THE HONORABLE 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 RESPONSE TO PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT [DKT. 96] AND REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT [DKT. 87]

ORAL ARGUMENT REQUESTED

NOTE ON MOTION CALENDAR:
November 21, 2022

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

TABLE OF CONTENTS

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

TABLE OF AUTHORITIES

Cases

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

Statutes

Rules

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

I. INTRODUCTION

The Court should deny Plaintiffs' Consolidated Cross-Motion for Summary Judgment and Opposition to Defendant's Motion for Summary Judgment ("Cross-Motion") in its entirety and grant summary judgment in BCBSIL's favor. Plaintiffs' Cross-Motion concedes a number of undisputed, material facts that defeat their claim for relief under Section 1557 of the Affordable Care Act ("ACA"). Plaintiffs concede that Plaintiff Patricia Pritchard's employer CHI,[1] not BCBSIL, wrote the exclusion in the CHI Plan. They concede that the operative regulations allow the exclusion. They concede that CHI informed them that CHI added the exclusion based on its religious beliefs. They concede that BCBSIL did not receive federal financial assistance to administer the CHI Plan.

Plaintiffs' Section 1557 discrimination claim fails because BCBSIL was not the source of the exclusion and because CHI retains final decision-making authority over transgender claims. The Department of Health and Human Services ("HHS") regulations control this case and allow exclusions for transgender-related services.

Plaintiffs' Section 1557 claim also fails because the exclusion is protected by the Religious Freedom Restoration Act ("RFRA"). RFRA is incorporated into the ACA, and a court cannot adjudicate a Section 1557 claim against any party without also addressing the limitations imposed by RFRA. The Supreme Court has held that a TPA cannot provide coverage that would violate the RFRA rights of a plan sponsor.

Plaintiffs' Section 1557 claim also fails because that statute only applies to healthcare operations that receive federal funding, and BCBSIL does not receive any federal financial assistance for its TPA activities.

Finally, Plaintiffs' Section 1557 claim fails because there is no medical consensus regarding transgender-related services, and thus the CHI Plan's exclusion does not discriminate on the basis of sex.

[1] "CHI" means CommonSpirit Health, f/k/a Catholic Health Initiatives, the employer for named plaintiff Patricia Pritchard.

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

II. STATEMENT OF MATERIAL FACTS[2]

Plaintiffs' Cross-Motion concedes a number of undisputed facts that defeat that motion and their claims for relief, and compel summary judgment in BCBSIL's favor.[3]

A. CHI, not BCBSIL, Wrote the Exclusion in the CHI Plan.

Plaintiffs do not dispute that CHI designed and wrote the CHI Plan, including the exclusion for transgender-related surgeries. *See* Dkt. 88-1, Ex. A (Q: "And who drafted [the gender reassignment surgery exclusion in the CHI Plan]?" A: "Catholic Health Initiatives ").

Likewise, it is undisputed that the CHI Plan is self-insured, so the CHI Plan – not BCBSIL – is responsible for paying all health care benefits to its members and is ultimately responsible for any claim. Am. Compl., App. A at 8.

B. The CHI Exclusion is Based on Religious Views.

There is no disputed issue of fact that CHI added the exclusion to the CHI Plan based on religious views. *See* Dkt. 1, App. H (the "CHI Letter"); Dkt. 38, App. H. Plaintiffs attached as an exhibit to their original and amended Complaints a letter from CHI stating that the only transgender-related service "specifically excluded under the Plan is gender reassignment surgery, as this surgery has been determined not to align with the teachings and doctrine of the Catholic Church." *Id.*

C. BCBSIL Does Not Receive Federal Financial Assistance to Administer the CHI Plan.

It is undisputed that BCBSIL does not receive federal financial assistance for any self-funded ERISA plans that it administers on behalf of employers such as CHI. Dkt. 88-1, Ex. I, ¶ 3. BCBSIL's affiliate Health Care Service Corporation ("HCSC") does receive federal financial

---

[2] BCBSIL incorporates the facts set forth in its Motion for Summary Judgment [Dkt. 87].

[3] Plaintiffs devote a substantial portion of their Cross-Motion to whether certification of the putative class is appropriate, but this has no bearing on summary judgment as to the named plaintiff, C.P. *See, e.g.*, Cross-Motion at 36 (speculating whether plans other than the named plaintiffs' plan were designed by BCBSIL); 37 (inaccurately claiming that BCBSIL administers all plans with exclusions in the same manner, even though there are more than sixteen different iterations of exclusion language).

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

assistance for other products, such as Medicare and Medicaid. *Id.* ¶ 4. However, BCBSIL accounts for all federal payments for those products separately from BCBSIL's administration of self-funded ERISA plans. *Id.* ¶ 5. It is undisputed that the federal government requires HCSC to provide an Assurance of Compliance when receiving federal financial assistance for certain programs from HHS. Motion at 16; Cross-Motion at 4. That Assurance requires only that HCSC comply with Section 1557 for all "health program[s] or activit[ies] **for which [HCSC] receives Federal financial assistance**." Motion at 16 (citing Dkt. 88-1, Ex. I) (emphasis added).

D. C.P. Never Received Any Mental Health Treatment from a Qualified Mental Health Professional.

It is undisputed that no psychiatrist or other "qualified mental health professional" ever examined C.P. to determine his ability to give informed consent prior to treatment or examined him for any underlying psychiatric conditions as part of determining the necessity and suitability of surgery. Motion at 22; Dkt. 88-1, Ex. K, ¶¶ 16-17, 187 *et seq*. Likewise, it is undisputed that Plaintiffs have offered no testimony from any treating psychiatrist concluding that C.P. was a suitable candidate for a double mastectomy at age 14. Motion at 21.

Prior to surgery, C.P. was only examined for two hours by Sharon Booker, a mental health counselor. Dkt. 94-3, Ex. M. Ms. Booker never spoke with C.P.'s doctors or reviewed any medical records. *Id.* Ms. Booker repeatedly admitted the only reason she met with C.P. was so Plaintiffs could get a letter required for C.P. to be allowed to get the double mastectomy. *Id.*, Exs. N-O. Ms. Booker has never declined to write such a letter. *Id.*, Ex. P. Ms. Booker has not met with or spoken to C.P. since she wrote the letter or since C.P. received the surgery. *Id.*, Ex. M.

As BCBSIL's expert Dr. Laidlaw has explained here and in testimony before the Ninth Circuit in *Doe v. Snyder*, there are concerns in the medical community about the insufficient quality of medical and mental health care minors receive before undergoing irreversible transgender-related services. Dkt. 88-1, Ex. K, ¶¶ 16, 247; *Doe v. Snyder*, 28 F.4th 103, 112-13 (9th Cir. 2022).

Plaintiffs' own experts agree with the Endocrine Society guideline that minors with gender

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

dysphoria should be diagnosed by a "qualified mental health professional" with training and expertise in (1) child and adolescent gender development, and (2) child and adolescent psychopathology. Dkt. 104-1, Ex. C at 63:2-17; Ex. F at 51:23-53:2; Ex. K at 46:6-47:6. Plaintiffs' expert Dr. Ettner admits that C.P. did not see any qualified mental health professional prior to starting puberty blockers or testosterone at age 11. Dkt. 104-1, Ex. C at 64:13-66:1.

III. ARGUMENT

A. BCBSIL Cannot Be Liable for Alleged Violations of Section 1557 Because BCBSIL is Not the Source of the CHI Plan Design.

There is no cause of action against a TPA under Section 1557 where the TPA did not design the plan. Plaintiffs concede, as they must, that HHS and the Office of Civil Rights ("OCR") will not enforce Section 1557 against a TPA when the plan sponsor, rather than the TPA, designed the benefit at issue. *See* Cross-Motion at 36 (conceding that HHS and OCR "will not enforce Section 1557 against a TPA with regards to benefit design when it concludes that the TPA has 'no control' over the discriminatory benefit design of the self-funded plan"). This is the death knell for Plaintiffs' claim against BCBSIL under the CHI Plan because there is no dispute that CHI, not BCBSIL, designed the CHI Plan.

This has been true since the 2016 HHS Rule[4] implementing Section 1557 and remains true today. HHS/OCR's 2022 Proposed Rulemaking implementing Section 1557 states as follows:

> We also newly address that a third party administrator may be liable under this part when it is responsible for the underlying discriminatory plan design feature that is adopted by a group health plan. This modification is consistent with subsequent case law holding the same. Accordingly, OCR will determine whether responsibility for the decision or alleged discriminatory action lies with the plan sponsor or with the third party administrator. Where the alleged discrimination relates to the administration of the plan by a covered third party administrator, OCR will process the complaint against the third party administrator because it is the entity responsible for the decision or other action being challenged in the complaint. For example, if a third party administrator denies a claim because the individual's name suggests that they are of a certain race or national origin, or threatens to expose an employee's transgender or disability status to the employee's employer, OCR will proceed against the third party administrator as the entity responsible for the decision. In addition, OCR will pursue claims against the third party administrator in circumstances where the third party administrator is the entity responsible for developing the discriminatory benefit design feature that was adopted by the employer. On the other hand, where the alleged discrimination

[4] *See* 81 Fed. Reg. 31,432 (May 18, 2016) (the "2016 Rule").

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

> relates to the benefit design of a self-insured group health plan that did not originate with the third party administrator, but rather with the plan sponsor, OCR will refer the complaint to the EEOC or the DOJ for potential investigation.

Nondiscrimination in Health and Health Education Programs or Activities, 87 Fed. Reg. 47,824, 47,876-47,877 (August 4, 2022) (the "2022 Proposed Rulemaking")). The 2022 Proposed Rulemaking emphasizes that BCBSIL may only be liable (1) when it is "responsible for the underlying discriminatory plan design feature"; or (2) when "responsibility for the decision or other action being challenged in the complaint" lies with BCBSIL, rather than with the plan sponsor. Neither is true here.

First, it is undisputed that CHI – not BCBSIL – drafted the exclusions for transgender-related surgeries in the CHI Plan. Dkt. 88-1, Ex. A. The CHI Plan is the only plan BCBSIL administers with that custom language. Dkt. 94-1, Ex. D; Dkt. 94-1, Ex. C, Addendum A. Because CHI was the one who designed its own unique exclusion, BCBSIL cannot be held "responsible for the underlying discriminatory plan design feature." 87 Fed. Reg. 47,824, 47,876-47,877.

Second, BCBSIL cannot be liable under Section 1557 because it did not have final authority to administer claims that fell under the CHI Plan's exclusion for transgender-related surgeries. Rather, CHI had a custom review process in which CHI itself reviewed all claims under the exclusion for transgender-related services. Dkt. 94-1, Ex. E. The claims administration process for the CHI Plan's exclusion was a unique, manual process whereby CHI had the final decision-making authority. *Id.* BCBSIL neither drafted nor had the final say in administering any exclusions for transgender-related services on behalf of CHI, so it was not responsible for "the decision or other action being challenged in the complaint." 87 Fed. Reg. 47,824, 47,876-47,877.

Plaintiffs repeatedly cite *Tovar v. Essentia Health*, 857 F.3d 771 (8th Cir. 2017), but that case supports BCBSIL, not Plaintiffs. *Tovar* demonstrates that, from the 2016 HHS Rule implementing Section 1557 through the present, a TPA cannot be held liable for any Section 1557 violation where the TPA was not responsible for plan design: "'third party administrators are generally not responsible for the benefit design of the self-insured plans they administer and …

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

ERISA (and likely the contracts into which third party administrators enter with the plan sponsors) requires plans to be administered consistent with their terms.'" *Id.* at 780 (Benton, J., concurring) (quoting the 2016 Rule).

In *Tovar*, the court reversed the district court's dismissal of the claims against the TPA in part because the plaintiff had sufficiently alleged that the TPA designed the plan language at issue. *See id.* at 778 (reasoning that, at the pleading stage, the plaintiff had sufficiently alleged that the "plan and its allegedly discriminatory terms originated with [the TPA] – not with [the plan sponsor]"). Here, by comparison, there is no dispute that the employer, CHI, designed the exclusion – not BCBSIL.

Plaintiffs also rely on *Doe v. CVS Pharmacy, Inc.*, 982 F.3d 1204 (9th Cir. 2020), *cert. granted in part*, 141 S. Ct. 2882 (2021), *and cert. dismissed sub nom. CVS Pharmacy, Inc. v. Doe, One*, 142 S. Ct. 480 (2021), which also supports BCBSIL. *Doe v. CVS* involved claims brought by individuals living with HIV/AIDS against CVS for allegedly administering pharmacy benefits in a discriminatory manner. The district court dismissed the claims against CVS on the pleadings, and the Ninth Circuit reversed. *Id.* at 1208. The alleged discrimination involved a plan design that originated with CVS. *See id.* at 1207 ("CVS Caremark, requires all health plan enrollees to obtain specialty medications, including HIV/AIDS drugs, through its designated specialty pharmacy for those benefits to be considered 'in-network.'"). Thus, *CVS* does not in any way support Plaintiffs' proposition that TPAs "may be liable for administrating a discriminatory exclusion – even if they did not design it," Cross-Motion at 35, because it was undisputed that CVS designed and implemented the allegedly discriminatory part of the plan.

The other cases Plaintiffs cite do not support the conclusion that a TPA can be liable under Section 1557. Plaintiffs cite *Fernandez v. Wynn Oil Co.*, 653 F.2d 1273 (9th Cir. 1981), to support their claim that a TPA "must always obey federal law, even when doing so would be inconsistent with a specific plan term or benefit design." Cross-Motion at 2. But *Fernandez* was an employment case, not a claim for health care benefits. The court rejected a claim that an employer violated Title VII by requiring that employees fulfill stereotypical gender roles as to keep their

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

jobs. *Id.* at 1276. That case did not involve any dispute over plan design and does not apply.

Plaintiffs' other cases do not help them because they did not involve claims against TPAs, but rather against employers or governments. *See Kadel v. Folwell*, No. 1:19-CV-272, 2022 WL 2106270, at *3 (M.D.N.C. June 10, 2022), *order corrected and superseded*, No. 1:19-CV-272, 2022 WL 3226731 (M.D.N.C. Aug. 10, 2022) (alleging claims against a state health department and state health plan, not a TPA); *Fain v. Crouch*, 342 F.R.D. 109 (S.D. W. Va. 2022) (suing state health department and its commissioner, not a TPA); *Fletcher v. Alaska*, 443 F. Supp. 3d 1024, 1026 (D. Alaska 2020) (suing the state, not a TPA); *Flack v. Wisconsin Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1006 (W.D. Wis. 2019) (suing the state health department, not a TPA); *Boyden v. Conlin*, 341 F. Supp. 3d 979 (W.D. Wis. 2018) (suing state agencies and officials, not a TPA). None of these cases support holding a TPA liable under Section 1557 for an exclusion designed by a plan sponsor.

Plaintiffs fail to cite any authority demonstrating that BCBSIL may be held liable for administering the CHI Plan even though CHI designed the exclusion and acted as the final arbiter for claims subject to the exclusion. For these reasons, BCBSIL cannot be held liable under Section 1557 for claims administered under the CHI Plan.

B. The 2020 Rule Applies to This Case and Allows Transgender Exclusions for Any Reason.

The 2020 Rule allows categorical exclusions of transgender related services for any reason, and it is the governing law. Plaintiffs argue that "the discrimination alleged in this case occurred while the original 2016 rulemaking was in effect (which required compliance by BCBSIL in all of its activities)." Cross-Motion at 30. However, federal courts have invalidated and permanently enjoined the 2016 Rule, and thus it has no force or effect. *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 695-96 (N.D. Tex. 2016) (declaring the 2016 Rule invalid in relevant part and entering a nationwide preliminary injunction to prohibit the enforcement of the 2016 Rule's "prohibitions on discrimination on the basis of gender identity"); *Franciscan All., Inc. v. Azar*, 414 F. Supp. 3d 928, 941, 944, 946 (N.D. Tex. 2019) (vacating the entire 2016 Rule); *Franciscan All.,*

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

Inc. v. Becerra, 47 F.4th 368, 368 (5th Cir. 2022) (permanently enjoining HHS's enforcement of the 2016 Rule); *see also Whitman-Walker Clinic, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 485 F. Supp. 3d 1, 48-49 (D.D.C. 2020), *appeal dismissed*, *Whitman-Walker Clinic, Inc. v. United States Dep't of Health & Hum. Servs*., No. 20-5331, 2021 WL 5537747 (D.C. Cir. Nov. 19, 2021) (confirming that the 2020 Rule eliminated the 2016 Rule's ban on categorical exclusions).

The 2022 Proposed Rulemaking could not return to the 2016 Rule's requirements because it would run afoul of the holdings in the *Franciscan* cases. Moreover, to the extent that the 2022 Proposed Rulemaking will change the 2020 Rule on this issue, the 2022 Proposed Rulemaking cannot be imposed retroactively to impair BCBSIL's rights. *See Henry Ford Health Sys. v. Dep't of Health & Hum. Servs*., 654 F.3d 660, 667 (6th Cir. 2011) ("Only express congressional authorization for the agency to regulate retroactively will defeat this presumption."). Congress has not authorized HHS to regulate under the ACA retroactively.

As a last resort, Plaintiffs request the Court to simply ignore "the various iterations of the federal regulations" and just apply "the plain language of Section 1557 and the ACA as a whole." Cross-Motion at 30. But under *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-43 (1984), the Court must give deference to HHS's regulations implementing Section 1557. *Chevron* requires the Court to first analyze whether the particular statute speaks directly and unambiguously to the issue. 467 U.S. at 842-43. Here, the answer is no. *Franciscan*, 227 F. Supp. 3d at 686 ("'Section 1557's definition of sex discrimination is ambiguous because it fails to explicitly address transgender individuals and the Rule simply fills the statutory gap, implementing Section 1557.'"). Where, as here, either the language of the statute is ambiguous or Congress's intent is not explicitly clear, "there is an express delegation of authority to the agency to elucidate a specific provision of the statute." *Chevron*, 467 U.S. at 843-44.

If Congress "has not directly addressed the precise question at issue," the Court cannot "simply impose its own construction on the statute" but rather must look to whether "the agency's answer is based on a permissible construction of the statute." *Chevron*, 467 U.S. at 843. This means the Court "may not substitute its own construction" for HHS's interpretation of Section

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

1557 in the 2020 Rule. *Id*. at 844. Courts "should not disturb" an agency interpretation unless it clearly contradicts Congress' intent. *Id.* at 845. Thus, this Court can only overturn the 2020 Rule if HHS never "'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Kreis v. Sec'y of the Air Force*, 406 F.3d 684, 686 (D.C. Cir. 2005) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). There is no dispute that HHS examined the relevant data or articulate a satisfactory explanation for the 2020 Rule. To the contrary: every court that has addressed HHS's implementation of Section 1557 has deferred to the 2020 Rule. *See Whitman-Walker,* 485 F. Supp. 3d 1 at 46 ("Even assuming that the 2016 Rule's prohibition on categorical coverage exclusions of gender-affirming care was lawful, the Court cannot presently conclude that the agency's decision to remove that prohibition was arbitrary and capricious."); *Religious Sisters of Mercy v. Azar*, 513 F. Supp. 3d 1113, 1131 (D.N.D. 2021) (noting that after *Whitman-Walker* and other cases enjoined parts of the 2020 Rule, the 2020 Rule's "repeal of the insurance coverage mandate for gender-transition services" remains effective); *Hennessy-Waller v. Snyder*, No. CV-20-00335-TUC-SHR, 2021 WL 1192842, at *7 (D. Ariz. Mar. 30, 2021) (denying injunctive relief under the 2020 Rule because plaintiffs were "unlikely to succeed on the merits of their claim" that Arizona's Medicaid program's policy of excluding gender reassignment surgery from coverage violates Section 1557).

The 2020 Rule is not arbitrary and capricious because HHS examined the relevant data and articulated a satisfactory explanation for the 2020 Rule. Plaintiffs do not argue that the 2020 Rule is arbitrary and capricious. HHS's interpretation of Section 1557 should receive deference and precludes Plaintiffs' Section 1557 claim. ‼

C. BCBSIL May Administer the Exclusion Because it is Protected by RFRA.

Plaintiffs' claims fail because of the limitations imposed on Section 1557 by RFRA. Plaintiffs make four arguments to try to avoid RFRA: (1) that RFRA does not apply because the government is not a party; (2) that "BCBSIL is a secular entity and cannot 'borrow' CHI's alleged RFRA protection"; (3) that the Court should decline to adjudicate CHI's rights under RFRA

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

because CHI is not a party; and (4) that RFRA does not protect the exclusion in the CHI Plan.

Each of these arguments fails. The fact that the government is not a party does not invalidate RFRA. The Supreme Court has repeatedly stated that courts must read RFRA and Section 1557 in conjunction and must consider any limitation imposed by RFRA when adjudicating whether there has been a Section 1557 violation. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2383 (2020) (RFRA and ACA are read in conjunction and courts must consider RFRA when analyzing the parameters of Section 1557). The question is not whether BCBSIL can assert a claim under RFRA (which it is not doing here), but rather whether the Court must consider the limitations imposed by RFRA on Section 1557 when adjudicating a Section 1557 claim.

1. RFRA is incorporated into Section 1557 and provides an exemption from its requirements.

Plaintiffs argue that BCBSIL cannot raise RFRA because this is a lawsuit between private parties. But asking the Court to adjudicate a Section 1557 claim with a blind eye to RFRA is the equivalent of asking the Court to ignore portions of the statute. The Supreme Court has been clear that any analysis of Section 1557 must take RFRA's limitations into account. *Little Sisters,* 140 S. Ct. at 2383-84. In the 2016 Rule, the 2020 Rule, and the 2022 Proposed Rulemaking, HHS consistently interprets Section 1557 in conjunction with RFRA and directs the courts to adjudicate all Section 1557 claims consistent with RFRA. *See* 2022 Proposed Rulemaking, 87 Fed. Reg. 47,824, 47,841.

The Court must consider and defer to HHS regulations when adjudicating Section 1557, regardless of whether the dispute involves the government or solely private parties. *See, e.g., Encino Motorcars, LLC v. Navarro,* 579 U.S. 211, 213 (2016); *Fed. Express Corp. v. Holowecki*, 552 U.S. 389 (2008) (deferring to EEOC regulations in an Age Discrimination in Employment Act action between private parties). The Court may not, as Plaintiffs repeatedly request, ignore the HHS regulations. "Courts also look to the regulations promulgated pursuant to the statute at issue to inform" interpretation of the ACA. *Doe v. CVS*, 982 F.3d at 1211 (citing *Alexander v. Choate*,

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

469 U.S. 287, 306 (1985)); *K.M. ex rel. Bright v. Tustin Unified Sch. Dist*., 725 F.3d 1088, 1102 (9th Cir. 2013)).

The Supreme Court and HHS agree the ACA cannot be read absent RFRA, and RFRA's requirements constitute an exception to the ACA. "No provision of the ACA abrogates RFRA," and the Supreme Court's "decision in *Hobby Lobby* . . . established that application of the [ACA] must conform to RFRA's demands." *Little Sisters*, 140 S. Ct. at 2389 (Alito, J., concurring) (citing *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 736 (2014)). As the court emphasized in *Religious Sisters*,

> The 2016 Rule excepted applications that "would violate applicable Federal statutory protections for religious freedom and conscience." 81 Fed. Reg. at 31,466 (formerly codified at 45 C.F.R. § 92.2(c)). More specifically, HHS explained that the RFRA "is the proper means to evaluate any religious concerns about the application of Section 1557 requirements." *Id.* at 31,380. HHS went on to note that it would evaluate "individualized and fact specific" RFRA claims "on a case-by-case basis."

Religious Sisters, 513 F. Supp. 3d at 1125; *Nondiscrimination in Health Programs and Activities*, 87 Fed. Reg. 47,824, 47,841. This Court therefore must yield to any limitations that HHS puts on its interpretation of the ACA as required by the Supreme Court. *See Little Sisters*, 140 S. Ct. at 2391 (a third-party providing coverage under a plan which violates the plan sponsor's religious belief violates RFRA).

A ruling that courts may only enforce RFRA when the government is a party would eviscerate Congress' intent. Title IX contains an exemption for religious organizations when compliance would conflict with religious beliefs. Title IX, at 20 U.S.C. section 1681(a)(3) (Title IX "shall not apply" to educational institutions that are "controlled by a religious organization," to the extent that application of Title IX "would not be consistent with the religious tenets of each organization."). However, Section 1557 does not incorporate Title IX's religious exemption. *See Whitman-Walker*, 485 F. Supp. 3d at 43. The 2016 Rule "decline[d] to ... import Title IX's blanket religious exemption into Section 1557." *Id.* The 2020 Rule reversed the 2016 Rule and explicitly incorporated Title IX's religious exemption into Section 1557. *See id.* But *Whitman-Walker* invalidated this this part of the 2020 Rule. *See id.* at 44.

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

However, when doing so, *Whitman-Walker* concluded that the Title IX exemption was unnecessary because it would be redundant with RFRA, and RFRA was part of Section 1557:

> In closing this particular area of discussion, the Court notes that nothing in this decision renders religiously affiliated providers devoid of protection. Far from it. To name a few safeguards: the ACA instructs that no provision "shall be construed to have any effect on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion." 42 U.S.C. § 18023(c)(2). The 2020 Rule, moreover, explicitly acknowledges that Section 1557 is subject to RFRA's protections of religious conscience from government-imposed burdens, *see* 45 C.F.R. § 92.6(b) — protections the Supreme Court has confirmed are "very broad." *Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 693, 134 S. Ct. 2751, 189 L. Ed. 2d 675 (2014). Nothing in the Court's decision today implicates in any fashion the applicability of these independent statutory safeguards.

Id. If RFRA only applies when the government is a party, such "independent statutory safeguards" are rendered meaningless. Because RFRA must be read alongside Section 1557, the government need not be a party for RFRA to apply.

The cases cited by Plaintiffs do not apply. In *City of Boerne v. Flores*, 521 U.S. 507 (1997), the Supreme Court held that RFRA does not apply to state and local law. *See Sutton v. Providence St. Joseph Med. Ctr.*, 192 F.3d 826, 832 (9th Cir. 1999) (characterizing *City of Boerne* as "holding that RFRA is unconstitutional as applied to state governments"). Here, Plaintiffs do not assert claims under any state or local law.

The other cases cited by Plaintiffs do not apply because none of them involves a statute that the courts and regulators have explicitly held must be read in conjunction with RFRA. In *Sutton*, 192 F.3d at 829, the plaintiff alleged that a hospital violated RFRA by refusing to hire him because he would not provide his social security number on religious grounds. But neither the Supreme Court nor any federal agency has found that the social security laws must be read in conjunction with RFRA (unlike the ACA). Similarly, in *Listecki v. Off. Comm. of Unsecured Creditors*, 780 F.3d 731 (7th Cir. 2015), the archbishop of a bankrupt archdiocese asserted RFRA as a defense to a claim by the unsecured creditors' committee to recover funds in a cemetery trust. Again, neither the Supreme Court nor any federal agency has found that the federal bankruptcy laws must be read in conjunction with RFRA (unlike the ACA). Likewise, in *Gen. Conf. Corp. of Seventh-Day Adventists v. McGill*,

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

617 F.3d 402 (6th Cir. 2010), the plaintiff alleged that RFRA protected his infringement of the Seventh Day Adventist church's trademarks. He alleged he had a sincere belief "that God requires him to continue his infringing use of the plaintiffs' marks. Being compelled to stop could substantially burden his religious practice." *Id.* at 410. Again, neither the Supreme Court nor any federal agency has found that federal trademark laws must be read in conjunction with RFRA, unlike the ACA. Finally, *Tomic v. Cath. Diocese of Peoria*, 442 F.3d 1036 (7th Cir. 2006), involved a suit by an organist of a Catholic diocese claiming a violation of the Age Discrimination in Employment Act (ADEA). Neither the Supreme Court nor any federal agency has found that the ADEA must be read in conjunction with RFRA (unlike the ACA).

None of the regulations implementing any of the statutes implicated in Plaintiffs' case explicitly state that RFRA is an exception to and must be analyzed in conjunction with the statute at issue. No court has applied RFRA to allow an exception to the trademark, social security, or bankruptcy laws or to the ADEA. In contrast, here, the Supreme Court has held that the ACA cannot be read without RFRA. *Little Sisters*, 140 S. Ct. at 2389 (citing *Burwell*, 573 U.S. at 736). RFRA limits the scope of Section 1557.

2. BCBSIL has standing to argue that Section 1557 does not prohibit BCBSIL from enforcing the Exclusion.

Plaintiffs argue that "BCBSIL is a secular entity and cannot 'borrow' CHI's alleged RFRA protection." Cross-Motion at 39. This is incorrect. Plaintiffs deliberately pled their complaint to sue the TPA and not the actual party responsible for the exclusion, but that does not allow them to avoid RFRA.[5] Both the Supreme Court and HHS prohibit requiring a TPA to take action that would violate an employer's sincere religious belief as reflected in the employer's self-funded ERISA plan.

[5] As stated in BCBSIL's Motion, Plaintiffs have sued the wrong party. Plaintiffs have put CHI's RFRA rights at issue by suing BCBSIL, yet strategically avoided suing CHI to tray to side-step RFRA. But the Court cannot compel BCBSIL to take any action related to gender reassignment surgery without impairing CHI's rights. *See Takeda v. Nw. Nat. Life Ins. Co.*, 765 F.2d 815, 819-20 (9th Cir. 1985) (noting that the absent defendant, Microdata, the employer who sponsored the plan, was a necessary party because, as here, the plan was self-funded "and in the event of an adverse result, Microdata would satisfy the judgment or would indemnify Northwestern").

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

The Supreme Court has rejected efforts to do an end-run around RFRA by claiming that the action is against the TPA, not the entity holding the religious belief. In *Little Sisters* and *Hobby Lobby*, the Supreme Court held that the contraception mandate violated RFRA even if the government provided coverage at no cost to plan members through the plan's TPA for claims that violated the plan sponsor's religious beliefs. *Little Sisters*, 140 S. Ct. at 2391 (a third-party providing coverage under a plan which violates the plan-sponsor's religious belief violates RFRA); *Hobby Lobby,* 573 U.S. at 731 (same). The Court held that the government could not force the plans' TPAs to administer coverage that violated the plan's religious views. *See Little Sisters,* 140 S. Ct. at 2391 ("[T]he contraceptive mandate imposes a substantial burden on any employer who, like the Little Sisters, has a sincere religious objection to the use of a listed contraceptive and a sincere religious belief that compliance with the mandate (through the accommodation [which required the TPA to administer contraception coverage] or otherwise) makes it complicit in the provision to the employer's workers of a contraceptive to which the employer has a religious objection."). HHS had developed an "accommodation" requiring TPAs to cover contraception and receive reimbursement from the government. *Id*. But the Supreme Court concluded that making the TPAs provide coverage under the plans still violated RFRA by making the TPAs "complicit in conduct [the religious employers] find immoral." *Id*. The Supreme Court concluded that it violated RFRA to force the employer's TPAs to administer the plan in a way that violated the employers' religious views. *Id.* at 2386.

Thus, *Hobby Lobby* and *Little Sisters* make clear that the courts cannot avoid RFRA just because the claim is against the TPA, not the employer.

Plaintiffs attempt to distinguish *Little Sisters* and *Hobby Lobby* by arguing that "TPAs have no independent legal obligation to comply with the contraception mandate when administering health plans, as that requirement applies only to group health plans and issuers, not TPAs." Cross-Motion at 41 (citing 42 U.S.C. § 300gg-13(a)(4)). But the Supreme Court has made clear that no reading of the ACA can override "RFRA's demands." *Little Sisters*, 140 S. Ct. at 2389. Moreover, TPAs have no independent legal obligation to comply with Section 1557 when the employer

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

designs the plan. *See* 2022 Proposed Rulemaking, 87 Fed. Reg. 47,824, 47,876-47,877. Unlike transgender exclusions, this Court has held that failure to provide benefits for contraception is discrimination on the basis of sex. *See Erickson v. Bartell Drug Co*., 141 F. Supp. 2d 1266 (W.D. Wash. 2001). With respect to RFRA, there is no distinction between the contraception mandate and the transgender-related services sought by Plaintiffs. RFRA applies as an exception to both.

3. RFRA protects the CHI exclusion.

The Court must deny Plaintiffs' effort to require BCBSIL to administer the CHI plan in a manner contrary to CHI's religious belief. Plaintiffs argue that the Court should invalidate the exclusion because "[u]nder RFRA, the government may impose even a substantial burden on a person's exercise of religion" if the "application of the burden to the person: (1) is in furtherance of a compelling governmental interest; and (2) is the least restrictive means of furthering that compelling governmental interest." Cross-Motion at 43. Plaintiffs argue that invalidation of the exclusion "'constitutes the least restrictive means of furthering the government's compelling interest in eradicating discrimination [] on the basis of sex.'" *Id.* at 44.

But the Supreme Court has already decided this issue. The Supreme Court has held that if a health care service violates an employer's religious belief, the consequent civil liability on the employer imposes a substantial burden. The Supreme Court held that "the [contraception] mandate substantially burdened respondents' free exercise, explaining that '[if] the owners comply with the HHS mandate, they believe they will be facilitating abortions, and if they do not comply, they will pay a very heavy price.'" *Little Sisters*, 140 S. Ct. at 2377 (quoting *Hobby Lobby*, 573 U.S. at 736). "'If these consequences do not amount to a substantial burden,' we stated, 'it is hard to see what would.'" *Id.* (quoting *Hobby Lobby*, 573 U.S. at 736). Indeed, the Supreme Court held that this burden could not be mitigated even if the TPA provided the coverage to the religious employer's plan members and was reimbursed by the government. *Id.* at 2391, 2386. In *Little Sisters*, the Supreme Court upheld HHS's "religious" and "moral" exemptions from the contraception mandate. *Id.* at 2386. This situation is no different. The only way to protect CHI's free exercise of religion is to uphold the exclusion.

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

4. There is no dispute that the CHI exclusion is religious-based.

The uncontradicted evidence establishes that the CHI exclusion is religious-based, and Plaintiffs have not presented any evidence to the contrary. Every court that has addressed transgender exclusions in Catholic health plans holds that the exclusions are religious based. *E.g.*, *Franciscan,* 47 F. 4th at 368; *Little Sisters*, 140 S. Ct. 2367; *Religious Sisters,* 513 F. Supp. 3d 1113. Plaintiffs now, for the first time, claim that a letter from CHI, as the plan sponsor, responding to their claim is "inadmissible unauthenticated hearsay." Cross-Motion at 6 n.6. Ironically, Plaintiffs attached and quoted from this letter in both their initial and amended complaints. Dkt. 1, App. H; Dkt. 38, App. H. The letter states that the transgender-related service "specifically excluded under the Plan is gender reassignment surgery, as this surgery has been determined not to align with the teachings and doctrine of the Catholic Church." Dkt. 1, App. H; Dkt. 38, App. H. *Id.*

Plaintiffs admitted the authenticity of the CHI letter when they attached and quoted it in their pleadings. *See, e.g.*, *Carolina v. JPMorgan Chase Bank NA*, No. CV-19-05882-PHX-DWL, 2021 WL 5396066, at *6 (D. Ariz. Nov. 17, 2021) ("Plaintiff does not develop any argument as to why the specific documents proffered by Defendants are inauthentic. Indeed, Plaintiff attaches many of the same exhibits to her summary judgment response.").

Moreover, the CHI Letter is not inadmissible hearsay, for numerous reasons. The CHI Letter is part of the ERISA administrative record because CHI, the plan sponsor, wrote to Plaintiffs as part of the ERISA-mandated claims process. *See Black v. Long Term Disability Ins.*, 582 F.3d 738, 746 n.3 (7th Cir. 2009) (considering consulting physicians' reports despite their lack of firsthand clinical knowledge because courts review the entire ERISA administrative record, including evidence otherwise considered hearsay); *Rice v. ADP TotalSource, Inc.*, 936 F. Supp. 2d 951, 961 (N.D. Ill. 2013) ("The Court is not bound by the Federal Rules of Evidence when reviewing an ERISA administrator's benefits determination."); *Koloff v. Metropolitan Life Ins. Co.*, No. 1:13-cv-02060, 2014 WL 3420990, at *3 (E.D. Cal. July 14, 2014) ("[H]earsay objections are not well-founded in an ERISA action where the Court 'review[s] the entire administrative

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

record, including hearsay evidence relied upon by the administrator.'").

The CHI letter is also admissible under the residual exception to the hearsay rule. *See* Fed. R. Evid. 807; *F.T.C. v. Figgie Intern, Inc.*, 994 F.2d 595, 608-09 (9th Cir. 1993) (finding consumer letters to the FTC regarding goods purchased were admissible under the residual exception because they were material and probative; independently sent and thus trustworthy; and the defendant had adequate notice of them). In *Steinberg v. Obstetrics-Gynecological And Infertility Grp., P.C.*, 260 F. Supp. 2d 492, 496-97 (D. Conn. 2003) (letter from the claimant's former attorney describing the claims administration process to the current attorney who took over the representation was admissible under the residual exception because it satisfied the requirements of trustworthiness, materiality, probative importance, and the interests of justice).

The CHI Letter, like the letters in *Figgie Intern* and *Steinberg*, is material to and probative of this dispute because it explains the basis for CHI's exclusion and its denial of services to C.P. As to trustworthiness, the CHI Letter is a pre-litigation transmission explaining C.P.'s denial of benefits and therefore is a trustworthy "explanatory" letter, and not an "advocacy piece." *Steinberg*, 260 F. Supp. 2d at 496 (describing the attorney letter as an "explanatory piece" and satisfying the trustworthiness requirement). Plaintiffs also had adequate notice of the CHI Letter being admitted into evidence, as Plaintiffs themselves attached the CHI Letter to their pleadings. The CHI letter is material, probative, trustworthy, and admissible and establishes that CHI added the exclusion in its plan because of sincere religious belief.

D. Section 1557 Does Not Apply Here Because BCBSIL Does Not Receive Any Federal Financial Assistance for its TPA Activities.

Section 1557 does not apply here because BCBSIL's operations as a TPA for self-funded ERISA plans do not receive federal financial assistance. The 2020 Rule specifies that healthcare entities are subject to Section 1557 only for the specific parts of their operations that receive and are earmarked for federal financial assistance. *See id.* § 92.3(b) ("For any entity not principally engaged in the business of providing healthcare, the requirements applicable to a 'health program or activity' under this part shall apply to such entity's operations **only to the extent any such**

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

operation receives Federal financial assistance.") (emphasis added).

Plaintiffs argue that BCBSIL is "an arm of" HCSC, which receives federal financial assistance for other activities. *See* Cross-Motion at 1. But Plaintiffs do not dispute that BCBSIL does not receive federal financial assistance for its administration of any self-funded ERISA plans, including the CHI Plan. Dkt. 88-1, Ex. I, ¶ 3. It is also undisputed that BCBSIL accounts for all federal payments separately from BCBSIL's administration of self-funded ERISA plans. *Id.* ¶ 5. Plaintiffs have offered no evidence to the contrary.

BCBSIL provides an Assurance of Compliance to the federal government in consideration for receiving federal financial assistance for certain parts of its operation. Motion at 16. That Assurance states only that it is in compliance with Section 1557 for all "health program[s] or activit[ies] **for which [HCSC] receives Federal financial assistance."** Motion at 16 (citing Dkt. 88-1, Ex. I, Exhibit A).

Moreover, HHS does not consider BCBSIL, as a TPA or insurer, to be principally engaged in providing health care. Under the 2020 Rule, "an entity principally or otherwise engaged in the business of providing health *insurance* shall not, by virtue of such provision, be considered to be principally engaged in the business of providing *healthcare*." *Id.* (emphases added); *see also Religious Sisters*, 513 F. Supp. 3d at 1128 (citing 2020 Rule, 85 Fed. Reg. at 37,160) (The "entirety of federally funded insurers' operations no longer automatically qualifies for regulation merely by virtue of selling *or administering* health insurance plans.") (emphasis added).[6]

Thus, a TPA such as BCBSIL that is not principally involved in providing health care (as compared to health insurance) and does not receive federal financial assistance as a TPA cannot be liable under Section 1557. Neither BCBSIL (as TPA) nor the plan sponsors can be held liable if they do not receive federal financial assistance. 85 Fed. Reg. at 37,173-74 ("[T]o the extent that

[6] Plaintiffs attempt to distinguish the opinion in *Religious Sisters* as "merely recount[ing] the changing regulatory landscape surrounding Section 1557." Motion at 29 n.13. Plaintiffs do not dispute, however, that the court in *Religious Sisters* properly relied on the 2020 Rule, which was in effect when that court rendered its opinion and is still in effect today. For the reasons described herein and in BCBSIL's Motion, Dkt. 87, the 2020 Rule is entitled to deference under *Chevron*.

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

employer-sponsored group health plans do not receive Federal financial assistance and are not principally engaged in the business of providing healthcare (as set forth in the rule), they would not be covered entities.").[7]

BCBSIL does not principally provide healthcare or receive federal financial assistance as a TPA, and therefore it cannot be held liable under Section 1557 for its TPA activities.

E. The Exclusion Does Not Discriminate on the Basis of Sex Because There is No Medical Consensus Regarding Transgender-Related Services.

The Court should grant summary judgment in favor of BCBSIL and deny Plaintiffs' Cross-Motion because the exclusion in the CHI Plan does not discriminate on the basis of sex. To prevail on summary judgment, Plaintiffs must show that the WPATH standards upon which they exclusively rely establish the medical consensus, and they have failed to make that showing. The lack of medical consensus regarding gender reassignment surgery defeats Plaintiffs' discrimination claim. In *Whitman-Walker*, the court upheld the 2020 Rule's determination that categorical exclusions for transgender-related services did not discriminate on the basis of sex because "HHS thoroughly considered the evidence Plaintiffs raise, but nevertheless concluded that 'there is no medical consensus to support one or another form of treatment for gender dysphoria.'" *Whitman-Walker*, 485 F. Supp. 3d at 48–49. Likewise, here the Court cannot find that the exclusion discriminates on the basis of sex because there is no medical consensus regarding transgender-related services. As in *Whitman-Walker*, Plaintiffs cannot 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.*

[7]Plaintiffs take a sentence from the 2022 Proposed Rulemaking out of context when they state that a TPA is subject to Section 1557 when it "receives Federal financial assistance and is deemed to be principally engaged in the provision or administration of health programs or activities." Motion at 35-36. That same paragraph of the 2020 Rule, however, then clarifies that TPAs cannot be liable under the statute if the allegedly discriminatory term did not "originate" with the TPA. 2020 Rule, 87 Fed. Reg. 47824, 47876. That is because, as the 2020 Rule recognizes, ERISA "requires group health plans to be administered consistent with their terms . . [TPAs] are unable to change any discriminatory design features in the self-insured plans they administer to comply with Section 1557's requirements." *Id.*

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

Plaintiffs recognize that, in order to establish that the exclusion in the CHI Plan discriminates on the basis of sex, they must prove that the surgery for which they seek coverage is "well-established, widely accepted, and evidence-based." Cross-Motion at 22. But they cannot establish this because "[t]here is ongoing debate and study in the medical community regarding gender affirmative treatment." Dkt. 88-1, Ex. K, ¶ 14 (analysis on the lack of consensus in the medical community). "The medical community is divided on many issues related to the appropriate medical care for gender identity, and the necessity or value of gender affirmative care. This is especially true for minors." *Id.; see also* Appendix 1 (Megan Twohey and Christina Jewett, *They Paused Puberty, but Is There a Cost?*, N.Y. TIMES (Nov. 14, 2022), https://www.nytimes.com/2022/11/14/health/puberty-blockers-transgender.html (noting growing concern in the medical community about use of puberty blockers)).

The fact that there is more gender reassignment surgery being done in the United States than in the past does not necessarily support that the medical community supports it with clear consensus. BCBSIL's expert, Dr. Laidlaw, explains that there is concern in the medical community regarding perfunctory treatment of minors, as it shows the insufficient quality of medical and mental health care minors receive before undergoing irreversible transgender-related services. Dkt. 88-1, Ex. K, ¶¶ 16, 247. Despite agreeing with the Endocrine Society's Guidelines mandating that a minor be diagnosed by a qualified mental health professional, Plaintiffs' expert reports ignore the Endocrine Society Guidelines recommending that minors with gender dysphoria be diagnosed by a qualified mental health professional with training and expertise in (1) child and adolescent gender development, and (2) child and adolescent psychopathology. Dkt. 104-1, Ex. C at 63:2-17; Ex. F at 51:23-53:2; Ex. K at 46:6-47:6.

In fact, the Ninth Circuit in *Snyder* concluded, based in part on Dr. Laidlaw's testimony, that the plaintiffs in that case had failed to prove medical necessity in part 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 himself is a suitable candidate for surgery and had not

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

met or examined Doe." *Snyder*, 28 F.4th at 112–13.

In *Snyder*, the Ninth Circuit distinguished *Edmo v. Corizon*, Inc., 935 F.3d 757, 784-85 (9th Cir. 2019). The Ninth Circuit found that in *Edmo*, following a bench trial, "the district court in a 'carefully considered, 45-page opinion,' supported by 'detailed factual findings [that] were amply supported by its careful review of extensive evidence and testimony,' determined that gender confirmation surgery was 'medically necessary to treat Edmo's gender dysphoria.'" *Snyder*, 28 F.4th at 113 (quoting *Edmo*, 935 F.3d at 780). Based on the cursory treatment of the minor in that case, *Snyder* concluded that "*Edmo* is factually and procedurally distinguishable." *Id.* at 113. Here, unlike *Edmo* and like *Snyder*, no treating psychiatrist or other qualified mental health professional examined C.P. to determine his ability to give informed consent nor examined him for underlying psychiatric conditions as part of determining the necessity and suitability of surgery. Motion at 22; Dkt. 88-1, Ex. K, ¶¶ 16-17, 187 *et seq*. Likewise, it is undisputed that no treating psychiatrist concluded that C.P. was a suitable candidate for a double mastectomy at age 14. Motion at 21.

Because there is no medical consensus regarding the propriety of gender-reassignment surgery and other transgender-related services, both for C.P. in particular and in the community as a whole, Plaintiffs' Section 1557 claim fails. As in *Whitman-Walker* and *Snyder*, Plaintiffs have not shown that the exclusion in the CHI Plan constitutes discrimination on the basis of sex.

IV. CONCLUSION

BCBSIL respectfully requests this Court grant BCBSIL's motion for summary judgment [Dkt 87] and deny Plaintiffs' cross-motion for summary judgment [Dkt. 96].

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

Dated this 14th day of November, 2022.

KILPATRICK TOWNSEND & STOCKTON LLP

By *s/ Gwendolyn C. Payton*

Gwendolyn C. Payton, WSBA No. 26752
gpayton@kilpatricktownsend.com
John R. Neeleman, WSBA No. 19752
jneeleman@kilpatricktownsend.com
1420 Fifth Ave., Suite 3700
Seattle, WA 98101
Telephone: (206) 626-7714
Facsimile: (206) 623-6793

Counsel for Blue Cross Blue Shield of Illinois

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 RESPONSE TO PLAINTIFFS' CROSS-MOTION FOR SUMMARY JUDGMENT [DKT. 96] AND REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT [DKT. 87] 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:

Eleanor Hamburger SIRIANNI YOUTZ SPOONEMORE HAMBURGER 3101 WESTERN AVENUE STE 350 SEATTLE, WA 98121 206-223-0303 Fax: 206-223-0246 Email: ehamburger@sylaw.com	☑ by CM/ECF ☐ by Electronic Mail ☐ by Facsimile Transmission ☐ by First Class Mail ☐ by Hand Delivery ☐ by Overnight Delivery
Jennifer C Pizer LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC 4221 WILSHIRE BLVD., STE 280 LOS ANGELES, CA 90010 213-382-7600 Email: jpizer@lambdalegal.org	☑ by CM/ECF ☐ by Electronic Mail ☐ by Facsimile Transmission ☐ by First Class Mail ☐ by Hand Delivery ☐ by Overnight Delivery
Omar Gonzalez-Pagan LAMBDA LEGAL DEFENSE AND EDUCATION FUND, INC. (NY) 120 WALL STREET 19TH FLOOR NEW YORK, NY 10005 212-809-8585 Email: ogonzalez-pagan@lambdalegal.org	☑ by CM/ECF ☐ by Electronic Mail ☐ by Facsimile Transmission ☐ by First Class Mail ☐ by Hand Delivery ☐ by Overnight Delivery

DATED this 14th day of November, 2022.

KILPATRICK TOWNSEND & STOCKTON LLP

By: */s/ Gwendolyn C. Payton*
Gwendolyn C. Payton, WSBA #26752
Counsel for Blue Cross Blue Shield of Illinois

KILPATRICK TOWNSEND & STOCKTON LLP
1420 FIFTH AVENUE, SUITE 3700
SEATTLE, WA 98101
(206) 626-7713 FAX: (206) 260-8946

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.

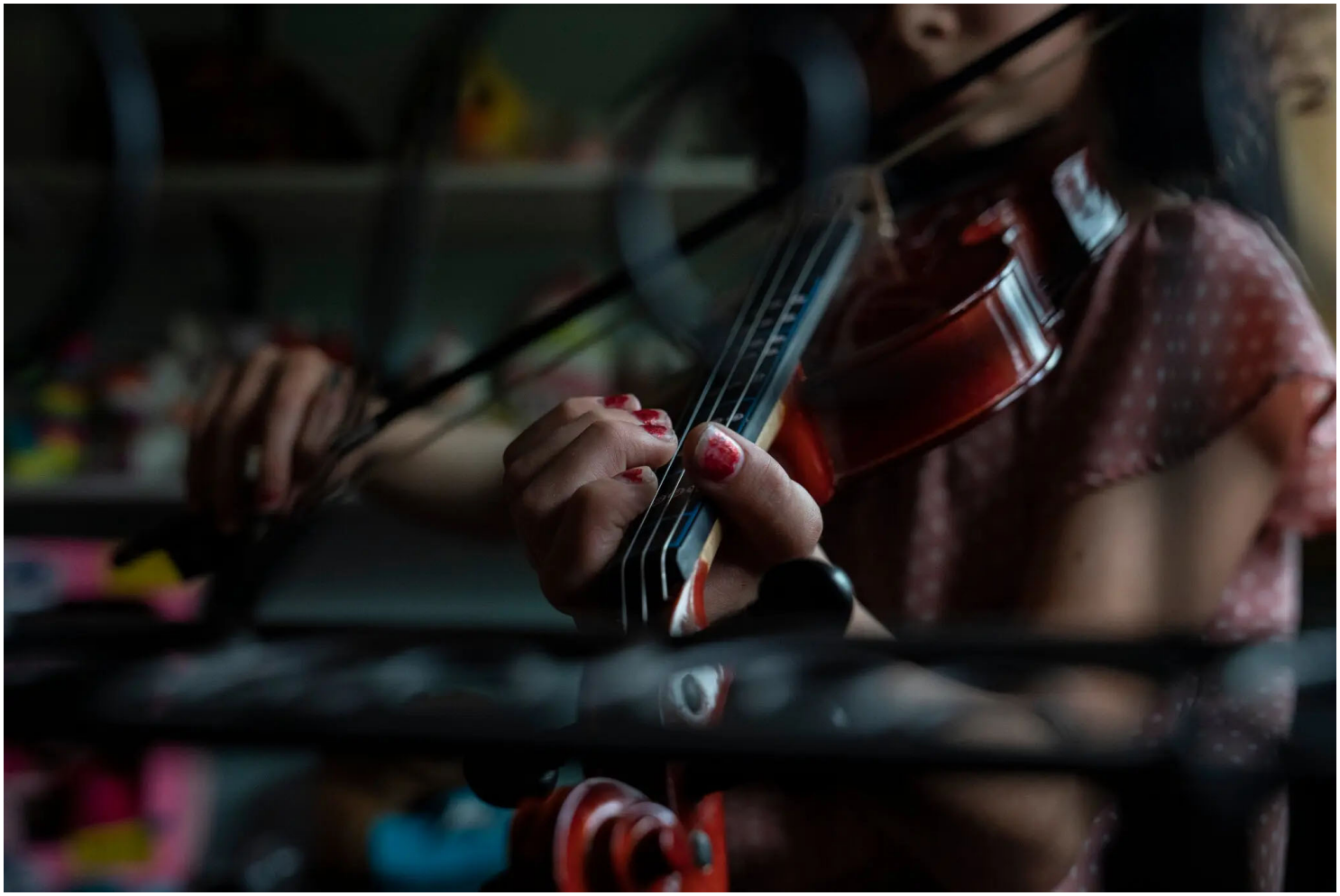
At 13, Jacy Chavira felt increasingly uncomfortable with her maturing body and was beginning to believe she was a boy. Use the drug, her endocrinologist in Southern California recommended, and puberty would be suspended.

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

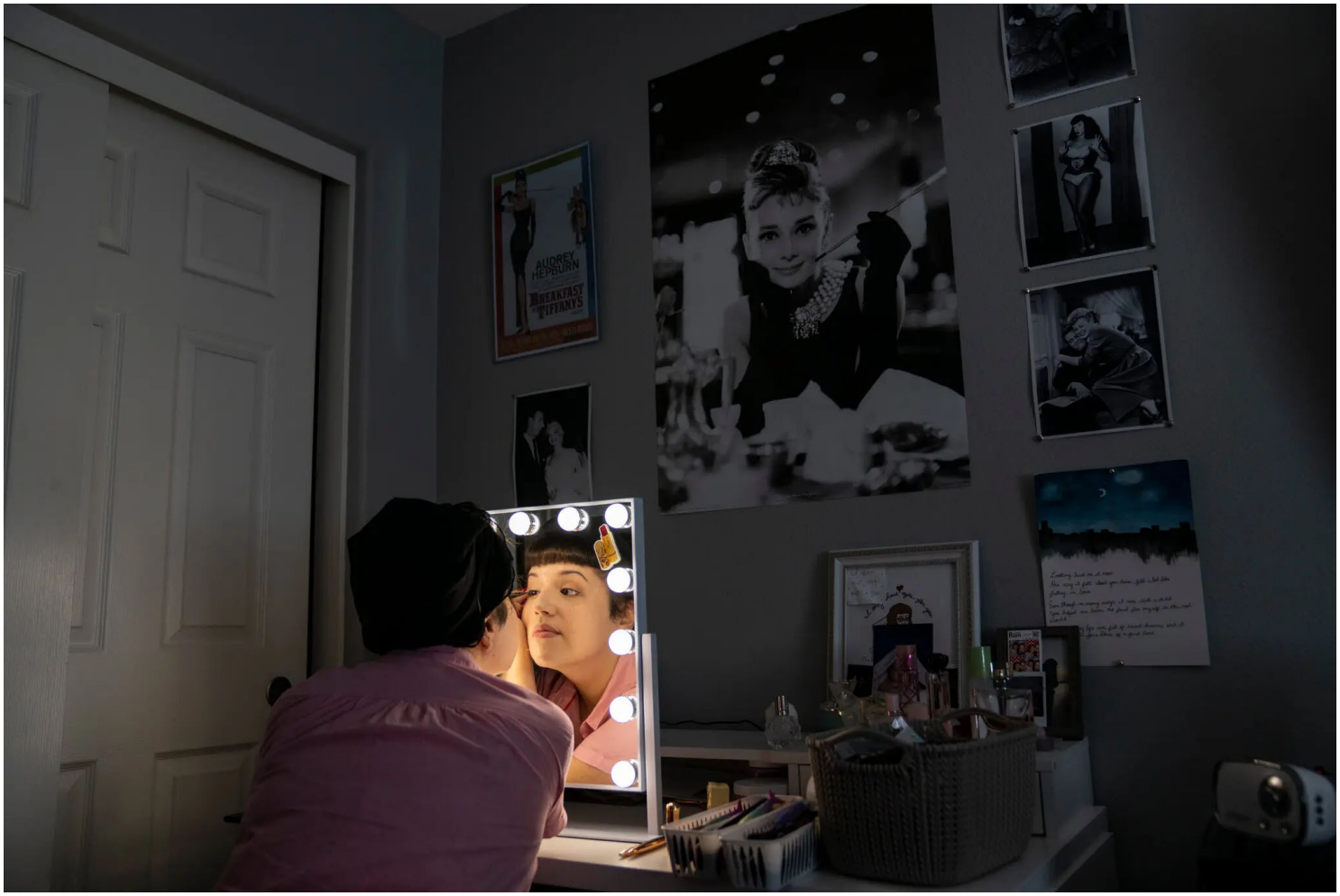
As growing numbers of adolescents who identify as transgender are prescribed drugs to block puberty, the treatment is becoming a source of confusion and controversy.

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.

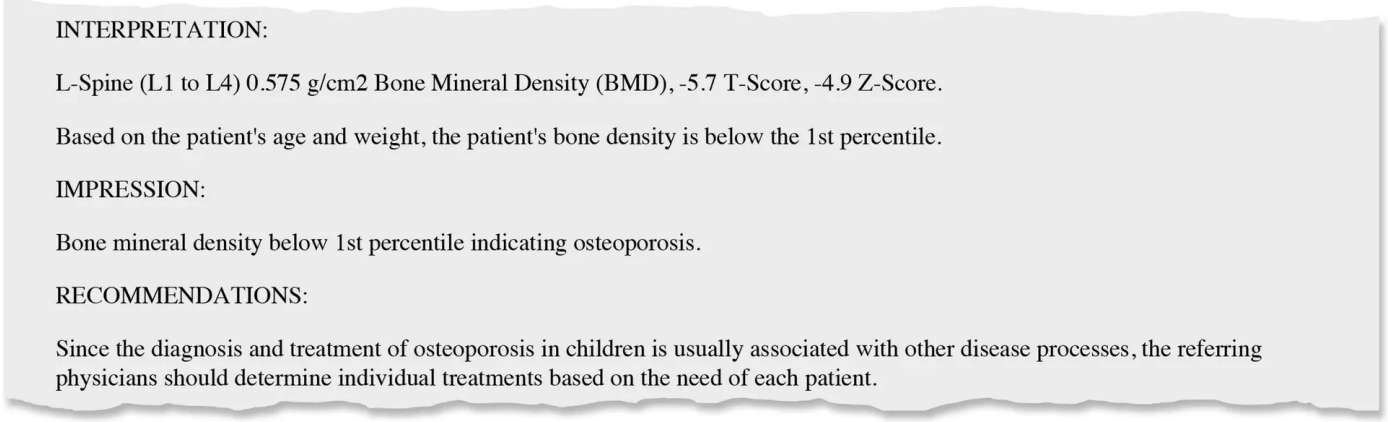
When the parents consented to blockers in 2018, they hoped the drug would bring emotional stability and time to consider next steps.

"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.”

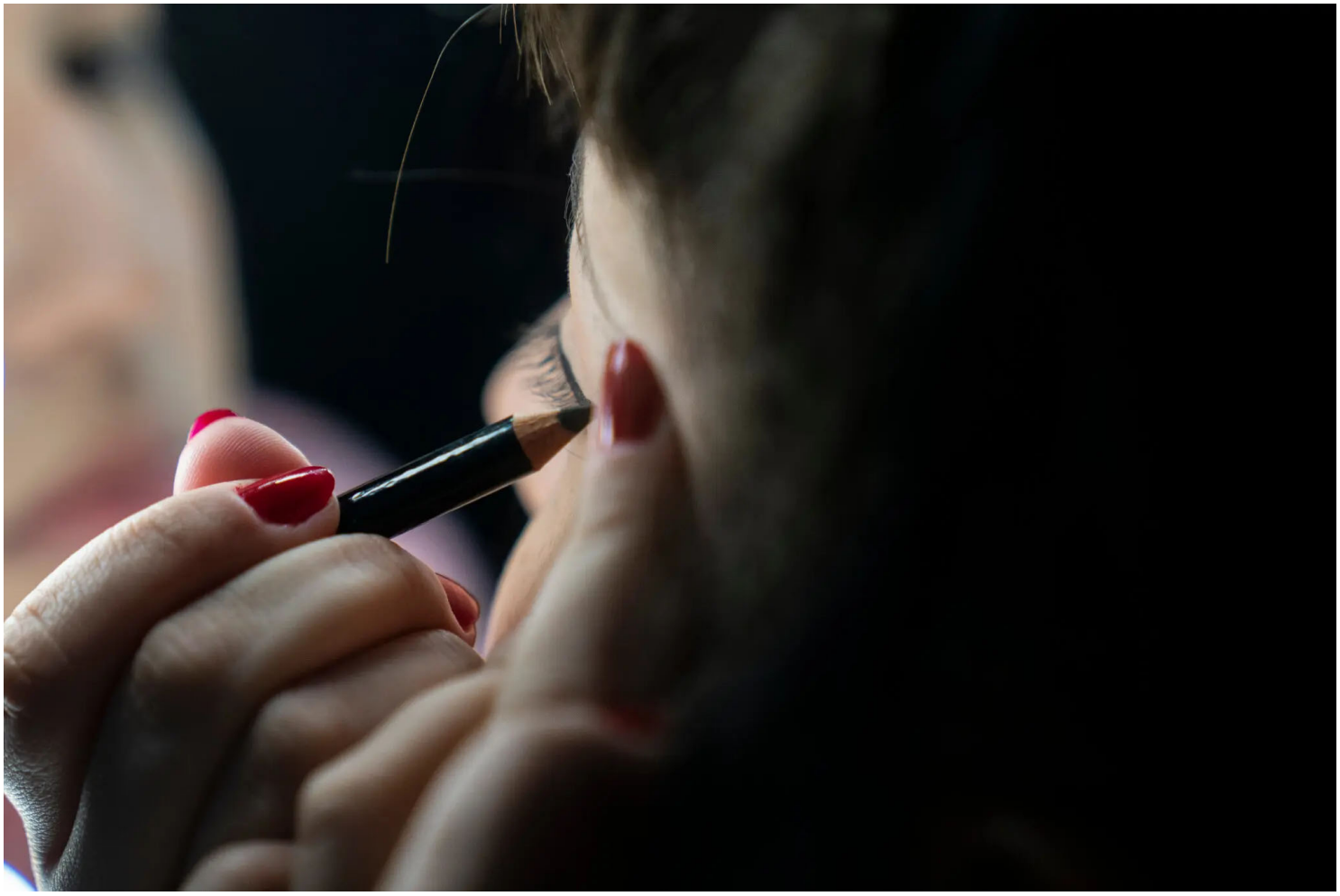
The physicians in the Amsterdam clinic, where the treatment began, have lowered their minimum ages for starting blockers and hormones. But they are very cautious in selecting patients.

“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.