August 5, 2024

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: Increased Risk of Suicide & Depression Linked to Puberty Blockers for Transgender Children

Dear FOIA Officer:

America First Legal Foundation ("AFL") 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 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 X page has over 255,000 followers, and the X page of our Founder and President has over 682,000 followers.

I. Background

In the past several years, several European countries have significantly pulled back on what is labeled "gender-affirming care" for minors. In reality, "gender-affirming care" involves the practice of prescribing puberty blockers and cross-sex hormones for children under 18, as well as using life-altering surgeries like mastectomies, vaginoplasty, phalloplasty, and metoidioplasty to give children the irreversible appearance of the opposite sex.

For example, in 2021, Swedish hospitals halted the use of puberty blockers in five out

of six clinics, with a single clinic only using them for clinical trials.[1] Sweden also now emphasizes psychotherapy for gender dysphoric minors instead of puberty blockers.

Last year, France's National Academy of Medicine warned medical professionals that the spike in demand for physicians to perform "gender-affirming care" on children is an "epidemic-like phenomenon" with the hallmarks of a social contagion, exacerbated by the "increasing supply of care."[2] The Academy stressed that the "risk of over diagnosis is real" and cited the high number of transgender young adults wishing to detransition. Thus, the Academy concluded that it was crucial to "extend as much as possible the psychological support phase" to guard against providing "irreversible" medical care for "transient dysphoria."

Finland has made similar findings, and its Council for Choices in Health Care stressed that "[r]esearch data on the treatment of dysphoria due to gender identity conflicts in minors is limited," that medical intervention should be deemphasized in favor of psychotherapy, and that surgery should not be part of any treatment.[3]

And just last week, the High Court of Justice in England upheld the NHS's March 2024 decision to ban puberty blockers for treatment of children with gender dysphoria.[4]

Despite the trend in Europe to change course amidst a clear social contagion, the risks of transitioning children socially and medically, and the growing population of detransitioners, the Biden-Harris Administration is taking an approach diametrically opposed to the trends in Europe and shocking evidence in the United States.

Over the past several years, AFL has launched a number of investigations into both the US Food and Drug Administration ("FDA") and the US Department of Health and Human Services ("HHS")[5] to determine the extent of the Biden-Harris Administration's official actions to promote this inhumane experimentation on children.

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[1] Mairead Elrodi, *Europe Dialing Back Shocking Policies on Transgender Kids and Medical Intervention*, Daily Wire (Jun. 16, 2022), https://tinyurl.com/3nmc7ef9.

[2] *Press Release, Medicine and Gender Transidentity in Children and Adolescents*, FRENCH NAT'L ACAD. MED. (Feb. 25, 2022), https://tinyurl.com/2p9fpjyd.

[3] COHERE FINLAND, Medical Treatment Methods for Dysphoria Associated With Variations in Gender Identity in Minors–Recommendation (Jun. 16, 2020), https://tinyurl.com/tzw7pusr.

[4] Puberty Blockers Ban is Lawful, Says High Court, BBC (Jul. 29, 2024), https://tinyurl.com/5n7xnm86.

[5] *America First Legal Launches Investigation Into Biden's HHS and Assistant Secretary Levine for Advancing Experimental Transgender Medical Procedures on Children*, America First Legal (Mar 23, 2023) https://tinyurl.com/2a2tzsu5; *America First Legal Launches Investigation into the Biden HHS' Role in the Federal Prosecution of Whistleblower Dr. Eithan Haim*, America First Legal (Jul. 22, 2024) https://tinyurl.com/3dteh9u5.

On September 29, 2022, AFL sent the FDA a FOIA request regarding the off-label use of puberty blockers in children. After the FDA failed to produce the requested documents, AFL sued. From this lawsuit, AFL discovered communications from FDA doctors admitting to an increased risk of suicide and depression for transgender children prescribed puberty blockers. Despite this admission, FDA doctors emphasized the importance of full FDA approval for the use of puberty blockers in transgender children.

From: Sullivan, Shannon <Shannon.Sullivan@fda.hhs.gov>
Sent: Tuesday, January 25, 2022 12:12 PM
To: Kehoe, Theresa <Theresa.Kehoe@fda.hhs.gov>
Cc: Lowy, Naomi <Naomi.Lowy@fda.hhs.gov>
Subject: Re: [EXTERNAL] question on puberty blocking drugs

Hi Theresa,
DMEP did do a safety review of the GnRH agonist class in pediatric patients in 2016/2017, which was initiated after publication of an article by Kaiser Health News in which adults with histories of CPP attributed multiple complaints to prior use of a GnRH agonist. The complaints were extensive and variable, and included fibromyalgia type symptoms, infertility, PCOS, and weight gain, among others. Our review focused on suicidal ideation/depression, seizures, and bone health, and we reviewed all cases of these AEs in pediatric patients exposed to a GnRH agonist. Most of these patients had CPP but a handful were transgender kids using the drugs off-label. We found no effect on bone (after factoring in catch-up growth), including no increase in fracture risk. We did find increased risk of depression and suicidality, as well as increased seizure risk and we issued SLCs to the entire class for these AEs (added to W&P in 2017).

Regarding use of GnRH agonists in the transgender population, no company has come in for this indication to date. DUOG has done a patient listening session with trans kids and separately with trans adults, which I participated in, and there is definitely a need for these drugs to be approved for gender transition, as they are typically not covered by insurance and are expensive out of pocket. It was my understanding that DUOG would take these applications if and when any do come in.

Let me know if I need to provide additional details on any of this.
Thanks
Shannon

Shannon Sullivan
Clinical Team Leader
Division of General Endocrinology

To better understand the FDA's activities with respect to the off-label use of puberty blockers in children, particularly as it relates to increased risk of suicide and

depression, AFL now requests the following pursuant to the Freedom of Information Act, 5 U.S.C. § 552(a).

II. 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
I. Shannon Sullivan, Medical Officer, Clinical Team Leader, Division of General Endocrinology

III. Requested Records

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

1. All records containing the following search criteria:

- ("child!" OR "minor" OR "pediatr!") AND
- ("Lupron" OR "Leuprorelin" OR "Fensolvi" OR "Synarel" OR "Nafarelin" OR "Supprelin" OR "Vantas" OR "Triptodur" OR "Histrelin" OR "puberty block!" OR "GnRH agonist" OR "GnRH analogues") AND
- ("suicid!" OR "depress!" OR "psych!") AND
- "approv!" AND
- ("off-label" OR "off label") AND
- ("gender dys!" OR "gender identity" OR "trans!").

IV. Fee Waiver

AFL requests a waiver of all search and duplication fees associated with this request under 5 U.S.C. § 552(a)(4)(A)(iii) and 21 C.F.R. § 20.46. First, AFL is a qualified non-commercial public education and news media requester. Our officials routinely appear on national television and use social media platforms to disseminate the information it has obtained about federal government activities. In this case, AFL will make your records and your responses publicly available for the benefit of citizens, scholars, and others, and the public's understanding of your policies and

practices will be enhanced through AFL's analysis and publication of the requested records. As a nonprofit organization, AFL does not have a commercial purpose, and releasing the requested information is not in AFL's financial interest.

V. Conclusion

If you have any questions about how to construe this request for records or believe further discussions regarding search and processing would facilitate a more efficient production of records of interest to AFL, please do not hesitate to contact me at FOIA@aflegal.org. Finally, if AFL's request for a fee waiver is not granted in full, please contact us immediately upon making that determination.

Thank you in advance for your cooperation.

Sincerely,

/s/ Ian D. Prior
Senior Advisor
America First Legal Foundation