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United States Senate

WASHINGTON, DC 20510

February 5, 2019

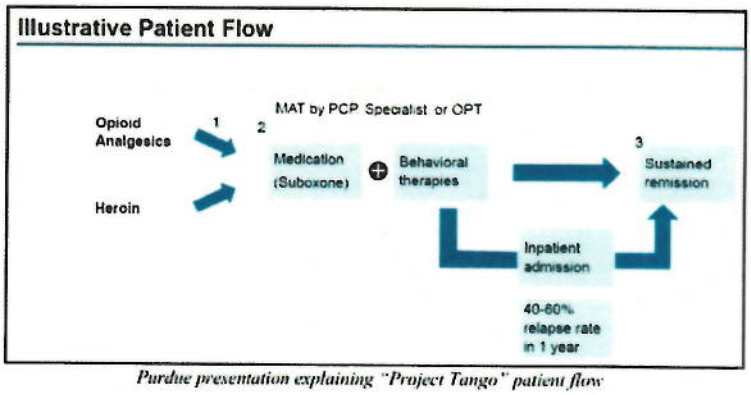
The Honorable Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
Department of Health and Human Services
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

I was alarmed by recent press reports relating to litigation surrounding Purdue Pharma Inc., in which it was revealed that Purdue Pharma sought to become an "end-to-end pain provider" that was capable of continuing to market addictive prescription opioids while also marketing anti-addiction medications that could later be used in opioid use disorder treatment. In light of these reports, I write to seek answers to questions concerning the prevalence of prescription opioid manufacturers pursuing the marketing of anti-addiction medications and the potential formation of these "end-to-end pain provider" structures.

According to the reporting,[1] Purdue Pharma envisioned a cynical prescription drug sales strategy under which a patient begins with pain treatment via the company's prescription opioids, falls into opioid addiction and then receives opioid addiction treatment that utilizes a related drug in the company's portfolio. In developing this plan, the Purdue Pharma staff described opioid addiction treatment as "an attractive market" and even went so far as to calculate the compound annual growth of opioid addiction to assess the potential market for reaping additional profits from patients who were addicted to opioids.[2] In illustrating the "end-to-end" system's potential, a Purdue Pharma staff presentation (see Exhibit 1 below)[3] noted that 40 to 60 percent of opioid use disorder patients who achieved remission would ultimately relapse, creating opportunities for additional revenue from the company's proposed opioid addiction therapies.

Exhibit 1



Purdue presentation explaining "Project Tango" patient flow

Purdue Pharma's efforts to profit off of the addiction treatment for patients whose addiction they may have contributed to is appalling. The company's ongoing profit from the sale of addictive prescription opioids causes grave concerns on its own and these new developments only add to those concerns.

I applaud the work that the Food and Drug Administration (FDA) has undertaken in recent years to help reduce the prevalence of opioid prescribing and appreciate the agency's commitment to helping to advance non-addictive pain treatment therapies that can act as alternatives to prescription opioids. We rely on the FDA to protect the public health, and while I understand that the agency's statutory mandate may be limited, I believe that it is necessary for federal regulators, including the FDA, to conduct additional oversight of this "end-to-end pain provider" issue. Drug manufacturers should not be given free rein to unleash addictive products onto the market, profit from the sale of those addictive products and then secure additional financial benefit from the addiction treatment that can become necessary as a result of the use of their addictive product.

In order to be able to help inform my future efforts to address these concerns and provide the public with a better understanding of the scope of this issue, I request answers to the following questions:

1. How many manufacturers of FDA-approved Schedule II narcotic opioid therapies also have obtained or are currently seeking FDA approval for indications for opioid addiction treatment?

2. What actions has the FDA taken, and what actions could the FDA take in the future, to help protect against these types of perverse incentives in the intersection between pain treatment drugs and drug therapies for addiction recovery? Are there additional federal authorities that Congress could provide to the FDA to help better address this issue?

I appreciate your ongoing commitment to ensuring that communities across the country are better protected from the dangers of prescription opioids. Your attention to this issue will help to make certain that we can tackle the opioid epidemic in the most effective and timely manner. Should your staff have any questions regarding this inquiry, please do not hesitate to contact [redacted].

Sincerely,

Jeanne Shaheen
United States Senator

[1] Erica Orden, "Purdue Pharma sought secret plan to become 'end-to-end pain provider,' lawsuit alleges," CNN, January 31, 2019, https://www.cnn.com/2019/01/31/health/purdue-pharma-unredacted-lawsuit/index.html (last visited Feb 1, 2019).

[2] Complaint at 154, *Massachusetts v. Purdue Pharma L.P.*, Massachusetts Superior Court, C.A. No. 1884-cv-01808, (2019). Accessed at: https://www.mass.gov/files/documents/2019/01/31/Massachusetts%20AGO%20Amended%20Complaint%202019-01-31.pdf

[3] Id. at 155.