HONORABLE JUDGE ROBERT J. BRYAN

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C. P., by and through his parents, Patricia Pritchard and Nolle Pritchard; and PATRICIA PRITCHARD,

Plaintiffs,

vs.

BLUE CROSS BLUE SHIELD OF ILLINOIS,

Defendant.

Case No. 3:20-cv-06145-RJB

BLUE CROSS BLUE SHIELD OF ILLINOIS'S REPLY IN SUPPORT OF MOTION TO EXCLUDE PLAINTIFFS' EXPERTS UNDER *DAUBERT*

FILED UNDER SEAL

NOTE ON MOTION CALENDAR: NOVEMBER 18, 2022

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I. INTRODUCTION

The Court should grant Defendant Blue Cross Blue Shield of Illinois ("BCBSIL")'s Motion to Exclude Plaintiffs' Experts Under *Daubert* [Dkt. 103, the "Motion"]. Plaintiffs' Opposition to BCBSIL's Motion to Exclude Plaintiffs' Experts Under Daubert (the "Opposition") fails to show that Plaintiffs' expert testimony is either relevant or reliable.[1]

II. ARGUMENT

A. The Court Should Exclude Dr. Ettner, Dr. Karasic, and Dr. Schechter Because Their Opinions Are Irrelevant.

Drs. Ettner, Karasic, and Schechter all opine in general terms that transgender-related services are medically necessary. These opinions are irrelevant. None of their opinions shed any light on whether BCBSIL may be liable under Section 1557, the principal issue in this case. The only possible relevancy of their testimony is to establish the medical consensus regarding transgender-related services. However, they could not do so because they rely exclusively on the WPATH standards, which multiple courts have held do not represent the medical consensus.

Nor could Drs. Ettner, Karasic, or Schechter determine medical necessity for the named Plaintiff C.P. because they have had minimal or no contact with him and have not conducted any psychiatric evaluation of C.P. Instead, they offer generalized statements regarding the medical necessity for transgender services, statements which do not meet the *Daubert* standards.

Contrary to Plaintiffs' assertion, *Doe v. Snyder* does not support the relevancy of their testimony. The court in *Snyder* addressed whether threat of irreparable harm justified an injunction prohibiting an exclusion for transgender-related services. The lower court in *Snyder* had held that (1) the exclusion was not discriminatory and did not violate Section 1557, and (2) the plaintiffs failed to prove irreparable harm if the plaintiff, a minor, did not receive the surgery for which benefits were sought. 28 F.4th at 110. In affirming, the Ninth Circuit held that there was no evidence of irreparable harm and in doing so acknowledged the disagreements in the medical community regarding the value of transgender-related services. *Id.* at 112.

[1] At 22 pages, Plaintiffs' Opposition is in excess of the 18-page limitation for *Daubert* response briefs.

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Thus, in *Snyder* medical necessity was relevant, in order to determine irreparable harm, but the court found that plaintiff's experts' exclusive reliance on the WPATH standards was not reliable. After considering the testimony of BCBSIL's expert Dr. Laidlaw, the Ninth Circuit concluded that the plaintiffs had failed to prove medical necessity because "Doe failed to provide a declaration from any psychiatrist or medical doctor who is treating him that attested to the necessity and suitability of the surgery in his particular case" and because "Doe's expert psychiatrist had not opined as to whether Doe himself is a suitable candidate for surgery and had not met or examined Doe." *Id*. at 112-13. Thus, *Snyder* fails to support the relevancy of Plaintiffs' experts.

The fact that Plaintiffs' experts have provided expert testimony in other transgender cases does not mean that their testimony is relevant to the issues in this case. *See, e.g., U.S. v. Cloud*, 576 F. Supp. 3d 827, 845-46 (E.D. Wash. 2021) (an expert was not qualified to testify in the case at hand despite being qualified in prior cases).

B. The Court Should Exclude Ettner, Karasic, and Schechter Because Their Methodology is Unreliable.

Drs. Ettner, Karasic, and Schechter's expert opinions are not sufficiently reliable because they engaged in impermissible results-driven methodology to reach their opinions and lack the necessary qualifications for their opinions.

1. Regarding Transgender Related Care, All Three Experts Exclusively Rely on Authority from an Advocacy Organization.

Plaintiffs claim that Dr. Ettner and Dr. Karasic "cite to, reference and rely on" both the World Professional Association for Transgender Health ("WPATH") and the Endocrine Society Guidelines. Opposition at 13. However, Plaintiffs experts' all selectively rely on WPATH to the exclusion of other studies and guidelines, because they are all closely affiliated with WPATH and WPATH supports the opinions Plaintiffs hired these experts to provide. *See* Dkt. 104-1, Ex. R, ¶¶ 12-25. WPATH is primarily an advocacy group that does not represent the medical consensus as to transgender related care, and the experts failed to consider the 2017 Endocrine Society Clinical Practice Guidelines on the Treatment of Gender-Dysphoric/Gender-Incongruent

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Persons in their reports.

The court in *Whitman-Walker* found that the plaintiffs' exclusive reliance on WPATH failed to establish that exclusions for gender reassignment surgery constituted discrimination on the basis of sex. *Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs*, 485 F. Supp. 3d 1, 46 (D.D.C. 2020). *Whitman-Walker* noted that "HHS explicitly considered [WPATH] in promulgating the 2020 Rule, referencing submissions from various commenters who agreed with [WPATH's] approach." *Id.* at 48. The court found that HHS's reasoned consideration of and subsequent rejection of WPATH's advocacy was not arbitrary and capricious: "HHS also agreed with comments it received that the 2016 Rule relied exclusively on WPATH," and WPATH is "an advocacy group." *Id.* The court stated that the plaintiffs had attempted to show that categorical exclusions for transgender-related services discriminate on the basis of sex "simply by pointing to evidence that the agency plainly took into account." *Id.* Here, the experts are only considering evidence—the WPATH—that supports their pre-determined opinions.

In *Snyder*, 28 F.4th 103, the court likewise found that exclusive reliance on the WPATH standards was not reliable. The Court affirmed the district court's refusal to enjoin the State's exclusion for gender-related services because the WPATH standards did not represent the medical consensus. The district court in *Snyder* had concluded that the medical consensus did not support the value of gender-affirmative treatments, and the Ninth Circuit affirmed that this decision was not clearly erroneous, emphasizing that the evidence offered by the defendants contradicted testimony from the plaintiffs' WPATH-affiliated experts. *See* BCBSIL's Motion for Summary Judgment [Dkt. 87] at 20-30. Thus, Plaintiffs' experts' mere regurgitation of the WPATH standards does not provide the reliability required for expert testimony under Rule 702.

2. Drs. Ettner, Karasic, and Schechter Fail to Assess the Impact of Side Effects.

Plaintiffs' experts are unreliable because they fail to address the significant issue of side effect of these treatments when concluding that transgender treatments are universally considered medically necessary. Plaintiffs attempt to salvage the opinions by claiming that Dr.

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Karasic "discusses" side effects by stating that some effects are reversible, while others are irreversible. Opposition at 19. Plaintiffs also claim that Dr. Ettner "discusses" side effects by listing "breast development, redistribution of body fat, cessation of male pattern baldness, and reduction of body hair" in her report. *Id*. However, this cursory treatment of side effects in these experts' reports does not sufficiently address the important issue of how side effects relate to medical necessity, and the absence of any meaningful discussion renders their opinions unreliable. Plaintiffs' expert reports also make no mention of other serious side effects, including impact on bone density and adolescent brain development.

There is growing concern in the medical community regarding the impact on bone density in particular.[2] In comparison, Dr. Laidlaw's report contains 14 pages of analysis and discussion about the adverse health effects of each of the four interventions of gender affirming surgery. Dkt. 104-1, Ex. R, 23-37. The lack of a meaningful discussion around side effects exemplifies how Drs. Karasic, Ettner, and Schechter's testimony is not "based on sufficient facts or data" as required under Rule 702(b).

3. Drs. Ettner, Karasic, and Schechter Ignore Relevant Medical Literature That Does Not Support Their Conclusions.

Plaintiffs' experts each ignore literature and guidelines from medical organizations that did not align with their own opinions. This type of selective reliance renders an expert's opinion inadmissible. *See Carnegie Mellon Univ. v. Hoffmann-LaRoche, Inc*., 55 F. Supp. 2d 1024, 1039 (N.D. Cal. 1999) ("The Ninth Circuit has upheld the exclusion of expert testimony where the expert selectively chose his support from the scientific landscape.") (citing *Lust v. Merrell Dow Pharmaceuticals, Inc.,* 89 F.3d 594, 598 (9th Cir. 1996)).

Drs. Karasic, Ettner, and Schechter failed to consider conflicting recommendations in the

[2] *See* Appendix 1 (Megan Twohey and Christina Jewett, *They Paused Puberty, but Is There a Cost?*, N.Y. TIMES (Nov. 14, 2022), *at* https://www.nytimes.com/2022/11/14/health/puberty-blockers-transgender.html (last visited Nov. 14, 2022) (citing two studies that tracked transgender patients' bone strength while using puberty blockers that found the bone density of many patients did not rebound when they stopped the blockers); *see also id.* (citing a doctor in the bone research lab at the Mayo Clinic, who stated that "There's going to be a price . . . and the price is probably going to be some deficit in skeletal mass.").

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2017 Endocrine Society Clinical Practice Guidelines on the Treatment of Gender-Dysphoric/Gender-Incongruent Persons (the "Endocrine Society Guidelines"). All three experts cite briefly to the Endocrine Society in their expert disclosures. *See* Dkt. 104-1, Ex. B ¶ 54; Ex. E ¶¶ 35-36; Ex. D ¶ 26. And during their depositions, all three experts agreed with the Endocrine Society's guidelines on mental health care; education for minors regarding the impacts of transgender-related services on fertility; and informed consent for minors and that those guidelines are authoritative. *Id.*, Ex. C at 63:2-17, 75:10-76:9; Ex. F at 51:23-53:2, 76:18-77:25, 85:21-86:13; Ex. K at 46:6-47:6, 50:15-51:18. Plaintiffs concede the importance of the Endocrine Society Guidelines. Opposition at 13. There is no question that the Endocrine Society Guidelines – and their recommendations regarding treatment by a qualified mental health professional – are considered relevant and reliable in the medical community.

Plaintiffs claim they were entitled to ignore other conflicting authority because they found some flaw with it. For example, they claim that the CMS decision memo is not "original research," that the COHERE Finland Report is a "government report" that was not peer reviewed, and that the Astrid Lindgren report is not "peer reviewed." Opposition at 17-18. But Plaintiffs' expert reports rely extensively on literature that is not "original research" or peer reviewed. Ex. C at 89:2-15; Ex. F at 109:18-110:18 (agreeing that his own report cites to non-peer reviewed studies); *see* BCBSIL's Motion to Exclude Plaintiffs' Experts Under *Daubert*, Dkt. 103, at 10 (pointing out that while Plaintiffs' experts dismissed the committee's recent findings as "not peer reviewed" and "not original research," they also acknowledged that their own reports cite to non-peer reviewed studies and analyze other committee position statements). Further, in *Snyder*, the Ninth Circuit, discussing Dr. Laidlaw's report, cited to the CMS memo in coming to its decision. *Snyder*, 28 F.4th at 112.

The selective reliance in Plaintiffs' experts Dr. Ettner, Dr. Karasic, and Dr. Schechter reports render them inadmissible.

4. Dr. Schechter's Opinion is Not Reliable Because he is Not Qualified to Determine Medical Need for Transgender Related Treatments.

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In addition, Dr. Schechter is not qualified to testify regarding gender dysphoria because he is a surgeon, not a mental health professional or an endocrinologist. Plaintiffs misconstrue BCBSIL's argument regarding Dr. Schechter's testimony. BCBSIL does not argue that gender dysphoria "can be treated with psychotherapy alone." Opposition at 8-9. Other medical professionals, such as endocrinologists like Dr. Laidlaw, are qualified to opine on gender dysphoria because endocrinology and hormones are directly related to gender dysphoria. *See* BCBSIL's Response to Plaintiffs' Motion to Exclude, Dkt. 115 at 9-10. But Dr. Schechter's expertise is limited to performing surgeries – he is not a psychiatrist, psychologist, or counselor of any kind, and he has no specialized education or training in the field of mental health disorders, let alone gender dysphoria. Dkt. 104-1, Ex. K at 18:22-19:13. While Dr. Schechter may be qualified to opine on certain surgeries he has performed, including how to perform sex reassignment surgery, he cannot opine on the medical necessity or any surgery as a *treatment* for gender dysphoria. *See id.*, Ex. D, ¶ 44.

C. Dr. Fox's Expert Opinion is Not Admissible Because It is Irrelevant.

Plaintiffs claim that Dr. Fox's opinion is relevant because his testimony aids in "class certification and appropriate equitable remedy [sic]." Opposition at 21. However, given that BCBSIL does not contest numerosity, nothing in Fox's opinion "will help the trier of fact to understand the evidence or to determine a fact issue." Fed. R. Evid. 702(a). Because Dr. Fox's testimony will not help the trier of fact in determining a fact issue, his opinion is not relevant and should be excluded.

D. The Court Should Exclude Dr. Fox's Expert Opinion Because It is Not Reliable.

Rule 702 and *Daubert* require that Dr. Fox's methodology and testimony must be reliable. Fed. R. Evid. 702(c)-(d). Plaintiffs claim that BCBSIL's arguments that Dr. Fox's opinion is unreliable go to the "weight of Dr. Fox's testimony not its admissibility." Opposition at 21. Plaintiffs are wrong: the reliability problems in Fox's report are so significant as to render it inadmissible. Dr. Fox assumes that the prevalence of transgender persons in the relevant BCBSIL plans is identical to the prevalence of transgender persons in the general population,

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includes duplicate enrollees in his enrollment counts, includes meaningless variables in his calculation, and cherry-picks percentages in the Quinn study for the prevalence of transgender people. *See* Dkt. 103 at 16-18. Plaintiffs do not respond to any of these arguments in their Opposition. Instead, Plaintiffs state generally that BCBSIL's arguments go to the "weight of Dr. Fox's testimony not its admissibility." Opposition at 21. Dr. Fox's estimate of individuals who would have been expected to seek gender-related care does not include C.P., the class representative in this case. Further, Dr. Fox's calculation method is flawed, as the study upon which Dr. Fox relies states that its values are merely "estimates" that may be inaccurate. Dkt. 104-1, Ex. S, at 7-8.

The cases Plaintiffs cite for this proposition are not on point. First, Plaintiffs inaccurately cite *Empire Health Found. v. CHS/Community Health Sys.*, No 2:17-cv-00209-SMJ, 2019 WL 2995913 (E.D. Wash. July 9, 2019) as support. Opposition at 21. But this case does not discuss the admissibility of expert testimony. Plaintiffs also cite *D.T. by and through K.T. v. NECA/IBEW Family Medical Care Plan*, No. 2:17-cv-00004-RAJ, 2020 WL 59647 (W.D. Wash. Jan. 6, 2020) for the same idea, a case in which the court allowed Dr. Fox's expert testimony. But in that case, the court denied the defendants' motion in limine to exclude Dr. Fox as "actuarial." *Id.* at *3. BCBSIL does not move to exclude Dr. Fox on this ground. In contrast, here BCBSIL has shown that Dr. Fox's data and methodology are unreliable under Rule 702. The fact that Dr. Fox's testimony was admitted in other cases does render his testimony relevant or reliable in this case. *See Cloud*, 576 F. Supp. 3d at 845-46. Thus, Dr, Fox's methodology and conclusions remain irrelevant, unsound, and unsupported.

III. CONCLUSION

For these reasons, BCBSIL respectfully requests that the Court fulfill its gatekeeper role by excluding the expert opinions of Drs. Ettner, Schechter, Karasic, and Fox in their entirety.

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Dated this 18th day of November, 2022.

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By *s/ Gwendolyn C. Payton*

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CERTIFICATE OF SERVICE

I certify that on the date indicated below I caused a copy of the foregoing document, BLUE CROSS BLUE SHIELD OF ILLINOIS'S REPLY IN SUPPORT OF MOTION TO EXCLUDE PLAINTIFFS' EXPERTS UNDER *DAUBERT*, to be filed with the Clerk of the Court via the CM/ECF system. In accordance with their ECF registration agreement and the Court's rules, the Clerk of the Court will send e-mail notification of such filing to the following attorneys of record:

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APPENDIX

The New York Times https://www.nytimes.com/2022/11/14/health/puberty-blockers-transgender.html

They Paused Puberty, but Is There a Cost?

Puberty blockers can ease transgender youths' anguish and buy time to weigh options. But concerns are growing about long-term physical effects and other consequences.


By Megan Twohey and Christina Jewett

Nov. 14, 2022 Updated 9:45 a.m. ET

The medical guidance was direct.

Eleven-year-old Emma Basques had identified as a girl since toddlerhood. Now, as she worried about male puberty starting, a Phoenix pediatrician advised: Take a drug to stop it.

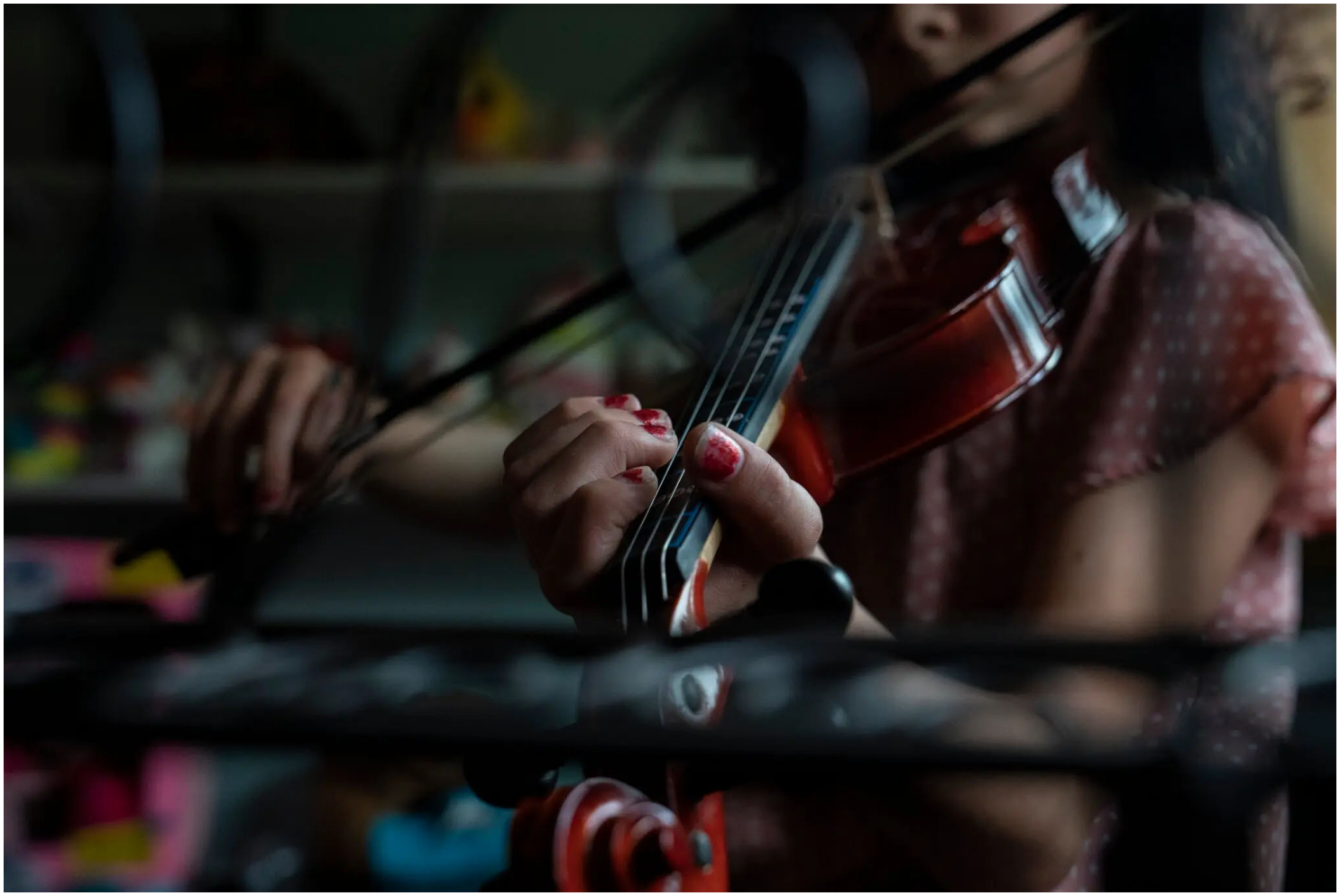
At 13, Jacy Chavira felt increasingly uncomfortable with her maturing body and was beginning to believe she was a boy. Use the drug, her endocrinologist in Southern California recommended, and puberty would be suspended.

An 11-year-old in New York with deepening depression expressed a desire to no longer be a girl. A therapist told the family the drug was the preteen's best option, and a local doctor agreed.

"'Puberty blockers really help kids like this,'" the child's mother recalled the therapist saying. "It was presented as a tourniquet that would stop the hemorrhaging."

As the number of adolescents who identify as transgender grows, drugs known as puberty blockers have become the first line of intervention for the youngest ones seeking medical treatment.

Their use is typically framed as a safe — and reversible — way to buy time to weigh a medical transition and avoid the anguish of growing into a body that feels wrong. Transgender adolescents suffer from disproportionately high rates of depression and other mental health issues. Studies show that the drugs have eased some patients' gender dysphoria — a distress over the mismatch of their birth sex and gender identity.



Emma, now 14, has identified as a girl since toddlerhood and feels that she's on the right path. Verónica G. Cárdenas for The New York Times

"Anxiety drains away," said Dr. Norman Spack, who pioneered the use of puberty blockers for trans youth in the United States and is one of many physicians who believe the drugs can be lifesaving. "You can see these kids being so relieved."

But as an increasing number of adolescents identify as transgender — in the United States, an estimated 300,000 ages 13 to 17 and an untold number who are younger — concerns are growing among some medical professionals about the consequences of the drugs, a New York Times examination found. The questions are fueling government reviews in Europe, prompting a push for more research and leading some prominent specialists to reconsider at what age to prescribe them and for how long. A small number of doctors won't recommend them at all.

Dutch doctors first offered puberty blockers to transgender adolescents three decades ago, typically following up with hormone treatment to help patients transition. Since then, the practice has spread to other countries, with varying protocols, little documentation of outcomes and no government approval of the drugs for that use, including by the U.S. Food and Drug Administration.

But there is emerging evidence of potential harm from using blockers, according to reviews of scientific papers and interviews with more than 50 doctors and academic experts around the world.

Behind Our Reporting on Puberty Blockers


Megan Twohey and Christina Jewett
Reporting for the Investigations Desk

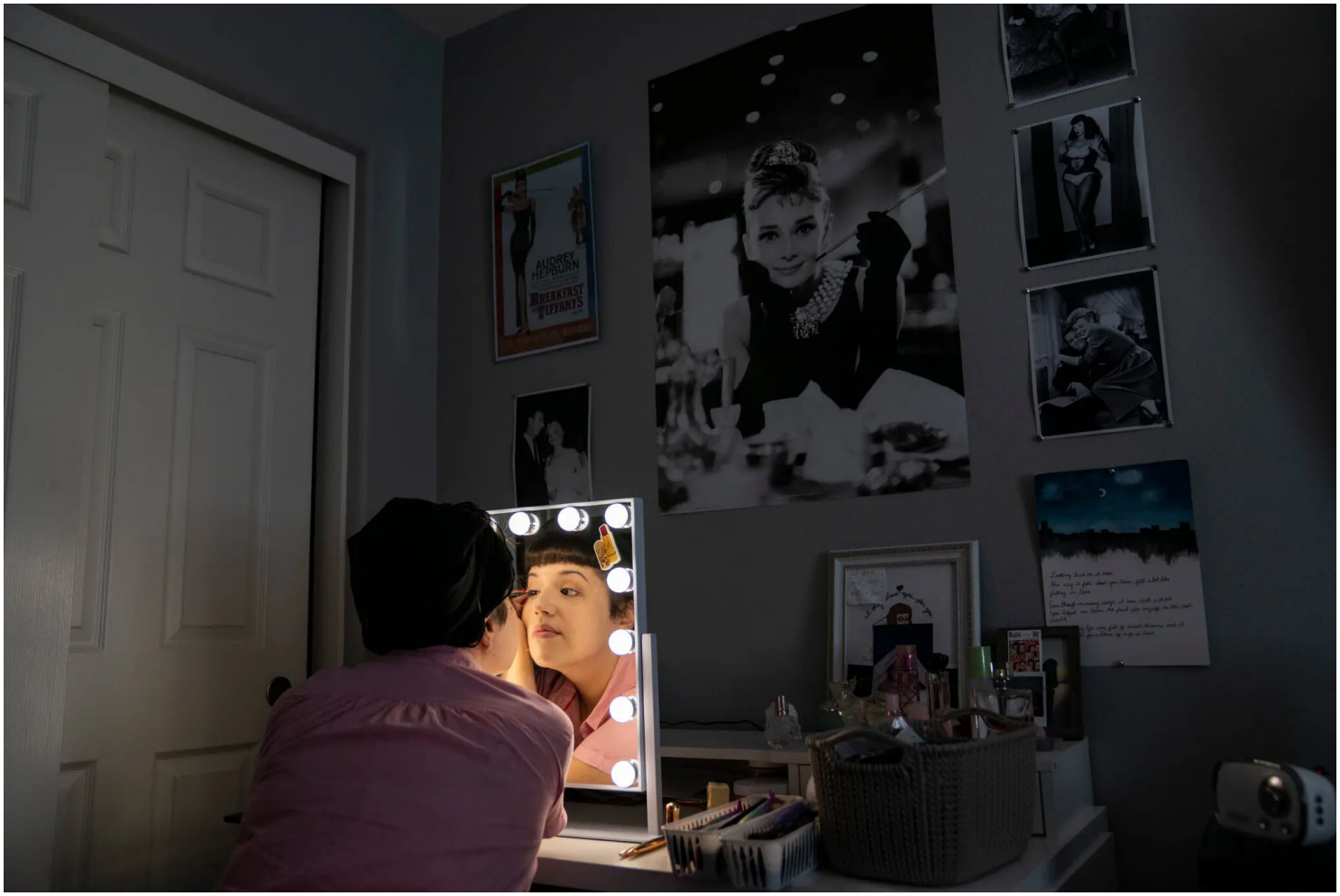
As growing numbers of adolescents who identify as transgender are prescribed drugs to block puberty, the treatment is becoming a source of confusion and controversy.

We spent months scouring the scientific evidence, interviewing doctors around the world and speaking to patients and families.

Here's a closer look at what we found →

The drugs suppress estrogen and testosterone, hormones that help develop the reproductive system but also affect the bones, the brain and other parts of the body.

During puberty, bone mass typically surges, determining a lifetime of bone health. When adolescents are using blockers, bone density growth flatlines, on average, according to an analysis commissioned by The Times of observational studies examining the effects.



Jacy Chavira, 22, thinks puberty blockers were prescribed to her too quickly. After treatment with blockers starting at 13, followed by testosterone, she has resumed her female identity. Verónica G. Cárdenas for The New York Times

Many doctors treating trans patients believe they will recover that loss when they go off blockers. But two studies from the analysis that tracked trans patients' bone strength while using blockers and through the first years of sex hormone treatment found that many do not fully rebound and lag behind their peers.

That could lead to heightened risk of debilitating fractures earlier than would be expected from normal aging — in their 50s instead of 60s — and more immediate harm for patients who start treatment with already weak bones, experts say.

"There's going to be a price," said Dr. Sundeep Khosla, who leads a bone research lab at the Mayo Clinic. "And the price is probably going to be some deficit in skeletal mass."

Many physicians in the United States and elsewhere are prescribing blockers to patients at the first stage of puberty — as early as age 8 — and allowing them to progress to sex hormones as soon as 12 or 13. Starting treatment at young ages, they believe, helps patients become better aligned physically with their gender identity and helps protect their bones.

But that could force life-altering choices, other doctors warn, before patients know who they really are. Puberty can help clarify gender, the doctors say — for some adolescents reinforcing their sex at birth, and for others confirming that they are transgender.

“The most difficult question is whether puberty blockers do indeed provide valuable time for children and young people to consider their options, or whether they effectively ‘lock in’ children and young people to a treatment pathway,” wrote Dr. Hilary Cass, a pediatrician leading an independent review in England of medical treatments of adolescents presenting as transgender.

“There’s going to be a price,” said Dr. Sundeep Khosla, who leads a bone research lab at the Mayo Clinic. “And the price is probably going to be some deficit in skeletal mass.” Jenn Ackerman for The New York Times

On her recommendation, England’s National Health Service last month proposed restricting use of the drugs for trans youths to research settings. Sweden and Finland have also placed limits on the treatment, concerned not just with the risk of blockers, but the steep rise in young patients, the psychiatric issues that many exhibit, and the extent to which their mental health should be assessed before treatment.

In the United States, though, there is no universal policy, and the public discussion is polarized.

Republican governors and lawmakers in more than a dozen states are working to limit or even criminalize the treatments, as some in their party also seek to restrict access to sports and bathrooms, ban discussion of gender in public schools, and call into question whether transgender identity even exists. (This month, the Florida medical board banned medications and surgeries for new patients under 18.) Meanwhile, the Biden administration describes transgender medicine as a civil right. And some advocates criticize anyone who questions the treatments’ safety.

Long-awaited research funded by the National Institutes of Health could provide more guidance. In 2015, four prominent American gender clinics were awarded $7 million to examine the effects of blockers and hormone treatment on transgender youth. In explaining their study, the researchers pointed out that the United States had produced no data on the impact or safety of blockers, particularly among transgender patients under 12, leaving a “gap in evidence for this practice.” Seven years in, they have yet to report key outcomes of their work, but say the findings are coming soon.

Many young patients and their families have concluded that the benefits of easing the despair of gender dysphoria far outweigh the risks of taking blockers. For others, the limited studies and politicization of trans medicine can make it difficult to fully evaluate the decision. A Reuters examination of a range of transgender treatments also found scant research into the long-term effects.

Three years after starting the drugs, Emma Basques believes she's on the right path.

Jacy Chavira, now 22, decided that the medical treatment was not appropriate for her and resumed her female identity.

And the New York adolescent had such a significant loss in bone density after more than two years on blockers that the parents halted use of the drugs.

"We went into this because we wanted to help," the mother said. "Now I worry that we got into a situation with a very powerful drug and don't understand what the long-term effects will be."

Emma's mother, Cherise Basques, right, and father let her grow her hair longer and take other steps to socially transition when she was 5. Verónica G. Cárdenas for The New York Times

'Time to Start'

It didn't take long for Cherise and Arick Basques to realize that their toddler was different. The child rejected pants, toy trucks and sports in favor of dresses, Barbie dolls and ballet. When Ms. Basques ran into a friend at a restaurant in their Phoenix suburb and introduced her then-4-year-old as her son, the child shouted: "No! I'm your daughter!"

The couple worked with children — Ms. Basques as an occupational therapist, her husband as a teacher and school administrator — but this was unfamiliar territory. None of the therapists the parents called felt equipped to help. Their pediatrician offered only that things could change once the child started school, Ms. Basques said. Eventually, the couple discovered a local support group for parents of transgender children.

The next year, they allowed the child, then 5, to begin using the name Emma, grow longer hair and take other steps to socially transition. In 2019, when Emma turned 11, a physician at a local gender clinic advised starting blockers.

"At the first subtle signs of puberty, it was like: 'Yep, that's it. Time to start!'" recalled Ms. Basques. Along with her husband and Emma, she asked that their full names be used because they consider themselves advocates of the treatment.

For decades, transgender medical treatment in multiple countries was restricted to patients 18 and older. But in the 1990s, a hospital clinic in Amsterdam began treating adolescents.

By the time Emma began taking blockers, in 2019, multiple medical groups had endorsed their use for gender dysphoria. Verónica G. Cárdenas for The New York Times

Puberty blockers can be given as an injection or an implant. (The best known is Lupron, made by AbbVie.) They were being used in the United States and elsewhere, with approval by the F.D.A. and its counterparts overseas, to treat prostate cancer; endometriosis, a painful disease that causes uterine tissue to grow elsewhere in the body; and the unusually early onset of puberty, typically age 6 or 7. If blockers were safe for patients with that rare condition, known as central precocious puberty, the Dutch doctors reasoned, they were likely to be safe for trans adolescents too.

The first trans patient treated with blockers, from age 13 to 18, moved on to testosterone, the male sex hormone. Halting female puberty had offered emotional relief and helped him look more masculine. As the Dutch clinicians prescribed blockers, followed by hormones, to a half-dozen other patients in those early years, the medical team found that their mental health and well-being improved.

“They were usually coming in very miserable, feeling like an outsider in school, depressed or anxious,” recalled Dr. Peggy Cohen-Kettenis, a retired psychologist at the clinic. “And then you start to do this treatment, and a few years later, you see them blossoming.”

In 1998, she worked with a small international group — which would later expand and become known as the World Professional Association for Transgender Health, or WPATH — to include puberty blockers and hormones for adolescents in their treatment guidelines.

The Dutch doctors had yet to publish any research findings, she acknowledged. Some other physicians, including the one overseeing transgender medical treatment in England, were wary of potential harm.

But doctors in the group considered the early results from Amsterdam as reassuring enough to move forward. They were eager to treat the psychological distress observed in many trans adolescents.

"It was just really exciting," Emma said of starting her transition. "I finally got to be who I was." Verónica G. Cárdenas for The New York Times

Doctors debated about whether "starting the puberty blockers would somehow damage the children," recalled Dr. Walter Meyer, a Texas pediatric endocrinologist and psychiatrist involved with the 1998 standards of care.

"The Dutch were saying, 'Oh, no, it's not causing a problem,'" said Dr. Meyer, who continues to support the use of the drugs.

Dr. Cohen-Kettenis hoped physicians in other countries would adopt the Dutch protocol, and document and share the outcomes as she and her colleagues in Amsterdam planned. Her clinic treated only patients who had consistently presented as transgender since early childhood and did not suffer from distinct psychiatric disorders that could interfere with diagnosis or treatment. They had to be at least 12 for puberty blockers, with the option of moving on to hormones at 16.

The international standards of care advised similar criteria. But they were recommendations, not requirements. Soon, the use of puberty blockers spread. In the United States and Canada, countries without centralized health systems, protocols were largely left to the discretion of individual clinics and practitioners. Dr. Spack, the pediatric endocrinologist who led U.S. adoption of the treatment, opened the first American clinic in 2007 at Boston Children's Hospital; others eventually followed in nearly every state.

Some started children on blockers at the first signs of puberty and prescribed testosterone or estrogen to patients 14 or younger. Doctors believed that earlier treatment would lead to more successful medical transitions, and wanted to spare patients the difficulty of watching their peers develop while their own bodies remained unchanged.

The doctor in Arizona who treated Emma, for example, tells preteen patients that if he prescribed blockers and didn't start hormones for five years, they would look 12 at age 16.

Dr. Peggy Cohen-Kettenis was a psychologist in the Dutch clinic that pioneered treatments for transgender youths. “They were usually coming in very miserable,” she recalled. With treatment, she said, “you see them blossoming.” Marlena Waldthausen for The New York Times

Transgender activists across the country pushed for early and easy access to the treatment. At a 2006 Philadelphia medical convention, Jenn Burleton, an advocate from Oregon, heard Dr. Spack describe his experience starting to treat adolescents with blockers. Like others of her generation, Ms. Burleton, now 68, could not medically transition until adulthood, and puberty had been traumatic. Treating adolescents with blockers was “game-changing,” she said.

Back home, Ms. Burleton prodded pediatric endocrinologists to adopt the practice for their patients. “We have a chance to prevent them from being emotionally broken,” she recalled saying.

Advocates successfully pushed Oregon, Massachusetts, California and other states to allow for Medicaid coverage of puberty blockers for adolescents identifying as trans. They also helped win approval in Oregon for a variety of medical workers — doctors, nurse practitioners, naturopaths — to administer blockers if overseen, even long-distance, by an endocrinologist.

“It went so quickly that not even centers but individual clinicians, people who were not knowledgeable, were just giving this kind of treatment,” said Dr. Cohen-Kettenis, the Dutch psychologist. “There was a great concern.”

By the time Emma Basques began taking blockers in 2019, multiple medical groups had endorsed their use for gender dysphoria. Among them were the American Academy of Pediatrics and the international Endocrine Society, which in 2017 had described the limited research on the effects of the drugs on trans youth as “low-quality.” Still, the organizations were encouraged by what they saw as a promising treatment.

Many doctors point out that it’s not unusual for research to lag behind the launch of new treatments and for drugs to be used off-label on patients without F.D.A. approval, especially in pediatric medicine.

Jenn Burleton, an advocate from Oregon, speaking at a support group for parents whose children identify as transgender. Verónica G. Cárdenas for The New York Times

An F.D.A. spokeswoman said in a statement that doctors have the discretion to do so, but also noted that just because a drug has been approved for one class of patients doesn't mean it's safe for another.

There is no centralized tracking of blocker prescriptions in the United States. Komodo Health, a health technology company, compiled private and public insurance data for Reuters, showing a sharp increase in the number of children ages 6 to 17 diagnosed with gender dysphoria, from about 15,000 in 2017 to about 42,000 in 2021. During that time, 4,780 patients with that diagnosis were put on puberty blockers covered by insurance, the data shows, with new prescriptions growing each year. But the data does not capture the many cases in which insurance does not cover the drugs for that use, leaving families to pay out of pocket.

Some leading American practitioners asked AbbVie and Endo Pharmaceuticals, maker of another blocker, to seek F.D.A. approval for the drugs' use among trans adolescents. The drugmakers would have to fund research for a patient population that made up just a small part of their market. But the physicians argued that regulatory approval could help establish the safety of the treatment and broaden insurance coverage of the drugs, which can cost tens of thousands of dollars a year. In the end, AbbVie and Endo said no. The companies declined to comment on the decision.

Emma Basques was on blockers for two years. Then, after she turned 13 in October of last year, a doctor in the Portland, Ore., suburb where her family had moved, prescribed estrogen, starting her transition. It had become increasingly awkward to feel left behind as her classmates physically matured. And she felt confident that she was ready.

"It was just really exciting," Emma said. "I finally got to be who I was."

A skeleton model at the Baylor College of Medicine in Houston. A full accounting of blockers' risk to bones is not possible. Because most treatment is provided outside of research studies, there's little public documentation of outcomes. Callaghan O'Hare for The New York Times

'We Need to Give This a Chance'

The 11-year-old in New York, who had begun puberty and started at a new school, was increasingly distressed — refusing to bathe or go to class and, for the first time, expressing a desire to no longer have a girl's body.

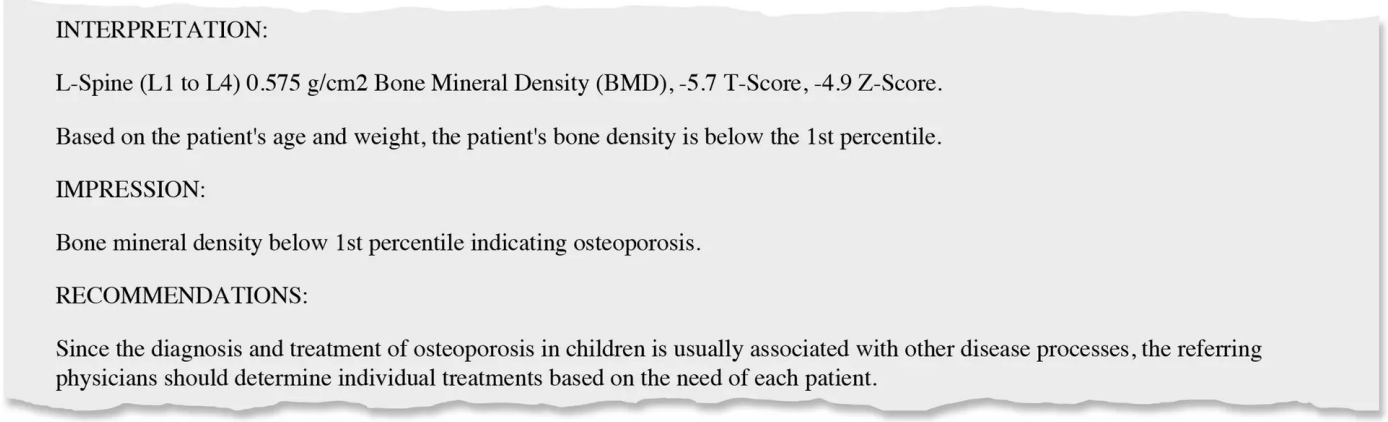
When the parents consented to blockers in 2018, they hoped the drug would bring emotional stability and time to consider next steps.

"If everyone thinks this will help, and it's reversible, then we need to give this a chance," said the mother, who asked that her name be withheld to protect the family's privacy.

The first two years were promising, with the patient, by then a teen, taking Prozac in addition to the blockers. But at the start of the third year, a bone scan was alarming. During treatment, the teen's bone density plummeted — as much as 15 percent in some bones — from average levels to the range of osteoporosis, a condition of weakened bones more common in older adults.

The doctor recommended starting testosterone, explaining that it would help the teen regain bone strength. But the parents had lost faith in the medical counsel.

"I was furious," the mother recalled. "I'm thinking, 'I worry we've done permanent damage.'"



INTERPRETATION:

L-Spine (L1 to L4) 0.575 g/cm2 Bone Mineral Density (BMD), -5.7 T-Score, -4.9 Z-Score.

Based on the patient's age and weight, the patient's bone density is below the 1st percentile.

IMPRESSION:

Bone mineral density below 1st percentile indicating osteoporosis.

RECOMMENDATIONS:

Since the diagnosis and treatment of osteoporosis in children is usually associated with other disease processes, the referring physicians should determine individual treatments based on the need of each patient.

A Texas teenager had very low bone density in the lumbar spine after a year on blockers, records show. No baseline bone scan had been performed at the outset of treatment. The New York Times

A full accounting of blockers' risk to bones is not possible. While the Endocrine Society recommends baseline bone scans and then repeat scans every one to two years for trans youths, WPATH and the American Academy of Pediatrics provide little guidance about whether to do so. Some doctors require regular scans and recommend calcium and exercise to help to protect bones; others do not. Because most treatment is provided outside of research studies, there's little public documentation of outcomes.

But it's increasingly clear that the drugs are associated with deficits in bone development. During the teen years, bone density typically surges by about 8 to 12 percent a year. The analysis commissioned by The Times examined seven studies from the Netherlands, Canada and England involving about 500 transgender teens from 1998 through 2021. Researchers observed that while on blockers, the teens did not gain any bone density, on average — and lost significant ground compared to their peers, according to the analysis by Farid Foroutan, an expert on health research methods at McMaster University in Canada.

The findings match what practitioners of the treatment have seen, including Dr. Catherine Gordon, a pediatric endocrinologist and bone researcher at Baylor College of Medicine in Houston. "When they lose bone density, they're really getting behind," said Dr. Gordon, who is leading a separate study on why the drugs have such an effect.

Many doctors caring for young trans patients are reassured by the rebounds seen in the children who take blockers for unusually early puberty. In most cases, their bone strength fully recovers after they stop the drugs at about age 11 and resume full puberty, which can last up to five years. But patients identifying as trans take the drugs later, interrupting their normally timed puberty and limiting that crucial period of development.

"That's the difference," Dr. Gordon said. "You shorten that critical window of puberty."

So far, only two small studies, published by Dutch doctors, have tracked the bone development of trans patients from beginning blockers through early hormone treatment. In both studies, dozens of patients started blockers at 14 or 15, on average, and began estrogen or testosterone at 16. The participants, followed in one study through age 18, and in the other through age 22, saw their bones strengthen, on average, once on hormones. Still, most patients continued to lag behind their peers; trans men neared average levels, but trans women fell far below.

Dr. Catherine Gordon, a pediatric endocrinologist and bone researcher at Baylor, is leading a study on the effects of puberty blockers on bone development in transgender youths. Callaghan O'Hare for The New York Times

“I think there’s a false sense of security,” said Dr. Khosla, the Mayo Clinic specialist, who is skeptical that all trans patients can catch up.

Dr. Khosla and Dr. Gordon don’t believe the effects on bones are reason for medical providers to halt use of the drugs in adolescents. But they think the risks should be factored into patient decisions and that bones should be carefully monitored.

If any harm resulted from the use of blockers, it likely would not be evident until decades later, with fractures. However, for children who already have weak bones as they start treatment, the dangers could be more immediate. While there is no systematic record-keeping of such cases, some anecdotal evidence is available.

After more than a year on blockers, a 15-year-old in Texas, who had not had a baseline scan, showed spinal bone density so low that it was below the first percentile for the teen’s age and weight, indicating osteoporosis, according to medical records from earlier this year.

Emma takes calcium, makes an effort to exercise and has undergone scans showing that her bones are healthy. Verónica G. Cárdenas for The New York Times

A transgender adolescent in Sweden who took the drugs from age 11 to 14 with no bone scans until the last year of treatment developed osteoporosis and sustained a compression fracture in his spine, an X-ray showed in 2021, as reported earlier in a documentary on Swedish television.

“The patient now suffers from continued back pain,” medical records note, describing a “permanent disability” caused by the blockers.

Some practitioners in the United States and Australia do not provide the drugs to patients who are well into puberty, concerned that the treatment poses the greatest threat to bones in that period.

“You’re potentially taking on risks that I felt should be avoided,” said Dr. Stephen Rosenthal, medical director of the University of California, San Francisco, Child and Adolescent Gender Center.

He won’t prescribe blockers as a stand-alone treatment to anyone over 14. That includes the growing number of nonbinary youths who don’t want to mature into either male or female bodies. “We make it very clear that no one stays on a blocker,” he said.

Dr. Rosenthal is a principal investigator in the yearslong N.I.H. study, which also involves gender clinics in Los Angeles, Chicago and Boston. Asked why they have yet to report on key outcomes, he said their research was delayed when the pandemic halted in-person treatment. Papers on the effects of blockers on bones and other findings should be published next year, he said.

Like many physicians, Dr. Rosenthal believes the benefits of using blockers to alleviate gender dysphoria are much greater than any risks to bones. (He was among the doctors who filed statements in a lawsuit against an Alabama ban on medical treatment of trans youth.)

Emma Basques, for example, takes calcium, makes an effort to exercise and has undergone scans that showed her bones are healthy. “I can’t even imagine how life would be for Emma,” said her mother, Ms. Basques, “if she was not given blockers and had to go through male puberty.”

Emma added: “I wouldn’t like my body at all.”

But the parents in New York insisted on ending treatment for their teen, who has yet to have a follow-up scan to see if bone density has improved since going off blockers.

"I don't think we have the science behind them to be prescribing these drugs," the mother said.

"I wish I hadn't been steered into transitioning the way I was, and that I had been told there were other ways to cope with the discomfort of puberty," Ms. Chavira said. Verónica G. Cárdenas for The New York Times

'I Wish There Had Been More Questions'

Jacy Chavira, in Southern California, had already cut her hair short and begun binding her chest when she was prescribed blockers at age 13. A therapist and her parents agreed that gender dysphoria, a condition Jacy learned about from a magazine, could explain the mounting anxiety and discomfort that she was experiencing during early puberty.

Once on blockers, Ms. Chavira said, she became fixated on moving ahead with a medical transition. She was thrilled shortly after turning 16 when her pediatric endocrinologist prescribed testosterone. But soon she started having doubts. Her body was growing more masculine, but she was secretly putting on dresses. At 17, in a consultation for breast removal, she worried aloud about the potential loss of feeling in the nipples. To her, this was a sign of not wanting to go through with the surgery.

She came to realize that her anguish had stemmed from a larger inner conflict, and that continuing with a gender transition would be a mistake. "I believe it was an issue with my identity, accepting who I was, and not just the physical female portion of it," she said.

Like Ms. Chavira, most patients who take puberty blockers move on to hormones to transition, as many as 98 percent in British and Dutch studies. While many doctors see that as evidence that the right adolescents are getting the drugs, others worry that some young people are being swept into medical interventions too soon.

Over the past decade, growing numbers of medical providers have lowered the ages at which they prescribe the treatments. Today, the WPATH and Endocrine Society advise that blockers can be prescribed at the first signs of puberty and hormone treatment, in some cases, earlier than 16. The American Academy of Pediatrics says blockers can be provided anytime during puberty and hormones from "early adolescence onward."

Some doctors and researchers are concerned that puberty blockers may somehow disrupt a formative period of mental growth. With adolescence comes critical thinking, more sophisticated self-reflection and other significant leaps in brain development. Sex hormones have been shown to affect social and problem-solving skills. It's believed that brain growth is connected to gender identity, but research in

these areas is still very new.

Jacy at age 14, while on blockers. “I believe it was an issue with my identity,” she said, “accepting who I was, and not just the physical female portion of it.” Verónica G. Cárdenas for The New York Times

In a 2020 paper, 31 psychologists, neuroscientists and hormone experts from around the world urged more study of the effects of blockers on the brain.

“If the brain is expecting to receive those hormones at a certain time and doesn’t, what happens?” said Dr. Sheri Berenbaum, head of a gender research lab at Penn State, and one of the authors of the paper. “We don’t know.”

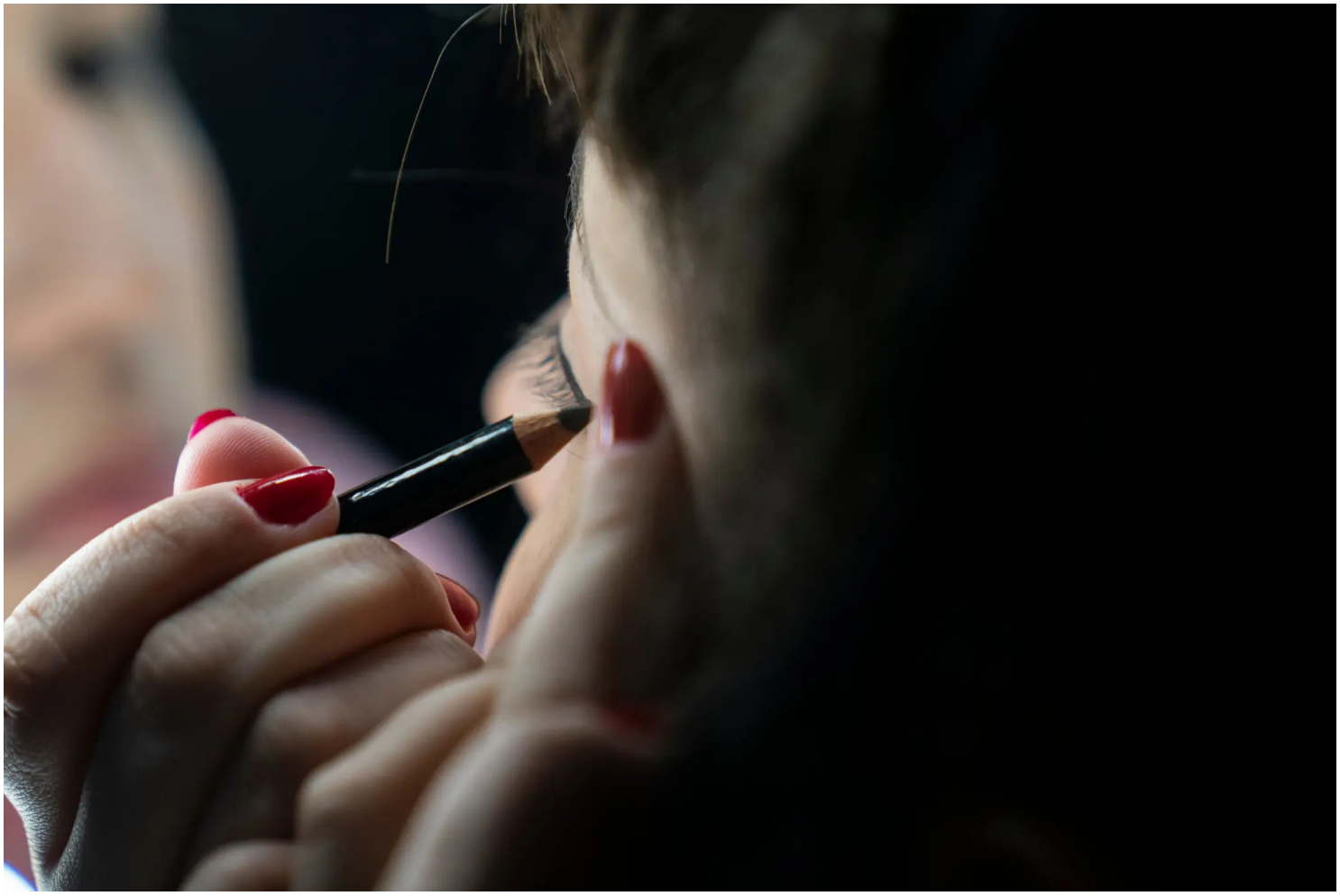
The physicians in the Amsterdam clinic, where the treatment began, have lowered their minimum ages for starting blockers and hormones. But they are very cautious in selecting patients.

“Our concern is always: When is gender identity fixed or not fluid anymore? And when do you fully understand the lifelong consequences of such treatment?” said Dr. Annelou de Vries, head therapist at the clinic.

For some medical professionals across the country, there are too many uncertainties about the effects of blockers to provide the treatment.

Among them are seven pediatric endocrinologists and pediatric endocrine nurse practitioners in Florida who recently wrote to the state health department that evidence to support the use of those treatments in adolescents “is simply lacking” and asking that it be confined to research settings.

“Without much data, it’s hard to make a conclusion that we’re doing the right thing,” said Dr. Matthew Benson, an assistant professor of pediatrics at Mayo Clinic College of Medicine in Jacksonville and an author of the letter. (He also voiced concerns at a state hearing in July on whether to stop allowing Medicaid coverage in Florida for transgender medical treatment.)



Ms. Chavira halted her medical treatment at 18, but she is left with a voice that sounds like a man's and other enduring physical changes. Verónica G. Cárdenas for The New York Times

Even enthusiasts, like Emma and her parents, acknowledge it can be hard to fully grasp all the potential results of treatment. Infertility is among other lasting effects for patients who start blockers at the first stage of puberty and proceed to hormones and surgery. Emma was advised that, to possibly preserve fertility, she would need to pause treatment at some point down the line, with the hopes of developing and freezing sperm.

"I knew what I wanted," Emma said of her medical transition. "But all this other stuff was kind of just confusing." Her father said, "We worked really hard to talk to her at her age level to make sure she understood some of these more complicated things."

When Dutch doctors launched the use of blockers and hormones on trans youth decades ago, they warned in their early papers of the possibility of "false positives" — patients who medically transition, then later declare they are not transgender.

There's no official tracking of those cases and many practitioners believe the total numbers are small. So far, scores of accounts have emerged in social media, news stories and published research.

Keira Bell, who was prescribed blockers at age 16, then moved on to testosterone and breast-removal surgery, no longer identified as transgender five years after starting to transition. She sued the Tavistock gender clinic in London where she had been treated. (A judge ruled that patients under 16 were unable to consent to puberty blockers — a decision later overturned on appeal.)

Jacy Chavira, looking back on her own experience, thinks that drugs were prescribed too quickly. At 18, she halted her medical treatment and resumed her female identity. Now, she is left with a voice that sounds like a man's and other enduring physical changes.

"I wish there had been more questions asked by the doctors," she said. "I wish I hadn't been steered into transitioning the way I was, and that I had been told there were other ways to cope with the discomfort of puberty."

Alarmed by the uncertain number of cases like Jacy's, as well as the rising numbers of patients with gender dysphoria and the psychiatric disorders many display, Sweden is working to standardize adolescent transgender medical treatment and restrict it to research settings.

Finland is also limiting treatment, more closely following the Dutch protocol, and doctors there remain concerned about the physical effects of blockers, including on brain development, said Dr. Riittakerttu Kaltiala, chief of adolescent psychiatry at a gender clinic in Tampere. (Dr. Kaltiala testified this fall before the Florida medical board as it was considering its ban on treatment.)

As European countries continue to examine and tailor their treatment, in the United States the public discourse about transgender care is growing more incendiary.

Last month, the American Academy of Pediatrics and other medical groups wrote to Attorney General Merrick B. Garland, urging the Justice Department to investigate growing threats of violence against physicians and hospitals that provide transgender medical treatment to adolescents. As more Republicans frame the treatment as child abuse, some doctors have become wary of discussing their work for fear of becoming targets.

More than a dozen doctors declined to be interviewed for this article, and several who spoke to The Times — some who support treatment, others who question it — asked not to be named.

The climate could have a chilling effect on research, said Dr. Natalie Nokoff, assistant professor of pediatric endocrinology at the University of Colorado, who recently conducted a soon-to-be-published study showing that a longer treatment period on puberty blockers was associated with a lower bone density.

“It’s leading to concerns that people’s well-intentioned scientific research could be misconstrued” and exploited for political gain, she said.

The prospect of such an outcome is disheartening for the families of Emma Basques, Ms. Chavira and the teen in New York. Despite their differing experiences, they share the same hopes for transgender medicine: less vitriol, more science.

Methodology

The analysis commissioned by The Times examined the findings of seven observational studies from the Netherlands, England and Canada, documenting the association between puberty blockers and bone density in about 500 adolescents.

In each study, bone density was measured at the spine and the hip using Dual-energy X-ray absorptiometry, or DEXA scan. The analysis looked at group means, because not every study released individual person data. Each study’s findings were weighted based on its number of participants.

The change in bone density while adolescents were on blockers was observed to be zero. The analysis also showed that the adolescents’ Z-scores, a measure of bone density that is benchmarked to peers, consistently fell during treatment with blockers.

The studies included are:

“Bone Mass in Young Adulthood Following Gonadotropin-Releasing Hormone Analog Treatment and Cross-Sex Hormone Treatment in Adolescents With Gender Dysphoria,” Klink et. al, Journal of Clinical Endocrinology & Metabolism, 2015

“Effect of Pubertal Suppression and Cross-Sex Hormone Therapy on Bone Turnover Markers and Bone Mineral Apparent Density (BMAD) in Transgender Adolescents,” Vlot et. al, Bone, 2017

“The Effect of GnRH Analogue Treatment on Bone Mineral Density in Young Adolescents With Gender Dysphoria: Findings From a Large National Cohort,” Joseph et. al, Journal of Pediatric Endocrinology and Metabolism, 2019

“Physical Changes, Laboratory Parameters and Bone Mineral Density During Testosterone Treatment in Adolescents With Gender Dysphoria,” Stoffers et. al, The Journal of Sexual Medicine, 2019

“Bone Development in Transgender Adolescents Treated With GnRH Analogues and Subsequent Gender-Affirming Hormones,” Schagen et. al, Journal of Clinical Endocrinology & Metabolism, 2020

“Short-Term Outcomes of Pubertal Suppression in a Selected Cohort of 12- to 15-Year-Old Young People With Persistent Gender Dysphoria in the U.K.,” Carmichael et. al, PLOS One, 2021

“Pubertal Suppression, Bone Mass and Body Composition in Youth With Gender Dysphoria,” Navabi et. al, Pediatrics, 2021

Julie Tate contributed research.