THOM TILLIS
NORTH CAROLINA
113 DIRKSEN SENATE OFFICE BLDG
WASHINGTON, DC 20510
PH: (202) 224-6342

https://tillis.senate.gov

United States Senate

WASHINGTON, DC 20510

COMMITTEES
ARMED SERVICES
BANKING, HOUSING, AND URBAN DEVELOPMENT
JUDICIARY
VETERANS' AFFAIRS

VIA ELECTRONIC TRANSMISSION

April 1, 2022

The Honorable Dr. Robert Califf, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Mr. Drew Hirshfeld
Commissioner for Patents
Performing the functions and duties of the
Under Secretary of Commerce for Intellectual Property and Director
United States Patent and Trademark Office
600 Dulany Street
Alexandria, Virginia 22314

Dear Dr. Califf and Mr. Hirshfeld,

I write you again regarding several sources that are often cited to advance the false narrative that patent protections are to blame for high drug prices.[1] I remain concerned that these sources are based on opaque methodologies, and appear to contain inaccurate or incomplete information that may be misleading policymakers.[2] In my previous letter, I requested that your agencies conduct an independent assessment of the accuracy and reliability of those sources.

As I explained in that letter, these commonly referenced sources claim that biopharmaceuticals are often protected by dozens or hundreds of patents each, with an alleged effect of blocking generic competition for 30 to 50 years or longer per drug. However, researchers who have analyzed these claims have identified what appear to be serious flaws, inaccuracies, and biases in the methods and calculations of those advancing the claims.

I am specifically concerned about work from the Initiative for Medicines, Access & Knowledge (I-MAK). When I last wrote you, I also sent a letter to I-MAK inviting it to disclose its underlying data set, or at least to provide a detailed explanation of its methods to enable others to check the accuracy of I-MAK's alleged patent count, and to assess the credibility of its other assertions. While I had hoped to receive a constructive response, I-MAK unfortunately declined

[1] *See, e.g.*, I-Mak, *Overpatented, Overpriced*, August 2018; and *America's Overspend*, October 25, 2017. https://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/; *see also Evergreen Drug Patent Database*

[2] *See* Letter from Senator Tillis to Acting Commissioner Woodcock and Commissioner/Performing Functions of Director Hirschfeld, dated January 31, 2022.

CHARLOTTE OFFICE:
10150 MALLARD CREEK RD
SUITE 508
CHARLOTTE, NC 28262
PH: (704) 509-9087

RALEIGH OFFICE:
310 NEW BERN AVE
SUITE 122
RALEIGH, NC 27601
PH: (919) 856-4630

HIGH POINT OFFICE:
1840 EASTCHESTER DR
SUITE 200
HIGH POINT, NC 27265
PH: (336) 885-0685

GREENVILLE OFFICE:
1694 E ARLINGTON BLVD
SUITE B
GREENVILLE, NC 27858
PH: (252) 329-0371

HENDERSONVILLE OFFICE:
1 HISTORIC COURTHOUSE SQ
SUITE 112
HENDERSONVILLE, NC 28792
PH: (828) 693-8750

to disclose its data, and instead largely repeated the same explanations it employs in its reports.[3] I have enclosed a copy of their response for your review.

I-MAK attempts to justify its refusal to disclose its data on the basis that anyone "familiar with patent searching techniques would be able to replicate" its methods to "arrive at the same or very similar datasets."[4] Its failure to disclose this information raises a new question that you may wish to include in the analysis I previously requested—namely, whether you can, by employing standard "patent searching techniques," in fact credibly arrive at similar patent numbers and similar effective patent terms as those claimed in I-MAK's reports.

However, other assertions and admissions in I-MAK's response to my office would seem to cast serious doubt on that possibility. For example, in its letter, I-MAK acknowledges that it is counting patent applications among its figures. But, in its October 2017 report on three cancer drugs, for instance, I-MAK calculates a figure that it terms "total patents," but this number includes not just patents, but also pending patent applications, and even fully abandoned patent applications.[5] My understanding is that others employing "patent searching techniques" certainly would not conflate pending and abandoned patent applications with granted patents and call them all "total patents."

With respect to the periods of market exclusivity that I-MAK claims extend for 30 to 50 years for most drugs, it represented to me that its reports "clearly state that the number of years of patent protection for each drug studied is [merely] the drugmakers' attempt or potential to extend its monopoly period that could block competition."[6] This is another admission that does not appear to be an accurate representation of what I-MAK's reports attempt to show. In its 2018 report, I-MAK's key metrics are the "years block competition," and not the attempted or potential patent term. I-MAK concedes in its response to my letter at least six of the twelve drugs in its 2018 report indeed face generic competitors today, years before its key metric of "years blocking competition." I also understand that two of the three drugs in its 2017 report are already generic, including one that, like one in the 2018 report, was indeed generic long before the report's publication date.[7]

As you can see, there remain concerns with I-MAK's work and methodology. Those concerns are much more fundamental than challenging a single or even several errors. Instead, my concern

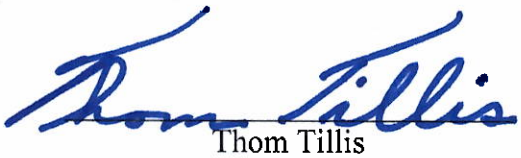
---

[3] I-Mak Letter to Senator Thom Tillis, March 9, 2022.
[4] *Id.*
[5] *See* I-Mak, *America's Overspend*, October 25, 2017 at 3 (Alleging that "105 patents cover the various hematology cancers and indications for which Revlimid has been approved," of which 29 are "abandoned patent applications," and another 10 are pending applications); *id.* at 5 (Alleging that a "total of 45 patents" protect Sovaldi,® of which 16 are "abandoned patent applications" and 2 are pending applications); *id.* at 7 (Alleging that "a total of 73 patents" cover Gleevec, of which the majority (44) are "abandoned applications" and another is a pending application).
[6] I-Mak Letter to Senator Thom Tillis, March 9, 2022.
[7] According to public sources, Revlimid went generic this month, contrary to the report's claims that the "patents enable a minimum exclusivity period from 2019 through 2028." *America's Overspend* at 7. Gleevec went generic in early 2016, almost two years before the report was published, despite the report's suggestion that is protected until 2029.

is to ensure that policymaking in this critical area is based on accurate, reliable, and replicable facts and evidence. Accordingly, I reiterate my request that your agencies conduct an independent assessment and study of these matters that will be completed by no later than December 31, 2022.

Please reply to me by May 1, 2022 indicating that you will conduct such an assessment. Having this valuable information before we begin a new Congress will ensure that lawmakers are armed with all the key facts and data needed to make sound public policy decisions regarding drug pricing. Thank you for your attention to this matter. If you have any questions, please do not hesitate to contact me.

Sincerely,



Thom Tillis
United States Senator