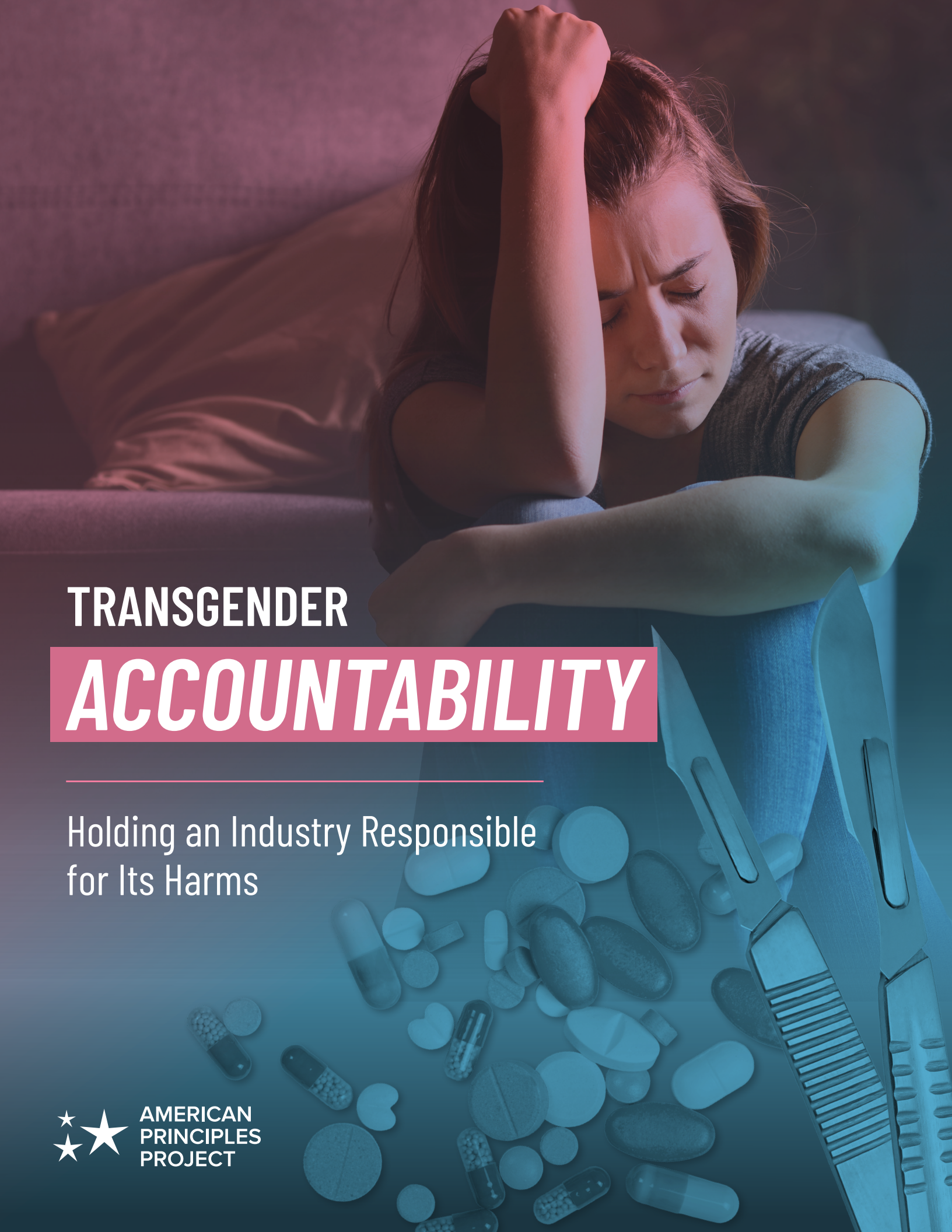

TRANSGENDER ACCOUNTABILITY

Holding an Industry Responsible for Its Harms

AMERICAN PRINCIPLES PROJECT

TOWARD GENDER-INDUSTRIAL COMPLEX ACCOUNTABILITY

Transgenderism was pushed into the national spotlight during the 2024 presidential election as never before. Though the political mainstream often framed it as an immaterial culture war issue, voters profoundly disagreed. Indeed, among the most devastating advertisements deployed by Republicans were those highlighting Vice President Kamala Harris's support for providing federal inmates with so-called "gender-affirming care" (GAC). According to our analysis, and multiple post-election reports from other groups, these ads were seen more often, and changed more minds, than nearly any other message the Trump campaign put forward.[1]

It isn't hard to figure out why these ads were so effective: as poll after poll confirms, a growing supermajority of Americans rejects the radical claims and practices of radical gender ideology, and demands political accountability. Around 70 percent of the country acknowledges that there are only two genders,[2] and that whether someone is a man or a woman is determined by his or her biological characteristics at birth,[3] and that sex-change procedures for minors should be disallowed entirely.[4] These margins have only grown larger in recent years.

At the same time, a growing body of robust literature confirms what most Americans seem to already know: the rapid proliferation of gender medicine — particularly in relation to minors — has not only been ill-advised but also dangerous. In nearly every instance that a disinterested party — for example, a national health authority — has reviewed the evidence in recent years, it has found the transgender industry's prevailing practices to be ethically unsound and scientifically undersupported. Contrary to the claims of GAC's proponents, recent studies suggest that sex-change surgeries may increase mental health problems rather than decrease them.

Nevertheless, the transgender industry has been booming. Over the past decade, the number of people undergoing medicalized gender transition has skyrocketed. At the same time, the number of detransitioners — those who eventually desist from identifying as transgender — has risen at a similar rate. Their stories paint a picture of a medical field totally divorced from any sense of responsibility for the patients they serve. Again and again, lawsuits and investigations uncover a routine failure among practitioners of gender medicine to treat underlying psychological issues, screen patients effectively, or adequately inform patients of the many risks and harms associated with these procedures.

Despite these cries for accountability — from detransitioners, from voters, and from the global medical community — there has been little to no justice for the gender industry's victims in the United States.

There are several reasons for this. For one thing, many detransitioners choose to move on with their lives or are unable to deal with the taxing process of litigation, which can take years.

1 https://americanprinciplesproject.org/wp-content/uploads/2025/01/APP2024_AfterElectionReport_web.pdf

2 https://www.documentcloud.org/documents/25919931-nbc-news-stay-tuned-poll-april-27/

3 https://apnorc.org/wp-content/uploads/2025/05/may-2025-topline-final.pdf

4 https://law.marquette.edu/poll/wp-content/uploads/2025/05/MLSPSC26Toplines.html#C11B:_TN_puberty_blockers_case

Litigation is expensive, time-consuming, and difficult for people who have already endured varying degrees of physical and psychological trauma. Some detransitioners will attempt to seek redress, only to then find the burden of having to relive the worst days of their lives too great to bear.

For another, the gender industrial complex plays an elaborate game of hide-the-ball to avoid political and legal accountability. Each facet passes responsibility onto somebody else. The pharmaceutical companies, who profit from the off-label use of their drugs for these procedures, plead ignorance of (and disclaim responsibility for) the decisions made by individual health care practitioners.[5] Health care professionals protest that they're only following the medical consensus within their field and can't be blamed for following established guidelines, even when doing so leads to irreparable harm. Meanwhile the World Professional Association for Transgender Health (WPATH), the professional association that writes these guidelines, leaves almost every part of the process up to the discretion of the individual medical professional, and massages its recommendations to serve political, rather than medical, ends.

Fundamentally, the goal of this report is to create a catalyst for accountability within the field of gender "medicine." To that end, this report analyzes accounts of detransitioners who underwent transition therapy and later regretted it. Each case study offers different examples of malpractice that could serve as grounds for action by federal agencies.

In almost any other circumstance, what these individuals underwent would result in serious professional or legal consequences for the responsible parties. It is only the ethical taboo, the erroneous notion that these treatments are medically necessary, akin to chemotherapy, that has shielded the perpetrators. However, as this taboo crumbles under the weight of the evidence, so too does their indemnity. Indeed, in May, the Department of Health and Human Services published a report titled "Treatment for Pediatric Gender Dysphoria: Review of Evidence and Best Practices," which concluded that "the best available evidence indicates that [puberty blockers], [cross-sex hormones], and surgery have not been shown to improve mental health outcomes."

> At the same time, there is increasing recognition of the risks and harms associated with [pediatric medical transition], which are supported by clinical research or grounded in established biological theory. While the value or disvalue of some outcomes, such as hirsutism in females, may be determined primarily by the preferences or tastes of patients, other possible outcomes, such as impaired cognitive function, greater susceptibility to hormone-sensitive cancers, cardiac disease, reduced bone density, sexual dysfunction, infection, and infertility are objectively detrimental to health. Such medical harms, or plausible risks thereof, should not be imposed on children or adolescents in the absence of a reasonable expectation of proportionate medical benefit.[6]

To say that this reflects a dramatic shift from just a few years ago would be an understatement.

[5] It is a mistake to assume that most of these procedures are administered by medical doctors. According to one source, prior to a change in Florida's law, around 80 percent of patients receiving "gender affirming care" in the state were receiving it from nurses and physician assistants. See: https://getplume.co/blog/transgender-healthcare-in-florida-what-you-need-to-know-in-2024/

[6] https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf

CASE STUDY: CAMILLE KIEFEL

Camille Kiefel is a 35-year-old woman who has suffered a variety of severe mental health issues from an early age, including complex post-traumatic stress disorder, major depressive disorder, generalized anxiety disorder, and attention-deficit/hyperactivity disorder. Her symptoms ranged from chronic anxiety to frequent suicidal ideation. Despite this long and well-documented history of emotional and psychological distress, Kiefel was allowed to undergo a double mastectomy, having been led to believe that it would resolve her gender dysphoria.

Around the age of six, Kiefel watched her parents go through a nasty divorce, which has been connected to dysphoria in adolescents. "Parental divorce and not living with both parents has been observed to be disproportionately common in several clinical samples of gender-referred youth in various countries," one study found.[7]

In Kiefel's case, the split embittered her father, who would often speak ill of women around her from a young age. "And so being a girl had negative connotations," she said. It was during this period that she underwent her first psychological evaluation. By the sixth grade, Kiefel was already suffering from childhood depression and Attention-Deficit/Hyperactivity Disorder (ADHD). Data shows that people living with ADHD are more likely to say they experience distress or confusion about their gender, as are those on the autism spectrum.[8]

It was also around this time that Kiefel's father warned that grown men would soon begin to take a sexual interest in her. Kiefel interpreted this as his way of encouraging her to dress modestly. However, it left her deeply unsettled. Kiefel's discomfort regarding her sexuality was dramatically exacerbated upon learning that her best friend had been raped by her brother before she even understood the meaning of that word.

As Kiefel's mental health worsened, she sought to escape from her female gender. By high school, Kiefel had begun to dress in a more masculine way, in part due to the discomfort and trauma she had endured in connection with femininity. She also made dietary changes that she believes exacerbated her mental health issues. In college, Kiefel became a women's studies major and was introduced to gender theory. She described the experience as providing her with a sense of identity but also, in a way, deepening her mental health issues.

After seeing a therapist in 2016, Kiefel began to identify as "non-binary." It was not so much that she felt masculine but rather that she wanted to "opt out" of gender altogether. She sought escape more than anything else. "I didn't want to be a man," she said. "I knew that, but I didn't want to be a woman." Kiefel characterized her non-binary identity as a coping mechanism. However, it did not work as she had hoped. Indeed, Kiefel proved resistant to a range of treatments for her underlying mental health issues, from various forms of psychotherapy to transcranial magnetic stimulation, a non-invasive procedure that uses magnetic fields to stimulate nerve activity in the brain.

Nothing worked for Kiefel. By 2018, she was on disability, struggling to function normally, and

[7] https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf

[8] https://link.springer.com/article/10.1007/s10508-014-0285-3

experiencing extreme psychological instability. During a particularly difficult period in 2020, at the height of the pandemic, Kiefel, who was still identifying as "non-binary," asked a doctor about "top surgery."

Kiefel was referred to a licensed clinical social worker affiliated with Brave Space, a limited liability company based in Oregon. According to state business records, the articles of dissolution for Brave Space were filed at the beginning of 2024.[9] An archived webpage shows that its mission was to facilitate "access to expert and knowledgeable providers for transgender and non-binary children, youth, adults, and their families."[10]

After a single, one-hour Zoom session with Kiefel, a clinical social worker named Amy Ruff at Brave Space prepared a referral for medical transition in May 2020. Ruff recommended that she receive "chest reduction to relieve gender dysphoria."

Ruff never obtained or reviewed Kiefel's medical or mental health treatment records before writing this referral, and Kiefel disclosed her history of mental illness during that initial meeting, including the unsuccessful attempts at treatment. Nevertheless, Ruff's referral indicated that Kiefel's mental health issues were "successfully managed" and should not be a barrier to medical transition. Ruff further stated that Kiefel had been informed of all the relevant expectations, outcomes, and risks associated with the procedure, a claim which Kiefel strongly disputes.

This is not the only allegation of unethical referral practices against employees at Brave Space. In 2017, the Oregon Board of Licensed Professional Counselors and Therapists (OBLPCT) accused the owner of Brave Space, Katherine J. Kauffman, of unethical conduct in relation to a surgery referral letter she prepared for her transgender-identifying "partner."[11] According to the filing, Kaufmann failed to disclose her personal relationship with the patient and instead misleadingly presented herself as a "counselor who had assessed, diagnosed, and recommended surgery for [the patient]." In fact, the Board alleged, Kauffman had written the letter after "reviewing the referral letter that was composed by another qualified mental health professional and deem[ing] that it was not adequate for insurance coverage."

Kiefel's desired breast removal surgery required a second assessment letter. In July 2020, Kiefel was scheduled for an appointment with Quest Center for Integrative Health, a registered 501(c)(3) non-profit that receives public and private funding, with an estimated annual revenue of $23 million.[12]

Kiefel spoke with licensed professional counselor Mara Burmeister for roughly 40 minutes over Zoom. Burmeister's surgery letter stated that Kiefel was "seeking gender affirming chest reconstruction surgery in order to align their anatomical body with his lived/preferred gender."[13] It also said that Kiefel has "explored the potential psychosocial impacts of surgery" and demonstrated "the ability and the capacity to make a fully informed decision and give consent." But, according to Kiefel, all of that was untrue.

Worse still, Burmeister failed to administer a comprehensive mental health assessment before she signed off on the procedure. Kiefel had experienced suicidal ideation not long before she met with Burmeister.

9 https://egov.sos.state.or.us/br/pkg_web_name_srch_inq.show_detl?p_be_rsn=1811611&p_srce=BR_INQ&p_print=FALSE

10 https://web.archive.org/web/20200808093031/https:/www.bravespacellc.com/

11 https://www.oregon.gov/oblpct/BoardAction/KAUFFMAN_1.pdf

12 https://growjo.com/company/Quest_Center_for_Integrative_Health

13 Although Kiefel was going by "she/they" pronouns at the time, the referral letter uses "she," "they," and "him."

Despite the obvious failures to screen her properly for the surgery, Kiefel was allowed to undergo a double mastectomy on August 27, 2020, just months after her first Zoom session. In the referral for medical transition she received, a medical provider recommended "that Camille Kiefel be referred to Dr. Tina Jenq at Oregon Cosmetic and Reconstruction Clinic for chest reduction to alleviate gender dysphoria."

Of course, the surgery did not alleviate anything — in fact, quite the opposite. Kiefel's surgery, paid for by Medicaid, did not improve her mental health issues, nor did it resolve her dysphoria. Instead, Kiefel began to feel profound regret for the irreversible damage to her body. The providers who were supposed to act in Kiefel's best interest set her up for even more pain and suffering. Her emotional, psychological, and physical health deteriorated after the procedure. Kiefel also developed complications afterward.

Within two years of the procedure, Kiefel detransitioned and embraced femininity. She is now seeking legal action against those who facilitated her brief but irreversibly damaging foray into gender medicine.

FAILING TO MEET THE STANDARD OF CARE

No reasonable person should have concluded, given Kiefel's history, that she should be fast-tracked towards an extreme, irreversible operation to permanently remove healthy body parts. Nor should any reasonable medical practitioner have shown such shocking disregard for both her mental state at the time of surgery and her documented record of severe psychological issues.

Unfortunately, Kiefel's experience is not unique among detransitioners. Many individuals who have undergone transgender hormone therapy or surgeries and eventually desisted have told essentially the same story: providers are more interested in ensuring that patients continue to receive invasive medical interventions than they are in ensuring the best possible outcome. Moreover, detransitioners often accuse their doctors, therapists, and counselors of using misleading or outright false claims in order to justify treatment.

These detransitioners often argue that they are victims of medical malpractice. But practitioners of gender medicine protest that they are only acting within the scope of established guidelines within their field, pointing especially to those put forward by WPATH.

These guidelines, most recently published as the "Standards of Care for the Health of Transgender and Gender Diverse People, Version 8" (SOC-8), purport to offer evidence-based recommendations for the "safe and effective" treatment of "Gender Diverse" populations, including those who identify as transgender, non-binary, or, most recently, those who identify as eunuchs. These standards have enormous influence over clinical practice and insurance coverage determinations, and were cited as authoritative by the Biden Justice Department.

One might hope that such an influential document would be carefully and rigorously drafted by impartial medical professionals, and based

on sound scientific evidence. Unfortunately, this is not the case.

WPATH is an advocacy group first, and a medical organization second. As the Department of Health and Human Services's recent review of pediatric medical transition points out, "[u]nlike most professional medical associations, WPATH does not require its members to be medical professionals. Full professional membership with voting privileges is also available to professionals in such fields as law, family studies, anthropology, and other areas. Reflecting the diverse aims of its broad membership, WPATH treatment guidelines are designed to serve multiple purposes, ranging from clinical care to political advocacy."[14] Authors of the guidelines were selected not based on their ability to impartially judge the weight of the medical evidence, but rather based on their history of advocacy in favor of "gender-affirming" treatments.

As the HHS report details, authors of the SOC-8 were particularly concerned, often explicitly, with crafting its language in order to advance policy goals and avoid political or legal scrutiny in the United States. The revelations, drawn from internal WPATH documents and legal depositions, are damning. Contributors to one chapter noted that "social justice lawyers" didn't want them to conduct evidence reviews, since if insufficient evidence were found for their claims it would put them "in an untenable position in terms of affecting policy or winning lawsuits." Authors insisted that procedures be described as "medically necessary," with one describing the term as "a tool for our attorneys to use in defending access to care" by compelling insurance companies to cover these interventions. One contributor urged that, overall, SOC-8 should "land in such a way as to have serious effect in the law and policy settings… even if the wording isn't quite correct for people who have the background you and I have."

These political considerations had profound effects on the final document. Most egregiously, WPATH was pressured into removing the minimum age recommendations for gender transitions from the final version of SOC-8. The Biden administration had instigated the change by warning that listing specific ages, as early drafts did, would only trigger further scrutiny and lead to unwelcome political consequences. Against the better judgment of WPATH members, the age recommendations were downgraded to "suggestions" before being ultimately removed.

While the political rationale for many of SOC-8's recommendations is clear, the scientific justification for them is lacking. This alone should draw regulatory attention. In 2020, the Federal Trade Commission warned companies, in the context of COVID treatments, that it is "unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product or service can prevent, treat or cure" a patient's or consumer's condition unless they "possess competent and reliable scientific evidence, including when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made."[15] Though medical professionals frequently frame gender transition surgeries as the solution for a patient's gender dysphoria — as Kiefel's doctor did — advertising the procedures as a cure could run afoul of FTC regulations without proper scientific backing.

There is a strong case to be made that WPATH's recommendations in general are not supported by "competent and reliable scientific evidence." There's no reason for WPATH to be surprised by this — this was the same conclusion drawn by the group's own advisors. During the SOC-8 drafting process, WPATH commissioned systematic reviews of evidence from Johns

[14] https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf

[15] https://www.ftc.gov/business-guidance/blog/2020/03/ftc-fda-warn-companies-making-coronavirus-claims

Hopkins University's Evidence-Based Practice Centers, hoping to find medical evidence to justify some of their claims. Previous guidelines had been largely based, among other things, on opinions of individual practitioners and shifting cultural norms. When these reviews returned "little to no evidence" to justify many of WPATH's claims, WPATH decided to exclude the reviews from the Standards and suppressed Johns Hopkins's ability to publish them elsewhere.

Again and again, the international medical community has challenged the WPATH standards of care for lacking sufficient evidence to justify its recommendations.

Outside the United States, the United Kingdom's National Health Service (NHS) has expressly distanced itself from WPATH's guidelines over the last few years. After an extensive review, NHS England concluded that there is not enough concrete evidence concerning the long-term effects of puberty blockers with regard to "sexual, cognitive or broader developmental outcomes."[16]

The UK is not alone. Finland also abandoned WPATH's guidelines for the same reason and adopted new, far more cautious standards of care. The decision followed a systematic review of the available scientific literature by Finland's national health authority, the Council for Choices in Health Care (PALKO/COHERE), which found insufficient hard evidence to support adherence to WPATH's standards of care. In Finland, the gender transition of minors is now considered "an experimental practice."

Finland's new policy recommended dramatically restricting GAC for minors, while highlighting that brain development continues until about age 25, "which also affects young people's ability to assess the consequences of their decisions on their own future selves for [the] rest of their lives."[17] These treatments are radical enough that even adults ought to exercise extreme caution before opting to undergo them.

Most importantly, PALKO/COHERE stated that a "lack of recognition of comorbid psychiatric disorders common among gender-dysphoric adolescents can also be detrimental."

> Since reduction of psychiatric symptoms cannot be achieved with hormonal and surgical interventions, it is not a valid justification for gender reassignment. A young person's identity and personality development must be stable so that they can genuinely face and discuss their gender dysphoria, the significance of their own feelings, and the need for various treatment options. For children and adolescents, these factors are key reasons for postponing any interventions until adulthood.

The Finnish guidelines emphasize the importance of stabilizing other mental health issues before proceeding with a gender transition. "In adolescents, psychiatric disorders and developmental difficulties may predispose a young person to the onset of gender dysphoria," PALKO/COHERE noted. "These young people should receive treatment for their mental and behavioral health issues, and their mental health must be stable prior to the determination of their gender identity."

In the US, this is not the general practice for transgender-identifying minors or adults. Instead of treatment for underlying mental and behavioral health issues, Kiefel — and so many others — received an express ticket to irreversible GAC and the removal of guardrails under the belief that immediate physical changes would improve their psychiatric condition. But as the

[16] https://www.nbcnews.com/nbc-out/out-news/england-limiting-gender-transitions-youths-us-legislators-are-watching-rcna144246

[17] https://segm.org/sites/default/files/Finnish_Guidelines_2020_Minors_Unofficial%20Translation.pdf

results of these experimental procedures pile up, there is only more evidence to the contrary.

In April, a study published in The Journal of Sexual Medicine matched cohorts of patients, male and female, with gender dysphoria who had and had not undergone surgery. The research aimed to evaluate "mental health outcomes in transgender individuals with gender dysphoria who have undergone gender-affirming surgery." They found:

> From 107 583 patients, matched cohorts demonstrated that those undergoing surgery were at significantly higher risk for depression, anxiety, suicidal ideation, and substance use disorders than those without surgery. Males with surgery showed a higher prevalence of depression (25.4% vs. 11.5%, RR 2.203, P<0.0001) and anxiety (12.8% vs. 2.6%, RR 4.882, P<0.0001). Females exhibited similar trends, with elevated depression (22.9% vs. 14.6%, RR 1.563, P<0.0001) and anxiety (10.5% vs. 7.1%, RR 1.478, P<0.0001). Feminizing individuals demonstrated particularly high risk for depression (RR 1.783, P=0.0298) and substance use disorders (RR 1.284, P<0.0001).[18]

Simply put, patients who underwent so-called "gender-affirming surgery" experience an *increased* risk of mental health issues.

The risk-benefit analysis simply does not favor gender transitions. As Justice Samuel Alito observed during oral argument in *Skrmetti,* "There is no evidence that gender-affirmative treatments reduce suicide."[19] And, as the HHS report concluded, "We can be certain in the ordinary sense of 'certain' that these interventions cause harm, even if we do not have 'high certainty' evidence in the technical sense employed in evidence-based medicine," because we "do not need results from [randomized controlled trials] to be certain that removing an adolescent's breasts will eliminate or substantially impair capacity for breastfeeding."[20]

A profound lack of evidence hasn't slowed the train of transitioners, but it has contributed to their regret and anger.

CASE STUDY: CLEMENTINE BREEN

In December 2024, Kaya Clementine Breen — now 20 years old — revealed that she was suing the California health providers and hospitals that she alleges wrongly diagnosed her as gender dysphoric. Breen claims to have been "fast-tracked onto the conveyor belt of irreversibly damaging" GAC, from puberty blockers to surgery, starting at age 14.

Clementine Breen never had a chance to have a normal childhood. Her brother suffered from autism so severe that it made him violently lash out at home. Those outbursts made a psychological mark on Breen, whose family on

[18] https://academic.oup.com/jsm/article-abstract/22/4/645/8042063

[19] https://www.supremecourt.gov/oral_arguments/argument_transcripts/2024/23-477_c07d.pdf

[20] https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf

both sides has a long and complex history of mental health issues ranging from depression, anxiety, bipolar disorder, and suicidal behavior. On top of a disruptive home life and a family history of psychological issues, Breen was sexually abused around age six or seven.

Breen started puberty around age 11. Like Kiefel, the sexual abuse that she had experienced made her deeply distressed by the very notion of being a woman. Breen fled from conventional femininity and identified as gay in 2016 at the age of 11. By this time, her mental health had been deteriorating, and she was being seen by a school counselor.

Breen felt that life would be easier if she were a boy, though she later realized that these feelings were triggered by her sexual abuse, with which she coped by trying to escape from being female.

Breen is far from alone in this experience; studies have drawn a connection between abuse and gender dysphoria. One paper published in *Pediatrics* reported that "transgender adolescents" (TGAs) had "elevated rates of psychological, physical, and sexual abuse compared with heterosexual" adolescents that it classified as "cisgender" (CGAs). "Risk for psychological abuse was highest among TGAs assigned female at birth," the study concluded. TGAs had more than twice the odds of reporting sexual abuse compared to their counterparts.[21]

Knowledge of Breen's abuse should have seemed like the obvious root of the problem to any reasonable provider. Instead, based on a few statements and conversations, the school counselor informed Breen's parents that she was transgender. Not long after that, Breen was placed under the care of Dr. Johanna Olson-Kennedy at the Center for Transyouth Health and Development (CTYHD) at Children's Hospital in Los Angeles. She had just turned 12.

Olson-Kennedy is an influential figure in the industry and takes a maximalist position on GAC. In 2015, the CTYHD received a $5.7 million award from the National Institutes of Health for a five-year study designed to support transgender medical interventions for young people.[22] As an executive board member of WPATH and the president-elect of the U.S. Professional Association for Transgender Health, Olson-Kennedy has more than 1,200 young patients under her belt and is directly involved in shaping guidelines and standards of care. She's advocated for bringing courts to bear against parents who refuse to transition their children once they've been diagnosed. Last year, Olson-Kennedy admitted to having suppressed a study on puberty-blocking drugs for fear that the results might lend support to critics of GAC for minors. "I do not want our work to be weaponized," she told *The New York Times*. "It has to be exactly on point, clear and concise. And that takes time."[23]

It's more likely that Olson-Kennedy understands that much of the evidence supporting these procedures is far from concrete and must therefore be carefully curated and presented to the public in the United States, even as the rest of the world retreats toward saner approaches.

Olson-Kennedy diagnosed Breen with gender dysphoria after a single brief visit based on utterly benign statements — like, "I mostly have boy friends." Notably, Olson-Kennedy separated Breen from her parents for the evaluation, which did not include a mental health assessment. There was no discussion about trauma, abuse, or anything of that nature. Indeed, Olson-Kennedy showed little interest in Breen's family history or psychological status. Her conclusion that Breen was "trans" hinged entirely on a handful of superficial remarks made by a deeply unwell pre-teen girl.

[21] https://pmc.ncbi.nlm.nih.gov/articles/PMC8344346/pdf/PEDS_2020016907.pdf

[22] https://sites.google.com/view/queeradvocacy4laschools/center-for-transyouth-health-development

[23] https://www.nytimes.com/2024/10/23/science/puberty-blockers-olson-kennedy.html

Olson-Kennedy swiftly recommended she start puberty blockers, which she presented as a "great option" with zero drawbacks. Further, the doctor specifically recommended a less common and more expensive option: Supprelin LA (histrelin acetate), delivered via a surgically implanted device in Breen's arm. A single Supprelin LA implant costs approximately $53,579,[24] but some have reported paying as much as $95,000.[25] Like AbbVie Inc.'s Lupron Depot, Supprelin LA, which is manufactured by Endo International, is not approved by the FDA for treating gender dysphoria and is used off-label in that capacity.

Within a year, Olson-Kennedy recommended that Breen start taking testosterone, again failing to disclose the associated risks or offer alternatives. When Breen's parents resisted, Olson-Kennedy separated her from her parents in order to speak to them alone. She claimed, falsely, that their daughter was suicidal and insisted that Breen would inevitably take her own life. When presented with what was an ultimately false choice of having "a living son or a dead daughter," they broke down in tears and gave their consent. Olson-Kennedy never explained to her the ramifications of suppressing puberty, let alone attempted to offer a less invasive alternative.

At 13, Breen started testosterone—and almost immediately began suffering adverse effects. The dosage quickly tripled, and Olson-Kennedy next recommended a double mastectomy. All it took was a letter of recommendation from a primary care physician and a mental health provider. At no point did anyone who interacted with Breen think to pause based on her history of physical and psychological trauma.

According to Breen, the recommendation letters contained a staggering number of misrepresentations:

> …such as that Clementine had "endorsed a male gender identity since childhood"; had "full understanding that chest reconstruction is a permanent intervention" (even though Clementine could not have and did not appreciate the impact of failing to be able to breastfeed a child and her potential (now actual) deep desire to do so (should she be able to conceive a child, which is highly unlikely)); had "no psychiatric contraindications to Gender Confirmation Surgery"; had "the capacity to give consent and make fully informed decisions about [her] care;" and that her "[d]iagnoses and treatment were conducted in accord with the standards of the World Professional Association for Transgender Health (WPATH)," when none of the diagnoses or treatments prescribed by Dr. Olson-Kennedy met even WPATH's deeply flawed and significantly discredited "standards." Ms. Landon's letter also added that the "surgery will remedy [Clementine's] persistent and unwavering gender dysphoria related to [her] chest and will bring [her] greater congruency, and add great quality to [her] life."[26]

Susan P. Landon was the therapist who referred Breen for surgery. She is the Director of the Child and Adolescent Program at the Los Angeles Gender Center and, along with Olson-Kennedy, sits on the board of Transforming Family, a "support group for families with

[24] https://www.drugs.com/price-guide/supprelin-la

[25] https://www.npr.org/sections/health-shots/2020/02/24/808049526/hormone-blocker-sticker-shock-kids-drug-costs-8-times-more-than-one-for-adults

[26] https://libertycenter.org/wp-content/uploads/2024/12/Complaint.pdf

transgender, non-binary, and gender-expansive children."[27]

The double mastectomy itself was treated as no more consequential than a body piercing or a tattoo. Breen had minimal contact with her surgeon, Dr. Scott Mosser, before the operation. In fact, she first met him on the morning before the procedure for a brief discussion that lasted roughly 30 minutes. It was during that time that Breen received a packet containing a form stating that "[t]he best candidates for surgery are those who are mature enough to understand the procedure and have realistic expectations about the results." No reasonable person would have assumed that Breen fit that description. Moreover, Mosser indicated on a form that her record of illness amounted to "gender dysphoria" and that it was "OK" to go ahead with the procedure based on her family and social history.

Even more alarming, on a form filled out following a post-mastectomy visit, Olson-Kennedy noted that Breen "[d]enies anxiety, [d]enies depression." In reality, Breen had, for the first time in her life, become suicidal. The intensity of her psychological distress was such that she began to self-harm and starve herself. She became completely incapable of focusing on anything other than how much she hated her body, which had become a kind of prison. When Landon and Olson-Kennedy were made aware of Breen's deteriorating condition, they dismissed the concerns as natural adjustment into being transgender.

There is growing evidence that "gender-affirming" interventions may increase suicidality. Several studies have established a correlation between testosterone levels and suicidal behavior in females, especially those with a history of mental illness. One paper published in the *Journal of Psychiatric Research* found that, controlling for sex, "testosterone levels positively correlated with the number of manic episodes and the number of suicide attempts" in patients with diagnoses of bipolar disorder.[28] And, according to Reuters, "in 2016, the FDA ordered makers of puberty blockers to add a warning about psychiatric problems to the drugs' label after the agency received several reports of suicidal thoughts in children who were taking them."[29]

Even though her psychological state was effectively in free fall, Breen's medical providers nevertheless dragged her along the transition roadmap. A physician who began to see her on October 14, 2019, five months after her double mastectomy, noted that she suffered from "trauma and stress related disorder," psychosis, anxiety, and depressive symptoms. The following month, Olson-Kennedy's name would appear on a paper published in Transgender Health that outlined the process of establishing the Trans Youth Care Research Network, which was "formed to design and implement research studies to better understand physiologic and psychosocial outcomes of gender-affirming medical care among [gender-diverse] youth."[30] Meanwhile, one of those youths — Breen — was experiencing terrifying auditory and visual hallucinations that would leave her paralyzed with fear. These episodes would become so severe that Breen would lose track of the passage of time and stay awake for days, which resulted in the prescription of selective serotonin reuptake inhibitors and an antihistamine used to treat insomnia. Her life had become a waking nightmare.

[27] https://transformingfamily.org/about-us/

[28] https://pmc.ncbi.nlm.nih.gov/articles/PMC3810946/

[29] https://www.reuters.com/investigates/special-report/usa-transyouth-care/

[30] https://pubmed.ncbi.nlm.nih.gov/31701011/

According to Breen, Olson-Kennedy was virtually unconcerned with these symptoms, describing her psychiatric state as essentially normal. Instead, Olson-Kennedy was chiefly concerned with the fact that, due to these bouts of mania, Breen had ceased taking her testosterone regularly.

A second psychiatrist around this time documented the shattering of Breen's mental state: she was hearing voices, harming herself, and had become essentially schizoaffective. In contrast, Olson-Kennedy's notes indicate that Breen was "still with anxiety but in good mental health." Olson-Kennedy increased Breen's recommended dose of testosterone, again.

The living nightmare began to end when Olson-Kennedy tried to push even further, recommending that Breen undergo a "gender-affirming" hysterectomy. As Breen realized that she may want to have children one day, Olson-Kennedy informed her that this was already likely impossible, due to her extended time on blockers and testosterone. She had not told Breen this at the outset.

Breen's and her parents' trust in Olson-Kennedy started to wane, and Breen began to be seen by a dialectical behavior therapist. Therapy clarified to her that her unresolved trauma from repeated sexual abuse was the root of her psychological suffering. She gradually stopped using testosterone, eventually ceasing completely, which corresponded with a marked improvement in her mental health.

Before long, Breen, for the first time in her life, healed. All it took was eschewing the path Olson-Kennedy and her other medical providers had put her on.

THE PURPOSE OF A SYSTEM IS WHAT IT DOES

Breen's case displays one of the most stunning, systematic failures to date by medical providers to abide by the Hippocratic Oath — do no harm — with regard to gender dysphoric youth. But it might be a mistake to say, in this case, that the guard rails were absent. They were there — but their purpose was to lock Breen into transitioning rather than to stop her from suffering harm. Her story is a textbook example of what the HHS report described as the penchant of GAC providers to act as hammers in search of nails, in which "the diagnosis of [gender dysphoria] tends to obscure causes of distress and crowd out other mental health care needs, particularly when patients are referred to specialty gender clinics."

The authors note: "To neglect the mental health care needs of members of an already vulnerable population of youth with complex psychiatric, neurodevelopmental, and psychosocial challenges is to deny them a benefit to which they are entitled, and to expose them to medically unnecessary risk of harm is to impose a burden unduly." But that is assuming GAC providers acted out of ignorance rather than intent.

Anthony Stafford Beer, a professor at the Manchester Business School, posited that the purpose of a system is what it does, or, in his own words, that there is "no point in claiming

that the purpose of a system is to do what it constantly fails to do." When reflecting upon Breen's patient experience in light of testimonies from other detransitioners, it is virtually impossible to come to any other conclusion than that the "point" was to advance her along the path of transitioning — regardless of whether that was actually in her best interest or not. The system was working as intended, and every time Breen indicated that it didn't seem to be having a beneficial effect on her, she was effectively told that all was going to plan. And it was, just not in the way she realized or had hoped.

The point of the gender medical industry is to provide medical transitions to almost anyone who walks into their clinics, and to continue treatment for, if possible, the rest of the patient's life. Anything that could potentially stand in the way of performing a sex-change procedure is treated as morally suspect at best, and morally despicable at worst. Evidence that the intervention is not working as intended is often dismissed.

Even major psychiatric problems generally do not mean a patient will be denied a medical transition. WPATH's guidelines remain largely ambiguous about how, if at all, dysphoria can be differentiated from other psychiatric disorders. SOC-8 suggests that providers should exclude other possible causes of "apparent gender incongruence," but is largely silent about how to do so. It offers one example — a patient who only shows "gender incongruence" during an "acute psychotic episode" should not be considered a good candidate for a medical transition.[31]

Apart from that, the guidelines emphasize that little should stand in the way of beginning "treatment." Psychosis or cognitive impairment, they point out, "does not necessarily equate to an inability to give consent." Further, "limits to capacity to consent to treatments should not prevent individuals from receiving appropriate [gender-affirming medical and/or surgical treatments]." For such patients, WPATH recommends the use of simple language and diagrams.[32] SOC-8's chapter on mental health recommends that psychotherapy should never be a prerequisite for medical intervention.[33]

While little should stand in the way of *beginning* treatment, the standard for *ceasing* treatment due to deteriorations in mental health is very high. SOC-8 explicitly counsels against stopping hormone treatment even when patients are admitted to an inpatient psychiatric unit, except in rare circumstances where a newly admitted patient is diagnosed with "a medical complication necessitating suspension of hormone treatment, for example an acute venous thromboembolism."[34]

The lead author of the SOC-8 chapter on mental health, Dr. Dan Karasic of the University of California San Francisco, seems to take a laissez-faire approach towards patients with co-existing psychiatric disorders. For example, in a 2017 presentation at the conference for the US branch of WPATH, Dr. Karasic stressed the importance of affirming patients with dissociative identity disorder (DID), also known as multiple personality disorder.

The WPATH Files, a report from the group Environmental Progress, describes one case study presented by Dr. Karasic:

> One patient was a male who identified as "genderqueer" and underwent "flat front" nullification surgery, or the amputation of the genitals to create a smooth, sexless appearance. This male suffered from bi-

[31] SOC-8, p. S36, https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644

[32] SOC-8, p. S38, https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644

[33] SOC-8, p. S175, https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644

[34] SOC-8, p. S174, https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644

> polar disorder and "alcohol use disorder" and was treated with spironolactone, an anti-androgen hormone blocker, followed by estradiol, or synthetic estrogen. Karasic reported that the patient had seven alters [i.e., alternate personalities], two of which were "agender" and one female. "Alters were in agreement about surgery," Karasic assured the audience.

Another patient mentioned in the talk claimed to have 85 other personalities and identified as a "genderqueer system." Karasic noted that he had treated several patients with DID, chalking it up to his reputation as a provider who is not "plural phobic."[35]

Because even major psychiatric disorders are seen as an impediment only in "rare" cases, WPATH protocols do not absolutely require psychological evaluation for patients, including minors. Although parts of the guidelines give lip service to the desirability of a "comprehensive biopsychosocial assessment" for adolescents starting the transition process, they note that the recommendations as a whole are meant to be "flexible" and "individual health care professionals and programs, in consultation with the [patient], may modify them" as they see fit.[36]

Departures from the standard generally only go in one direction. The original protocols for psychological assessment of transgender-identifying youth, approvingly cited by WPATH in SOC-8 as the best supported, call for an extensive, months-long process. Actual adherence to this protocol in the US, however, seems to be vanishingly rare. In 2022, Reuters interviewed staff at 18 clinics and found that none were doing "anything like" what those protocols recommend.[37] Even the more cautious protocol, despite WPATH's claims, is unsupported by the evidence,[38] but medical practitioners have recklessly chosen to relax the standards anyway.

It seems that many professionals consider relaxation of the guidelines to be morally necessary. Although SOC-8 recommends psychological assessment of patients and "several years" of gender incongruence before prescribing hormones to adolescents, many practitioners denounce these standards in very emphatic terms. One psychiatrist at Fenway Health in Boston described SOC-8's assessment recommendation as "unnecessary gatekeeping and also stigmatizing and pathologizing and a waste of resources."[39] Another psychologist described the recommendation of "several years" of incongruence as "harmful and destructive and abusive and unethical and immoral[.]"

[40]Assessment times for transgender-identifying patients overall have dropped dramatically. Planned Parenthood, one of the nation's leading providers of hormones for transgender-identifying young adults, seems to generally prescribe them during the first visit, with the whole process taking around half an hour or less. Some medical professionals in the field have blamed Planned Parenthood's quick prescriptions for putting pressure on the entire industry to remove safeguards,[41] but whatever the cause, shorter assessment times are now the norm. In

[35] https://static1.squarespace.com/static/56a45d683b0be33df885def6/t/6602fa875978a01601858171/1711471262073/WPATH+Report+and+Files111.pdf

[36] SOC-8, p. S6, https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644

[37] https://www.reuters.com/investigates/special-report/usa-transyouth-care/

[38] HHS Report, p. 184. https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf

[39] https://www.nytimes.com/2022/01/13/health/transgender-teens-hormones.html

[40] https://www.nytimes.com/2022/06/15/magazine/gender-therapy.html

[41] https://freebeacon.com/latest-news/planned-parenthood-is-helping-teenagers-transition-after-a-30-minute-consult-parents-and-doctors-are-sounding-the-alarm/

the case of one prominent pediatric gender clinic, the amount of time devoted to assessments of patients fell around 90 percent between 2013 and 2021, down to just two hours, a development the clinic's founder calls "shocking."[42] In Clementine Breen's case, Olson-Kennedy diagnosed her with gender dysphoria within minutes and ordered a puberty-blocker implant the very same day.[43]

Consistent with the industry's widespread opposition to denying or discouraging treatment, practitioners often downplay or omit discussion of potential side effects and risks. Again, Planned Parenthood provides a particularly egregious example. One potential side effect of testosterone injections for women is the atrophy of the entire reproductive tract. As The Free Press reported: "Planned Parenthood's materials for clinicians state atrophy can begin within just 3–6 months of exposure. But on the brief patient consent form [...] this was referred to only as 'genital dryness.'" One transgender-identifying former employee raised concerns about this, only to be told "that protocols were set by the national office, and in any case, informing patients of lesser-known side effects 'would scare them.'" A Planned Parenthood medical director interviewed by The Free Press defended the practice, "saying it would be wrong to point patients to things that might happen 10 or 20 years down the road when 'they're having life-saving care right now.'"[44]

In the case of minors, it is unclear how, if at all, they can meaningfully understand even those risks and side effects that doctors choose to discuss. During the drafting process for SOC-8, WPATH commissioned a study from Johns Hopkins University into whether adolescents had the ability to consent to medical transition. WPATH abandoned the study prematurely once researchers informed the drafting committee that evidence was likely insufficient to support their claims.[45]

WPATH is well aware of children's inability to understand these procedures or the complications that come with them. As one doctor put it in a leaked recording of a WPATH panel, "we're often explaining these sorts of things to people who haven't even had biology in high school yet." "[I]t's always a good theory that you talk about fertility preservation with a 14 year old, but I know I'm talking to a blank wall," the doctor said, adding that, like most 14-year-olds, "They'd be like Ew, kids, babies, gross."[46] As Justice Thomas noted in his opinion in United States v. Skrmetti, "Analogizing a teenage patient's comprehension to that of a blank wall should raise serious concerns regarding the patient's ability to provide informed consent."[47]

Providers are so intent on medical transition, no matter the risks or costs, that it can also lead to sloppy mistakes. That is what happened in the case of Clementine Breen. They were so focused on ensuring that she transitioned that they failed to follow established guidelines of care. While puberty-blocker implants are usually removed after two years at the latest, Breen's implant was left in for more than four years — well after even Olson-Kennedy noted it should be removed.

Olson-Kennedy also seems to have been lax in monitoring for known side effects. Studies

42 HHS Report, p. 189. https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf

43 HHS Report, p. 189. https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf

44 https://www.thefp.com/p/how-did-planned-parenthood-become

45 HHS Report, p. 155. https://opa.hhs.gov/sites/default/files/2025-05/gender-dysphoria-report.pdf

46 The WPATH Files. https://static1.squarespace.com/static/56a45d683b0be33df885def6/t/6602fa875978a01601858171/1711471262073/WPATH+Report+and+Files111.pdf

47 https://www.supremecourt.gov/opinions/24pdf/23-477_2cp3.pdf

indicate that extended use of puberty blockers can result in decreased bone mineral density,[48] and numerous cases of that have been documented in connection to GAC. Breen has no way of measuring precisely how it may have affected her in that regard because Olson-Kennedy only conducted a single baseline bone density scan and then never again for the entire course of treatment.

Most shocking of all was the blatant disregard and distortion by Landon and Olson-Kennedy of Breen's medical history. Their letters contained numerous misrepresentations, such as that Breen had "endorsed a male gender identity since childhood." On top of that were the consistently manipulative rhetoric and tactics employed by Olson-Kennedy to overcome resistance from Breen and her parents, like asking them, "Would you rather have a dead daughter or a living son?" According to Olson-Kennedy, this specific line was one that she would employ "often."[49] GAC is not only portrayed as necessary but as an existential, life-saving panacea — a kind of universal remedy for all ailments.

Again, there is insufficient evidence to support such strong claims for fundamentally radical treatments. Consider the recent sea change in Denmark, which was until recently home to a very permissive approach toward GAC for minors. In 2023, *Ugeskrift for Læger*, the Journal of the Danish Medical Association, noted a major shift had occurred in how young patients experiencing gender dysphoria are treated.[50] Notably, the authors of this paper are clinicians who are directly involved with patient care.

The authors pointed to the explosion in referrals for adolescents — mostly 11 to 18 year old girls — as a serious cause for concern. In Finland — which, again, has now implemented a more restrictive approach to GAC — fully 75 percent of those referred had psychiatric diagnoses: "The most common psychiatric diagnoses are depression, anxiety, suicidal thoughts/self-harm, autism and ADHD." They also highlighted the role that "social influence" plays in shaping the way gender dysphoria presents and spreads. Further, the Danish clinicians noted that increasing rates of detransitioners has resulted in a reevaluation of guidelines around the globe.

In April of this year, The Federal Council of Medicine (CFM) in Brazil approved a resolution to ban the use of hormone blockers for GAC in children and adolescents. It also raised the minimum age for cross-sex hormone therapy from 16 to 18 and raised the age from 18 to 21 for procedures where treatment results in sterilization.[51] The CFM is an independent agency of the Ministry of Work and Employment and, as the country's official medical licensing body, has the power to revoke the licenses of doctors who do not abide by the new policy.

Likewise, in March, the Association of the Scientific Medical Societies in Germany made a revealing concession in the final version of the Clinical Practice Guidelines on the Diagnosis and Treatment of Adolescent Gender Dysphoria and Gender Incongruence.[52] The report explains that most young people experiencing some form of gender dysphoria are likely only experiencing temporary "gender non-contentedness" and should not be allowed to transition. The guidelines are not as restrictive as those found in the UK or Finland now, but that revision is nevertheless crucial. Even relatively permissive countries contradict the claims of the transgender medical industry.

48 https://pmc.ncbi.nlm.nih.gov/articles/PMC4206646/

49 https://abcnews.go.com/Health/transgender-kids-pioneer-early-identity-body/story?id=14404963

50 https://ugeskriftet.dk/videnskab/sundhedsfaglige-tilbud-til-born-og-unge-med-konsubehag

51 https://www1.folha.uol.com.br/internacional/en/scienceandhealth/2025/04/brazils-federal-council-of-medicine-bans-hormone-blockers-for-trans-children-and-adolescents.shtml

52 https://segm.org/German-guidelines-gender-dysphoria-youth-2025

ELEPHANT IN THE ROOM: OFF-LABEL DRUG USE

It is impossible to deny that there is a growing body of evidence that is leading governments around the world to either dramatically limit or outright prohibit puberty blockers, cross-sex hormones, and surgeries for minors. There is also an ever-increasing number of lawsuits filed by individuals against those who ushered them along the road to transitioning against their own best interests. And yet, the manufacturers of the devices and drugs used off-label as part of these treatments have so far gone untouched.

That's partially due to the fact that the legal implications of off-label use are notoriously unclear. The issue is not something unique to GAC, but this application is arguably one of the most ethically dubious practices, considering both the novelty of GAC and its shaky scientific foundations. A doctor might reasonably prescribe a patient antidepressants for a headache, which is not their intended use and would, therefore, be considered off-label. However, that is very different from, say, administering blockers to stall the emergence or development of puberty as part of what is essentially experimental medicine whose guidelines throw caution to the wind.

That is not to say off-label drug use (OLDU) is without problems in other areas. A study published in *Mayo Clinic Proceedings* reported that OLDU has been "associated with an increase in medication errors."[53] Critically, the authors highlighted an analysis of pediatric antidepressant drug use in a national error-reporting database and found that "77% involved off-label prescribing." Moreover, the HHS report found that the "unfavorable risk/benefit profile distinguishes [pediatric medical transition] from many other off-label uses of drugs and medical devices." Indeed, the report outlines a comprehensive ethical case against the incumbent use of OLDU in GAC:

> Advocates for [pediatric medical transition] point to the prevalence of off-label prescribing in pediatrics, but the legitimacy of some off-label uses does not license the prescription of any pharmaceutical to any patient for any reason. The favorable risk/benefit threshold, or, more minimally, the precautionary threshold, must be met irrespective of whether the intervention is approved by FDA. Off-label use of an intervention is sometimes justifiable based on studies of the intervention in a different patient population or for a different indication. Such use may be warranted when there is a reasonable expectation of benefit, when there are no superior alternatives, and when the prognosis, absent medical intervention, is predicted to be worse for the patient than the negative effects of the off-label drug. This is decidedly not the situation with [pediatric medical transition]. The natural history of pediatric [gender dysphoria] is poorly understood and decades of research has shown that early-onset [gender dysphoria] usually resolves without medical intervention. There is no compelling evidence that the same will not prove true in the case of adolescent-onset symptoms, and limited

[53] https://pmc.ncbi.nlm.nih.gov/articles/PMC3538391/

> evidence suggesting it will. And in any case, it is widely acknowledged that clinicians are unable to distinguish patients whose [gender dysphoria] will persist from those whose [gender dysphoria] will resolve. Further, there are concerns about the role medicalization itself may play in contributing to the persistence of the conditions being treated, and less invasive and less risky interventions are available. Lastly, medical intervention has known and plausible harms, and decades of research conducted by leading academic institutions have failed to produce reliable evidence of medical benefit.

It is hard to think of a more overwhelmingly negative assessment, which makes the liberal prescription of these drugs off-label with impunity all the more horrifying.

In order to establish liability under medical negligence standards, patients must prove without a doubt that their provider deviated in some way that resulted in harm. But there is a kind of chicken-and-egg game here. The FDA does not allow pharmaceutical manufacturers to promote or market off-label uses of their products. That also means that these companies are prohibited from sponsoring physician education for OLDU of their medications, which may provide a degree of coverage. These same physicians have also had the benefit of being able to point to dubious standards of care established by ideologically driven organizations like WPATH, though that is changing.

Still, there are examples of major pharmaceutical manufacturers being sued over marketing certain drugs for off-label use. In 2012, GlaxoSmithKline agreed to pay $3 billion in fraud settlement for promoting a handful of its antidepressants for unapproved uses, as well as for failing to report safety data for another drug.[54]That same year, Abbott Laboratories agreed to pay $1.6 billion over its marketing for an antiseizure drug. Notably, AbbVie, the company that manufactures Lupron, a blocker used in transitioning, originally spun out of Abbot Laboratories.

The question is what constitutes marketing. AbbVie, for example, is careful enough to avoid explicitly promoting its relevant offering, Lupron Depot, as safe for underage transitioners. But it does lobby a tremendous amount, and its contributions to organizations that support liberalizing access to treatments that would utilize its products and, therefore, generate increased profits for AbbVie arguably constitute a form of marketing by another name.

In the last decade, AbbVie has hired more than 214 lobbyists around the United States, according to the National Institute on Money in Politics.[55] As of 2024, 72 percent of its lobbyists previously held government jobs.[56] AbbVie's charitable arm, the AbbVie Foundation, gave $50,000 in 2019[57] to the Trevor Project, a nonprofit that champions GAC, with $50,000 more in each of 2020[58] and 2021.[59] Those donations did not go to waste. A study produced by the group was cited by the Biden administration to defend the use of blockers for minors.[60] That, of course, would benefit AbbVie, seeing as how

54 https://www.nytimes.com/2012/07/03/business/glaxosmithkline-agrees-to-pay-3-billion-in-fraud-settlement.html

55 https://www.followthemoney.org/entity-details?eid=18929519

56 https://www.opensecrets.org/orgs/abbvie-inc/summary?id=D000066804

57 https://projects.propublica.org/nonprofits/organizations/460827839/202041679349100129/full

58 https://projects.propublica.org/nonprofits/organizations/460827839/202113159349102971/full

59 https://projects.propublica.org/nonprofits/organizations/460827839/202221369349101482/full

60 https://freebeacon.com/biden-administration/white-house-pushes-puberty-blockers-for-trans-kids/

more minors undergoing GAC would mean more scripts for blockers.

In 2021, AbbVie signed an open letter in support of the Equality Act, emphasizing the importance of patient access to care that would include the use of its products, albeit masked in the language of social justice and innocent philanthropy. "The Equality Act protects the basic human rights of LGBTQ people in the United States," AbbVie said. "Every member of the #LGBTQ+ community—including our patients, health care providers, suppliers and employees—deserves these protections."[61]

AbbVie is not, of course, the only pharmaceutical company engaged in this type of behavior, nor is the influence of Big Pharma limited to lobbying and nonprofits. Databases like Open Payments track information about the financial relationships between drug and medical device manufacturers and health care providers, which can range from payments for things from research to meals and speaking fees. An illustrative example for the purposes of this report is Joshua Safer.

Safer is the executive director of the Mount Sinai Center for Transgender Medicine and Surgery in New York. He is also a WPATH board member and has been instrumental in developing guidelines for GAC — according to the Mount Sinai website, Safer "is a co-author of the Endocrine Society guidelines for the medical care of transgender people, the WPATH guidelines for the medical care of transgender people and the gender affirming hormone treatment sections in UpToDate."[62] In 2018, Safer gave a talk entitled "An Evidence-Based Approach to Understanding Transgender Medicine." He argued in favor of giving blockers to minors, dismissed concerns over adverse effects, and advocated eliminating psychiatric guardrails that slow the process of transitioning. According to the Open Payments database, Safer received money from Endo Pharmaceuticals related to Supprelin LA — the puberty blocker given to Clementine Breen — the same year he delivered that presentation.[63]

Often, these payments can only be identified by digging into whatever public information one can find. However, in the case of Jeremi Carswell, the director of the Boston Children's Hospital Gender Multispecialty Clinic, it showed up in the footnotes of a paper Carswell co-wrote entitled "Pubertal suppression for transgender youth and risk of suicidal ideation."[64] The paper argued that suppressing puberty with blockers could reduce the occurrence of suicidal ideation, against all the evidence to the contrary. However, the paper initially ran without disclosing that Carswell "has received an advisory board stipend from Endo Pharmaceuticals." That omission was only addressed after publication. According to the Stop the Harm database, the Boston clinic has written more than 750 scripts for puberty blockers or gender-affirming hormones and has seen more than 300 sex-change patients.[65]

Based in Oregon, Kara Connelly is the director of the Gender Clinic at Doernbecher Children's Hospital. Like Safer, she has received payment from Endo for expenses related to Supprelin LA,[66] which her clinic administers in GAC, along with Lupron Depot, while adhering to WPATH care guidelines.[67] Connelly was also

61 https://web.archive.org/web/20240226014249/https:/www.fair360.com/abbvie-joins-over-400-leading-us-employers-in-the-human-rights-campaigns-business-coalition-for-the-equality-act-2/

62 https://profiles.mountsinai.org/joshua-d-safer

63 https://openpaymentsdata.cms.gov/physician/1251744

64 https://psycnet.apa.org/record/2020-08381-001

65 https://stoptheharmdatabase.com/hospital/boston-childrens-hospital/

66 https://openpaymentsdata.cms.gov/physician/839798

67 https://www.ohsu.edu/doernbecher/doernbecher-gender-services

a co-author on a paper that attempted to refute the findings of the Cass Review, a four-year-long inquiry commissioned by the UK's NHS that was published last year.[68] The 388-page review, named after lead researcher Dr. Hillary Cass, led to the NHS restricting access to GAC for minors, including prohibiting the use of blockers for anyone under 18 outside of a research setting. UK Health Secretary Wes Streeting went so far as to cite the review as the basis for criminalizing the act of providing blockers to underage patients, calling their use up to that point a "scandal."[69]

In San Diego, Dr. Maja Marinkovic is co-director of the Center for Gender-Affirming Care at Rady Children's Hospital, which offers everything from surgical referrals to "gender-affirming vocal therapy." According to the ProPublica Dollars for Docs database, Marinkovic was ranked ninth for most payments received in the U.S. for Supprelin LA in 2018.[70] As reported by KPBS, puberty-blocker medications are a "common treatment at the Rady clinic."[71] Indeed, the total number of scripts for puberty blockers or "gender-affirming hormones" at Rady Children's Hospital is estimated to be over 500, according to the Stop the Harm database.[72]

In one case, a 14-year-old named Sam received GAC from the clinic, which included blockers and testosterone.[73] Sam went on to undergo a double mastectomy at the age of 14 at the Kryger Institute for Plastic Surgery in Thousand Oaks. Further, in 2022, Dr. David Inwards-Breland, a former Rady clinic co-director, bylined a paper entitled "Medically assisted gender affirmation: when children and parents disagree," in which the authors "discuss three potential avenues for providing gender-affirming care over parental disagreement: legal carve-outs to parental consent, the mature minor doctrine and state intervention for neglect."[74] In a word, they discuss three ways of transitioning a child without and over parental consent.

To be sure, many or most of the providers who have received money in connection to certain drugs used off-label in GAC are true believers. Their beliefs are not necessarily linked to monetary gain. Nevertheless, money matters. An analysis by ProPublica found that "doctors who received payments linked to specific drugs prescribed more of those drugs." Moreover, on average, "across all drugs, providers who received payments specifically tied to a drug prescribed it 58% more than providers who did not receive payments."[75]

The question, then, is whether these practices constitute advertising and promotion of OLDU. Texas Attorney General Ken Paxton launched an investigation in 2022 into Endo and AbbVie under the Texas Deceptive Trade Practices Act. The point of the inquiry is to determine whether these companies have advertised and promoted their blockers for off-label

68 https://law.yale.edu/sites/default/files/documents/integrity-project_cass-response.pdf

69 https://www.bbc.com/news/articles/cly2z0gx3p5o

70 https://projects.propublica.org/docdollars/products/14414

71 https://www.kpbs.org/news/midday-edition/2015/06/22/clinic-helps-san-diego-trans-youth

72 https://stoptheharmdatabase.com/hospital/rady-childrens-hospital/

73 https://www.sandiegouniontribune.com/2016/04/07/how-a-girl-born-at-2-pounds-became-a-happy-boy/#article-copy

74 https://pubmed.ncbi.nlm.nih.gov/31892617/#full-view-affiliation-5

75 https://www.propublica.org/article/doctors-prescribe-more-of-a-drug-if-they-receive-money-from-a-pharma-company-tied-to-it/amp

use in GAC. As of this writing, the investigation is still underway.

AVENUES TO ACCOUNTABILITY

On April 22, U.S. Attorney General Pam Bondi issued a memo that outlined a plan of action by the Department of Justice to "prevent the mutilation of American children."[76] There are five interlocking components: treating certain surgeries as female genital mutilation (FGM), a crime that carries a maximum prison sentence of 10 years; launching investigations under the Food, Drug, and Cosmetic Act; institutionally disconnecting from guidelines proposed by organizations like WPATH; organizing state and federal partnerships; and promoting new legislation that prohibits minors from undergoing these procedures.

The second point, making use of the Food, Drug, and Cosmetic Act, offers one of the most potent instruments against the real culprits: pharmaceutical giants. In particular, the Justice Department would probe whether manufacturers and distributors made false claims about drugs used in GAC, on- or off-label, and whether they were promoted for off-label use, even informally.

Moreover, the DOJ does not have to wait to begin bringing cases that meet the definition of FGM under 18 U.S.C. § 116 and where evidence indicates that the necessity or appropriateness is highly questionable under reliable medical and scientific measurements established by unbiased researchers.

That is a great start. But there is no reason that Justice should go it alone. The Federal Trade Commission can and should launch its own multifront campaign, investigating whether companies engaged in deceptive or unfair practices. Some similar efforts are already underway in the states. Of particular concern are the growing transgender telehealth industry as well as especially irresponsible actors such as Planned Parenthood.

The FTC could impose orders on GAC providers who are found guilty of making deceptive representations regarding the efficacy and safety of these services or who fail to disclose the potential risks and experimental nature of the relevant procedures. These can range from restrictive court orders to the freezing of assets and civil penalties. At a minimum, the agency could order providers to make disclosures to patients and the general public that these procedures are experimental or founded on unreliable evidence or even whether a particular provider has a financial or ideological stake in promoting GAC.

The FTC could also initiate a separate inquiry into OLDU. The intimate relationship that pharmaceutical entities like AbbVie have with the transgender movement, their advocacy for liberalizing access to treatments that include their products, and the payments to physicians in relation to their offerings are all deeply unsettling. The first step on this front would be to issue subpoenas or civil investigative demands to these companies in order to obtain all relevant

[76] https://s3.documentcloud.org/documents/25912589/bondi-memo-42225.pdf

material pertaining to gender care, especially for minors.

There is fertile ground here for the FTC to explore, and it connects directly to the question of collaboration. Beyond providing funding, grants, and sponsorships to physicians, nonprofits, and clinics, there is also the matter of "patient assistance programs" or "prescription assistance programs" (PAPs). The Federal Anti-Kickback Statute made it illegal for pharmaceutical and medical device companies to offer money or "anything of value in any form whatsoever" in exchange for on- or off-label prescriptions administered by providers. Writing in JACC: Basic to Translational Science, Gail Van Norman MD, a professor of anesthesiology and pain medicine, noted:

> Potentially illegal kickbacks to prescribers include cash payments, travel expenses to medical conferences, employment of the physician in some capacity by the company, and "honoraria" paid to physicians as "consultants" or "speakers" at medical conferences. Kickbacks and incentives need not be cash payments or gifts, however. Provision to a prescriber of anything that can be translated into monetary or professional value violates the law.[77]

While commercial companies are more constrained when it comes to publicly discussing OLDU, physicians have more flexibility. As Norman writes, physicians "are allowed to discuss off-label uses with individual patients, and at medical conferences with other providers, but they are not allowed to promote off-label use to the general public, to a general practice, or to groups of physicians." This dynamic allows physicians to effectively do the off-label marketing and promotion that drug companies cannot do themselves, albeit within the parameters established by the FDA. There is a game at play here for all those with eyes to see.

The Federal Anti-Kickback Statute didn't really end kickbacks. It made companies get creative, and PAPs, according to Norman, are often violations of the statute because they are funded by tax-exempt contributions from the pharmaceutical companies themselves and, therefore, functionally serve as kickbacks by another name. Norman points to 2019, the year in which three pharmaceutical companies paid $122 million in penalties to "to resolve allegations that they paid kickbacks through PAPs."

Many of the drugs and devices used in GAC are eligible for patient PAPs. AbbVie, for example, offers patient assistance through a program called AbbVie Assist that offers free medications, including puberty blockers. Whether it also offers them to patients seeking to transition is a question that an FTC inquiry could illuminate. Several of these companies, including AbbVie, already have track records of misleading practices that result in adverse patient outcomes.[78]

Bringing the FTC to bear on these companies, compelling the production of all relevant marketing and promotional documents, records of financial relationships and communications with clinics, physicians, and nonprofits alone would likely be enough to trigger a sea change by elevating the risk associated with providing GAC to minors. The FDA could buttress these efforts by commissioning a long-term systematic review of OLDU of puberty blockers in children and put both manufacturers and providers on notice about the consequences that promoting their use could invite. It should immediately freeze all pending requests for permission to conduct trials on the use of cross-sex hormones in GAC for minors and require black box warnings — the most serious kind of warning

[77] https://pmc.ncbi.nlm.nih.gov/articles/PMC10077121/

[78] https://kffhealthnews.org/news/women-fear-drug-they-used-to-halt-puberty-led-to-health-problems/

label — on all drugs and devices used off-label in this context while issuing warning letters to companies suspected of engaging in off-label promotion. Alternatives, such as psychological and behavioral treatments, should be promoted by the agency instead. The agency should also encourage whistleblowers to come forward with any information they might have about fraud and offer them protection from retaliation.

This wide-net approach, with the combined arms of the DOJ, FTC, and FDA, may seem like overkill, but it is the only hope to secure a modicum of accountability for the victims. The entire industry is corrupt. Doctors rush to prescribe unproven and harmful treatments that no reasonable person would conclude are helpful. Organizations like WPATH publish guidelines that they know to be scientifically dubious, and which are written to support an ideological agenda. And drug manufacturers continue to profit from the off-label use of their drugs for these dangerous purposes.

These victims' lives have been irreparably altered and damaged by individuals and entities that subordinated their best interests to an ideological agenda or greed. It would be unjust for all those involved to be able to simply wash their hands and walk away, claiming ignorance. The window of opportunity will not remain open for long. With public sentiment on its side for the moment, the federal government, from the DOJ to the FTC and FDA, has a unique opportunity to advocate for victims who are otherwise facing an army of pharmaceutical and medical goliaths. Failing that would mean consigning a generation of victims to voicelessness.

The obstacles faced by individuals seeking redress are practically insurmountable. They have neither the means nor the time and energy to prosecute campaigns against some of the most powerful corporate and medical entities in the world. Accountability requires the state to intervene in their defense.Failing that would mean consigning a generation of victims to voicelessness.

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