September 29, 2022

Via FOIA Portal

Food and Drug Administration
Division of Freedom of Information
Office of the Executive Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Freedom of Information Act Request: Off-Label Puberty Blockers

Dear FOIA Officer:

America First Legal Foundation is a national, nonprofit organization working to promote the rule of law in the United States, prevent executive overreach, and ensure due process and equal protection for all Americans, all to promote public knowledge and understanding of the law and individual rights guaranteed under the Constitution and laws of the United States. To that end, we file Freedom of Information Act (FOIA) requests on issues of pressing public concern, then disseminate the information we obtain, making documents broadly available to the public, scholars, and the media. Using our editorial skills to turn raw materials into distinct work, we distribute that work to a national audience through traditional and social media platforms. AFL's email list contains over 34,000 unique addresses; our Facebook page has nearly 75,000 followers; our Twitter page has 20,500 followers; the Twitter page of our Founder and President has 221,300 followers, and we have another 31,300 followers on GETTR.

The FDA recently added a warning about the risk of pseudotumor cerebri to the labeling for gonadotropin-releasing hormone (GnRh) agonists.[1] GnRh agonists are FDA approved for treating precocious puberty, prostate and breast cancer, endometriosis, for use in in vitro fertilization, and to perform chemical castration on sex offenders. While they have been approved for treating early puberty in pediatric patients, they have not been approved for use as puberty blockers in children with gender dysmorphia. Despite this, they have been prescribed by doctors as puberty blockers and have been advertised as drugs for transgender children.

[1] Food and Drug Administration, *Risk of pseudotumor cerebri added to labeling for gonadotropin-releasing hormone agonists".* FDA Update (July 1, 2022), https://bit.ly/3SHS0lZ.

To better understand the FDA's activities with respect to the off-label use of puberty blockers in children, AFL now requests the following pursuant to the Freedom of Information Act, 5 U.S.C. § 552(a).

I. Custodians

A. Patrizia Cavazzoni, Director, Center for Drug Evaluation and Research
B. Theresa Kehoe, Director, Division of General Endocrinology
C. Naomi Lowy, Deputy Director, Division of General Endocrinology
D. Elisabeth Hanan, Chief, Project Management Staff
E. LaiMing Lee, Associate Director for Labeling
F. Lynne Yao, Director, Division of Pediatric and Maternal Health
G. Leyla Sahin, Senior Medical Officer
H. Lily Mulugeta, Associate Director

II. Requested Records

The relevant time frame is January 21, 2021, to the date processing is completed:

All records containing the terms, "child" or "minor" *and* "Lupron," "Leuprorelin," "Fensolvi," "Synarel," "Nafarelin," "Supprelin," "Vantas," "Triptodur", "Histrelin," "puberty blocker," "GnRH agonist," or "GnRH analogues."

III. Processing

Processing should occur in strict compliance with the processing guidance in the Attorney General's Memorandum on Freedom of Information Act Guidelines.[2] If you have any questions about our request or believe further discussions regarding search and processing would facilitate a more efficient production of records of interest to AFL, then please contact me at FOIA@aflegal.org.

IV. Fee Waiver

Per 5 U.S.C. § 552(a)(4)(A)(iii) and 6 CFR § 5.11(k), AFL requests a waiver of all search and duplication fees associated with this request. We believe AFL's noncommercial commitment to public education and transparency justifies this fee waiver. We are, of course, available to provide additional information in writing or offline in support of this request.

[2] U.S. Dep't Just. (Mar. 15, 2022), https://bit.ly/3zvpxb6.

V. Production

To accelerate the release of responsive records, AFL welcomes production on an agreed rolling basis. If possible, please provide responsive records in an electronic format by email. Alternatively, please provide responsive records in native format or in PDF format on a USB drive to America First Legal Foundation, 611 Pennsylvania Ave SE #231, Washington, DC 20003.

Thank you in advance for your cooperation.

Sincerely,

/s/ Reed D. Rubinstein
Reed D. Rubinstein
America First Legal Foundation