



## USPATH and WPATH Confirm Gender-Affirming Health Care is Not Experimental; Condemns Legislation Asserting Otherwise

March 22, 2023 - The United States Professional Association for Transgender Health (USPATH) and the World Professional Association for Transgender Health (WPATH) denounces the emergency regulation halting gender-affirming healthcare for transgender and gender diverse (TGD) children and adolescents issued by Missouri Attorney General Andrew Bailey as lacking scientific grounding.

The WPATH Standards of Care for the Health of Transgender and Gender Diverse People, now in its 8th version (SOC8), is the foremost evidence-based guideline for the provision of TGD healthcare. SOC8 is based on the best available science with input from over 100 global medical professionals and experts and represents best-practice guidelines for the provision of gender-affirming healthcare. Gender-affirming interventions are based on decades of clinical experience and research and are not considered experimental. Gender affirming hormone therapy (GAHT) is a component of widely accepted medically necessary care for TGD people.

In addition to WPATH, the largest establishment medical associations (including the American Medical Association, the American College of Physicians, the Endocrine Society, the American College of Obstetricians and Gynecologists, the American Academy of Pediatrics, and the American Psychiatric Association, among others) have supported the provision of genderaffirming care for TGD people as medically necessary care.

Attorney General Bailey's claims were either taken out of context, cherry-picked, or from unverified sources. In some situations, the excerpted statements used in the regulation are later contradicted in the same study or article from which they were pulled. The resulting regulation from the AG's office strings together non sequitur misinformation in their attempt to prohibit safe and legal health care. For example, there are no formal Food and Drug Administration (FDA) approvals for many hormonal therapies across all of endocrinology, not limited to hormone replacement therapies for TGD patients, despite the medications themselves having been approved by the FDA. FDA regulations do not directly or explicitly prohibit the promotion of offlabel uses and, per the FDA Modernization Act of 1997, the FDA must review all materials and peer-reviewed articles about off-label use.<sup>1</sup> Off-label use is neither uncommon nor illegal.

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<sup>&</sup>lt;sup>1</sup> Ventola, C. Lee. "Off-Label Drug Information." *Pharmacy and Therapeutics*, vol.34, no. 8, Aug. 2009, pp. 428–40. *PubMed Central*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2799128/.

AG Bailey's information about brain swelling and blindness as a result of puberty blockers or hormone suppression therapy was taken from a 2022 FDA statement that referenced six patients who identified a plausible association between gonadotropin-releasing hormone (GnRH) and pseudotumor cerebri. Of the six cases that were identified, all were assigned female at birth and five were undergoing treatment for precocious puberty - only one case identified was for transgender care.<sup>2</sup> According to the Mayo Clinic, pseudotumor cerebri can occur in children but is most common in women of childbearing age who are obese. The most common treatment for pseudotumor cerebri is weight loss.<sup>3</sup> Notably, at the time of the FDA's review, symptoms had resolved in three patients and were resolving in another. In the same statement, the FDA asserts that "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." The full FDA statement asserts a lack of information to draw such conclusions, yet AG Bailey has done so in his efforts to ban gender-affirming care.

AG Bailey's reference to Sweden's National Board of Health and Welfare (NBHW) recent declaration about the risks of puberty suppression therapy and gender-affirming hormone replacement therapy outweighing the possible benefits is also taken out of context; in their press release, NBHW recommends restraint and further study regarding GAHT for people under 18, not a total ban on care.<sup>5</sup> Furthermore, this statement includes no citations to literature or studies. In a July 2022 article published by the American Academy of Pediatrics, Dr. Kristina R. Olson et al reports that five years after their initial social transition, 97.5% of TGD youth continued to identify as transgender or nonbinary.<sup>6</sup> A peer-reviewed study from Dr. Jack Turban et al in June 2021 found that among adults who detransition or retransition, 82.5% reported at least one external driving factor including family and social stigma.<sup>7</sup> Instead of issuing blanket bans on gender-affirming care because some TGD people may detransition or retransition, we need fewer invasive laws and policies that further entrench social and cultural stigma about TGD people and identities and more support and resources for those who detransition or retransition.

Further, AG Bailey's emergency regulation incorrectly cites "one scientific study" that claims an exponential increase in individuals identifying as transgender because of "social factors." WPATH is unaware of any scientific study of this nature. Likely, however, the AG's office is referring to a 2018 report by Lisa Littman based upon parent observations and

<sup>2</sup> Risk of Pseudotumor Cerebri Added to Labeling for Gonadotropin-Releasing Hormone Agonists. Food and Drug Administration (FDA), 1 July 2022, https://www.fda.gov/media/159663/download.

<sup>&</sup>lt;sup>3</sup> "Pseudotumor Cerebri (Idiopathic Intracranial Hypertension) - Symptoms and Causes." *Mayo Clinic*, https://www.mayoclinic.org/diseases-conditions/pseudotumor-cerebri/symptoms-causes/syc-20354031. Accessed 20 Mar. 2023.

<sup>&</sup>lt;sup>4</sup> Risk of Pseudotumor Cerebri Added to Labeling for Gonadotropin-Releasing Hormone Agonists. Food and Drug Administration (FDA), 1 July 2022, https://www.fda.gov/media/159663/download.

<sup>&</sup>lt;sup>5</sup> "Updated recommendations for hormone therapy for gender dysphoria in young people." *Socialstyrelsen*, 22 Feb. 2022, https://www.socialstyrelsen.se/om-socialstyrelsen/pressrum/press/uppdaterade-rekommendationer-for-hormonbehandling-vid-konsdysfori-hos-unga/.

<sup>&</sup>lt;sup>6</sup> Kristina R. Olson, PhD, et al. "Gender Identity 5 Years After Social Transition." *Pediatrics*, vol. 150, no. 2, Aug. 2022, https://doi.org/10.1542/peds.2021-056082.

<sup>&</sup>lt;sup>7</sup> Turban, Jack L., et al. "Factors Leading to 'Detransition' Among Transgender and Gender Diverse People in the United States: A Mixed-Methods Analysis." *LGBT Health*, vol. 8, no. 4, 2021, pp. 273–80. *PubMed*, https://doi.org/10.1089/lgbt.2020.0437.

perceptions of their TGD child, adolescent, or young adult.<sup>8</sup> At no point during this process did Littman interview, survey, or evaluate any TGD people themselves and in 2019, she issued a correction to the report stating that,

"Rapid-onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time. This report did not collect data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon."

With this, Littman effectively disproves her own initial report. AG Bailey has used outdated information from a report that was later challenged by the reports' author, yet AG Bailey's inaccurate information remains in the emergency regulation.

Finally, AG Bailey's citation about a study from the Endocrine Society and the rates of gender incongruence in TGD children is also cherry-picked, this time from the 2017 Endocrine Society Guidelines referencing Dr. Peggy Cohen-Kettenis' data that only evaluated gender nonconforming children who were not necessarily transgender. This claim from AG Bailey is therefore not only factually inaccurate but unrepresentative of those who would be affected by this emergency regulation. More accurate data about persistence of gender identity for TGD youth can be found in Dr. Olson's peer-reviewed study which, as noted above, reports that 97.5% of TGD youth continue to identify as transgender or nonbinary 5 years after their initial social transition. Further, a January 2023 longitudinal study from Dr. Diane Chen published in the New England Journal of Medicine shows an increase in positive affect and life satisfaction and a decrease in depression and anxiety for TGD youth after 2 years of hormones.

The emergency regulation issued by Missouri Attorney General Andrew Bailey is based upon manipulated statistics, flawed reports, and incomplete data, and prevents the provision of medically necessary care. Medical decisions must remain between providers and patients and their families. Consistent with earlier statements, WPATH and USPATH condemn any legislative actions to restrict or prohibit access to gender-affirming health care.

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<sup>&</sup>lt;sup>8</sup> Littman, Lisa. "Parent Reports of Adolescents and Young Adults Perceived to Show Signs of a Rapid Onset of Gender Dysphoria." *PLOS ONE*, vol. 13, no. 8, Aug. 2018, p. e0202330. *PLoS Journals*, https://doi.org/10.1371/journal.pone.0202330.

<sup>&</sup>lt;sup>9</sup> Hembree, Wylie C. "Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society\* Clinical Practice Guideline." *The Journal of Clinical Endocrinology & Metabolism*, vol. 102, no. 11, Nov. 2017, pp. 3869–903, https://doi.org/10.1210/jc.2017-01658.

<sup>&</sup>lt;sup>10</sup> Kristina R. Olson, PhD. "Gender Identity 5 Years After Social Transition." *Pediatrics*, vol. 150, no. 2, Aug. 2022, https://doi.org/10.1542/peds.2021-056082.

<sup>&</sup>lt;sup>11</sup> Chen, Diane, et al. "Psychosocial Functioning in Transgender Youth after 2 Years of Hormones." *New England Journal of Medicine*, vol. 388, no. 3, Jan. 2023, pp. 240–50. *DOI.org (Crossref)*, https://doi.org/10.1056/NEJMoa2206297.