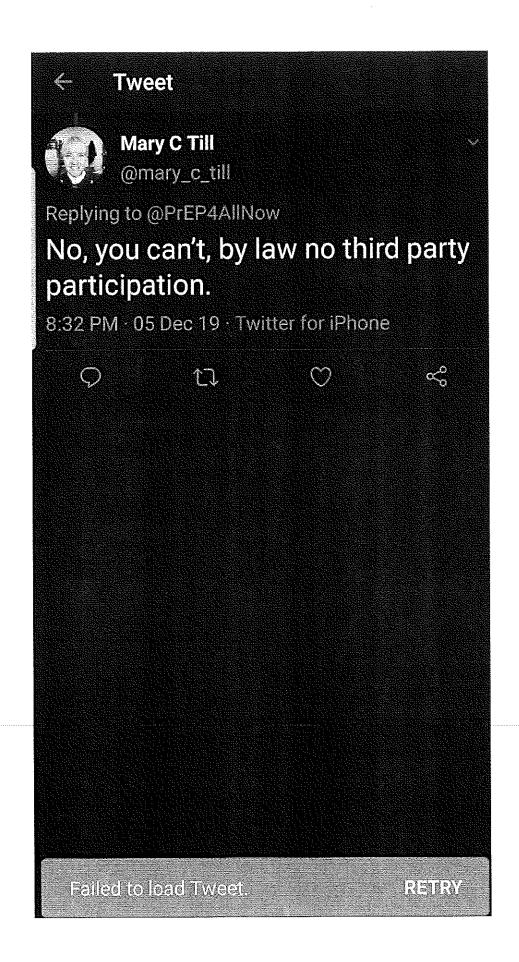


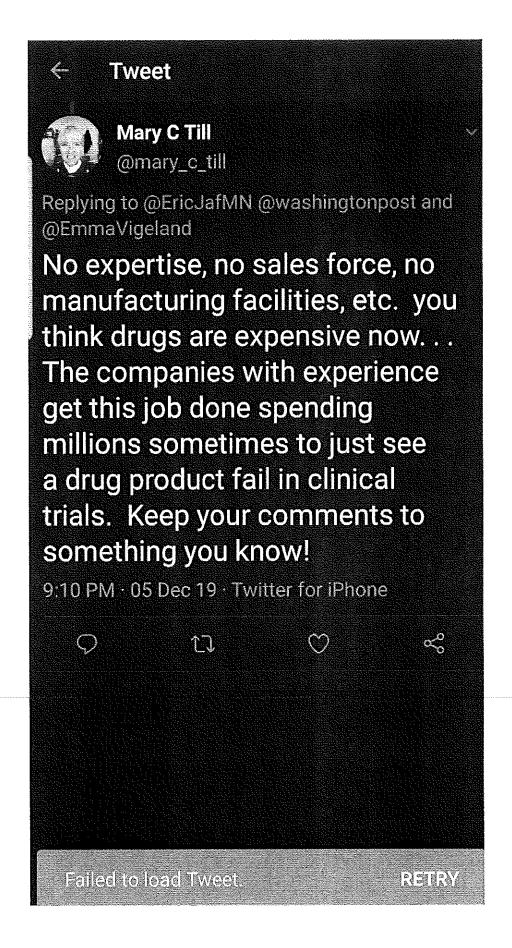


Note: Thomas Blake (Twitter handle: @ThomasBlake2) is a senior member and cofounder of PrEP4All.







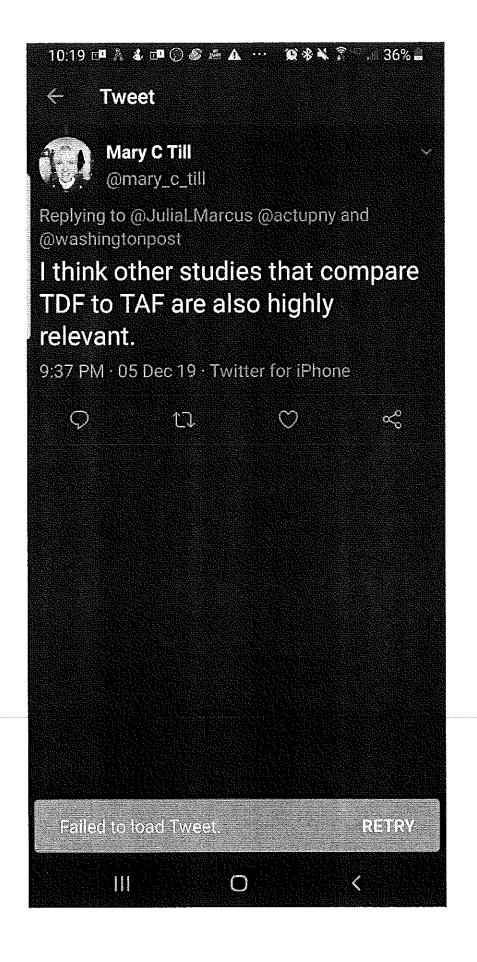




Mary C Till @mary_c_till · 13h

Replying to @JuliaLMarcus @actupny and @washingtonpost

So you don't believe the data on decreased renal toxicity and less effective t on bone density??? The multiple clinical studies are all lies??? Proof please.



Mary C Till 251 Tweets Media Likes Tweets & replies Tweets Gilead delayed safer HIV drug to extend monopoly profits, advocates... washingtonpost.com (~) 190 11 The second secon $\bigcirc 1$ ↑ 140 Show more replies Doug Murphy @Douglas_Murphy · 6h



Why is a USPTO attorney commenting on matters before the USPTO? Do ethics even matter to you?

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Mary C Till @mary_c_till · 1h My comment was about the proof of the allegation, not a comment on the merits of anything pending at USPTO.