United States Senate

COMMITTEE ON HEALTH, EDUCATION, LABOR,
AND PENSIONS

WASHINGTON, DC 20510–6300

October 23, 2023

The Honorable Christi A. Grimm
Inspector General
U.S. Department of Health and Human Services
Office of Inspector General
330 Independence Avenue, SW
Washington, DC 20201

Dear Inspector General Grimm:

With a budget of more than $47 billion, the U.S. National Institutes of Health (NIH) is the largest funder of medical research in the world. This research has led to new treatments and prescription drugs that have significantly improved the lives of the American people and people throughout the world.

Having said that, as the Chairman of the Health, Education, Labor, and Pensions (HELP) Committee, I am growing increasingly alarmed that not only has the NIH abdicated its authority to ensure that the new drugs it helps develop are reasonably priced, it may actually be exceeding its authority to grant monopoly licenses to pharmaceutical companies that charge the American people, by far, the highest prices in the world for prescription drugs.

One particularly egregious example has recently been brought to my attention that I believe demands your immediate attention.

On September 21st of this year, the NIH proposed to grant an exclusive patent license to Scarlet TCR for a treatment for cervical cancer that could potentially be worth hundreds of millions if not billions of dollars in the Federal Register. This is a treatment that was invented, manufactured and tested by the NIH. One of the leading NIH researchers of this cancer treatment appears to have a direct relationship with Scarlet TCR and may stand to gain a massive financial windfall as a result of this exclusive patent license.

Under the Bayh-Dole Act, the NIH is only supposed to provide an exclusive license to a private company on government-owned inventions when the monopoly would be a “reasonable and necessary incentive” to help advance the product, per 35 U.S.C. § 209(a)(1).

There does not appear to be anything reasonable and necessary about granting a monopoly for a treatment that was invented, manufactured and tested by the NIH, is already in late stage trials

and could potentially enrich a former NIH employee who was one of the major government researchers of this treatment. Based on current law and the best interest of U.S. taxpayers who paid for this cancer therapy, it would seem to make more sense for the NIH to offer non-exclusive licenses so that multiple manufacturers can produce this important cancer therapy at reasonable and affordable prices.

The apparent abuse of the system by the NIH with respect to the exclusive patent license for this cancer therapy is so egregious that it has been characterized as a "how-to-become-a-billionaire program run by the NIH."

If accurate that would be absolutely unacceptable. The NIH should be doing everything within its authority to lower the outrageously high price of prescription drugs. It should not be granting a monopoly on a promising taxpayer-funded therapy that could cost hundreds of thousands of dollars for cancer patients in a way that appears to exceed its statutory authority.

Therefore, I am writing to request that the Office of Inspector General for the Department of Health and Human Services immediately initiate an investigation into this matter.

As part of your investigation, I ask that you specifically address the following issues:

1. Did NIH properly determine that an exclusive license is a reasonable and necessary incentive and that the proposed scope of exclusivity is reasonably necessary in the decision to prospectively grant an exclusive license to Scarlet TCR, Inc. – a company so obscure that it does not have a website and has not made a single filing to the Securities and Exchange Commission?
2. Were any ethics rules violated in the prospective grant of an exclusive license to a company linked to a former employee at NIH who was one of the leading researchers on this cancer therapy?
3. How does NIH assess whether an exclusive license is a "reasonable and necessary incentive to call forth the investment capital and expenditures needed to bring the invention to practical application, or otherwise promote the invention's utilization by the public" per 35 U.S.C. § 209(a)(1)?
4. What steps does NIH take to explore non-exclusive licensing?
5. How does NIH assess whether the proposed scope of an exclusive license is "reasonably necessary to provide the incentive for bringing the invention to practical application, as proposed by the applicant, or otherwise to promote the invention's utilization by the public" per 35 U.S.C § 209(a)(2)?

I thank you for your prompt attention to this matter.

Sincerely,

Bernard Sanders
Chair
U.S. Senate Committee on Health, Education, Labor, and Pensions