United States Senate
WASHINGTON, DC 20510

VIA ELECTRONIC TRANSMISSION

June 22, 2022

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

Dear Dr. Califf,

I write you today, for a third time, regarding my prior two letters regarding my concern over several sources that are often cited to advance the false narrative that patent protections are to blame for high drug prices.

My first letter was sent on January 31, 2022, and it requested that an independent assessment and a study be completed by no later than December 31, 2022. My second letter was sent on April 1, 2022, and it (1) again requested that an independent assessment and study be completed by no later than December 31, 2022, and (2) requested a reply to me by May 1, 2022, indicating that you will conduct such an assessment.

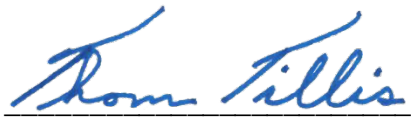
No formal reply from you was received regarding an indication that you will conduct such an assessment. In addition, I understand from my staff that your agency refuses to reply to emails or to engage. This is unacceptable.

Your prompt attention to this matter is greatly appreciated as having this valuable information before we begin a new Congress will ensure that lawmakers are armed with all of the key facts and the data needed to make sound public policy decisions regarding drug pricing.

I hope that you will reply to both letters by July 13, 2022.

Please do not hesitate to contact me should you have any questions.

Sincerely,



Thom Tillis
United States Senator

ANNEX

THOM TILLIS
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United States Senate

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VETERANS' AFFAIRS

VIA ELECTRONIC TRANSMISSION

January 31, 2022

Dr. Janet Woodcock
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

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

Dear Dr. Woodcock and Mr. Hirshfeld:

I write you today in my capacity as Ranking Minority Member of the Senate Judiciary Committee Subcommittee on Intellectual Property. As the Ranking Member—and as a Senator from a State with a number of leading innovative biotech, pharmaceutical, and medical device companies—I am keenly aware of the role that strong intellectual property rights play in enabling the development of lifesaving, innovative biopharmaceuticals and other medical treatments.

Unfortunately, I am also aware of the false narrative being advanced by some that patents are being systemically used in ways not contemplated by our patent laws to delay generic drug competition. While I share the important goal of lowering drug prices for all Americans, I also believe it is imperative that any proposed solutions are fact-driven, objective, and take into account the many facets of this highly complex issue. Any solutions to this difficult and important issue must ensure that we do not undermine the robust intellectual property protections needed to enable the development of new medicines in the first place.

In order to ensure an objective, measured, and appropriate approach to this issue, it is fundamental that assumptions and premises be based on accurate facts and data from reliable, unbiased sources. Sadly, it has recently come to my attention that several of the main sources driving the narrative that patents are to blame for high drug prices do not appear to meet these fundamental criteria. Specifically, I am referring to research from the Initiative for Medicines,

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Access & Knowledge (I-MAK) and a separate project from the University of California (UC) Hastings Law School project called the "Evergreen Drug Patent Search."[1]

I-MAK appears to be a primary source of data regarding the role of patents in drug pricing that is cited during these debates. I-MAK concludes that all of the top-selling drugs are protected by dozens or hundreds of patents that supposedly have the effect of blocking generic competition for an average of 30 to 50 years each.[2] But according to at least one new analysis that looks more closely at I-MAK's figures, the organization does not transparently disclose or explain its underlying data, and the data differs by orders of magnitude from public sources like the US Orange Book and court filings.[3] It also appears that many of the drugs alleged to be protected by "patent thickets" blocking competition for decades to come have already gone generic, in some cases before the reports making these allegations were even published.

The "Evergreen Drug Patent Search" database similarly suggests that nearly every FDA-approved drug has amassed unduly large numbers of "protections" that "artificially extend" exclusivity far into the future. As with the I-MAK reports, however, a subsequent analysis of this source has raised concerns about inaccuracy in the underlying data, inadequate transparency, and flawed methodology, and warns that the database risks causing policymakers to be "misled by the statistics."[4] As one illustration, the database apparently contains multiple entries for aspirin and suggests that it is still enjoying exclusivity under an "evergreening" strategy, even though aspirin has been available in generic form for over 100 years.

Both drug pricing, and matters of patent law and policy that impact the development of innovative medicines, are too important to this country to rely on sources whose accuracy and reliability are in question. For this reason, I request that your agencies conduct an independent assessment and analysis of the sources and data that are being relied upon by those advocating for patent-based solutions to drug pricing. It is my hope and belief that a clearer and more accurate picture of the underlying facts will help to reveal whether, and to what extent, patent-related issues are really contributing to high drug prices, and help to focus future policymaking in the right areas.

It is my hope that such an independent assessment and study will be completed by no later than December 31, 2022. 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.

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[1] *See* https://sites.uchastings.edu/evergreensearch/about/#.YfbYL-rMKkw

[2] *See, e.g.,* I-MAK, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving Up Drug Prices* (2018); https://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/ .

[3] Mossoff, Adam, *Unreliable Data Have Infected the Policy Debates Over Drug Patents,* Hudson Institute.

[4] George Mason University Center for Intellectual Property x Innovation Policy, UC Hastings' Evergreen Drug Patent Search Database: A Look Behind the Statistics Reveals Problems with this Approach to Identifying and Quantifying So-Called "Evergreening."

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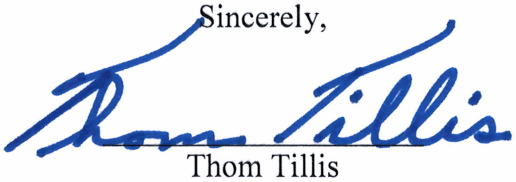

Thom Tillis
Ranking Member
Subcommittee on Intellectual Property

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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.

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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

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[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.

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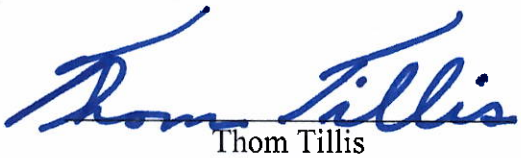

Thom Tillis
United States Senator