KNOWLEDGE ECOLOGY INTERNATIONAL

110 Maryland Avenue NE
Suite 308
Washington, DC 20002
www.keionline.org

July 28, 2025

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857
Via Email: FDA FOIA Portal

Re: Freedom of Information Act Request Related to FDA Orphan Products Grant Program

Dear FOIA Officer:

Under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, Knowledge Ecology International (KEI) requests electronic copies of records concerning the Food and Drug Administration (FDA) Orphan Products Grant Program. The program is administered by the FDA's Office of Orphan Products Development (OOPD) and provides grants for clinical trials.[1]

A search of the Orphan Products Grant Program returns a list of over 700 grants related to orphan clinical trials.[2] The information provided by this search includes: Title, PI, Institution, Location, Start Date, and End Date. KEI seeks further metadata concerning these grants. For each of these grants, KEI seeks the NIH Project Number (as used in the NIH RePORTER), NCT identifier of the trial, the enrollment and the grant amount.

If the FOIA office is unable to provide this metadata for the grants in the Orphan Products Grant Program, KEI will submit a FOIA request for copies of all 700+ grant agreements.

The period of this request is from January 1, 1983 (the year of the earliest grant on the list) to the present.

KEI notes that we have tried to match the data from the FDA's publicly posted grant data with information available in the NIH RePORTER and the NIH ClinicalTrials.Gov databases.

[1] https://www.fda.gov/industry/orphan-products-grants-program/clinical-trials-grants-program
[2] https://www.accessdata.fda.gov/scripts/opdlisting/oopdgrants/

However, this process has proven challenging, and in many cases we cannot confirm whether the datasets align. These difficulties have arisen with several recurring problems:

- The projects with similar or identical titles often appear in different years, with different associated institutions, and locations, making it unclear whether they refer to the same award.
- Sub-projects frequently lack descriptive information (often the abstract text), leaving the grant title as the only indicator. Even then, titles differ across the FDA, NIH RePORTER, and CinicalTrials.gov databases.
- Principal Investigators (PIs) listed in the FDA data sometimes do not appear for a single project in NIH RePORTER, or the search returns unrelated projects.
- Even when the related record can be located, most entries do not include key information, such as the NCT number or a link to ClinicalTrials.gov. Moreover, when NCT information is listed, sometimes it is linked to the incorrect and unrelated clinical study. For example, a project on pancreatic cancer included, in the clinical studies section, a study on hormones in premenopausal women.

Having accurate information on the amount of federal subsidy for these trials, and being able to determine the per patient costs of the trials, is important for evaluating the efficacy and efficiency of incentives and subsidies for the development of treatments for orphan diseases, and the reasonableness of prices. This is especially important given that treatments for rare disease currently make up roughly half of all new drugs approved by the FDA and have significant impacts on U.S. spending on medicines.

Request for Full Waiver of Fees

KEI requests that the processing fee be waived pursuant to 5 U.S.C. § 552(a)(4)(A) and 45 C.F.R. § 5.45, which stipulate that FOIA fees must be waived where disclosure “is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government,” and “is not primarily in the commercial interest of the requester.”

The subject of this request concerns the operations of the federal government because it pertains to the FDA’s grantmaking programs and how it supports biomedical research and development for rare diseases.

The disclosures will likely contribute to public understanding of the extent to which the FDA has supported rare disease biomedical research and development, and how its support has changed over time.

KEI has published or been quoted widely with respect to issues concerning government management of biomedical R&D and intellectual property as it relates to the public interest, consumer interest, and public health. James Love, Director of KEI, has personally written on

these issues in publications such as *the Financial Times* and in several academic and policy journals, and has been named as one of the 50 most influential persons in intellectual property, by *Managing Intellectual Property*, three times, including in 2019.[3]

The stories listed in the Annex demonstrate how KEI effectively uses FOIA requests to widely disseminate information that is in the public interest.

The request is not in KEI's commercial interest because KEI is a nonprofit, 501(c)(3) public interest organization. Granting this fee waiver request would fulfill Congress's legislative intent in amending the Freedom of Information Act. *See Judicial Watch, Inc. v. Rosetti*, 326 F.3d 1309, 1312 (D.C. Cir. 2003)("Congress amended FOIA to ensure that it be liberally construed in favor of waivers for noncommercial requesters.")(quotation marks omitted).

Additional Comments

Please provide the documents requested in electronic format.

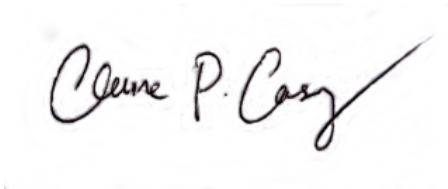
We request the identification of any withheld records with specificity, including descriptions of the withheld material in detail, the specific statutory exemption or basis for denial, the reasons that the statutory exemption or denial applies in this instance, and the interests that would be foreseeably harmed by disclosure of the record. If this request is denied in whole or part, please justify all such denials by reference to specific exemptions, and provide an explanation of why HHS "reasonably foresees that disclosure would harm an interest" protected by that exemption or why "disclosure is prohibited by law[.]" 5 U.S.C. § 552(a)(8).

Please also ensure that all segregable portions of otherwise exempt material are released.

Please contact us if you have any questions about our request for records or if you require additional information in support of our request for a fee waiver.

Thank you in advance for your assistance.

Sincerely,



Claire Cassedy
Knowledge Ecology International
110 Maryland Avenue NE, Suite 308

[3] https://www.managingip.com/Article/3907375/The-50-most-influential-people-in-IP-2019.html.

Washington, DC 20002
claire.cassedy@keionline.org

ANNEX 1

KEI is a not-for-profit non-governmental organization that searches for better outcomes, including new solutions, to the management of knowledge resources. KEI has particular expertise on issues relating to intellectual property rights, technology transfer, the economics of innovation including the incentives to invest in biomedical research and development and the production of data, software and cultural works, policies regarding privacy, and more generally the production and management of and access to knowledge goods.

KEI has the ability and intention to effectively convey the information contained in the requested records to the public. KEI operates websites including keionline.org and drugdatabase.info that are used to disseminate information to the public, at no charge and without advertising, as well as several listservs, such as ip-health, which also has an open archive.

KEI is regularly consulted by advocates, academics, the press, legislators and officials working in governments and intergovernmental bodies. KEI seeks the requested records to provide fact-based and useful commentary on public policy issues. KEI uses social media as well as its own websites and listservs to directly distribute that analysis to the broad audience of persons interested in the subject of the request. KEI also publishes research and commentary in a variety of widely read news outlets, journals and blogs.

The following are examples of KEI's use of FOIA responses to inform the public, published on KEI's website, www.keionline.org.

- KEI's web page of COVID-19 Contracts: https://www.keionline.org/covid-contracts
- 2022:1 KEI Briefing Note: Selected U.S. Government COVID Contracts with Authorization and Consent to Non-Voluntary Use Of Third Party Patents.
- 2021:1 KEI Research Note: US government COVID contracts and the definition of practical application.
- 2019 September 11. "FOIA: Records of USTR Lighthizer Bilateral Meetings at 2018 World Economic Forum in Davos";
- 2017 February 28. "CDC FOIA shows US, WHO opposed request to discuss UNSG's High-Level Panel on Access to Medicines Report at EB";
- 2016 October 18. "Kite Pharma Uses CRADAs to Conduct Important Clinical Research on New Cancer Treatments";

- 2016 September 19. "500+ Pages of Documents on NFL Attempts to Influence NIH Funding of Concussion Studies";
- 2016 September 16. "NIH Waivers for U.S. Manufacturing Requirements for Federally-Funded Drugs"; and
- 2017 June 8. "FOIA documents: In 2015 Novartis asked U.S. Dept of Commerce to Pressure Colombia Against Compulsory License on Glivec."

The following are examples of KEI's use of data from FOIA requests published in the open source database drugdatabase.info:

- http://drugdatabase.info/fda-orange-book-patents/;
- http://drugdatabase.info/nih-exclusive-licenses/; and
- http://drugdatabase.info/cradas/.

Additionally, KEI works closely with journalists to provide analysis of documents obtained by KEI under the FOIA. KEI does not merely distribute documents to journalists, but provides in-depth analysis that later becomes the basis for stories. These are a few examples:

- 2022. August 23. Lee Fang. "Moderna among Firms Quietly Granted Powers to Seize Patent Rights During Early Days of COVID Pandemic." *The Intercept.*
- 2021. August 25. Sydney Lupkin. "The U.S. Paid Billions To Get Enough COVID Vaccines Last Fall. What Went Wrong?" *NPR.*
- 2017 March 3. Vidya Krishnan, "U.S. nixed India's plea on reforms in medicine," *The Hindu*.
- 2016 December 31. Dan Vergano, "If Taxpayers Invent A Drug, Should The Government Just Give It Away?," *Buzzfeed News*.
- 2016 December 19. Matt Richtel and Andrew Pollack, "PUBLIC LABS, CORPORATE GAINS: Harnessing the U.S. Taxpayer to Fight Cancer and Make Profits," *New York Times*. Front page.
- 2013 June 22, Kimberly Kindy, "Filmmakers' group tries to reshape treaty that would benefit the blind," *the Washington Post*.
- 2013 June 24. Paige McClanahan, "US film industry tries to weaken copyright treaty for blind people: Treaty to make copyrighted works available for visually impaired people – 90% of whom live in global south – coming up against film lobby," *The Guardian*.

Examples of articles written by KEI staff include the following:

- 2019 September 18. James Love, "Why didn't nonprofits and the NIH require 'reasonable' pricing for Zolgensma? That may happen in France," *STAT News;*
- 2019 April 2. "USMCA Agreement and the Remedies for Patent Infringement." *Bill of Health*, Petrie-Flom Center at Harvard Law School;
- 2019 May 21. Luis Gil Abinader and Jorge L. Contreras, "The Patentability of Genetic Therapies: CAR-T and Medical Treatment Exclusions Around The World," *American University International Law Review*;

- 2019 July 2. James Love and Ellen't Hoen, "Time to make essential cancer drugs more affordable: Governments can do more to pressure makers to bring down prices," *Financial Times;*
- 2018 September 24. Michael S. Sinha, Mehdi Najafzadeh, Elizabeth K. Rajasingh, James Love, Aaron S. Kesselheim, "Labeling Changes and Costs for Clinical Trials Performed Under the US Food and Drug Administration Pediatric Exclusivity Extension, 2007 to 2012," *JAMA Intern Med.* (doi:10.1001/jamainternmed.2018.3933);
- 2017 Oct 21. James Love, "Errors in Patent Grants: More Common in Medical Patents," *Bill of Health*, Petrie-Flom Center at Harvard Law School; and
- 2015 December 3. James Love and Andrew S. Goldman, "Colombia Asked To Declare Excessive Price For Cancer Drug Contrary To Public Interest, Grounds For Compulsory License," Inside Views, *IP-Watch.Org.*