

Office of Commissioner Melissa Holyoak UNITED STATES OF AMERICA Federal Trade Commission WA SHINGTON, D.C. 20580

 $\label{eq:protecting} Protecting \ Children \ From \ Unfair \ and \ Deceptive \ Practices \ in \ Healthcare$ 

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PREPARED REMARKS FOR THE FTC WORKSHOP ON EXPLORING UNFAIR OR DECEPTIVE TRADE PRACTICES IN "GENDER-AFFIRMING CARE" FOR MINORS WASHINGTON, D.C.

\* The views expressed in these remarks are my own and do not necessarily reflect the views of the Federal Trade Commission or any other Commissioner.

Good afternoon. Thank you all for being here. Thank you to Chairman Ferguson, all of our panelists, and to the FTC staff who are contributing to today's workshop. I'll start with a disclaimer: the views I express today are my own. They do not necessarily reflect the views of the Commission or any other Commissioner.

Right after I gave birth to my second daughter, it became immediately apparent that she was very ill. There had been no indication during my pregnancy that she had any medical problems, so we, like other unfortunate parents, experienced the trauma of having our newborn whisked away unexpectedly to the NICU. My husband and I learned that part of her heart was swollen and she was suffering from persistent pulmonary hypertension. It was one of the most frightening and trying periods we ever experienced. This was not the way it was supposed to be, and this was not what I had envisioned and dreamed of for nine months. I had never felt so helpless in my life as I watched her fight for her life over the coming days. During that time, we relied on the doctors to provide us complete and truthful information as we made medical decisions to treat my daughter. Thankfully, my daughter recovered. She is now a healthy 16-year-old who has blessed our lives in countless ways. I can't imagine our family without her.

My heart is with those parents who have had similar experiences, faced with watching their children suffer from injury, illness, or disease. I empathize in particular with parents whose children experience mental health challenges: treatments are often complex and may involve a combination of psychotherapy, medication, and other therapies. But whatever health problem a child may be experiencing, it is *critical* that medical professionals provide parents with complete and truthful information in order for parents to make those difficult medical decisions.

Today, the Commission is exploring whether to address unfair and deceptive practices in what is sometimes called gender-affirming care for minors. Recent reports estimate "1.6 million Americans over the age of 13 identify as transgender."<sup>1</sup> "Some transgender individuals suffer from gender dysphoria, a medical condition characterized by persistent, clinically significant distress resulting from an incongruence between gender identity and biological sex. Left untreated, gender dysphoria may result in severe physical and psychological harms."<sup>2</sup> While some have questioned the FTC's role here, there are three principal reasons why the FTC should use its authority to combat unfair or deceptive practices related to gender-affirming care.

*First*, the FTC has a strong history of enforcement actions against unfair and deceptive healthcare-related claims. In December 2022, the FTC published a *Health Products Compliance Guidance*, ("Guidance") which notes that, since 1998, the Commission has "settled or adjudicated more than 200 cases involving false or misleading advertising claims about the benefits or safety of dietary supplements or other health-related products."<sup>3</sup> For enforcement purposes, the

<sup>&</sup>lt;sup>1</sup> United States v. Skrmetti, 145 S.Ct. 1816, 1824 (2025).

 $<sup>^{2}</sup>$  Id.

<sup>&</sup>lt;sup>3</sup> Fed, Trade Comm'n, *Health Products Compliance Guidance*, at 1 (Dec. 2022), https://www.ftc.gov/system/files/ftc\_gov/pdf/Health-Guidance-508.pdf.

advertisement of purported health benefits may be accomplished through a variety of marketing techniques, including by medical practitioners.<sup>4</sup>

The Guidance further explains that "claims about the health benefits or safety of foods, dietary supplements, drugs, and other health-related products require substantiation in the form of competent and reliable scientific evidence."<sup>5</sup> Importantly, such substantiation cannot be based solely on a medical practitioner's experience: "a healthcare practitioner's observation about the effect of a health product on patients is anecdotal and doesn't provide evidence of a causal relationship."<sup>6</sup> Nor can substantiation be based on "advisories from a medical organization" because those are based on best currently available evidence rather than a "causal link between the recommended course of action and the health benefit."<sup>7</sup> Further, the Guidance instructs that a claim may be misleading if it fails to inform about significant safety concerns.<sup>8</sup>

Simply put, it is blackletter law that misleading and unfair health-related claims can violate Section 5. And it is increasingly clear that there are serious questions about the risks and purported benefits of medical transition treatments for children with gender dysphoria. Justice Thomas described the risks in the U.S. Supreme Court's recent decision, *United States v. Skrmetti*, which involved a challenge to Tennessee's law restricting sex transition treatments for minors. For example, there are significant safety risks relating to the use of puberty blockers. Using puberty blockers "to suppress normal puberty has multiple organ system effects whose long-term consequences have not been investigated."<sup>9</sup> Such use may lead to decreased bone density and impacts on brain development.<sup>10</sup> It also remains "unclear whether patients ever develop normal levels of fertility if puberty blockers are terminated after a prolonged delay of puberty."<sup>11</sup>

<sup>&</sup>lt;sup>4</sup> *Id.* at 2 (citing material including, Compl., *FTC v. NourishLife, LLC*, No. 1:15-cv-00093 (N.D. Ill. Jan. 7, 2015), at 4 (alleging that dietary supplements were marketed and distributed directly and through a "network of distributors, which, among others, include[d] physicians, therapists, and pharmacies")).

<sup>&</sup>lt;sup>5</sup> Id.

<sup>&</sup>lt;sup>6</sup> *Id.* at 14; *see also id.* ("Anecdotal evidence about the individual experiences of consumers, including surveys of consumer experiences, are never sufficient to substantiate claims about the effects of a health product." (citing *FTC v. QT, Inc.*, 512 F.3d 858, 862 (7th Cir. 2008) (testimonials "are not a form of proof because most testimonials represent a logical fallacy: post hoc ergo propter hoc," *i.e.*, "[a] person who experiences a reduction in pain after donning the bracelet may have enjoyed the same reduction without it"))).

<sup>&</sup>lt;sup>7</sup> *Id.* at 14 (citing *POM Wonderful, LLC v. FTC*, 777 F.3d 478, 495 (D.C. Cir. 2015) (expert's acknowledgement that health recommendations made when the data is not supported by randomized, controlled human clinical trials are based on "best available evidence," which is "not the same as stating that a causal link has been established.")). <sup>8</sup> *Id.* at 7 (citing *In re Snore Formula, Inc.*, 136 F.T.C. 214, 296 (2003) (consent order) (requiring that snoring treatment claims be accompanied by a disclosure about the dangers of sleep apnea and the need for those with certain symptoms to consult a physician); *In re Formor, Inc.*, 132 F.T.C. 72, 101-02 (2001) (consent order) (requiring that ads and labels making efficacy or performance claims for St. John's Wort products disclose potentially dangerous drug interactions even when no safety claims are made); Stip. Final Order, *FTC v. Christopher Enters., Inc.*, No. 201 CV-0505ST (D. Utah Dec. 6, 2001), at 6 (requiring disclosure of risks from certain uses of comfrey regardless of whether safety claims are made); Compl., *In re Fitnness Quest, Inc. and Consumer Direct, Inc.*, 113 F.T.C. 923, 925-26 (1990) (challenging the failure to disclose the risk of injury from exercise device's spring snapping or breaking)).

<sup>&</sup>lt;sup>9</sup> Skrmetti, 145 S. Ct. at 1842 (Thomas, J., concurring) (quoting 2 App. 677).

<sup>&</sup>lt;sup>10</sup> Id. (citing M. Cretella, Gender Dysphoria in Children, 32 Issues in L. & Med. 287, 297 (2017)).

<sup>&</sup>lt;sup>11</sup> Id. (internal quotations omitted) (2 App. 678).

There are also significant safety risks relating to cross-sex hormone treatments, which involve very high doses of hormones of the opposite sex.<sup>12</sup> For girls, the treatments can cause increased cardiovascular risk, irreversible changes to vocal cords, atrophy of the lining of the uterus and vagina, and ovarian and breast cancer.<sup>13</sup> For boys, cross-sex hormones can cause increased cardiovascular risk, breast cancer, as well as sexual dysfunction.<sup>14</sup> "And, for girls and boys alike, 'it is generally accepted, even by advocates of transgender hormone therapy, that hormonal treatment impairs fertility, which may be irreversible."<sup>15</sup>

The asserted health benefits of treatments for transgender adolescents include the reduction of anxiety, depression, and risk of suicide.<sup>16</sup> Yet just last week, an article in *The Atlantic* discussed how these benefits have been presented to parents, reporting that a physician with Children's Hospital Los Angeles explained: "We often ask parents, Would you rather have a dead son than a live daughter?"<sup>17</sup> Similar reports in *The New York Times* indicate that parents were presented with this Hobson's choice, which felt like "emotional blackmail."<sup>18</sup>

But as *The Atlantic* article reveals, the question medical providers have posed to parents did not present a truthful representation of the consequences of gender-affirming treatment. When Justice Alito asked at oral argument in the *Skrmetti* case about suicide rates, the ACLU lawyer confirmed that there was no evidence to support the idea that medical transition reduces adolescent suicide rates.<sup>19</sup> Indeed, in 2024, the United Kingdom's National Health Service (NHS) commissioned an "independent review of the use of puberty blockers and cross-sex hormones to treat children with gender dysphoria," which review found a lack of evidence to "support the conclusion that hormone treatment reduces the elevated risk of death by suicide."<sup>20</sup>

Parents *deserve*—and the law demands—complete and truthful information regarding the grave health risks of transition treatments for minors, as well as complete and truthful information regarding health benefits that are actually substantiated.

After weighing the risks and benefits, "more than 20 States have enacted laws banning . . . sex transition treatment to minors."<sup>21</sup> In affirming the Tennessee law, the U.S. Supreme Court acknowledged the "fierce scientific and policy debates about the safety, efficacy, and propriety of medical treatments in [this] evolving field," but that the Court's role was not "to judge the wisdom,

https://www.supremecourt.gov/oral\_arguments/argument\_transcripts/2024/23-477\_c07d.pdf (ACLU lawyer arguing that there were studies showing reduction in suicidality but no evidence relating to reduction in suicide rates). <sup>20</sup> *Id.* at 1845 (Thomas, J., concurring) (cleaned up).

 $<sup>^{12}</sup>$  *Id*.

<sup>&</sup>lt;sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> *Id.* at 1842-43.

<sup>&</sup>lt;sup>15</sup> *Id.* at 1843 (quoting 2 App. 772-779).

<sup>&</sup>lt;sup>16</sup> Id. at 1869 (Sotomayor, J., dissenting).

<sup>&</sup>lt;sup>17</sup> Helen Lewis, *The Liberal Misinformation Bubble About Youth Gender Medicine*, THE ATLANTIC (June 29, 2025), https://www.theatlantic.com/ideas/archive/2025/06/transgender-youth-skrmetti/683350/.

<sup>&</sup>lt;sup>18</sup> Pamela Paul, *Gender Dysphoric Kids Deserve Better Care*, N.Y. TIMES, Feb. 4, 2024, at SR8.

<sup>&</sup>lt;sup>19</sup> Lewis, *supra* note 17; *see* Oral Argument Transcript, U.S. v. Skrmetti, No. 23-477 at 88,

<sup>&</sup>lt;sup>21</sup> Skrmetti, 145 S. Ct. at 1825.

fairness, or logic of the law before it but only to ensure that it d[id] not violate the equal protection guarantee of the Fourteenth Amendment."<sup>22</sup>

Similarly, the FTC plays an important but limited role in this area. The FTC does not regulate the practice of medicine. The FTC cannot make policy decisions limiting sex transition treatments for minors. But what the FTC can and should do, is protect children from deceptive statements regarding such treatments. The FTC has previously enforced—and will continue to enforce—against deceptive representations made by medical practitioners,<sup>23</sup> including claims in connection with treatments for transgender children.

*Second*, reviewing claims of health benefits for transgender minors is particularly important given the significant and evolving changes in protocols for treating gender dysphoria. In the *Skrmetti* case, the Supreme Court detailed these evolving changes in clinical guidelines. WPATH, the World Professional Association for Transgender Health, published one of the first set of guidelines in 1979 where it advised that hormone and surgical treatments should only be provided to adults.<sup>24</sup> It later changed that recommendation in 1998 to permit hormone treatments for minors in rare circumstances.<sup>25</sup> WPATH further relaxed its guidelines for minors in 2022 to allow puberty blockers, hormone treatments, and surgical procedures at the onset of puberty while still recognizing that "our understanding of gender identity development in adolescence is continuing to evolve."<sup>26</sup>

Importantly, WPATH's changes do not necessarily reflect widely-accepted practices. In fact, recent changes across the world show that there really are *no* widely-accepted practices, but instead, drastically evolving standards in this area. After the UK's National Health Service published its 2024 report on the topic, "NHS England enacted prohibitions on the administration of puberty blockers to new patients under the age of 18 outside of research settings and instituted a process for reviewing referrals for hormones for adolescents under the age of 16."<sup>27</sup> England is not alone. "Finland, Norway, and Sweden have also raised concerns about using puberty blockers or hormone treatments on juveniles with gender dysphoria and have limited such treatments, in some cases by allowing them to go forward only in a research setting."<sup>28</sup> And in Australia, after the state of Queensland placed age restrictions on puberty blockers and hormones, the Australian government began developing new clinical practice guidelines.<sup>29</sup>

Reviews of these clinical guidelines conclude, and as *The Atlantic* article describes, "the fairest thing to say about the evidence surrounding medical transition for adolescents ... is that it

<sup>&</sup>lt;sup>22</sup> Id. at 1837 (internal quotation marks omitted).

<sup>&</sup>lt;sup>23</sup> See, e.g., FTC v. Nat'l Urological Grp., Inc., 645 F. Supp. 2d 1167, 1208 (N.D. Ga. 2008), aff'd, 356 F. App'x 358 (11th Cir. 2009) ("Because Dr. Wright did not base his endorsements on the substantiation that a similarly positioned expert in his field would require when making such endorsements, his endorsements were deceptive.").

<sup>&</sup>lt;sup>24</sup> *Skrmetti*, 145 S. Ct. at 1825.

<sup>&</sup>lt;sup>25</sup> Id.

<sup>&</sup>lt;sup>26</sup> Id. (brackets omitted); id. at 1843-44 (Thomas, J., concurring).

<sup>&</sup>lt;sup>27</sup> *Id.* at 1837.

<sup>&</sup>lt;sup>28</sup> Id. at 1852 (Barrett, J., concurring).

<sup>&</sup>lt;sup>29</sup> Alex Byrne, *I Co-Wrote the Anonymous HHS Report on Pediatric Gender Medicine*, WASH. POST (June 26, 2025), https://www.washingtonpost.com/opinions/2025/06/26/hhs-review-anonymous-author/.

is weak and inconclusive."<sup>30</sup> While relevant legal precedent already recognizes that advisory guidelines cannot serve as the basis for substantiation, what these evolving guidelines emphasize is that the risks and benefits of transition treatments for minors are nowhere settled, and any definitive claims or statements should be carefully examined.

*Finally*, the FTC should prioritize enforcement against unfair and deceptive practices especially when there is potential for serious harm to children. As previously mentioned, these treatments result in increased risk of cancer, infertility, and sexual dysfunction; decreased cognitive development; as well as irreversible physical changes. Given the very serious safety risks, potential for permanent harm, and the inconclusive evidence of health benefits,<sup>31</sup> it is appropriate for the Commission to ensure that parents are receiving accurate information. We will continue to prioritize enforcement that protects the most vulnerable among us, especially our children.

A recent op-ed in the Washington Post said the quiet part out loud. There, MIT Professor Alex Byrne discussed his participation in a review of gender dysphoria treatments published by the United States Department of Health and Human Services. He explained: "I am hardly a fan of the current administration: I have never voted Republican, and as an academic from Cambridge, Massachusetts, I hold many of the liberal beliefs of my tribe. That includes support for the right of transgender people to live free from discrimination and prejudice."<sup>32</sup> But, as he explained, "[m]edicalized treatment for pediatric gender dysphoria needs to be dispassionately scrutinized like any other area of medicine, no matter which side of the aisle is cheering it on."<sup>33</sup>

From the opposite side of the aisle, I agree that we should work together to scrutinize and ensure complete and truthful information about the risks and purported benefits of medical transition treatments. We owe this to our children.

<sup>&</sup>lt;sup>30</sup> Lewis, *supra* note 17; *see also* Byrne, *supra* note 29 (describing reviews of clinical guidelines as resting on "very weak evidence"); Department of Health and Human Services, *Treatment for Pediatric Gender Dysphoria, Review of Evidence and Best Practices, Foreword & Executive Summary*, May 1, 2025, at 7-9,

https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report-exec-summary.pdf.

<sup>&</sup>lt;sup>31</sup> In addition to no evidence of decreased suicide rates, *The Atlantic* article also reports that Dr. Olson-Kennedy's broad study shows "no significant changes in reported anxious/depressed, withdrawn/depressed, somatic complaints, social problems, thought problems, attention problems, aggressive behavior, internalizing problems or externalizing problems" in the two years after starting puberty blockers. Lewis, *supra* note 17. Dr. Olson-Kennedy delayed release of the report because she was concerned the results would be "weaponized." *Id.* 

<sup>&</sup>lt;sup>32</sup> Byrne, *supra* note 29; *see also* Andrew Sullivan, *How the Gay Rights Movement Radicalized and Lost Its Way*, N.Y. TIMES (June 26, 2025), https://www.nytimes.com/2025/06/26/opinion/gay-lesbian-trans-rights.html (questioning medical transition for minors but recognizing politicization prevents scrutiny—"it would be incredibly healthy if we were to allow an actual debate in the community about the direction we are headed in and treat dissenters less like bigots and traitors.").

<sup>&</sup>lt;sup>33</sup> Byrne, *supra* note 29.