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Chair Lipps, Vice Chair Stewart, Ranking Member Liston, and members of the House Public Health Policy Committee

I write in support of HB 68 or the Save Adolescents from Experimentation Act (the SAFE Act). My testimony is strictly my own and does not represent any health care or professional organization.

I am a licensed pharmacist in Ohio and am certified by the Board of Pharmacy Specialties in both Pediatrics and Infectious Diseases. I have practiced in Ohio from 1986 until my retirement in 2020. I have participated on an Institutional Review Board (IRB) at a pediatric institution for over 20 years and have provided input on numerous pediatric clinical trials.

I wish to focus my testimony on the term "experimentation" in the title of the bill. Because there is a paucity of registered clinical trials and resulting data to support the safe and effective use of gonadotropin releasing hormone agonists (GnRHa) as well as testosterone and estrogen derivatives in gender dysphoric children less than 18 years of age, use of such agents lacking legal and ethical investigative oversight in this setting, must be considered experimental.

Historically, the first U.S. Federal law to require clinical trial registration was the Food and Drug Administration Modernization Act of 1997 (FDAMA) (PDF). Section 113 of FDAMA (FDAMA 113) required the National Institutes of Health (NIH) to create a public information resource on clinical trials pertaining to investigational new drugs.

In 2000, the NIH released Clinicaltrials.gov, a database of privately and publicly funded clinical studies conducted around the world and managed by the National Library of Medicine at the National Institutes of Health (NIH). The database currently encompasses 455,101 research studies in all fifty states and in 221 countries.

The requirements for submission to ClinicalTrials.gov were later expanded after Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA) (PDF). Section 801 of FDAAA (FDAAA 801) required more types of trials to be registered and submission of additional trial registration information. The law also included penalties for noncompliance, such as the withholding of NIH grant funding and civil monetary penalties of up to $10,000 a day.

Finally in 2016, Title VIII of the Food and Drug Administration (FDA) Amendments Act of 2007 (FDAAA) further expanded the legal mandate for sponsors and others responsible for certain clinical trials of FDA-regulated drug products to register their studies and report summary results information to ClinicalTrials.gov.[1] This Act also defines "applicable clinical trial" (ACT) and now provides a checklist of mandatory registration data elements to allow responsible parties and members of the public to evaluate whether a study is an ACT. (see Section IV.B.2 of the final rule). Types of trials identified as an ACT includes those which study an FDA related drug product which include previously mentioned GnRH agonists (leuprolide acetate, histrelin, and triptorelin) as well as "gender affirming" agents such as estradiol and testosterone. As an additional note, although these medications are approved by the FDA for certain indications, none of the FDA approved indications include gender dysphoria.

Please note that ACTs do not include observational trials (in contrast to interventional trials in which the effects of drugs are studied) which have been used by many who support transgender therapy in youth to justify the use of these medications.

A search of the ClinicalTrials.gov website on June 9, 2023 reveals only nine studies (see Appendix) pertaining to gender dysphoria in children younger than 18 years. Only two of these trials studied the use of drugs including GnRH agonists and none pertained to "gender affirming" hormones such as testosterone or estrogen derivatives. Seven of these studies were not drug related. None of these nine studies has reported any results to date. This search indicates that any scientific justification for the use of GnRH agonists and "gender affirming" hormones agents appear to be lacking.

By way of contrast, the website provides 225 studies pertaining to otitis media (middle ear inflammation which is a common pediatric condition), 52 of which have provided results to scientifically guide therapeutic decision making and development of evidence-based guidelines.

Currently, use of GnRH agonists and "gender affirming" hormone therapy with testosterone and estrogen derivatives in children less than 18 years of age not only has no FDA approval for the treatment of gender dysphoria but has no support from properly conducted scientific trials in children with gender dysphoria. Such treatment is truly experimental and should only be conducted in approved clinical trials, subject to the regulations provided by NIH and ClinicalTrials.gov and with Institutional Review Board oversight.

References

1. Zarin, D et al. Trial Reporting in ClinicalTrials.gov – The Final Rule. NEJM 2016;375(20):1998-2004. Doi:10.1056/NEJMsr1611785

Appendix

ClinicalTrials.gov Search Results 06/09/2023

	Title	Status	Study Results	Conditions	Interventions	Locations
1	Psychological Vulnerabilities and Transgender Adolescents: A Descriptive Epidemiology Study	Completed	No Results Available	•Gender Dysphoria, Adolescent	•Diagnostic Test: KSADS (Kiddie Schedule for Affective Disorders and Schizophrenia)	•Chu Toulouse, Toulouse, France
2	Gender Dysphoria Among Adolescents (Norwegian Title: Kjønnsdysfori Blant Ungdom)	Unknown status	No Results Available	•Gender Dysphoria	•Other: Qualitative interview	•Oslo university hospital, Oslo, Norway
3	Chest Dysphoria in Transmasculine Spectrum Adolescents	Completed	No Results Available	•Gender Dysphoria	•Procedure: Mastectomy and chest masculinization	•Ann and Robert H Lurie Children's Hospital of Chicago, Chicago, Illinois, United States •Northwestern University, Chicago, Illinois, United States •University of Illinois Chicago, Chicago, Illinois, United States
4	Counseling Among Gender Diverse Adolescents Who Use Depot Medroxyprogesterone	Recruiting	No Results Available	•Gender Dysphoria, Adolescent	•Drug: Depo-subQ Provera Injectable Product	•Comprehensive Women's Health Center, Denver, Colorado, United States
5	Skeletal Health and Bone Marrow Composition Among Youth	Recruiting	No Results Available	•Gender Dysphoria in Children •Puberty •Bone Development	•Device: GnRH Agonist	•Boston Children's Hospital, Boston, Massachusetts, United States •Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, United States
6	Pubertal Blockade and Hormone Therapy in Transgender Youth	Completed	No Results Available	•Gender Identity •Gender Dysphoria •Gender Identity Disorder in Adolescence and Adulthood		•Children's Hospital Colorado, Aurora, Colorado, United States
7	Sleep and IR in Transgender Adolescents	Recruiting	No Results Available	•Sleep Disorder •Insulin Resistance •Gender Dysphoria		•Duke University, Durham, North Carolina, United States
8	The Relation of GnRH Treatment to QTc Interval in Transgender Females	Terminated	No Results Available	•Gender Dysphoria	•Drug: Treatment with a GnRh agonists	•University of California, San Francisco, San Francisco, California, United States
9	Pubertal Blockade and Estradiol Effects on Cardiometabolic Health for Transitioning Youth	Recruiting	No Results Available	•Transgenderism •Gender Dysphoria •Insulin Sensitivity		•Children's Hospital Colorado, Aurora, Colorado, United States

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Filters used on the ClinicalTrials.gov website included condition: gender dysphoria and age range: 0-17 years.