DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

December 29, 2022

The Honorable Rand Paul, M.D.
United States Senator
Washington, DC 20510

Dear Senator Paul:

Thank you for your letter to Dr. Lawrence Tabak, who is Performing the Duties of the Director, National Institutes of Health (NIH), requesting the disclosure of royalty payments made by third-party providers to NIH employees. As Acting Principal Deputy Director of NIH, I am pleased to respond to your request.

NIH contributes to the development of biomedical products to improve the health of Americans in many ways. One is by managing inventions made by employee intramural research program (IRP) scientists, including the responsibility for seeking patent protection and licensing to the private sector for commercial development. Examples include the first AIDS drugs (antiretrovirals), vaccines against hepatitis and HPV, treatments for cancer, and diagnostics for HIV and the rare genetic disease, familial Mediterranean fever.[1] NIH can also license biological materials to companies for use in commercial products. One example, Synagis, used for the prevention and treatment of serious lower respiratory tract disease in children, traces its beginnings to the IRP as the monoclonal antibody palivizumab.

NIH and the grantee institutions it supports license inventions to private entities to bring the products to market. Those licenses generate ongoing payments in varying amounts, known as royalties, which are authorized by law, and which support the cost the Federal Government bears in the licensing and patenting activities needed to support future commercialization. Some portion of the total royalties NIH receives must by law be paid to the inventors according to a statutory formula (15 U.S.C. 3710c).[2] The statutory formula includes a per-inventor cap on annual royalty payments.[3] Scientists who invent new technologies using taxpayer dollars receive royalties when those inventions are licensed to the commercial sector, whether those scientists are employed by NIH directly or any one of our grantee institutions. At NIH, Technology Transfer offices are responsible for negotiation of the financial terms. Scientists have no role in the decision to patent, the prosecution of the patent (other than to give technical input where requested), or in the licensing of the invention. NIH scientist inventors are prevented from participating in that process via a firewall. This is an important check on potential conflict of interest.

NIH does not release information pertaining to royalties paid to individual inventors for a variety of reasons. The foremost reason is that under 15 U.S.C. § 3710a(c), and 35 U.S.C. § 209(f) and associated regulations, information pertaining to royalties is the commercial and financial information of a non-federal party and not subject to disclosure as privileged and confidential

[1] irp.nih.gov/our-research/commercializing-inventions
[2] uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title15-section3710c&num=0&edition=prelim
[3] techtransfer.nih.gov/royalty/information-nih-inventors#3

information. Moreover, royalties that NIH inventors receive in the performance of their official duties are considered income from the Federal Government because the payments are determined and transmitted by NIH, not by the licensee, as compensation from the government.[4] Salary and other compensation/benefit payments received from the U.S. Government (USG) are not required to be reported via the public financial disclosure reporting requirements of the Ethics in Government Act of 1978, 5 U.S.C. App (as amended).[5] Additionally, a licensee company's sales figures may be calculated from the statutory formula outlining royalty payments. For that reason, individual inventor royalty payments may constitute confidential business information, which is protected from disclosure.

Importantly, NIH has numerous policies and procedures to ensure the Nation's investment in biomedical research is held to the highest standards, is conducted in accordance with its mission, and is not steered by potential personal financial interests of researchers. NIH aims to ensure that (1) scientific findings are objective, credible, and readily available to the public, and (2) the development and implementation of policies and programs is transparent, accountable, and evidence based. To help ensure the high quality and integrity of its intramural programs, NIH has developed and implemented NIH-wide policies and review standards for research, training, and technology transfer. Intramural research at NIH is reviewed by committees of scientists from outside NIH. Policies and procedures for (1) outside scientific review and evaluation of intramural research at NIH by Boards of Scientific Counselors (BSCs) and (2) review of the Scientific Directors' scientific and administrative leadership by National Advisory Councils or Boards, as assisted by *ad hoc* subcommittees, are outlined in the NIH Policy Manual under Section 3005, Review and Evaluation of Intramural Programs.[6] The BSCs comprise individuals who themselves have outstanding scientific credentials and who are committed to providing rigorous, objective reviews to assist in evaluating the quality of the intramural research programs. BSC evaluations are also distributed to the NIH Deputy Director for Intramural Research, the appropriate NIH Institute, Center, or Office (ICO) Director, and the ICO Scientific Director. The BSC also reports annually to the ICO National Advisory Council or Board.

Managing real or apparent conflicts of interest in the IRP is vital to the integrity of the biomedical research enterprise. As members of the executive branch of the USG, NIH intramural scientists are subject to the Standards of Ethical Conduct for Employees of the Executive Branch.[7] In addition, NIH scientists are also subject to numerous other federal regulations and requirements in intramural research activities, including:

- 5 CFR Part 2634 - Executive Branch Financial Disclosure, Qualified Trusts, and Certificates of Divestiture[8]
- 5 CFR Part 2636 - Limitations on Outside Earned Income, Employment and Affiliations for Certain Noncareer Employees[9]

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[4] *Ethics Issues Related to the Federal Technology Transfer Act of 1986*, 17 Op. O.L.C. 46 (1993).
[5] https://www.oge.gov/web/278eguide.nsf/2cf9ac792bc0654a85257ea1005f838a/e73a0ba513ffb4b285257f45007628e0?OpenDocument
[6] policymanual.nih.gov/3005
[7] oge.gov/web/oge.nsf/resources_standards-of-conduct
[8] www.govinfo.gov/app/details/CFR-2012-title5-vol3/CFR-2012-title5-vol3-part2634
[9] www.govinfo.gov/app/details/CFR-2012-title5-vol3/CFR-2012-title5-vol3-part2636

- 5 CFR Part 2640 - Interpretations, Exemptions and Waiver Guidance Concerning 18 U.S.C. 208 (Acts Affecting a Personal Financial Interest)[10]
- 5 CFR Part 2641 - Post-Employment Conflict of Interest Restrictions[11]
- 5 CFR Part 5501 - Supplemental Standards of Ethical Conduct for Employees of the Department of Health and Human Services[12]
- 5 CFR Part 5502 - Supplemental Financial Disclosure Requirements for Employees of the Department of Health and Human Services[13]

Each NIH ICO employs ethics officials who are assigned to assist NIH researchers in understanding and complying with ethics rules. Additional information on the ethical conduct laws, regulations, and policies can be found at https://ethics.od.nih.gov/.

When an NIH investigator submits a covered clinical research protocol for review by the NIH Institutional Review Board (IRB), they must indicate if they are an inventor for any intellectual property that is related to the research. The Office of Human Subjects Research Protections works with the ICO Technology Transfer office to determine if the invention is licensed and if the investigator is receiving any royalty payments related to the object of the clinical research. If the investigator is receiving royalties, the NIH IRB determines if additional protections for human subjects are needed. The NIH IRB is not informed of the amount of royalty payments received by any NIH investigator.

Finally, the NIH Division of Program Integrity[14] is responsible for conducting reviews of allegations involving: (1) misuse of NIH grant or contractor funds, (2) grantee or contractor conflicts of interest, and (3) other misconduct or misuses of NIH resources by NIH employee or others doing business with NIH. NIH also maintains a dedicated email address NIHHotline@mail.nih.gov and phone hotline (301) 496-5586 for confidentially reporting information.

Thank you for your interest in the integrity of NIH research. I hope that this information is helpful to you. An identical response has been provided to the co-signers of your letter.

Sincerely,

Tara A. Schwetz, Ph.D.
Acting Principal Deputy Director
National Institutes of Health

[10] www.ecfr.gov/current/title-5/chapter-XVI/subchapter-B/part-2640
[11] www.ecfr.gov/current/title-5/chapter-XVI/subchapter-B/part-2641
[12] www.ecfr.gov/current/title-5/chapter-XLV/part-5501
[13] www.ecfr.gov/current/title-5/chapter-XLV/part-5502
[14] oma.od.nih.gov/DPI/Pages/Home.aspx