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FDA: Puberty Blockers May Cause Brain Swelling, Blindness

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The U.S. Food and Drug Administration (FDA) added a warning to the label of gonadotropin-releasing hormone (GnRH) agonists, commonly known as puberty blockers, indicating that young people who take them might develop serious adverse reactions such as brain swelling and vision loss.

According to the FDA update posted on the American Academy of Pediatrics (AAP) on July 1, the new warning includes recommendations to monitor patients taking GnRH agonists for signs and symptoms of pseudotumor cerebri. That is a condition that occurs when pressure inside the skull increases "for no obvious reason," according to the Mayo Clinic. Its definition adds, "Symptoms mimic those of a brain tumor. The increased intracranial pressure can cause swelling of the optic nerve and result in vision loss."

Other symptoms include headache, papilledema (swelling of the optic nerve inside of the eye), blurred or loss of vision, diplopia (double vision), pain behind the eye or pain with eye movement, tinnitus (perception of sound when no corresponding external sound is present), dizziness, and nausea.

The article says that according to the post-marketing data submitted by the manufacturer of the puberty blocker in question, six cases of brain swelling and the associated symptoms were reported in girls ages 5 to 12 years. "Five were undergoing treatment for central precocious puberty and one for transgender care," notes the agency.

To treat the affected girls, the doctors used such invasive procedures as lumbar puncture (insertion of a needle into the spinal canal, most commonly used to collect cerebrospinal fluid for diagnostic testing) and ventricular peritoneal shunting (insertion of a medical device that relieves pressure on the brain caused by fluid accumulation), as well as therapy with acetazolamide (a diuretic and protein inhibitor medication).

By the time the FDA looked into what happened to these girls, symptoms had resolved in three of them and were resolving in one. One was still suffering. What happened to the last one is "unknown." "Treatment" with puberty blockers was discontinued in just three girls. The FDA said it had no knowledge of the remaining three patients getting off the GnRH agonist.

The FDA determined that the link between the severe condition and the medication is vague:

> The incidence rate of pseudotumor cerebri associated with GnRH agonist use in pediatric patients could not be reliably established due to the small number of cases and data limitations.

Yet the change of labeling appears to be made even earlier, in May, as reported by Formulary Watch, and applies to such medications as Fensolvi Kit, Lupron Depot-Ped Kit, Supprelin LA, Synarel, and Triptodur Kit.

GnRH is prescribed to stop the production of female hormones such as estrogen and progesterone, and is used to treat advanced prostate cancer, endometriosis, uterine fibroids, cancer, precocious puberty, and infertility.

The new warning reads:

> Pseudotumor cerebri (idiopathic intracranial hypertension) has been reported in pediatric patients receiving GnRH agonists, including leuprolide acetate. Monitor patients for signs and symptoms of pseudotumor cerebri, including headache, papilledema, blurred vision, diplopia, loss of vision, pain behind the eye or pain with eye movement, tinnitus, dizziness, and nausea.

Speaking with the outlet, the FDA spokesperson clarified that the cases were serious enough for the agency to warn parents and caregivers about them.

"The agency considered the cases clinically serious and, based on these reviews, determined that pseudotumor cerebri (idiopathic intracranial hypertension) should be added as a warning and precaution in product labeling for all GnRH agonist formulations approved for use in pediatric patients," the representative stated, adding that youths diagnosed with central precocious puberty (CPP), or premature puberty, may be at a higher risk of developing pseudotumor cerebri compared with children without CPP.

The Family Research Council's director of the Center for Family Studies, Dr. Jennifer Bauwens, told *The Washington Stand* that because "Our bodies were not made for these drugs," giving them to children "isn't going to have a good outcome."

The latest development around puberty blockers went unnoticed by the mainstream media, yet it raises a serious question about the official position of the Biden administration, which views them as "lifesaving drugs."

Speaking in June, Assistant Secretary for Health "Rachel" Levine, the highest ranking "trans" person in the government, said that "gender-reaffirming" medical "care" is a "life-saving, medically necessary," and "age-appropriate critical tool" to keep children "happy and healthy."

At the end of April, Levine said that medical professionals have reached a consensus on the value of gender-affirming care for "transgender" children.

"There is no argument among medical professionals — pediatricians, pediatric endocrinologists, adolescent medicine physicians, adolescent psychiatrists, psychologists, etc. — about the value and the importance of gender-affirming care," Levine, a medical doctor trained in pediatrics and adolescent medicine, told NPR.

In May, Health and Human Services (HHS) Secretary Xavier Becerra went so far as to state that he was all for "transgender" children and their physicians deciding to use off-label, experimental puberty blockers.

As reported by *The New American*, Becerra testified before the U.S. Senate that if any medication was unsafe, the FDA would "raise the alarm" about it.

And as we reported in late March, the HHS launched a new website that offers "resources for transgender and LGBTQI+ youth, their parents, and providers," the goal of which is to "affirm an LGBTQI+ child." According to the site, when children and adolescents believe that their "gender identity" does not match their biology, they should be offered not only support from mental-health "councils" to "reaffirm" the perceived "identity," but could also be prescribed medications blocking their biological hormones and life-altering surgeries on their faces, breasts, and genitals.

The HHS resource is only a tiny part of the Biden administration's much broader pro-trans agenda, which includes policies ranging from "reinforcing federal protections for transgender children" to improving transgender travel experiences.