IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI WESTERN DIVISION

| McComb Children's Clinic, LTD., |) |
|---------------------------------|---|
| Plaintiff, |) |
| v. |) |
| Xavier Becerra, et al., |) |
| Defendants. |) |

Case No. 5:24-cv-48-KS-LGI

ORAL ARGUMENT REQUESTED

PLAINTIFF'S MOTION FOR A DELAY OF EFFECTIVE DATE AND FOR PRELIMINARY INJUNCTION

Plaintiff McComb Children's Clinic ("MCC") respectfully moves this Court for an order under 5 U.S.C. § 705 and Fed. R. Civ. P. 65, delaying the effective date of and enjoining Defendants from enforcing a new rule from the U.S. Department of Health and Human Services ("HHS") that, for reasons explained in the accompanying memorandum, is illegal, unconstitutional, and causes irreparable injury to MCC and its patients. *See* Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522 (May 6, 2024).

Specifically, this Motion seeks the following relief:

1. An order delaying the effective date of the rule's provisions at 45 C.F.R. \S 92.5, 92.6, 92.7, 92.8, 92.9, 92.10, 92.101, 92.206–211, 92.301, 92.303, 92.304, and any provision of the rule applied with respect to "sex" discrimination encompassing gender identity or sex stereotypes, or with respect to notices or speech made by entities pertaining to pregnancy-related conditions encompassing "termination of pregnancy" (*i.e.*, abortion).

2. A preliminary injunction against Defendants implementing, enforcing, or applying those provisions; in particular that they may not require covered entities to:

a. Perform, provide, offer, refer for, facilitate, make arrangements for, endorse, or refrain from criticizing or from categorically rejecting "gender transition";

b. Allow members of one sex into the private spaces or sex-specific programs of the other sex in their facilities, such as by allowing males into female restrooms, lactation rooms, or lactation training program referrals;

c. Speak in ways that the entities contend inaccurately refers to a patient's sex, such as in pronoun usage, coding, charting, or conversation, or be forced to say that a boy is a girl or vice versa, or say that men can get pregnant, give birth, or breastfeed;

d. Stay silent on the negative impacts of "gender-transition" efforts, including by being unable to say that they do not provide, offer, refer for, or endorse those procedures, or by being pressured to withhold criticism or their complete opinions on these subjects, or by being unable to use accurate sexspecific language in speech or writing;

e. Affirm "gender-transition" efforts, or refrain from providing criticism or their full opinions to patients on these subjects; or

f. Make statements in their policies, notices, or website statements, or train staff, or speak to patients or visitors, or submit assurances or certifications of compliance, to the effect that the entity will not discriminate on the basis of gender identity or termination of pregnancy; or

g. To do any of the above based on alternative language or theories Defendants may derive from the rule.

3. That the injunction run against Defendants' officials, agents, employees, and all persons in active concert or participation with them, including their successors in office; including any actions to deny federal financial assistance or qualification for participation in federally funded programs or activities.

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4. Counsel for Plaintiff has conferred with Counsel for Defendants, Liam C. Holland, Trial Attorney, Civil Division, Federal Programs Branch, U.S. Department of Justice, (202) 514-4964, Liam.C.Holland@usdoj.gov, who represented that Defendants oppose this Motion.

5. This motion is supported by the accompanying memorandum, Plaintiff's complaint [ECF 1 & 1-2], and this motion's exhibit (Exhibit A: Declaration of James M. Cantor PH.D, attached hereto).

Respectfully submitted this 3rd day of June, 2024.

/s/D. Michael Hurst., Ir.

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Counsel for Plaintiff McComb Children's Clinic, LTD.

CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2024, I electronically filed the foregoing and its attachment with the Clerk of the Court for the United States District Court Southern District of Mississippi by using the CM/ECF system. I further certify that I served Defendants by emailing them to Counsel for Defendants, Liam C. Holland, Trial Attorney, Civil Division, Federal Programs Branch, U.S. Department of Justice, who represented to counsel for Plaintiff that Defendants would accept service of this motion and its accompanying papers by email to him.

/s/D. Michael Hurst, Jr.

Counsel for Plaintiff McComb Children's Clinic, LTD.

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DECLARATION OF JAMES M. CANTOR PH.D.

I, James M. Cantor, Ph.D., pursuant to 28 U.S.C. § 1746, declare under penalty of perjury of the laws of the United States of America that the following is true and correct.

| EXHI | BIT |
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| A | |

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I. Credentials and Qualifications

A. Education and professional background

1. I am a sexual behavior scientist, with an internationally recognized record studying the development of human sexualities, and an expert in research methodology of sexuality. My curriculum vitae is attached as Appendix 1 to this report. My publication record includes both biological and non-biological influences on sexuality, ranging from pre-natal brain development, through adulthood, to senescence. The primary, but not exclusive, focus of my own research studies has been the development of atypical sexualities. In addition to the studies I myself have conducted, I am regularly consulted to evaluate the research methods, analyses, and proposals from sexual behavior scientists throughout the world. The methodologies I am qualified to assess span the neurochemical and neuroanatomic level, individual behavioral level, and social and interpersonal levels.

2. I am trained as a clinical psychologist and neuroscientist, and I am the author of over 50 peer-reviewed articles in my field, spanning the development of sexual orientation, gender identity, hypersexuality, and atypical sexualities collectively referred to as *paraphilias*. Although I have studied many atypical sexualities, the most impactful of my work has been MRI and other biological studies of the origins of pedophilia. That work has revolutionized several aspects of the sex offender field, both with regard to the treatment of offenders and to the prevention of sexual abuse of children. In 2022, I received the Distinguished Contribution Award from the Association for the Treatment and Prevention of Sexual Abuse in recognition of my research and its integration into public policy. My efforts in this regard have been the subject of several documentary films.

3. Over my academic career, my posts have included Senior Scientist and Psychologist

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at the Centre for Addiction and Mental Health (CAMH), and Head of Research for CAMH's Sexual Behaviour Clinic. I was on the Faculty of Medicine of the University of Toronto for 15 years and have served as Editor-in-Chief of the peer reviewed journal, *Sexual Abuse*. That journal is one of the top-impact, peer-reviewed journals in sexual behavior science and is the official journal of the Association for the Treatment and Prevention of Sexual Abuse. In that appointment, I was charged to be the final arbiter for impartially deciding which contributions from other scientists in my field merited publication. I believe that appointment indicates not only my extensive experience evaluating scientific claims and methods, but also the faith put in me by the other scientists in my field. I have also served on the Editorial Boards of *The Journal of Sex Research*, the *Archives of Sexual Behavior*, and *Journal of Sexual Aggression*. I am currently the Director of the Toronto Sexuality Centre in Canada. Thus, although I cannot speak for other scientists active in our field today, within the United States and throughout the world.

4. For my education and training, I received my Bachelor of Science degree from Rensselaer Polytechnic Institute, where I studied mathematics, physics, and computer science. I received my Master of Arts degree in psychology from Boston University, where I studied neuropsychology. I earned my doctoral degree in psychology from McGill University, which included successfully defending my doctoral dissertation studying the effects of psychiatric medication and neurochemical changes on sexual behavior, and included a clinical internship assessing and treating people with a wide range of sexual and gender identity issues.

5. I have a decades-long, international, and award-winning history of advocacy for destigmatizing people with atypical sexualities. While still a trainee in psychology, I founded the

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American Psychological Association's (APA) Committee for Lesbian, Gay, and Bisexual Graduate Students. Subsequently, I have served as the Chair for the Committee on Science Issues for APA's Division for the Psychology of Sexual Orientation and Gender Diversity and was appointed to its Task Force on Transgender Issues. Throughout my career, my writings and public statements have consistently supported rights for transgender populations and the application of science to help policy-makers best meet their diverse needs. Because my professional background also includes neurobiological research on the development of other atypical sexualities, I have become recognized as an international leader also in the destigmatizing of the broader range of human sexuality patterns.

6. I am highly experienced in the application of sex research to forensic proceedings: I have served as the Head of Research for the Law and Mental Health Program of the University of Toronto's psychiatric teaching hospital, the Centre for Addiction and Mental Health, where I was appointed to the Faculty of Medicine.

7. I have served as an expert witness in 21 cases in the past four years, as listed on my *curriculum vitae*. These cases included criminal, civil, and custody proceedings, preliminary injunction and Frye hearings, as well as trials. I have testified in courts in Canada and throughout the U.S., including Alabama, Arizona, Florida, Illinois, Indiana, Kansas, Kentucky, Massachusetts, New York, Texas, Utah, and West Virginia. I have provided expert testimony concerning the nature and origins of atypical sexualities, as well as concerning gender dysphoria and gender identity in children.

8. For my work in this case, I am being compensated at the hourly rate of \$400 per hour. My compensation does not change based on the conclusions and opinions that I provide here or later in this case or on the outcome of this lawsuit.

B. Clinical expertise vs. scientific expertise

9. In clinical science, there are two kinds of expertise: Clinicians' expertise regards applying general principles to the care of an individual patient and the unique features of that case. A scientist's expertise is the reverse, accumulating information about many individual cases and identifying the generalizable principles that may be applied to all cases. Thus, different types of decisions may require different kinds of experts, such that questions about whether a specific patient represents an exception to the general rule might be better posed to a physician's expertise, whereas questions about establishing the general rules themselves might be better posed to a scientist's.

10. In legal matters, the most familiar situation pertains to whether a given clinician correctly employed relevant clinical standards. Often, it is other clinicians who practice in that field who will be best equipped to speak to that question. When it is the clinical standards that are themselves in question, however, it is the experts in the assessment of scientific studies who are the relevant experts.

C. The professional standard to evaluate treatment models is to rely on objective assessors, not treatment model users in a conflict of interest with its results.

11. I describe in a later section the well-recognized procedures for conducting reviews of literature in medical and scientific fields to evaluate the strength of evidence for particular procedures or treatments. Importantly, the standard procedure is for such evaluations to be conducted by objective assessors with expertise in the science of assessment, and not by those with an investment in the procedure being assessed. Because the people engaged in providing clinical services are necessarily in a conflict of interest when claiming that their services are effective, formal evaluations of evidence are routinely conducted by those *without* direct

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professional involvement and thus without financial or other personal interest in whether services are deemed to be safe or effective. This routine practice standard is exemplified by each of the only three systematic reviews that have been conducted of the safety and efficacy of puberty blockers and cross-sex hormones as treatments for gender dysphoria in children.

12. In 2020, England's National Health Service (NHS) commissioned a major review of the use of puberty blockers and cross-sex hormones in children and young people and appointed prominent pediatrician Dr. Hilary Cass to lead that review, explicating that "Given the increasingly evident polarization among clinical professionals, Dr. Cass was asked to chair the group as a senior clinician with no prior involvement or fixed views in this area." (Cass 2022 at 35, italics added.) Dr. Cass's committee in turn commissioned a series of formal systematic reviews of evidence. The first set (summarized in Section V.C.) were commissioned from the England National Institute for Health & Care Excellence (NICE), a government entity of England's Department of Health and Social Care, established to provide guidance to health care policy, such as by conducting systematic reviews of clinical research, doing so without direct involvement in providing treatment to affected individuals, in this case, gender dysphoric individuals. (https://www.nice.org.uk/.) The second, and more extensive, set of systematic reviews to be commissioned were conducted by the Centre for Reviews and Dissemination of University of York, again independent of any direct involvement in the provision of clinical care for gender dysphoria. (Cass, 2024). The process of The Cass Review received input from a team of advisors, called the "Assurance Group" who were experts in the conduct of such reviews. The review's documentation noted of the Assurance Group that:

Members are independent of NHS England and NHS Improvement and of providers of gender dysphoria services, and of any organisation or association that could reasonably be regarded as having a significant interest in the outcome of the Review. (https://cass.independent-review.uk/about-the-review/assurance-group/).

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The second set of systematic reviews (summarizing in Section V.H.), were much more extensive, yet came to the same conclusion as the first: The existing research is of poor quality, inadequate for justifying the medicalized transition of minors with gender dysphoria.

13. Similarly, the Finnish health care council commissioned its systematic review to an external firm, Summaryx Oy. (Pasternack 2019.) Summaryx Oy is a "social enterprise" (a Finnish organization analogous to a non-profit think-tank) that conducts systematic research reviews and other analyses for supporting that nation's medical and social systems. Its reviews are conducted by assessment professionals, not by clinicians providing services. (www.summaryx.eu/en/.) The systematic review by Sweden's National Board of Health and Welfare (NBHW) included four experts. (SBU Scoping Review 2019.) In addition to their own research fields, they provided clinical services in areas adjacent to but apart from gender dysphoric children, such as physical disorders of sexual development (Dr. Berit Kriström) or gender dysphoria in adults (Dr. Mikael Landén).

14. My own most-cited peer-reviewed paper relating to gender dysphoria in minors illustrates the expertise in the evaluation of scientific evidence that I have and am recognized for. That is, that paper provided not clinical advice or a clinical study, but rather a review and interpretation of the available evidence concerning desistance in children who suffer from gender dysphoria, as well as of evidence (and lack of evidence) concerning the safety and efficacy of medical transition to treat gender dysphoria in minors. (Cantor 2019.)

15. My extensive background in the assessment of sexuality research and in the development of human sexuality places me in exactly the position of objectivity and freedom from conflict-of-interest required by the universal standards of medical research science.

16. I do not offer opinions about the best public policy. Multiple jurisdictions have

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attempted multiple different means of implementing that science into various public policies. Although I accept as an axiom that good public policy must be consistent with the scientific evidence, science cannot objectively assess societal values and priorities. Therefore, my opinions summarize and assess the science on which public policy is based, but I can offer no opinion regarding which public policy mechanisms would be best in light of that science.

II. Multiple international health care systems that had initially expanded medicalized transition to include minors have reversed that policy, as research on safety and effectiveness accumulated, in a growing international trend against the medicalized transition of minors.

17. Medicalized interventions for minors originated in European clinics (most prominently in the Netherlands and Sweden), and these precedents (and in particular the socalled "Dutch Protocol") are frequently cited by American clinicians. However, growing concerns about safety together with the continuing absence of reliable evidence of benefit even after more than 20 years of experience have led respected and far-from "conservative" European health care ministries to step back and discourage or even cease providing medicalized transition of minors, other than in exceptional and carefully limited circumstances, such as within registered and approved research trials. Instead, these authorities now endorse psychotherapy as the treatment of choice for minors, with medical interventions representing a method of last resort, if permitted at all. These range from medical advisories to outright bans on the medical transition of minors. I provide details concerning these policy changes below, and provide additional details regarding the underlying systematic reviews in Sections V and VI below.

A. England

18. The National Health Service (NHS) of England centralized gender counselling and transitioning services into a single clinic, the Gender Identity Development Service (GIDS) of the Tavistock and Portman NHS Foundation Trust. Between 2008 and 2018, the number of referrals to the clinic had increased by a factor of 40, leading to a government inquiry into the causes. (Rayner 2018.) The GIDS was repeatedly accused of approving and endorsing medical transition in minors without adequate justification, including by 35 members of the GIDS own staff, who resigned by 2019. (BBC News 2021; Donnelly 2019). An ex-governor and psychotherapist of the Trust who resigned, Marcus Evans, said staff feared being called

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transphobic, which was impacting their objectivity in their work. (Doward 2019).

19. In 2020, a former patient of the GIDS, Keira Bell, brought a lawsuit alleging that the GIDS practices with respect to prescribing puberty blockers for minors were unproven and potentially harmful in ways that meant that it was impossible for minors to give meaningful informed consent. After taking extensive expert evidence, the trial court concluded that puberty blockers might have "potentially irreversible" and "life-changing" effects on a young person (*Bell v. Tavistock*, [2020] EWHC 3274 (Admin), ¶148, 151), that there was "very limited evidence as to its efficacy" (¶134) such that "it is right to call the treatment experimental" (¶148), and that use of puberty blockers almost always led to use of cross-sex hormones that "may well lead to a loss of fertility" (¶¶ 137–138). While an appeals court later concluded that the trial court had exceeded the proper role of the court in making factual findings on these questions, the appeals court acknowledged that "Medical opinion is far from unanimous about the wisdom of embarking on treatment before adulthood. The question raises not only clinical medical issues but also moral and ethical issues, all of which are the subject of intense professional and public debate." (Bell v. Tavistock 2021 at ¶3.)

20. Perhaps prompted by the Keira Bell litigation, also in 2020 the English National Health Service ("NHS") commissioned the thorough independent review of the use of puberty blockers and cross-sex hormones to be chaired by Dr. Cass that I have described above. After an extensive process that included obtaining the systematic reviews of all published studies bearing on safety or efficacy of these hormonal interventions in minors as well as "extensive" listening sessions with clinicians, patients, and families, in February 2022 Dr. Cass issued an extensive "Interim Report" summarizing the state of the relevant medical science and in particular highlighting the presence of serious but unstudied risks and the lack of strong evidence of

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efficacy. I will quote specific items from Dr. Cass's Review as relevant to specific topics below. At a high level, Dr. Cass concluded that to date there has been "very limited research on the sexual, cognitive, or broader developmental outcomes" from the use of puberty blockers for gender dysphoria (Cass 2022 at 19), that it is an unanswered question "whether the evidence for the use and safety of [puberty blockers] is strong enough as judged by reasonable clinical standards" (at 37), and that "the available evidence was not strong enough to form the basis of a policy position" with regard to use of both puberty blockers and cross-sex hormones in minors (at 35).

21. Following issuance of Dr. Cass's Interim Report, the National Health Service of England (NHS England) published a consultation document concerning a proposed revised service specification under which "NHS England will only commission [puberty blockers] in the context of a formal research protocol." (NHS Interim Service Specification at 12.) NHS England announced its implementation of that policy reiterating that "there is not enough evidence to support their safety or clinical effectiveness as a routinely available treatment" and that it will limit the use puberty-blockers to formal clinical trials. (Ghorayshi 2023; Moss & Parry 2023). Upon the release of the final report of The Cass Review, NHS England confirmed "The clinical approach set out in our published interim service specification remains consistent with the findings and recommendations of [Dr. Cass'] review" and that they will continue implementation of this "new evidence based clinical policy on puberty suppressing hormones (also called puberty blockers) that makes clear access is no longer routinely available as part of the NHS children and young people's gender service." (NHS England, 2024-Apr-10.)

B. Finland

22. In Finland, minors were made eligible for medicalized transition in 2011 by that

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country's health care service, the Council for Choices in Health Care in Finland (COHERE). Assessments of mental health and preparedness were centralized by law into two research clinics, Helsinki University Central Hospital and Tampere University Hospital.

23. In 2019, the Service Selection Council (Palko) of the Finnish Ministry of Social Affairs and Health commissioned a systematic review of the effectiveness and safety of medicalized transition (Pasternack 2019), and in 2020, Finnish researchers published an analysis of the outcomes of adolescents diagnosed with gender dysphoria and receiving cross-sex hormone treatment in Finland's Tampere University Hospital. (Kaltiala 2020.) Despite the purpose of medical transition being to improve mental health, the study showed:

Medical gender reassignment is not enough to improve functioning and relieve psychiatric comorbidities among adolescents with gender dysphoria. Appropriate interventions are warranted for psychiatric comorbidities and problems in adolescent development. (Kaltiala 2020 at 213.)

They concluded that the youth who were functioning well after transition were those who were already functioning well before transition, and those who were functioning poorly before transition continued to function poorly after transition.

24. Importantly, the results of this study exemplify why correlations reported from surveys cannot be interpreted as evidence of causality. Mental health assessment would exclude the most poorly functioning youth from among those permitted to transition, but transition itself did not improve the functioning of those who were permitted to transition.

25. Consistent with the results of the independent evidence review by Summaryx Oy and analysis of the ethical issues involved, Finland's health care service ended the surgical transition of minors, ruling in 2020 that "Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors." (COHERE Summary 2020.) The review of the research concluded that "[N]o conclusions can be drawn on the stability of gender identity

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during the period of disorder caused by a psychiatric illness with symptoms that hamper development." (COHERE Summary 2020.) COHERE also greatly restricted access to pubertyblocking and cross-sex hormonal treatments, explicating that they may be considered for minors "only if it can be ascertained that their identity as the other sex is of a permanent nature and causes severe dysphoria," and only "if the need for it continues *after* [any] other psychiatric symptoms have *ceased* and adolescent development is progressing normally." (COHERE Summary 2020, italics added.) They restricted the procedures to their centralized research clinics. The council was explicit in noting the lack of research needed for decision-making, "There is also a need for more information on the disadvantages of procedures and on people who regret them." (COHERE Summary 2020.) In light of the special developmental and ethical considerations surrounding minors, COHERE recommended that "no decisions should be made that can permanently alter a still-maturing minor's mental and physical development."

C. Sweden

26. Sweden's national health care policy regarding trans issues has developed quite similarly to that of the England. Already in place 20 years ago, Swedish health care policy permitted otherwise eligible minors to receive puberty-blockers beginning at age 14 and cross-sex hormones at age 16. At that time, only small numbers of minors sought medical transition services. An explosion of referrals ensued in 2013–2014. Sweden's Board of Health and Welfare ("Socialstyrelsen") reported that, in 2018, the number of diagnoses of gender dysphoria was 15 times higher than 2008 among girls ages 13–17. (Swedish Socialstyrelsen Support 2022 at 15.)

27. Sweden has long been very accepting with regard to sexual and gender diversity. In2018, a law was proposed to lower the age of eligibility for surgical care from age 18 to 15,

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remove the requirement for parental consent, and lower the legal age for change of gender to age 12. A series of cases of regret and suicide following medical transition were reported in the Swedish media. (Orange 2020.) In 2019, the Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) therefore initiated its own systematic review of the research. The SBU released English-language results first as a summary and then published as a peer reviewed article. (Ludvigsson et al., 2023.) Like England, the Swedish investigation employed standardized review methods to ensure the encapsulation of all the relevant evidence and came to the same conclusions: "This systematic review of almost 10 000 screened abstracts suggests that long-term effects of hormone therapy on psychosocial and somatic health are unknown, except that GnRHa treatment seems to delay bone maturation and gain in bone mineral density." (Ludvigsson 2023 at 12.) They emphasized, "The absence of long-term studies is worrying because many individuals start treatment as minors (<18 years) and CSHT is lifelong." (Ludvigsson 2023 at 10.) Regarding the full set of studies, "No randomised controlled trials were found, but we could identify 24 relevant observational studies. However, these were limited by methodological weaknesses, for instance lack of or inappropriate control group, lack of intra-individual analyses, high attrition rates that precluded conclusion to be drawn." (Ludvigsson 2023 at 9–10.)

28. In 2021, the leading Swedish pediatric gender clinic, at the Karolinska Institute, issued a new policy statement in which it stated that the Swedish evidence review "showed a lack of evidence for both the long-term consequences of the treatments, and the reasons for the large influx of patients in recent years." (Karolinska 2021.) The Karolinska Institute further stated that "These treatments are potentially fraught with extensive and irreversible adverse consequences such as cardiovascular disease, osteoporosis, infertility, increased cancer risk, and

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thrombosis." In a dramatic reversal of its policy, the Institute announced that "In light of the above, and based on the precautionary principle, which should always be applied, it has been decided that hormonal treatments (i.e., puberty blocking and cross-sex hormones) will not be initiated in gender dysphoric patients under the age of 16." Further, the Karolinska clinic announced that patients ages 16–18 would receive such treatments *only* within research settings (clinical trials monitored by the appropriate Swedish research ethics board). (Karolinska 2021.)

In 2022, the Swedish National Board of Health and Welfare published a major new 29. national policy document concerning "Support, investigation and hormone therapy in gender incongruence in children and youth," including an English-language summary. (Swedish Socialstyrelsen Support 2022.) The National Board of Health noted "the continued lack of reliable scientific evidence concerning the efficacy and the safety of both [puberty blockers and cross-sex hormones]," and concluded (based on the commissioned evidence reviews) that "the evidence on treatment efficacy and safety is still insufficient and inconclusive for all reported outcomes. Further, it is not possible to determine how common it is for adolescents who undergo gender-affirming treatment to later change their perception of their gender identity or interrupt an ongoing treatment." As a result, the Board of Health concluded that, "[f]or adolescents with gender incongruence, the . . . risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits." (Swedish Socialstyrelsen Support 2022 at 10-12.) Accordingly, the Swedish Board of Health and Welfare "recommends restraint when it comes to hormone treatment." (Swedish Socialstyrelsen Updated Recommendations 2/22/22.)

D. France

30. While medical authorities in France have not issued any actual restriction, in 2022,

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the Académie Nationale de Médecine of France issued a strongly worded statement, citing the Swedish ban on hormone treatments:

[A] great medical caution must be taken in children and adolescents, given the vulnerability, particularly psychological, of this population and the many undesirable effects, and even serious complications, that some of the available therapies can cause...such as impact on growth, bone fragility, risk of sterility, emotional and intellectual consequences and, for girls, symptoms reminiscent of menopause." (Académie Nationale de Médecine 2022.)

For hormones, the Académie concluded "the greatest reserve is required in their use," and for surgical treatments, "[T]heir irreversible nature must be emphasized." The Académie warned "the risk of over-diagnosis is real, as shown by the increasing number of transgender young adults wishing to 'detransition'." Rather than medical interventions, it advised health care providers "to extend as much as possible the psychological support phase." The Académie reviewed and emphasized the evidence indicating the very large and very sudden increase in youth requesting medical transition. It attributed the change, not to society now being more accepting of sexual diversity, but to social media, "underlining the addictive character of excessive consultation of social networks which is both harmful to the psychological development of young people and responsible, for a very important part, of the growing sense of gender incongruence." (Académie Nationale de Médecine 2022.)

E. Norway

31. In 2022, Norway's Healthcare Investigation Board (Ukom) began a review of that country's guidelines for the medicalized transition of minors. (Block, Norway's Guidance, 2023.) In 2023, it released its report, which concluded that the evidence for the use of puberty blockers and cross-sex hormone treatments in youth was insufficient, and acknowledged the international recognition of the dearth of evidence of safety and effectiveness. The report deemed medicalized transition to be experimental. (Ukom 2023, Summary and Section 11.) The report

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faulted the existing Norwegian guidelines, published in 2020, for concentrating on "equality and rights" while "deviating from the requirements for the development of knowledge-based guidelines." (Ukom 2023, Summary.)

32. The Norwegian report concluded that "The knowledge base, especially researchbased knowledge for gender-affirming treatment (hormonal and surgical), is insufficient and the long-term effects are little known" and that "This applies particularly to the teenage population, which accounts for a large part of the increase in referrals to the specialist health service in the last decade." (Ukom 2023, Summary and Section 7.)

33. In an interview about the report with the *British Medical Journal*, the Ukom Medical Director, Stine Marit Moen, said, "We're concerned that there may be undertreatment, overtreatment, and the wrong treatment" and added:

We've seen a marked increase in referrals to specialised healthcare services in Norway for teenagers, as seen in many other western countries, and nobody knows the reason. The stability of the gender dysphoria of these teenagers is not known, and the evidence of long term effects of gender affirming treatments for this young population is insufficient. (Block, Norway's Guidance, 2023.)

34. Ukom noted that referrals to its national treatment service increased by a factor of eight between 2007 and 2018, and that this increase was largely from young biological females. Seventy-five percent of the referrals to its National Treatment Service had other co-morbid psychiatric diagnoses, including not only depression and anxiety but also autism spectrum disorders, ADHD, and Tourette's Syndrome. (Ukom 2023, Summary and Section 7.)

F. Assertions by U.S. organizations and officials that there is 'no debate' over medicalized transition are false.

35. The international consensus is clearly demonstrated by the multiple recent analyses, statements, and policy decisions from the health care service systems around the world. These include England's National Health Service, which noted the "Scarce and inconclusive evidence

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to support clinical decision making [which] has led to a lack of clinical consensus on what the best model of care for children and young people experiencing gender incongruence and dysphoria should be." (NHS 2022 at 5.)

36. As these several recent national policy reviews, statements, and recommendations make very clear, there is a great deal of doubt and debate among the sophisticated international medical and mental health community as to whether the administration of puberty blockers and cross-sex hormones to children and young people is the best clinical practice, and as to whether these treatments have been shown to be safe and effective. Indeed, the lack of scientifically reliable data concerning safety and efficacy highlighted by the systematic evidence reviews commissioned by the English National Health Service, by the Swedish National Board of Health and Welfare, and by the Finnish Council for Choices in Health Care in Finland have caused those national health authorities and others to move sharply away from approving puberty blockers, cross-sex hormones, or surgery for minors.

37. In this report, I explain the evidence and lack of evidence behind that doubt, that debate, and the emerging international consensus of caution reflected in the several recent European policy statements or changes.

III. Clinical research has a standard Pyramid of Evidence that summarizes the relative strength of potential sources of information.

38. The widely accepted starting point in evidence-based medicine is the recognition that clinical experiences and recollections of individual practitioners (often called "expert opinion" or "clinical anecdote") do not and cannot provide a reliable, scientific basis for treatment decisions. Rather, in evidence-based medicine, clinical decision-making is based on objectively demonstrated evidence of outcomes from the treatment options. An essential first step in evidence-based medicine is identifying the relevant findings from among the immense flood of clinical journal articles published each year. Those studies and the evidence they report are then assessed according to the strength offered by the research methods used in each study. The research methods used in a study determine its reliability and generalizability, meaning the confidence one may have that using the same treatment again will have the same result again on other people. In this section, I explain the well-accepted criteria for evaluating the evidentiary value of clinical studies.

A. Clinical research comprises a standard *Pyramid of Evidence*, wherein studies from higher levels of evidence outrank even more numerous studies from lower levels of research.

39. The accepted hierarchy of reliability for assessing clinical outcomes research is routinely represented as a "Pyramid of Evidence" (Figure 1). Scientific questions are not resolved by the number of studies coming to one versus another conclusion. Studies representing higher levels of evidence outrank studies from lower levels. Even large numbers of lower-level studies cannot overcome a study representing a higher level of evidence. Indeed, because lower-level studies are generally faster and less expensive to conduct, it is typical for them to outnumber higher level studies. This is the property meant to be reflected by the pyramid's shape, which is larger at the base and smaller at the apex.



Figure 1: Pyramid of Standards of Evidence

Source: Cass, H. (2022, February). *The Cass Review: Independent review of gender identity services for children and young people Interim report*. National Health Service (NHS), UK. Available from https://cass.independent-review.uk/publications/interim-report/, citing OpenMD, retrieved from https://openmd.com/guide/levels-of-evidence.

B. The highest level of evidence for safety and effectiveness research is the systematic review of clinical experiments.

40. The most reliable and conclusive method of determining what is actually known or not known with respect to a particular treatment is the *systematic review*. Systematic reviews employ standardized procedures to assess comprehensively all available evidence on an issue, minimizing opportunities for bias in gathering and evaluating research evidence. As described by Dr. Gordon Guyatt, the internationally recognized pioneer in medical research who invented the term *evidence-based medicine*, "A fundamental principle to the hierarchy of evidence [is] that optimal clinical decision making requires systematic summaries of the best available evidence." (Guyatt 2015 at xxvi.)

1. Systematic reviews prevent the 'cherry-picking' of studies that favor a particular result.

41. Because systematic reviews are designed to prevent researchers from including only

the studies they favor and other biases, systematic reviews are the routine starting point for

developing clinical practice guidelines. (Moher 2009.) The methods of a systematic review

include:

- Define the scope, including the "PICO": Population/Patient, Intervention, Comparison/Control, and Outcome(s);
- Select and disclose the keywords used to search the (massive) available clinical research database(s) for potentially relevant articles, identify the databases they were applied to, and the date(s) of the searches, including any subsequent updates;
- Select and disclose the inclusion/exclusion criteria to be used to filter the "hits" from the keyword searches to identify research studies to be included in the detailed review;
- Review abstracts to select the final set of studies, using at least two independent reviewers to allow for measuring inter-rater reliability on the criteria;
- Code each study's results impacting the research question(s), disclosing the list of all studies and the results coded from each;
- Evaluate the reliability of the results [risk of bias] of each included study, applying uniform criteria across them all.
- 42. As detailed in Section V, several systematic reviews have been conducted of the

outcomes of medicalized transition of gender in minors. Their conclusions are highly consistent with each other. Many contrary views, however, depend on levels of evidence far lower on the pyramid of evidence (e.g., "expert opinion") or beneath the pyramid entirely (e.g., survey studies) while ignoring the thorough, high-quality systematic reviews available in the research literature. Doing so is in direct conflict with foundational principles of evidence-based medicine.

2. Systematic reviews prevent biased assessment of individual studies by uniformly applying standard criteria to each study reviewed. The most widely used criteria set is "GRADE."

43. In order to produce unbiased assessment of the studies within the systematic review,

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all the studies must be evaluated using the same evaluation criteria. Without such criteria, assessments can become influenced by researchers who, intentionally or not, hold the evaluative bar higher or lower for studies according to whether the studies' conclusions support or challenge that researcher's perspective. Several such systems have been developed. The most widely used system is the "Grading of Recommendations, Assessment, Development and Evaluations" (GRADE). (Goldet & Howick 2013.) In the GRADE system, studies' findings are downgraded for:

- Risk of bias:¹
 - Lack of clearly randomized allocation sequence,
 - Lack of blinding,
 - Lack of allocation concealment,
 - Failure to adhere to intention-to-treat analysis,
 - Trial is cut short,
 - Large losses to follow-up;
- Inconsistency;
- Indirectness of evidence;
- Imprecision; and
- Publication bias (when studies with 'negative' findings remain unpublished).

Studies' ratings are upgraded if their findings identify:

- A large effect of the treatment;
- A dose-response relationship (the size of the effect has a systematic association with the dose of the treatment given); or
- That all plausible biases only *reduce* the apparent effect of the treatment (necessarily making the estimated effect sizes conservative estimates).
- 44. GRADE assessments yield a four-point score representing the certainty that a

reported treatment effect is true. These certainty scores are (GRADE Handbook, Section 5):

<u>Certainty</u> <u>Meaning</u>

High We are very confident that the true effect lies close to that of the estimate of the effect.

¹ In science, including in the GRADE system, the term "bias" refers to any external influence leading to a systematic over- or underreporting of the outcome being measured. That is, in this context "bias" is not used in the sociopolitical sense of personal values.

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| Moderate | We are moderately confident in the effect estimate: The true effect is likely to |
|----------|--|
| | be close to the estimate of the effect, but there is a possibility that it is |
| | substantially different. |
| Low | Our confidence in the effect estimate is limited: The true effect may be |
| | substantially different from the estimate of the effect. |
| Very Low | We have very little confidence in the effect estimate: The true effect is likely |
| | to be substantially different from the estimate of effect. |

C. The highest level experimental study of clinical safety and effectiveness is the Randomized Controlled Trial (RCT). RCTs can demonstrate that a given treatment causes (rather than only correlates with) a given outcome.

45. Randomized Controlled Trials are the gold standard method of assessing the effects caused by an experimental treatment. The great scientific weight of RCTs follows from the randomization: People do not pick which research group they are in—a treatment group or a control group. Without random group assignment, it is not possible to identify which, if any, changes are due to the treatment itself or to the factors that led to who did and did not receive treatment.

46. Levels of evidence lower than RCTs are unable to distinguish when changes are caused by the experimental treatment, or by factors that can mimic treatment effects, such as 'regression to the mean' and the placebo effect.

47. In the absence of evidence that X causes Y, it is a scientific error to use language indicating there is causal relationship. In the absence of evidence of causality, it is scientifically unsupportable to describe a correlation with terms such as: increases, improves, benefits, elevates, leads to, alters, influences, results in, is effective for, causes, changes, contributes to, yields, impacts, decreases, harms, and depresses. Scientifically valid terms for correlations include: relates to, is associated with, predicts, and varies with.

1. RCTs, but not lower levels of evidence, overcome biases representing 'regression to the mean' and other factors that can mimic clinical improvement.

48. 'Regression to the mean' arises when researching issues, such as mood, depression, or levels of emotional distress that typically fluctuate over time. People are more likely to seek out treatment during low points rather than high points in their emotional lives. Thus, when tracking emotional states over time, the average of a group of people in a treatment group may often show an increase; however, without an untreated control group to which to compare them, researchers cannot know whether the group average would have increased anyway, with only the passage of time.

49. Blinding or masking participants in an RCT from which group they are in has been described as a preferred strategy since the 1950s, in order to exclude the possibility that a person's expectations of change caused any changes observed (the "placebo effect"). In practice, however, it has often made little or no significant difference. For example, a study using very high quality methods—meta-analysis of meta-analysis research—has revealed no statistical difference in the sizes of the effects detected by blinded/placebo-controlled studies from non-blinded/non-placebo-controlled studies of depression. (Moustgaard 2019.) That is, the pre-/post-treatment differences found in placebo groups are not as attributable to participants' expectations of improvement as they are to expectable regression to the mean. (Hengartner 2020.)

2. When a 'no treatment control group' is untenable, RCTs use an 'active comparator' group instead.

50. It is not always possible to compare a group receiving a treatment to a group receiving only an inactive procedure, such as a placebo treatment or no treatment at all. In such situations, the standard, ethical, clinical research method is to compare two active treatments with each other.

51. The systematic reviews from England explicitly called for 'active comparator' studies to test whether medicalized transition of minors shows mental health benefits superior to those obtained from psychotherapy. (NICE 2020a at 40; NICE 2020b at 47.) Risk:benefit analysis cannot justify the greater risks associated with medicalization without evidence of correspondingly greater benefit.

D. Cohort studies are the highest level of evidence about medicalized transition currently available.

52. The highest-level study of medicalized transition of minors conducted thus far are cohort studies: gathering a sample of individuals who chose to undergo treatment and tracking them over time. Cohort studies are able to answer some questions that lower-level studies cannot, such as whether a high-functioning group improved over time versus having been composed of people who were already high-functioning. Cohort studies are, however, unable to demonstrate causality, to identify how much of any change was due to regression to the mean, or to detect any placebo effects.

E. Expert opinion represents the least reliable evidence.

53. As Figure 1 illustrates, in evidence-based medicine, opinion based on clinical experience is identified as the *least* reliable source of medical knowledge. Among other reasons, this is because non-systematic recollections of unstructured clinical experiences with self-selected clientele in an uncontrolled setting is the most subject to bias. Indeed, mere "clinical experience" was long the basis of most medical and mental health clinical decisions, and it was precisely the scientific and clinical inadequacy of this type of "knowledge" that led to the development and widespread acceptance of the importance of evidence-based medicine. As Dr. Guyatt has written, "EBM places the unsystematic observations of individual clinicians lowest on the hierarchy," both because EBM "requires awareness of the best available evidence," and

because "clinicians fall prey to muddled clinical reasoning and to neglect or misunderstanding of research findings." (Guyatt 2015 at 10, 15.)

F. Surveys and cross-sectional studies cannot demonstrate treatment effectiveness.

54. Surveys represent observational research rather than experimental research. (In science, experiments are studies involving a manipulation, not merely observation, by the researcher.) Surveys and cross-sectional studies can provide only correlational data and cannot demonstrate causality. (See Section IV below). It is not possible for a survey to yield evidence that a treatment is effective. No number of surveys can test a treatment, advancing it from 'experimental' to 'established' status.

55. Survey studies do not even appear on the *pyramid of evidence*. In accordance with the routine standards, systematic reviews of treatment studies exclude surveys.

G. Evidence-Based Medicine (EBM) and Evidence-Based Care warn against strong recommendations based on low quality evidence.

56. Within Evidence-Based Medicine model, strong recommendations generally require having strong evidence, weak evidence can support only weak recommendations. The World Health Organization makes this explicit in the *WHO Handbook for Guideline Development*. EBM refers to this issue as "discordance," and Chapter 14 of the WHO Handbook, *Strong recommendations when the evidence is low quality*, includes:

GRADE guidance *warns against discordant recommendations* because when either the benefits or harms of an intervention are uncertain, one cannot be confident that an intervention does more good than harm. Strong recommendations are directives that are meant to be followed by all or almost all guideline users and under all or almost all foreseeable circumstances. [...] Because of this, discordant recommendations may entrench practices whose benefit is uncertain. For instance, a discordant recommendation may lead the users of a WHO guideline to carry out interventions that are detrimental individually or collectively or to waste scarce resources on ineffective interventions. (WHO 2014 at 170–71, emphasis added.) 57. A peer-reviewed article, published in *BMC Medical Research Methodology*, compared quality of evidence with strength of recommendations for all the National Clinical Guidelines (NCGs) of Ireland after 2019, when that country's national health care system adopted the GRADE approach to evidence-based medicine—Chong et al. (2023). Chong et al. first summarized the basic principle behind evidence-based medicine:

1) Strong recommendations confirm confidence that the desirable effects outweigh the undesired consequences and 2) conditional/weak recommendations are made when there is uncertainty regarding potential harms or disadvantages. [...] For the development of trustworthy guidelines there should be concordance between the quality (certainty) of the evidence and the strength of the recommendations. (Chong et al. 2023 at 2.)

58. There can exist exceptions in which EBM will support a discrepant recommendation: These typically pertain to strong recommendations *against* a treatment made on the bases of only weak evidence of harm. Thus, it is not possible to assess treatment recommendations without knowing whether they are recommendations for or against that treatment.

59. As Chong et al. noted: When the evidence of benefit is of low or very low quality, but the evidence of harm is high or moderate, then the recommendation is a strong recommendation *against* the treatment, and when the evidence shows that two treatments have potentially equivalent effectiveness but that one clearly poses less risk (such as with psychotherapy versus medicalized transition), then the recommendation is a strong recommendation *against* the higher risk treatment. (Chong et al. 2023 at 3.)

60. WHO (2014) provides the same instructions:

When guideline development groups are confident that the desirable consequences (benefits) of an intervention outweigh its undesirable consequences (risks or harms), they will likely issue a strong recommendation in favour of the intervention; when they are confident that the opposite is true, they issue a strong recommendation against the intervention. In cases in which the balance between desirable and undesirable consequences is less certain, the guideline development group will issue a conditional recommendation. (WHO 2014 at 169.)
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For example, when there is only low or very low quality evidence of benefit (such as with mental health benefits from medicalized transition), but high or moderate level evidence of harm (such as with the sterilization from cross-sex hormones administered to prepubescent reproductive organs), the proper application of the principles of GRADE as clearly set out in these sources yields a strong recommendation *against* the intervention, not for it.

61. Both Chong et al. (2023) and WHO (2014) do identify five situations which represent exceptions to the concordance principle, in which strong recommendations may be appropriate despite low quality evidence. These give situations are listed below. Notably, four of them are recommendations *against* the treatment:

| Situation | Evidence Quality | | Decommendation |
|---|-------------------------------------|-------------------------------------|---|
| Situation | Benefits | Harms | Recommendation |
| Uncertain benefit, certain harm | Low or very low | High or moderate | Strong recommendation <i>against</i> the more harmful/costly option |
| Potentially equivalent options, one clearly less risky or costly than the other | Low or very low | High or moderate | Strong recommendation <i>against</i> the more harmful/costly option |
| High confidence in benefits being similar, but one option potentially more risky/costly | High or moderate | Low or very low | Strong recommendation <i>against</i> the potentially more harmful/costly option |
| Potential catastrophic harm | Immaterial (very low to high) | Low or very low | Strong recommendation <i>against</i> the more harmful/costly option |
| Life-threatening situation | Low or very low | Immaterial (very low to high) | Strong recommendation in favor of the intervention |

Situations in which a strong recommendation may be indicated despite low quality evidence.

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62. A "life-threatening situation" is one for which it is well documented that death would result in very substantial proportion of the affected individuals. The *WHO Handbook* offers as an example that, because multidrug resistant tuberculosis so often results in death, that it is acceptable to recommend a fluoroquinolone, despite the evidence of its lesser generally effectiveness and greater toxicity than front-line treatment (p. 172). As the science I have reviewed makes very clear, it is not possible to assert that a child or adolescent presenting at gender clinic presents a comparable "life-threatening situation." Nor does any responsible voice (nor even WPATH) assert that the risks posed by administering puberty blockers or cross-sex hormones to minors are "immaterial." In short, the *only* situation in which the principles of evidence-based medicine permit a strong recommendation based on low quality evidence does not apply.

IV. Methodological defects limit or negate the evidentiary value of many studies of treatments for gender dysphoria in minors.

A. In science, to be valid, a claim must be objective, testable, and falsifiable.

63. In behavioral science, people's self-reports do not represent objective evidence. It is when emotional and other pressures are strongest that the distinction between and need for objective over subjective evidence is greatest. Surveys do not represent objective evidence. This is especially true of non-random surveys and polls, recruited through online social networks of the like-minded.

B. Correlation does not imply causation.

64. Studies representing lower levels of evidence are often used because they are faster and less expensive than studies representing higher levels. A disadvantage, however, is that they are often limited to identifying which features are *associated* with which other features, but they cannot show which ones are *causing* which. It is a standard property of statistical science that when a study reports a correlation, there are necessarily three possible explanations. Assuming the correlation actually exists (rather than represents a statistical fluke or bias), it is possible that X causes Y, that Y causes X, or that there is some other variable, Z, that causes both X and Y. (More than one of these can be true at the same time.) To be complete, a research analysis of a correlation must explore all three possibilities.

65. For example, assuming a correlation between treatment of gender dysphoria in minors and mental health actually exists (rather than is a fluke): (1) It is *possible* that treatment causes improvement in mental health. (2) Yet, it is also possible that having good mental health is (part of) what enabled transition to occur in the first place. That is, because of gate-keeping procedures in the clinical studies, those with the poorest mental health are typically not permitted to transition, causing the higher mental health scores to be sorted into the transitioned group.

(See Section IV.E on *Selection Bias*.) (3) It is also possible that a third factor, such as wealth or socioeconomic status, causes both the higher likelihood of transitioning (by being better able to afford it) and the likelihood of mental health (such as by avoiding the stresses of poverty or affording psychotherapy).

66. This principle of scientific evidence is why surveys do not (cannot) represent evidence of treatment effectiveness: Surveys are limited to correlations. (See Section III.F. on *Surveys.*)

C. When two or more treatments are provided at the same time, one cannot know which treatment caused observed changes (i.e., 'confounding').

67. Confounding is a well-known issue in clinical research design. As detailed in the present report, it applies throughout treatment studies of gender dysphoria. Patients who undergo medical transition procedures in research clinics routinely undergo mental health treatment (psychotherapy) at the same time. Without explicit procedures to distinguish them, it cannot be known which treatment produced which outcome (or in what proportions). Indeed, that mental health improvement came from mental health treatment is a more parsimonious (and therefore, scientifically superior) conclusion than is medicalized treatment causing mental health improvement.

D. Extrapolation to dissimilar populations and dissimilar conditions.

68. The purpose of clinical science is to establish from a finite sample of study participants information about the effectiveness and safety, or other variables, of a treatment that can be generalized to other people. Such extrapolation is only scientifically justified with populations matched on all relevant variables. The identification of those variables can itself be a complicated question, but when an experimental sample differs from another group on variables already known to be related, extrapolation cannot be assumed but must be demonstrated directly

and explicitly.

69. Each of the systematic reviews from Sweden, Finland, and England (both Interim and Final) emphasized that the recently observed, greatly increased numbers of youth coming to clinical attention are a population different in important respects from the subjects of often-cited research studies. Conclusions from studies of adult-onset gender dysphoria and from childhood-onset gender dysphoria cannot be assumed to apply to the current patient populations of adolescent-onset gender dysphoria. The Cass Interim Report correctly advised:

It is also important to note that any data that are available do not relate to the current predominant cohort of later-presenting birth-registered female teenagers. This is because the rapid increase in this subgroup only began from around 2014-15. Since young people may not reach a settled gender expression until their mid-20s, it is too early to assess the longer-term outcomes of this group. (Cass 2022 at 36.)

The report also indicated:

[I]t is important that it is not assumed that outcomes for, and side effects in, children treated for precocious puberty will necessarily be the same in children or young people with gender dysphoria. (Cass 2022 at 63.)

70. The Final Report of The Cass Review reiterated these same points, noting "This is a

different cohort from that looked at by earlier studies." (Cass 2024 at 26.) Specifically:

Today's population is different from that for which clinical practice was developed with a higher proportion of birth-registered females presenting in adolescence. They are a heterogenous group with wide-ranging co-occurring conditions, often including complex needs. (Cass 2024 at 97.)

The experiences reported by adults cannot be generalized to minors exactly because "There are

different issues involved in considering gender care for children and young people than for

adults." (Cass 2024 at 26.) Moreover:

This is a heterogenous group, with broad ranging presentations often including complex needs that extend beyond gender-related distress...Too often this cohort are considered a homogenous group for whom there is a single driving cause and an optimum treatment approach, but this is an over-simplification." (Cass 2024 at 27.)

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The final report of the Cass Review refuted that the use of puberty-blockers to treat precocious puberty justifies its use with gender dysphoric children. The report noted that puberty-blockers "have undergone extensive testing for use in precocious puberty" (Cass 2024 at 173), but that:

The situation for the use of puberty blockers in gender dysphoria is different. Although some endocrinologists have suggested that it is possible to extrapolate or generalise safety information from the use of puberty blockers in young children with precocious puberty to use in gender dysphoria, there are problems in this argument. In the former case, puberty blockers are blocking hormones that are abnormally high for, say, a 7-year-old, whereas in the latter they are blocking the normal rise in hormones that should be occurring into teenage years, and which is essential for psychosexual and other developmental processes. (Cass 2024 at 174.)

71. Finland's review repeated the observation of greatly (20 times) increased numbers, an entirely different demographic of cases, and increased proportions of psychiatric co-morbidities. (Finnish Palko Preparation Memo at 4-6.) The Swedish review highlighted "the uncertainty that follows from the yet unexplained increase in the number of care seekers, an increase particularly large among adolescents registered as females at birth." (Swedish Socialstyrelsen Support 2022 at 11.)

72. It is well known that males and females differ dramatically in the incidence of many mental health conditions and in their responses to treatments for mental health conditions. Thus, research from male-to-female transitioners (the predominant population until recent years) cannot be extrapolated to female-to-male transitioners (the predominant population presenting at clinics today). Outcomes from patients who experienced clear pre-pubertal childhood gender dysphoria cannot be extrapolated to patients who first manifest diagnosable gender dysphoria well into puberty. Outcomes from clinics employing rigorous and openly reported gate-keeping procedures cannot be extrapolated to clinics or clinicians employing only minimal or perfunctory assessments without external review. Developmental trajectories and outcomes from before the social media era cannot be assumed to apply to those of the current era or the future. Research

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from youth with formal diagnoses and attending clinics cannot be extrapolated to self-identifying youth and those responding to surveys advertised on social media sites.

73. Further, treatment of gender dysphoria in children and adolescents presents novel-use cases very dissimilar to the contexts in which puberty blockers and cross-sex hormones have previously been studied. Whereas use of puberty blockers to treat precocious puberty *avoids* the medical risks caused by undergoing puberty growth before the body is ready (thus outweighing other risks), use of blockers to treat gender dysphoria in patients already at their natural puberty pushes them *away* from the mean age of the healthy population. Instead of avoiding an objective problem, one is created: Among other things, patients become subject to the issues and risks associated with being late-bloomers, *very* late-bloomers. This transforms the risk:benefit balance, where the offsetting benefit is primarily (however validly) cosmetic.

74. Similarly, administering testosterone to an adult male to treat testosterone deficiency addresses both a different condition and a different population than administration of that same drug to an adolescent female to treat gender dysphoria; the benefits and harms observed in the first case cannot be extrapolated to the second.

E. Mental health assessment used for gate-keeping medicalized transition establishes a *selection bias,* creating a statistical illusion of mental health improvement among the selected.

75. Importantly, clinics are expected to conduct mental health assessments of applicants seeking medicalized transition, disqualifying from medical services patients with poor mental health. (The adequacy of the assessment procedures of specific clinics and clinicians remains under debate, however.) Such gate-keeping—which was also part of the original "Dutch Protocol" studies—can lead to misinterpretation of data unless care is explicitly taken. A side-effect of excluding those with significant mental health issues from medical transition is that

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when a researcher compares the average mental health of the gender dysphoric individuals first presenting to a clinic with the average mental health of those who completed medical transition, then the post-transition group would show better mental health—but only because of the *selection bias*, (Larzelere 2004; Tripepi 2010) even when the transition had no effect at all.

V. Systematic reviews of safety and effectiveness have been conducted by the health care ministries/departments of several governments. They *unanimously* concluded the evidence on medicalized transition in minors to be of poor quality.

A. Understanding safety and efficacy.

76. Activists have asserted that use of puberty blockers and cross-sex hormones on adolescents is "safe." This claim is unsupported by any substantial scientific evidence, depreciates widely recognized risks of serious harm to minors so medicalized, and ignores both the many unknowns and the growing international doubts about their use.

77. At the outset, it is important to understand the meaning of "safety" in the clinical context. The criteria for assessing safety involve two independent components, and discussion of the safety of hormonal interventions on the natural development of children requires consideration of both of them. The term *safety* in the clinical context represents a "risk:benefit ratio," not an absolute statement that can be extrapolated across applications. In clinical research, assessing safety requires simultaneous consideration of both components of the risk:benefit ratio. That is, treatments are not deemed simply "safe" or "unsafe," as activists repeatedly use those words. These dual components are reflected in FDA regulation:

There is reasonable assurance that a device is safe when it can be determined, based upon valid scientific evidence, that *the probable benefits* to health from use of the device for its intended uses and conditions of use, when accompanied by adequate directions and warnings against unsafe use, outweigh *any probable risks*. (Code of Federal Regulations Title 21 Sec. 860.7, italics added.)

78. Thus, for example, as I explain in further detail below, because the Endocrine Society did not undertake (or rely on) any systematic review of the efficacy of hormonal interventions to relieve gender dysphoria in minors (i.e., their benefits), and WPATH did not undertake (or rely on) any systematic review of the safety of hormonal interventions in minors (i.e., their risks), neither gathered the evidence necessary to assess the risk:benefit ratio of medicalized transition

in minors.

79. In fact, as I also review below, after conducting systematic reviews, the English, Finnish, and Swedish national health care institutions all concluded that there is insufficient evidence to determine that hormonal interventions as treatments for gender dysphoria in minors are safe. Reasons for these consistent conclusions include lack of research, insufficient research quality among the existing investigations, and insufficient investigation of long-term safety.

80. To understand the uniform conclusions of these national health care bodies, it is important to understand that—at least where there is *prima facie* reason to be concerned that certain harms may result—when the research has not been done, the absence of evidence cannot be taken as evidence of the absence of such harms. "We don't know" does not permit the conclusion "It is safe." Many activists and advocates in the field of transgender treatment make this error.

B. Sweden (2019)

81. Sweden similarly commissioned a systematic review, published in 2022 and charged with addressing these three questions:

Are there any scientific studies explaining the increase in numbers seeking for gender dysphoria?

Are there any scientific studies on long-term effects of treatment for gender dysphoria?

What scientific papers on diagnosis and treatment of gender dysphoria has been published after the National Board of Health and Welfare in Sweden issued its national support for managing children and adolescents with gender dysphoria in 2015? (SBU Scoping Review Summary 2019.)

The databases searched included CINAHL (EBSCO), Cochrane Library (Wiley), EMBASE

(Embase.com), PsychINFO (EBSCO), PubMed (NLM), Scopus (Elsevier), and SocINDEX

(EBSCO). A total of 8,867 abstracts were identified, from which 315 full text articles were

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assessed for eligibility. The review concluded that "literature on management and long-term effects in children and adolescents is sparse," that no RCTs have been conducted, and that there remains no explanation for the recent and dramatic increases in numbers of minors presenting with gender dysphoria. (SBU Scoping Review Summary 2019.) I have quoted other conclusions from the Swedish systematic review in Section II above.

C. England (2020)

82. England's National Health Service (NHS) conducted a comprehensive, independent review of its services for minors with gender dysphoria spanning four years and included an interim report released in 2022 and a final report released in 2024. (Cass 2022; Cass 2024.) The interim report incorporated two systematic reviews of the research literature, conducted by England's National Institute for Health Care Excellence (NICE) in 2020. (The final report and its systematic reviews are described in its own section of the present report, to follow.) Of the two NICE reviews, one regarded the efficacy, safety, and cost-effectiveness of Gonadotrophin-Releasing Hormone (GnRH) analogs (or "puberty blockers") in minors. (NICE 2020a.) The other regarded the efficacy, safety, and cost-effectiveness, or "gender-affirming hormones," in minors. (NICE 2020b.) (Only efficacy and safety are relevant to the present report.)

83. The puberty-blocker review was tasked with reviewing the research on two relevant questions. For one:

In children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? (NICE 2020a at 4.)

Clinical effectiveness of puberty-blockers was composed of three factors deemed "critical outcomes": impact on gender dysphoria, impact on mental health, and impact on quality of life.

The second question addressed in the review was:

In children and adolescents with gender dysphoria, what is the short-term and longterm safety of GnRH analogues compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? (NICE 2020a at 6.)

Puberty-blocker safety was assessed as its effect on three categories of health: bone density,

cognitive development or functioning, and "other."

84. The second review, for cross-sex hormone treatment, was tasked with the

corresponding questions. For one:

In children and adolescents with gender dysphoria, what is the clinical effectiveness of treatment with gender-affirming hormones compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? (NICE 2020b at 4.)

The critical outcomes were again deemed to be impact on gender dysphoria, on mental health,

and on quality of life. The impact on mental health was composed of indicators of depression,

anxiety, and suicidality and self-injury. The second question was:

In children and adolescents with gender dysphoria, what is the short-term and longterm safety of gender-affirming hormones compared with one or a combination of psychological support, social transitioning to the desired gender or no intervention? (NICE 2020b at 7.)

Cross-sex hormone treatment safety was assessed as its effect on bone density and on "clinical parameters," which included insulin, cholesterol, and blood pressure levels.

85. These two reviews included a systematic consolidation of all the research evidence,

following established procedures for preventing the "cherry-picking" or selective citation

favoring or down-playing any one conclusion, carefully setting out the criteria for including or

excluding specific studies from the review, and providing detailed analyses of each included

study. The whole was made publicly available, consistent with good practice.

86. The reviews' results were unambiguous: For both puberty blockers and cross-sex

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hormones, "The critical outcomes for decision making are the impact on gender dysphoria, mental health and quality of life." The quality of evidence for these outcomes was assessed as "very low" using the established GRADE procedures for assessing clinical research evidence. (NICE 2020a at 4; NICE 2020b at 4.) The reviews also assessed as "very low" the quality of evidence regarding "body image, psychosocial impact, engagement with health care services, impact on extent of satisfaction with surgery and stopping treatment" or (in the case of cross-sex hormones) of "detransition." (NICE 2020a at 5; NICE 2020b at 6.) The review of puberty blockers concluded that of the existing research, "The studies included in this evidence review are all small, uncontrolled observational studies, which are subject to bias and confounding," "They suggest little change with GnRH analogues [puberty blockers] from baseline to followup." (NICE 2020a at 13.) The cross-sex hormone review likewise reported a lengthy list of methodological defects or limitations affecting all available studies. (NICE 2020b at 13-14.)

87. The NHS changed the language on its website describing puberty blockers and cross sex hormones. It removed the statement that "The effects of treatment with GnRH analogues are considered to be fully reversible,"² replacing that text with:³

Little is known about the long-term side effects of hormone or puberty blockers in children with gender dysphoria. . . . [I]t is not known what the psychological effects may be. It's also not known whether hormone blockers affect the development of the teenage brain or children's bones.

88. As mentioned in the McMaster review, the highly respected Cochrane Library, based in England, undertook a systematic review of studies of the safety and efficacy of the administration of cross-sex hormones to natal males. That review focused primarily on adults (age 16 and older). The results, including a detailed explanation of methodology and inclusion

² BBC. Retrieved from https://www.bbc.co.uk/sounds/play/m000kgsj; Kurkup, J. (2020, June 4). *The Spectator*. Available from https://www.spectator.co.uk/article/the-nhs-has-quietly-changed-its-trans-guidance-to-reflect-reality/ ³ NHS. Retrieved from https://www.nhs.uk/conditions/gender-dysphoria/treatment/

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criteria, were published in 2020. Unfortunately, but importantly, the Cochrane review found *zero* studies, globally, that were sufficiently reliable to meet the inclusion criteria even at a "very low" level of evidentiary quality. The authors reported:

Despite more than four decades of ongoing efforts to improve the quality of hormone therapy for women in transition, we found that no RCTs or suitable cohort studies have yet been conducted to investigate the efficacy and safety of hormonal treatment approaches for transgender women in transition....We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches...for transgender women in transition. The evidence is very incomplete, demonstrating a gap between current clinical practice and clinical research. (Haupt 2020 at 10-11.)

The authors' frustration at the total lack of reliable research was evident: "The lack of reliable data on hormone therapy for transitioning transgender women should encourage the development of well-planned RCTs and cohort studies to evaluate widespread empirical practice in the treatment of gender dysphoria." (Haupt 2020 at 10.)

D. Finland (2020)

89. Finland's Ministry of Social Affairs and Health commissioned a systematic review, completed in 2019, of the effectiveness and safety of medicalized transition. (COHERE Recommendation 2020.) The review spanned both minors and adults and included both puberty blockers and cross-sex hormones (Pasternack 2019). Three reviewers tabulated the results. In total, 38 studies were identified, of which two pertained to minors: de Vries (2011) and Costa (2015). The report noted that, because the methodological quality of the studies was already "weak" (no study including any control groups), the assessors declined detailed quality assessment of the existing studies. (Pasternack 2019 at 3.) I have quoted other conclusions from the Finnish systematic review in Section II above.

E. The McMaster University systematic review of systematic reviews (2022).

90. McMaster University is recognized as a center of expertise in the performance of

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methodologically sound systematic reviews. In 2022, authors associated with that McMaster University team (Dr. Romina Brignardello-Petersen and Dr. Wojtek Wiercioch) conducted a systematic review, "Effects of gender affirming therapies in people with gender dysphoria: evaluation of the best available evidence," spanning all the available systematic reviews in this area, including their methodological strength, the evidence they cited, and the conclusions they reached. (Brignardello-Petersen & Wiercioch 2022.) Applying carefully disclosed criteria and methods, they identified on-point systematic reviews, and graded the methodological quality of each on-point review as high, moderate, low, or critically low. With regard to systematic reviews relating to the effects of puberty blockers or cross-sex hormones, the authors included in their analysis all reviews that achieved at least a "low" rating of methodological quality, while excluding those rated as "very low." No systematic reviews earned a "high" methodological rating, except a review performed by the highly respected Cochrane Library of the effects of cross-sex hormones on transitioning natal males (Haupt 2020), but that most careful reviews in turn found no published studies on this topic of sufficient methodological soundness to satisfy its inclusion criteria and thus merit review. After this careful review of the data and analysis contained in available systematic reviews, the McMaster authors concluded:

Due to important limitations in the body of evidence, there is great uncertainty about the effects of puberty blockers, cross-sex hormones, and surgeries in young people with gender dysphoria. This evidence alone is not sufficient to support whether using or not using these treatments. (Brignardello-Petersen & Wiercioch 2022 at 5.)

F. Norway (2023)

91. Norway's investigation of its health care policy for gender dysphoric minors also revealed substantial safety concerns:

There are unsettled questions related to puberty blockers in young people. A published study shows that puberty-inducing hormones cause slower height growth

and a slower increase in bone density. It is also noted that the effects on cognitive development have not been mapped. Unexplained side effects and long-term effects of both puberty blockers (hormone treatment) and gender-affirming hormone treatments are increasingly being questioned. However, experience with other patient groups shows that long-term use of sex hormones can affect disease risk. When people with gender incongruence are treated, it is with significantly longer duration and intensity of hormone treatment than hormone treatments for other conditions. (Ukom 2023.)

G. Non-governmental systematic review re-confirms the absence of reliable evidence supporting medical transition as a safe and beneficial treatment for gender dysphoric adolescents.

92. Thompson et al. (2023) published a new systematic review in the peer-reviewed

journal, *PLoS Global Public Health*, spanning the physical and mental health outcomes of puberty-blocking medications, of cross-sex hormone administration, and of surgery (primarily, double mastectomy) in adolescents between ages 12 and 18. The Thompson review identified 19 relevant research reports from six countries. Of the 19 studies, five reported on the mental health outcomes (benefits to mental health being the goal of the physical transition). The physical health outcomes assessed were bone density, liver enzymes, haemoglobin, glucose metabolism, lipid profile, and blood pressure—such risks to physical health are among the harms which must be weighed against proven benefits to assess treatment risk:benefit ratios.

93. The review employed the widely recognized procedures for reducing bias, including: pre-registration (in the publicly available PROSPERO database of systematic reviews) to prevent "publication bias"; explication of its data extraction methods (employing the PRISMA guidelines), to prevent incomplete assessments of studies; full disclosure of inclusion/exclusion criteria and a listing of all the studies included and all the studies excluded (along with specifying which criteria excluded studies failed to meet), to prevent cherry-picking of studies favoring any one conclusion; and a standard criterion-based assessment of the risk of bias posed

by each study it included.⁴

94. The Thompson et al. (2023) systematic review reiterated the conclusions of the prior

systematic reviews:

The evidence base for the outcomes of gender dysphoria treatment in adolescents is lacking. It is impossible from the included data to draw definitive conclusions regarding the safety of treatment. (at 2.)

It is clear that we simply do not know enough about the observed phenomenon referred to as AOGD [adolescent-onset gender dysphoria], nor do we fully understand the huge increase in numbers of adolescents (and especially NF [natal females]) presenting for GD [gender dysphoria] intervention in recent years, nor the comorbidities and long-term outcomes. (at 42.)

[A]s pointed out in the interim report for the Cass review...good quality evidence is most definitely still lacking. (at 42.)

This review series has highlighted a lack of quality evidence in relation to adolescent GD [*gender dysphoria*] in general: epidemiology, comorbidity, and treatment impact is difficult to robustly assess. Without an improvement in the scientific field, clinicians, parents, and young people are left ill-equipped to make safe and appropriate decisions. (at 43.)

95. Regarding the levels of evidence of the existing research, Thompson et al. noted that

no survey studies were of sufficient quality for inclusion, that the pertinent studies are at the

"cohort study" level of evidence, and that no randomized controlled trials (RCTs) yet exist. As

quoted above, Thompson et al. called for improvement in the science of this question, and

included no indication that RCTs could not be conducted.

H. England (2024) completed the single most comprehensive evaluation of the research on the medicalized transition of minors (The Cass Review, Final Report), unambiguously confirming that the procedures fail meet the

⁴ Although the most widely used instrument for assessing risk of bias is GRADE, Thompson et al. used the Crowe Critical Appraisal Tool (CCAT, version 1.4). The GRADE method focuses on the research methods used in conducting a study, whereas the CCAT method includes several aspects about the article reporting those findings. Thus, GRADE assessments emphasize the reliability of findings, whereas CCAT assessments also reflect the introduction to and discussions of those results from that study's authors.

standards of evidence-based medicine and their implementation to be unjustified.

96. The final report of *The Cass Review* represents one of the largest assessments ever conducted for any medical issue. As noted in the present report, the standard for evidence-based practice begins with a systematic review of research. The Cass Review encompasses a total of *seven* independent systematic reviews, addressing medical transition, non-medical (social) transition, the clinical guidelines and recommendations from professional associations or government health care systems, and the treatment patterns of minors with gender dysphoria. Also examined were the clinics throughout the European Union that provide gender services to minors. Each of these documents underwent peer review, and have been published in the

Archives of Disease in Childhood:

- Hall, R., Taylor, J., Heathcote, C., Langton, T., Hewitt, C. E., & Fraser, L. (2024). Gender services for children and adolescents across the EU-15+ countries: An online survey. *Archives of Disease in Childhood*. doi: 10.1136/archdischild-2023-326348
- Hall, R., Taylor, J., Hewitt, C. E., Heathcote, C., Jarvis, S. W., Langton, T., & Fraser, L. (2024). Impact of social transition in relation to gender for children and adolescents: A systematic review. *Archives of Disease in Childhood*. doi: 10.1136/archdischild-2023-326112
- Heathcote, C., Taylor, J., Hall, R., Jarvis, S. W., Langton, T., Hewitt, C. E., & Fraser, L.(2024). Psychosocial support interventions for children and adolescents experiencing gender dysphoria or incongruence: A systematic review. *Archives* of Disease in Childhood. doi: 10.1136/archdischild-2023-326347
- Taylor, J., Hall, R., Heathcote, C., Hewitt, C. E., Langton, T., & Fraser, L. (2024a).
 Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: A systematic review of guideline quality (part 1). *Archives of Disease in Childhood.* doi: 10.1136/archdischild-2023-326499
- Taylor, J., Hall, R., Heathcote, C., Hewitt, C. E., Langton, T., & Fraser, L. (2024b). Clinical guidelines for children and adolescents experiencing gender dysphoria or incongruence: A systematic review of recommendations (part 2). Archives of Disease in Childhood. doi: 10.1136/archdischild-2023-326500
- Taylor, J., Hall, R., Langton, T., Fraser, L., & Hewitt, C. E. (2024). Care pathways of children and adolescents referred to specialist gender services: A systematic

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review. *Archives of Disease in Childhood.* doi: 10.1136/archdischild-2023-326760

- Taylor, J., Hall, R., Langton, T., Fraser, L., & Hewitt, C. E. (2024). Characteristics of children and adolescents referred to specialist gender services: A systematic review. Archives of Disease in Childhood. doi: 10.1136/archdischild-2023-326681
- Taylor, J., Mitchell, A., Hall, R., Langton, T., Lorna Fraser, & Hewitt, C. E. (2024). Masculinising and feminising hormone interventions for adolescents experiencing gender dysphoria or incongruence: A systematic review. Archives of Disease in Childhood. doi: 10.1136/archdischild-2023-326670
- Taylor, J., Mitchell, A., Hall, R., Heathcote, C., Langton, T., Fraser, L., & Hewitt, C. E. (2024). Interventions to suppress puberty in adolescents experiencing gender dysphoria or incongruence: A systematic review. *Archives of Disease in Childhood.* doi: 10.1136/archdischild-2023-326669

97. The systematic reviews were commissioned from University of York researchers

implementing and following the widely-established methodological standards for conducting and reporting such investigations. These included pre-registration of the project's protocols, the keywords and search methods employed, use of established criteria for assessing the studies identified, and releasing the data tables to ensure transparency. Assessment of studies was based on the Newcastle-Ottawa Scale, which is designed specifically for evaluating observational studies (studies below the RCT level on the *Pyramid of Evidence*). Results were stratified by the studies' design; that is, cohort studies would be compared with cohort studies, etc.

98. The systematic reviews of the effects of puberty-blockers and of cross-sex hormones in minors confirmed the conclusions reached by the prior systematic reviews, demonstrating the evidence of any potential benefits to be of poor quality, inadequate for justifying the risks association with gender transition. The systematic review of puberty blockers found that "[n]o conclusions can be drawn about the effect on gender- related outcomes, psychological and psychosocial health, cognitive development or fertility" and that "bone health and height may be compromised during treatment." (Taylor, Mitchell, Hall, et al. 2024a, p.13.) Likewise, the systematic review of cross-sex hormones found that "[n]o conclusions can be drawn about the

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effect on gender-related outcomes, body satisfaction, psychosocial health, cognitive development or fertility" and that "[u]ncertainty remains about the outcomes for height/growth, cardiometabolic and bone health." (Taylor, Mitchell, Hall, et al. 2024b, p.7.)

99. The systematic reviews also assessed the quality of a total of 23 publications providing clinical guidelines and clinical recommendations. The set of guidelines identified and assessed included those from WPATH (both the current and the prior versions), the Endocrine Society (both the current and the prior versions), and the American Academy of Pediatrics. The appraisal applied a validated and widely accepted assessment method (called AGREE-II), which confirmed their lacking an evidence-based approach. The evaluation revealed widespread failure to adhere to evidence-based methods for establishing clinical guidelines, including the lack of systematic reviews of research and failing to report how guidelines were developed and how experts were selected for writing the guidelines. As summarized by the review of guideline quality:

The findings from this review, therefore, raise questions about the credibility of currently available guidance, despite the majority being published in the last 5 years. Most guidelines have not followed international standards for guideline development set out by the AGREE2 initiative, and/or provide insufficient information about their development. Because of this, the review team only recommended two guidelines for practice—the Finnish guideline published in 2020 and the Swedish guideline published in 2022. (Taylor, Hall, Heathcote, et al., 2024a, p. 6).

100. None of the guidelines from WPATH, the Endocrine Society, or American Academy of Pediatrics were recommended for practice. The two guideline documents that were recommended (from Finland and from Sweden) provided "the recommendation for a more cautious approach to treatment" (p. 6) and were the "only guidelines to publish details of how developers reviewed and utilised the evidence-base and the decision-making behind their recommendations" (p. 6). As summarized by the review of the clinical recommendations:

Published guidance recommends a care pathway for children and adolescents experiencing gender dysphoria/incongruence for which there is limited evidence about benefits and risks, and long-term effects. Divergence of recommendations in recent guidelines suggest there is no current consensus about the purpose and process of assessment, or about when psychosocial care or hormonal interventions should be offered and on what basis. (Taylor, Hall, Heathcote, et al., 2024b, p. 8).

101. Importantly, the reviews also identified a lack of independence across the guidelines, with recommendations being adopted from or based on those from WPATH (version 7) and Endocrine Society rather than on any review of the evidence of their own. WPATH's recently released guideline (version 8) then "cites the APA, Australian, New Zealand, and University California, San Francisco guidelines multiple times to support recommendations, all of which were themselves influenced considerably by WPATH V.7." (Taylor, Hall, Heathcote, et al., 2024a, p. 6). That is, rather than being based on the research evidence, the WPATH guidelines are based on itself. As already noted in the present report, the person who led the development of WPATH version 8 "was appointed by the WPATH board to maintain a continuity from previous SOC editions." (SOC-8 at S248).

VI. The Endocrine Society, WPATH, and the American Academy of Pediatrics did not conduct systematic reviews of safety and efficacy in establishing clinical guidelines, despite systematic reviews being the foundation and gold standard of evidence-based care.

102. I have also examined the reviews conducted by the U.S.-based professional associations that have published standards and guidelines for the treatment of gender dysphoric youth. As detailed herein, and unlike the European reviews, none of the U.S.-based professional associations conducted a systematic review of both effectiveness and safety, without which they are unable to assess the risk:benefit ratio posed by medicalized transition of minors.

A. The Endocrine Society reviewed cross-sex hormones, but not puberty blockers. They reviewed safety, but did not review effectiveness research.

103. The Endocrine Society appointed a task force which commissioned two systematic reviews as part of updating their 2009 recommendations. (Hembree 2017.) The scopes of the two reviews were limited to physiological effects of cross-sex hormones, narrowly defined: "The first one aimed to summarize the available evidence on the effect of sex steroid use in transgender individuals on lipids and cardiovascular outcomes....The second review summarized the available evidence regarding the effect of sex steroids on bone health in transgender individuals." (Hembree 2017 at 3873.) As described in the Endocrine Society Guidelines, those reviews did not, however, include the effectiveness of any treatment on mental health (quality of life, suicidality, rates of detransition, cosmetic or functional outcomes, or improvements in feelings of gender dysphoria). What appears to be the referenced review of lipids and cardiovascular outcomes (Maraka 2017) did not identify any study of adolescents, noting "literature addressing this clinical question in the pediatric/adolescent population is completely lacking." (Maraka at 3921.) What appears to be the referenced review of bone health (Singh-Ospina 2017) identified only one small study on adolescents, involving 15 male-to-female and 19 female-to-male cases.

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(Klink 2015.) Notably, the median duration of puberty-blocker administration was 1.2 years, leaving unknown the effects on children receiving blockers from puberty onset (usually age 9–10) to age 14 or 16.

104. Further, the Endocrine Society does not claim to have conducted or consulted any systematic review of the efficacy of puberty blockers or cross-sex hormones to reduce gender dysphoria or increase mental health or well-being by any metric. Nor does it claim to have conducted or consulted any systematic review of safety of any of these treatments for minors with respect to brain development, future fertility, actual reversibility, or any other factor of safety or adverse event other than cardiovascular disease and bone strength.

105. For all these reasons, I concur with the opinion of Dr. Guyatt, who has said that he finds "serious problems" with the Endocrine Society guidelines, among other reasons because the only systematic reviews those guidelines refer to did not look at the efficacy of the recommended hormonal interventions to improve gender dysphoria, which he termed "the most important outcome." (Block, Gender Dysphoria 2023 at 4.)

106. The current Endocrine Society guidelines, released in 2017, include this disclaimer:

The Endocrine Society makes no warranty, express or implied, regarding the guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein. (Hembree 2017 at 3895.)

The previous, 2009, version included no disclaimers. (Hembree 2009.)

B. WPATH reviewed effectiveness, but not the safety of medicalized transition of minors.

107. WPATH engaged in a multi-step process in updating its Standards of Care from version 7 to version 8. That process included commissioning a systematic review, which was published as Baker, *et al.* (2021) which included the disclaimer "The authors are responsible for

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its content. Statements in this report do not necessarily reflect the official views of or imply endorsement by WPATH." (Baker 2021 at 14.)

108. The literature search was completed in June 2020, and spanned 13 questions. Two questions related to the effectiveness of medicalized transition of minors: Question #10 was "[W]hat are the effects of suppressing puberty with GnRH agonists on quality of life?", and question #11 was "[W]hat are the psychological effects (including quality of life) associated with hormone therapy?" (Sharma 2018; Baker 2021.) That is, the review included studies of the effectiveness of puberty blockers and cross-sex hormones, but, remarkably, did not include any effort to determine the *safety* of either.

109. Baker (2021) identified that among all experimental evidence published on medicalized transition, a total of "Three studies focused on adolescents." (Baker 2021 at 1.) These were Achille, *et al.* (2020), López de Lara, *et al.* (2020), and de Vries, *et al.* (2011, 2014). (Baker 2021 considered the two de Vries articles as a single study, because the later one included the subset of patients from the earlier one who continued in treatment. I will refer to this set as four studies, however, to be consistent with the other reviews.) Notably, in contrast with WPATH's review, the Swedish review entirely excluded Achille *et al.* (2020), López de Lara *et al.* (2020), and de Vries *et al.* (2011) due to their high risks of bias. (SBU Scoping Review Appendix 2.) The Baker team did not use the GRADE system for assessing the quality of evidence, instead using the Methods Guide for Conducting Comparative Effectiveness Reviews.

110. The Baker team noted "no study reported separate results by gender identity for transgender youth." (Baker 2021 at 3.) They also found that "No study reported on hormone therapy among nonbinary people." (at 3.) (Despite this finding, WPATH SOC-8 now includes recommendations for people who identify as nonbinary.)

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111. My assessment of the Baker review revealed that there were substantial discrepancies and misleading ambiguities in their reporting: Baker, *et al.* indicated in the abstract that "Hormone therapy was associated with increased QOL [quality of life], decreased depression, and decreased anxiety" (Baker 2021 at 1,) and that "Associations were similar across gender identity and age" (Baker 2021 at 12). This is not what its actual data tables showed, however. Table 2 presented the only study of QOL specifically among adolescents included in the review and indicated that "Mean QOL scores did *not* change." (Baker 2021 at 7, italics added.)

112. The review, however, did not rate the quality of the studies of adolescents on their own, instead combining them with the studies of adults. (at 10, italics added.) Table 4 of that study presented three analyses of anxiety: One showed a decrease, and on the other two, "Mean anxiety score did *not* change." (at 11, italics added.) Finally, the review also concluded, "It was impossible to draw conclusions about the effects of hormone therapy on death by suicide." (at 12.) Even for the combined set, the review read the strength of evidence to be "low" for each of QOL, depression, and anxiety, and to be "insufficient" for death by suicide. (Baker 2021 at 13, Table 6.) Specifically, the review indicated, "There is insufficient evidence to draw a conclusion about the effect of hormone therapy on death by suicide among transgender people." (at 13, Table 6.) Overall, "The strength of evidence for these conclusions is low due to methodological limitations." (at 12.) Of particular concern was that "Uncontrolled confounding was a major limitation in this literature." (at 12.)

113. Additionally, although WPATH commissioned the Baker review, WPATH did not follow its results. Baker 2021 indicated the use of two systematic quality assessment methods, called RoB 2 and ROBINS-I (Baker 2021 at 3); however, WPATH modified the conclusions that that process yielded. WPATH SOC-8 states, "This evidence is not only based on the published

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literature (direct as well as background evidence) but also on consensus-based expert opinion." (Coleman 2022 at S8.) Moreover:

Recommendations in the SOC-8 are based on available evidence supporting interventions, a discussion of risks and harms, as well as feasibility and acceptability within different contexts and country settings. Consensus on the final recommendations was attained using the Delphi process that included all members of the guidelines committee and required that recommendation statements were approved by at least 75% of members. (Coleman 2022 at S8.)

114. By allowing "consensus-based expert opinion" to modify or overrule conclusions supported by systematic reviews that apply accepted criteria of evidentiary strength, WPATH has explicitly abandoned evidence-based medicine. As indicated already by the Pyramid of Evidence, "expert opinion" represents the *lowest* level of evidence in science, whereas systematic review, the highest. (Also, it is unclear what the authors mean by "background evidence.") To modify systematic results according to committee opinion is to re-introduce the very biases that the systematic process is meant to overcome. The WPATH document attempts to claim the authority of a systematic review, while reserving the ability to "overrule" results that WPATH members did not like.

115. As to evidence supporting hormonal interventions in minors, WPATH asserted that "a systematic review regarding outcomes of [hormonal] treatment in adolescents is not possible" due to the lack of "outcome studies that follow youth into adulthood." (Coleman 2022 at S46.) WPATH is correct that essential outcome studies have not been done, but incorrect that this authorizes issuance of guidelines or standards in the absence of a systematic review. As Dr. Guyatt has stated, "systematic reviews are always possible"—and indeed an important conclusion from such a review may be (as here) that insufficient evidence exists to support any evidence-based guideline. As Dr. Guyatt further elaborated, if an organization issues recommendations without performing an on-point systematic review, "they'd be violating

standards of trustworthy guidelines." (Block, Dysphoria Rising, 2023 at 3.)

116. Finally, the WPATH SOC-8 were revised immediately after their release, removing all age minimums to all recommendations. None of these studies and none of these reviews support such a change, and WPATH cites no studies or other document in support of the change.

117. In sum, the WPATH SOC8 cannot be called evidence-based guidelines under any accepted meaning of that term.

C. The American Academy of Pediatrics did not conduct a systematic review either of safety or effectiveness.

118. While the AAP policy statement is often referenced, the AAP did not report conducting any systematic review of any aspect of transgender care in producing its policy statement on gender-diverse children and adolescents. (Rafferty 2018.) Further, the AAP policy statement on its face is the work of a single author rather than of any committee or the membership more broadly (Dr. Rafferty "conceptualized," "drafted," "reviewed," "revised," and "approved" the statement), and the statement explicitly states that it does not "indicate an exclusive course of treatment" nor "serve as a standard of medical care." (Rafferty 2018 at 1.)

VII. Definitions of sex, gender identity, and gender dysphoria.

A. Sex and sex-assigned-at-birth represent objective features.

119. Sex is an *objective* feature: It can be ascertained regardless of any declaration by a person, such as by chromosomal analysis or visual inspection. Gender identity, however, is *subjective:* There exists no means of either falsifying or verifying people's declarations of their gender identities. In science, it is the objective factors—and only the objective factors—that matter to a valid definition. Objectively, sex can be ascertained, not only in humans or only in the modern age, but throughout the animal kingdom and throughout its long history in natural evolution.

120. I use the term "sex" in this report with this objective meaning, which is consistent with definitions articulated by multiple medical organizations:

Endocrine Society (Bhargava 2021 at 220.)

"Sex is dichotomous, with sex determination in the fertilized zygote stemming from unequal expression of sex chromosomal genes."

American Academy of Pediatrics (Rafferty 2018 at 2 Table 1.):

"An assignment that is made at birth, usually male or female, typically on the basis of external genital anatomy but sometimes on the basis of internal gonads, chromosomes, or hormone levels."

American Psychological Association (APA Answers 2014): "Sex is assigned at birth, refers to one's biological status as either male or female, and is associated primarily with physical attributes such as chromosomes, hormone prevalence, and external and internal anatomy."

American Psychological Association (APA Resolution 2021 at 1): "While gender refers to the trait characteristics and behaviors culturally associated with one's sex assigned at birth, in some cases, gender may be distinct from the physical markers of biological sex (e.g., genitals, chromosomes)."

American Psychiatric Association (Am. Psychiatric Ass'n Guide): "Sex is often described as a biological construct defined on an anatomical, hormonal, or genetic basis. In the U.S., individuals are assigned a sex at birth based on external genitalia."

121. The phrases "assigned male at birth" and "assigned female at birth" are increasingly

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popular, but they lack any scientific merit. Science is the systematic study of natural phenomena, and nothing objective changes upon humans' labelling or re-labelling it. That is, the objective sex of a newborn was the same on the day before as the day after the birth. Indeed, the sex of a fetus is typically known by sonogram or amniocentesis many months before birth. The use of the term "assign" insinuates that the label is arbitrary and that it was possible to have been assigned a different label that is equally objective and verifiable, which is untrue. Infants were born male or female before humans invented language at all. Indeed, it is exactly because an expected child's sex is known before birth that there can exist the increasingly popular "gender reveal" events. Biologically, the sex of an individual (for humans and almost all animal species) as male or female is irrevocably determined at the moment it is conceived. Terms such as "assign" obfuscate rather than clarify the objective evidence.

B. Gender identity refers to subjective feelings that cannot be defined, measured, or verified by science.

122. It is increasingly popular to define gender identity as a person's "inner sense," however, neither "inner sense" nor any similar phrase is scientifically meaningful. In science, a valid construct must be both objectively measurable and falsifiable with objective testing. The concept of an "inner sense" fits none of these requirements.

VIII. Gender Dysphoria is a mental health diagnosis.

A. Gender Dysphoria cannot be diagnosed by any physical feature.

123. Gender Dysphoria is a mental health condition identified by diagnostic criteria set out in the *Diagnostic and Statistical Manual of Mental Disorders* ("DSM") 5-TR. (American Psychiatric Ass'n 2022.) While the criteria contain multiple components and vary modestly for children, adolescents, and adults, all cases are characterized by a strong and lasting desire to be the opposite sex, and "clinically significant" distress of sufficient severity to impair the individuals' ability to function in their daily life setting. Gender dysphoria is nowhere defined as a medical (as opposed to mental health) diagnosis, and it is not characterized by any disability or impairment or ill health affecting any part of the physical body.

B. Social transition is not associated with improvement in mental health.

124. Before 2023, all studies of the social transition of minors were highly limited, due to their being based on subjective descriptions—either the self-reports of the socially transitioning youth or reports from their parents. (Section VII.B.). Often, these studies relied not merely on self-reports, but on self-reported retrospective memory—that is, subjects' recollections of how they felt at prior times. Those studies yielded contradictory results: Some reported social transition to be associated with improved mental health and well-being (e.g., Kuvalanka et al. 2017; Olson et al. 2016), and others reported a lack of improvement (e.g., Sievert et al. 2021; Wong et al. 2019).

125. In 2023, the first study of the mental health impact of social transition based on objective and contemporaneous assessments conducted by professionals was published in the peer-reviewed literature: Morandini et al. (2023) is a study by a team of co-authors including one from the gender dysphoria clinic at Vrije University, Amsterdam (a widely recognized source of

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the most-cited literature in *support* of medical transition of minors). The authors examined "whether children and adolescents diagnosed with gender dysphoria who socially transitioned showed fewer psychological difficulties than those (also with gender dysphoria) who were still living in their birth-assigned gender." (Morandini et al. 2023 at 1052.)

126. The study improved on prior studies in multiple aspects, including the use of objective and comprehensive mental health assessments conducted by professional clinicians instead of only subjective self-reports; having a larger sample for analysis; conducting separate analyses for: i) the prepubescent versus adolescent age youth, ii) the male-to-female versus female-to-male transitioners, and iii) living status (biological sex or adopted gender) versus the names used (birth name versus new name). Ultimately, the analyses identified no significant differences in any of the mental health indicators (mood disorders, anxiety disorders, or suicide attempts).⁵

127. The researchers concluded that, for children and adolescents diagnosed with gender dysphoria:

Overall, there were no significant effects of social transition or name change on mental health status. (Abstract.)

Living in role and birth-assigned gender were not associated with mood, anxiety, or suicide attempts. (at 1052.)

The present findings, although preliminary, suggest that social gender transition is not associated with mental health status in children and adolescents, at least in the short term. These findings are consistent with the only other study that directly compared clinic-referred youth experiencing gender dysphoria who had socially transitioned with those who had not. (at 1058.)

128. In reporting their results, the researchers also warned against over-interpreting or

⁵ The study noted a single potential exception among the 12 analyses conducted, suggesting the possibility that, among the male-to-female transitioners, when social transition was defined as living status, the frequency of mood disorders might have been lower. Subsequent analysis, however, suggested that to be a statistically spurious finding, "as more sensitive analyses that treated age as a continuous rather than as a categorical variable, failed to support that finding." (Morandini et al. 2023 at 1053.)

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over-simplifying their findings. Although their study represents an improvement on prior studies analyzing social transition, I agree with these researchers' reminder that cross-sectional evidence such as theirs can be superseded in the future by studies using still superior methods, such as randomized, controlled trials (RCTs), as explained herein. (Section III.C.)

129. The University of York systematic reviews confirm the dearth of evidence on the effects of social transition. The systematic review focussing on that issue noted that "there are no prospective longitudinal studies with appropriate comparator groups which have assessed the impact of social transition on the mental health or gender- related outcomes for children or adolescents." (Hall, Taylor, Hewitt, et al. 2024, p.6.) It went on to criticize WPATH SOC8's recommendation in favor of early social transition as "not supported from the findings of this systematic review." (p.6.) Thus, the review concluded that "we have little evidence of the benefits or harms of social transition for children and adolescents." (p.6.)

IX. Distinct mental health phenomena must not be—but frequently are confused or conflated.

130. One of the most widespread public misunderstandings about people expressing gender dysphoria is that all such cases represent the same phenomenon; however, the clinical science has long and consistently demonstrated that prepubescent children expressing gender dysphoria represent a phenomenon distinct from that of adults starting to experience it. That is, gender dysphoric children are not simply younger versions of gender dysphoric adults. They differ in virtually every objective variable measured, including in their responses to treatments. A third presentation has recently become increasingly observed among people presenting to gender clinics: these cases appear to have an onset in adolescence—after the onset of puberty and before adulthood—and occur in the absence of any childhood history of gender dysphoria. Such cases have been called adolescent-onset or "rapid-onset" gender dysphoria (ROGD). Despite having only recently been observed, they have quickly and greatly outnumbered the better characterized types. Moreover, large numbers of adolescents are today self-identifying in surveys as "gender fluid" and "non-binary." These are not recognized mental health diagnoses, and do not relate in any known way to gender dysphoric groups that have been the subject of previous treatment outcome studies. Because each of these phenomena differ in multiple objective features, it is scientifically invalid to extrapolate findings from one type to the others.

A. Adult-Onset Gender Dysphoria consists predominantly of males sexually attracted to females.

131. Whereas Childhood-Onset Gender Dysphoria occurs in biological males and females and is strongly associated with later homosexuality (next section), Adult-Onset Gender Dysphoria consists primarily of biological males sexually attracted to females. (Lawrence 2010.) They typically report being sexually attracted to women and rarely showed gender atypical

(effeminate) behavior or interests in childhood (or adulthood). Some individuals express being sexually attracted to both men and women, and some profess asexuality, but very few indicate having a primary sexual interest only in men. (Blanchard 1998.) Cases of adult-onset gender dysphoria are typically associated with a sexual interest pattern involving themselves in female form (a paraphilia called autogynephilia). (Blanchard 1989a, 1989b, 1991.)

132. Because of the numerous objective differences between adult-, childhood-, and adolescent-onset gender dysphoria, it is not possible to extrapolate from these results to juvenile populations, which responsible authors are careful not to do.

B. Childhood-onset gender dysphoria (prepubertal-onset) is a distinct phenomenon characterized by high rates of desistance in the absence of social or medical transition.

133. For many decades, small numbers of prepubescent children have been brought to mental health professionals for help with their unhappiness with their sex and in the belief they would be happier living as the other sex. The large majority of childhood onset cases of gender dysphoria occur in biological males, with clinics reporting 2–6 biological male children to each female. (Cohen-Kettenis 2003; Steensma Evidence 2018; Wood 2013.)

1. Eleven cohort studies followed children not permitted social transition, all showing the majority to desist feeling gender dysphoric upon follow-up after puberty.

134. Currently, the studies of outcomes among children who experience gender dysphoria before puberty that provide the most evidentiary strength available are only "cohort studies," which follow people over time, recording the outcomes of the treatments they have undergone. Such studies supersede (i.e., overrule) the outcomes of surveys, which are much more prone to substantial error. As I have explained above, however, cohort studies can describe developmental pathways, but cannot provide evidence of causation.

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135. In total, there have been 11 cohort studies showing the outcomes for these children, listed in Table 2. I first published this comprehensive list of studies in my own peer-reviewed article on the topic. (Cantor 2019.)

| Count | Group | Study |
|------------------------------|--|---|
| 2/16 4/16 10/16 | gay trans-/crossdress straight/uncertain | Lebovitz, P. S. (1972). Feminine behavior in boys: Aspects of its outcome. <i>American Journal of Psychiatry</i> , <i>128</i> , 1283–1289. |
| 2/16 2/16 12/16 | trans- uncertain gay | Zuger, B. (1978). Effeminate behavior present in boys from childhood: Ten additional years of follow-up. <i>Comprehensive Psychiatry</i> , <i>19</i> , 363–369. |
| 0/9 9/9 | trans- gay | Money, J., & Russo, A. J. (1979). Homosexual outcome of discordant gender identity/role: Longitudinal follow-up. <i>Journal of Pediatric Psychology</i> , <i>4</i> , 29–41. |
| 2/45 10/45 33/45 | trans-/crossdress uncertain gay | Zuger, B. (1984). Early effeminate behavior in boys: Outcome and significance for homosexuality. <i>Journal of Nervous and</i> <i>Mental Disease</i> , 172, 90–97. |
| 1/10 2/10 3/10 4/10 | trans- gay uncertain straight | Davenport, C. W. (1986). A follow-up study of 10 feminine boys. <i>Archives of Sexual Behavior</i> , <i>15</i> , 511–517. |
| 1/44 43/44 | trans- cis- | Green, R. (1987). The "sissy boy syndrome" and the devel- opment of homosexuality. New Haven, CT: Yale University Press. |
| 0/8 8/8 | trans- cis- | Kosky, R. J. (1987). Gender-disordered children: Does inpatient treatment help? <i>Medical Journal of Australia, 146,</i> 565–569. |
| 21/54 33/54 | trans- cis- | Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. <i>Journal of the American Academy of Child and Adolescent Psychiatry</i> , <i>47</i> , 1413–1423. |
| 3/25 6/25 16/25 | trans- lesbian/bi- straight | Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J. (2008). A follow-up study of girls with gender identity disorder. <i>Developmental Psychology</i> , <i>44</i> , 34–45. |
| 47/127 80/127 | trans- cis- | Steensma, T. D., McGuire, J. K., Kreukels, B. P. C., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: A quantitative follow-up study. <i>Journal of the American Academy of Child and Adolescent Psychiatry</i> , <i>52</i> , 582–590. |
| 17/139 122/139 | trans- cis- | Singh, D., Bradley, S. J., Zucker, K. J. (2021). A follow-up study of boys with Gender Identity Disorder. <i>Frontiers in Psychiatry</i> , 12:632784. |

Table 2. Cohort studies of gender dysphoric, prepubescent children.

*For brevity, the list uses "gay" for "gay and cis-", "straight" for "straight and cis-", etc.
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136. The children in these studies were receiving professional mental health support during the study period, but did not "socially transition." In sum, despite coming from a variety of countries, conducted by a variety of labs, using a variety of methods, at various times across four decades, every study without exception has come to the identical conclusion: among prepubescent children who feel gender dysphoric, the majority cease to want to be the other gender over the course of puberty—ranging from 61–88% desistance across the large, prospective studies. Such cases are often referred to as "desisters," whereas children who continue to feel gender dysphoric are often called "persisters."

137. This interpretation of these studies is widely accepted, including by the Endocrine Society, which concluded:

In most children diagnosed with GD/gender incongruence, it did not persist into adolescence. . . . [T]he large majority (about 85%) of prepubertal children with a childhood diagnosis did not remain GD/gender incongruent in adolescence. (Hembree 2017 at 3879.)

The developers of the Dutch Protocol, at the Vrije University gender clinic, likewise concluded based on these studies that "Although the persistence rates differed between the various studies...the results unequivocally showed that the gender dysphoria remitted after puberty in the vast majority of children." (Steensma & Cohen-Kettenis 2011 at 2.)

138. The consistent observation of high rates of desistance among pre-pubertal children who present with gender dysphoria demonstrates a pivotally important—yet often overlooked feature: because gender dysphoria so often desists on its own, clinical researchers cannot assume that therapeutic intervention cannot facilitate or speed desistance for at least some patients. That is, it cannot be assumed that gender identity is immune to influence such as from psychotherapy. Such is an empirical question, and there has not yet been any such research.

139. These same studies are often vaguely cited to assert that the high desistance rates

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uniformly reported in these 11 studies do not apply to children who have persisted until "the start of puberty" (which is taken to mean Tanner Stage 2), or in an alternative phrasing, that children "who persist until the start of puberty" are likely to continue to persist into adulthood. But these studies taken together do not support that degree of precision. Rather, the studies do not specify at exactly what developmental stage the reported desistance occurred—what they report is that the subjects had desisted by late adolescence or early adulthood. I am aware of no systematic study that establishes that—in the absence of social and/or medical transition—children who experience gender dysphoria are unlikely to desist if they have not desisted by the start of Tanner Stage 2.

2. One cohort study followed children who were permitted social transition. In contrast with children not permitted to transition socially, most persisted in expressing gender dysphoria.

140. In contrast, Olson et al. have now published a single cohort study of prepubescent children, ages 3–12 (average of 8), who had already made a complete, binary (rather than intermediate) social transition, including a change of pronouns. (Olson 2022.) The study did not employ DSM-5 diagnosis, as "Many parents in this study did not believe that such diagnoses were either ethical or useful and some children did not experience the required distress criterion." (Olson 2022.) Unlike the prior research studies, only 7.3% of these (socially transitioned) children ceased to feel gender dysphoric.

141. Although the team publishing this cohort study did not discuss it, their finding matches the prediction of other researchers, that social transition itself represents an active intervention, such that social transition may *cause* the persistence of gender dysphoria when it would have otherwise resolved, avoiding any need for subsequent medicalization and its attendant risks. Conversely stated, social transition seems to prevent desistance. (Singh 2021;

Zucker 2018, 2020.)

142. As recognized by multiple authors, the potential impact of social transition on rates of desistance is pivotal. The Endocrine Society cautions that "social transition...has been found to contribute to the likelihood of persistence." (Hembree 2017 at 3879.) WPATH has stated that after social transition, "A change back to the original gender role can be highly distressing and [social transition can] even result in postponement of this second transition on the child's part." (Coleman 2012 at 176.) In 2013, prominent Vrije University researchers observed:

Childhood social transitions were important predictors of persistence, especially among natal boys. Social transitions were associated with more intense GD in childhood, but have never been independently studied regarding the possible impact of the social transition itself on cognitive representation of gender identity or persistence. [Social transition] may, with the hypothesized link between social transitioning and the cognitive representation of the self, influence the future rates of persistence. (Steensma 2013 at 588-589.)

3. There is no reliable method for predicting for which children who present with gender dysphoria will persist versus desist.

143. The Endocrine Society Guidelines stated in 2017 that "With current knowledge, we cannot predict the psychosexual outcome for any specific child" (Hembree 2017 at 3876), and this remains true today. Research has not yet identified any reliable procedure for discerning which children who present with gender dysphoria will persist, as against the large majority who will desist, absent transition and "affirmation." Such a method would be valuable, as the more accurately that potential persisters can be distinguished from desisters, the better the risks and benefits of options can be weighted. Such "risk prediction" and "test construction" are standard components of applied statistics in the behavioral sciences. Multiple research teams have reported that, on average, groups of persisters are somewhat more gender non-conforming than desisters, but not so different as to usefully predict the course of any particular child. (Singh 2021; Steensma 2013.)

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In contrast, one research team (the aforementioned Olson group) claimed the 144. opposite, asserting that they developed a method of distinguishing persisters from desisters, using a single composite score representing a combination of children's "peer preference, toy preference, clothing preference, gender similarity, and gender identity." (Rae 2019 at 671.) They reported a statistical association (mathematically equivalent to a correlation) between that composite score and the probability of persistence. As they indicated, "Our model predicted that a child with a gender-nonconformity score of .50 would have roughly a .30 probability . . . of socially transitioning. By contrast, a child with gender-nonconformity score of .75 would have roughly a .48 probability." (Rae 2019 at 673.) Although the Olson team declared that "social transitions may be predictable from gender identification and preferences" (Rae 2019 at 669), their actual results suggest the opposite: the gender-nonconforming group who went on to transition (socially) had a mean composite score of .73 (which is less than .75), and the gendernonconforming group who did not transition had a mean composite score of .61, also less than .75. (Rae 2019, Supplemental material at 6, Table S1.) Both of those are lower than the value of .75, so both of those would be more likely than not to desist, rather than to proceed to transition. That is, Olson's model does not distinguish likely from unlikely to transition; rather, it distinguishes unlikely from even less likely to transition.

145. Further, in the absence of long-term follow-up, it cannot be known what proportion of those who transition and persist through the early stages of puberty will later (for example as young adults) come to regret having transitioned and then *de*transition. Because only a minority of gender dysphoric children persist in feeling gender dysphoric in the first place, "transition-on-demand" increases the probability of unnecessary transition and unnecessary medical risks.

4. Temple Newhook's attempts to dismiss evidence of high rates of desistance from childhood gender dysphoria are invalid.

146. The unanimous consistency across all 11 cohort studies of (non-transitioned) gender dysphoric children offers high confidence in the conclusion that most childhood-onset cases desist during the course of puberty. In 2018, however, a commentary was published, contesting that conclusion, criticizing four studies. (Temple Newhook 2018.) Multiple accomplished international researchers studying outcomes of gender dysphoric children responded (Zucker 2018; Steensma & Cohen-Kettenis 2018), to which the Temple Newhook team wrote a rejoinder. (Winters 2018.) I have reviewed each of these arguments, finding that the Temple Newhook comments rely on demonstrable falsehoods, whereas the responses remain consistent with the peer-reviewed evidence. The Temple Newhook commentary has not altered the consensus of the international medical community, which continues to cite and rely upon these cohort studies.

147. Before delineating each of their arguments, it should be noted that the Temple Newhook team based their analysis on the wrong research reports, attacking only a straw-person version of the contents of the research literature. Table 3 repeats the 11 cohort studies (on the left left) and the four studies Temple Newhook criticized (right): Table 3.

- Lebovitz (1972)
- Zuger (1978)
- Money & Russo (1979)
- Davenport (1986)
- Green (1987)
- Kosky (1987)
- Wallien & Cohen-Kettenis (2008)
- Drummond, *et al.* (2008)
- Steensma, *et al.* (2013)
- Singh, 2012/Singh, *et al.* (2021)⁶

Wallien & Cohen-Kettenis (2008) Drummond, *et al.* (2008) Steensma, *et al.* (2011, 2013)

148. It should also be noted that the Temple Newhook 2018 commentary does not represent a systematic review. Temple Newhook did not indicate search strategies, inclusion/exclusion criteria, coding methods, reliability checks, or other standard procedures used for ensuring objective and unbiased assessment of all relevant studies. Rather, the Temple Newhook analysis targeted a small and selective subset of the research available—a scientifically invalid endeavor, which the systematic review process is meant to prevent. Not only did Temple Newhook skip most of the relevant science, but conversely, Temple Newhook inserted the Steensma 2011 study, which should have been rejected. (The data it reported was already included in Wallien & Cohen-Kettenis 2008.) The Temple Newhook commentary claimed it was "systematically engaging scholarly literature." (Temple Newhook 2018 at 2.) However, as the above reference lists demonstrate, that commentary involved no such systematic procedures.

149. Temple Newhook does not report any research evidence of its own. Rather, the commentary hypothesizes issues they assert could, theoretically, have affected the rates of desistance consistently detected. Scientifically, such a criticism is vacuous: In science, it is always possible for additional, external factors to have affected what was observed.

⁶ At the time of the 2018 Temple Newhook commentary, the Singh *et al.*, 2021 study was available as Singh, 2012.

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150. Also, as already detailed herein, the currently available level of evidence for outcomes of medicalized transition is the cohort study. The methodological issues highlighted by Temple Newhook are exactly why randomized, controlled trials (RCTs) need to be conducted, as such studies would be capable of resolving exactly those questions (in whichever direction). In the absence of randomized, controlled studies, however, the correct scientific process is to follow the results of the cohort studies (that is, the systematic reviews of the cohort studies).

151. In the science process, one cannot merely continue to retain a desired hypothesis, rejecting all counter-evidence until a perfect study emerges. This is especially important in clinical science, when the hypothesis relates to physical interventions, in children, with the potential to affect them for their entire lives. Rather, the scientific process proceeds by successive approximation, with results from the best available research replacing lesser quality research, increasing in confidence, but always with the possibility of changes imposed by future evidence.

152. By involving only a few of the full set of cohort studies, the Temple Newhook commentary removes one of the most compelling implications of the existing (cohort) studies: Their results are unanimous. However unlikely it might be for four studies to produce the same result randomly, it is even more unlikely for eleven studies all to come to the same result randomly.

153. Temple Newhook emphasized that gender identity issues differ across times and contexts/political environments, hypothesizing that children attending her clinic might differ from children attending the Toronto and the Amsterdam clinics. Returning once again to the full set of all studies, however, the evidence shows the very opposite: All studies yielded the same result, whether from the 1970s, 80s, 90s, 2000s, 2010s, and wherever in the world any clinic

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was. Acknowledging the possibility that future studies may lead to a different conclusion, the existing evidence shows majority desistance, constantly and across all time periods.

154. Consideration of the full set of studies also indicates that the contrast is not Toronto and Amsterdam versus whatever "reality" Temple Newhook perceives. Rather, they show the contrast is between Temple Newhook and every facility in every country ever reporting desistance data on childhood-onset gender dysphoria. Moreover, despite Temple Newhook's mention of influences of political cultures, that commentary does not point out that Canada and the Netherlands are much more politically liberal than the U.S. Although the commentary offers the hypothesis that the Canadian and Dutch contexts might decrease persistence, the commentary does not include the inverse possibility: that these liberal environments might be "*iatrogenic*" that is, causing dysphoria to continue when it might otherwise remit.

155. Also, the very evidence suggesting that gender dysphoria can be influenced by local environmental factors is itself evidence that gender identity is not, in fact, an innate and immutable feature, potentially amenable to change.

C. Adolescent-Onset Gender Dysphoria, the predominant clinical population today, is a distinct and largely unstudied phenomenon.

156. Concurrent with the advent of social media, a third profile began appearing clinically and socially, characteristically distinct from the two previously identified profiles. (Kaltiala-Heino 2015; Littman 2018.) As described by Chen et al., "[Y]outh who first recognize their gender incongruence in adolescence may represent a distinct subgroup of transgender and nonbinary youth who have more psychosocial complexities than youth recognizing gender incongruence in childhood." (Chen 2023 at 245.)

157. Despite lacking any history before the current generation, this profile has now numerically overwhelmed the previously known and better characterized types in clinics and on

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Internet surveys. Unlike adult-onset or childhood-onset gender dysphoria, this group is predominately biologically female. This group typically presents in adolescence, but lacks the history of cross-gender behavior in childhood like the childhood-onset cases have. It is that feature which led to the term Rapid Onset Gender Dysphoria (ROGD). (Littman 2018.)⁷ Cases commonly appear to occur within clusters of peers in association with increased social media use (Littman 2018), and among people with autism or other mental health issues. (Kaltiala-Heino 2015; Littman 2018; Warrier 2020.) (See section XI on Mental Health.) The patterns reported by Littman have recently been independently replicated by another study which also found it to be a predominantly female phenomenon, associated with very high rates of social media use, among youth with other mental health issues, and in association with peers expressing gender dysphoria issues. (Diaz 2023.)⁸ Due to the multiple differences across the epidemiological and other objective variables, there is no justification for extrapolating findings from adult-onset or childhood-onset gender dysphoria to this new presentation.

158. There do not yet exist any cohort studies of people with adolescent-onset gender dysphoria undergoing medicalized transition. Current studies are limited to surveys typically of volunteers from activist and support groups on the Internet.

159. Moreover, no study has yet been organized in such a way as to allow for a distinct analysis of the adolescent-onset group, as distinct from childhood-onset or adult-onset cases. Many published studies fail to distinguish between people who had childhood-onset gender dysphoria and have aged into adolescence versus people whose onset was not until adolescence.

⁷ After initial criticism, the publishing journal conducted a reassessment of the article. The article was expanded with additional detail and republished. The relevant results were unchanged. Littman's paper as revised has been widely cited.

⁸ This peer-reviewed article was originally published in the *Archives of Sexual Behavior* became a subject of protest, including by WPATH President, Dr. Marci Bowers, demanding the retraction of the article and the dismissal the journal's Editor, Dr. Kenneth Zucker. No action was taken against Zucker and the article was re-published in the *Journal of Open Inquiry in the Behavioral Sciences*. The latter version is cited in the reference list of the present report.

(Analogously, there are reports failing to distinguish people who had adolescent-onset gender dysphoria and aged into adulthood from adult-onset gender dysphoria.) Studies selecting groups according to their current age instead of their ages of onset produces confounded results, representing unclear mixes according to how many of each type of case wound up in the final sample.

D. Epidemiological evidence supports the hypothesis that adolescent-onset gender dysphoria (ROGD) is merely one symptom of a wide pattern of sharp declines in the mental health of especially female adolescents, corresponding with the increased social pressures introduced by social media in the smartphones era.

160. Some advocates reject the social contagion explanation of the sudden epidemiological change, citing political, social, and therapeutic implications they claim follow from that conclusion (Section IX.B., above); however, no other interpretation has been offered that is capable of explaining the evidence, and multiple, highly reliable sources (including national surveys), confirm the patterns predicted by the social contagion explanation. Large quantities of mental health data have been produced recently due to the interest in investigating the impact of COVID on public mental health. What this research has repeatedly revealed is that, although there have been some decreases in mental health indicators during the COVID era, the major decline began nearly a decade before the COVID era (Villas-Boas et al. 2023) and instead corresponds with the new ubiquity of smartphones and social media among adolescents.

161. As demonstrated by the following sources, each of these exponential changes has occurred simultaneously and primarily within the same demographic group: adolescent, biological females, with psychosocial vulnerabilities making them more susceptible to social influence. Neither the claims of sexual minority stress nor any other hypothesis apart from the new influence of smartphones and social media predicts or provides any explanation for these

several concurrent and ubiquitous patterns, below.

1. The data show an exponential increase in the presence and timing of gender dysphoria referrals throughout the industrialized world coincident with the wide uptake of social media.

162. Australia: The Royal Children's Hospital gender service reports the following data

on referrals to its gender service, with an exponential rise beginning in 2011–2012. (Bachelard

2023.)



163. **United Kingdom:** The Cass Review provides the following data on referrals of minors for gender dysphoria in the U.K., following almost exactly the same timing and curve. (Cass 2024 at 85.)



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164. **The Netherlands:** Data from the Netherlands shows the same pattern and timing and breaks out the fact that the phenomenon is primarily affecting biological females. (Arnoldussen 2020.)



2. Additional data also show a sharp increase in mental health conditions broadly among teens occurred concurrent with the wide uptake of social media.

165. Brunette et al. (2023) plotted data from U.S. National Survey on Drug Use and Health demonstrating that increases in depression began at the same time and occurred among younger rather than older adults:



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166. Data from the U.S. Substance Abuse and Mental Health Services Administration (SAMHSA 2022) likewise show the rapid rise in depressive episodes, more than doubling, accompanying the social media age, and mostly affecting youth under 25:



3. The post-2011 crisis in mental health, like the explosion of gender dysphoria referrals, has been a largely female phenomenon.

167. The sudden and dramatic increases in depression primarily occurred among

biologically *female* adolescents. The U.S. Centers for Disease Control and Prevention (CDC) released the results of its biannual *Youth Risk Behavior Survey* (CDC 2023). The report confirmed that mental health and suicidal thoughts and behaviors worsened significantly between 2011 and 2021. It also found these problems primarily affecting biological females, noting:

Across almost all measures of substance use, experiences of violence, mental health, and suicidal thoughts and behaviors, female students are faring more poorly than male students. These differences, and the rates at which female students are reporting such negative experiences, are stark. [...] In 2021, almost 60% of female students experienced persistent feelings of sadness or hopelessness during the past year and nearly 25% made a suicide plan. (CDC 2023 at 2.)

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168. Twenge (2022) showed an exponential increase in major depression rates among U.S. adolescents (ages 12–17) beginning in 2011, as reported by the U.S. National Study of Drug Use and Health, illustrating again this to be primarily among females:



(Twenge 2022 at 3.)

169. Tragically, the same pattern extends beyond depression and mental health to actual completed suicide. While suicide rates for most groups have fallen or remained constant since 2011, completed suicide rates for adolescent girls instead have skyrocketed:

Suicide rates have been falling overall, but girls—who kill themselves less often than other groups—are an exception. Among girls aged 10–19, suicide rates rose from an average of 3.0 per 100,000 people in 2003 to 3.5 per 100,000 in 2020. The rate among boys, although higher at 6.1 per 100,000 population, has barely changed. (Economist 2023.)



Changes in suicide rates, by biological sex and age group. (Economist 2023.)

170. Twenge (2020) compared multiple indicators of poor mental health among U.S. girls and young women across 2001–2018, again illustrating the dramatic worsening beginning in 2011. "In most cases, the increases in indicators of poor mental health have been larger among girls and young women than among boys and young men" (Twenge 2020 at 19.). These findings confirm the patterns I have previously identified.



4. The 2011 onset of increased mental health problems and increased gender dysphoria referrals has been recognized as co-occurring with the uptake of smartphones among adolescents.

171. New reports increasingly recognize social media and smartphone usage as the

common link behind the proliferation of mental health disorders among adolescents (Brunette et

al. 2023; Haltigan et al. 2023), including the recent health advisory by the American

Psychological Association on social media use among adolescents (APA (2023).). The APA

advisory concluded:

Research suggests that using social media for social comparisons related to physical appearance, as well as excessive attention to and behaviors related to one's own photos and feedback on those photos, are related to poorer body image, disordered eating, and depressive symptoms, *particularly among girls*. (APA 2023 at 8, emphasis added.)

These conclusions further confirm the conclusions of systematic review associating smartphone usage and poorer mental health (Sohn et al. 2019).

172. The timing of the increase in gender dysphoria referrals exactly correspond with the penetration of smartphones and social media into adolescent lives: Data published by Pew Research illustrates that the rates of smartphone usage among teenagers also began its dramatic

rise in 2011–2012:



(Lebrow 2022.)

173. Twenge (2020) documents that it is precisely the heavy users of social media who are most likely to report being depressed, feeling unhappy, or exhibiting suicidality. Again, the association is, by far, most striking for adolescent girls:



(Twenge 2020 at 22.)

174. In their peer-reviewed, nation-wide analysis of Finland's centralized gender identity

services (GIS), Kaltiala et al. observed:

The increase in all the younger people contacting GIS and in psychiatric needs among them have taken place simultaneously with the emergence of the widely recognized crisis in mental health among adolescents and young adults throughout the Western world [44, 45], largely associated with the increasing use of social media [44–46]. Social influences that reduce stigma and barriers to care for people suffering from incongruence between their sexed body and lived gender experience likely improve mental health in this group and social media may offer invaluable support and belongingness that buffers against minority stress. However, social media influences may also result in adolescent and emerging adult females – who present particularly frequently with identity confusion [47] – seeking for a solution to their distress through GR [11] and overshadow the need for psychiatric treatment. (Kaltiala et al. 2023 at 6.)

The sources cited by Kaltiala et al. in this paragraph are:

- 11: Marchiano, L. (2017). Outbreak: On transgender teens and psychic epidemics. *Psychological Perspectives, 60,* 345–366.
- 44: Twenge, J. M. (2020). Increases in depression, self-harm, and suicide among U.S. adolescents after 2012 and links to technology use: Possible mechanisms. *Psychiatric Research and Clinical Practice*, *2*, 19–25.
- 45: Krokstad, S., Weiss, D. A., Krokstad, M. A., Rangul, V., Kvaløy, K., Ingul, J. M., Bjerkeset, O., Twenge, J., & Sund, E. R. (2022). Divergent decennial trends in mental health according to age reveal poorer mental health for young people: Repeated cross-sectional population-based surveys from the HUNT Study, Norway. *BMJ Open*, 12, e057654.
- 46: Abbasi, J. (2023). Surgeon general sounds the alarm on social media use and youth mental health crisis. *JAMA*, *330*, 11–12.
- 47: Bogaerts, A., Claes, L., Buelens, T., Verschueren, M., Palmeroni, N., Bastiaens T., & Luyckx, K. (2021). Identity synthesis and confusion in early to late adolescents: Age trends, gender differences, and associations with depressive symptoms. *Journal of Adolescence*, 87, 106–116.

E. Multiple detransition studies confirm features consistent with the hypothesis that ROGD is largely a social contagion phenomenon.

175. Respected national health care systems of several countries have warned of the risk

that medical transition of minors can lead to detransition and severe regret due to irreversible

physical harms. (See Section V.) Because detransition (1) can occur several years after

transition, (2) is not typically reported to the clinic that provided transition (Littman 2021),

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(3) thus cannot be distinguished by the clinic from dropping out of a clinical study for other reasons, and (4) is not systematically tracked by any centralized database in the U.S., reliable knowledge about the features and frequencies of detransition cannot develop at the same rate as other aspects of study. The scientific study of detransition has only just begun, with even the Version 8 of WPATH's Standards of Care (SOC-8) noting that basic information about detransition remains unknown (SOC-8 at S77.). In this situation, it is unjustified and misleading to claim that the paucity of evidence suggests that rates of detransition are low, rather than merely reflecting the difficulty of data collection and as a result the greater the time that will be required for such research to be completed.

176. Scientific interest in this issue is extremely high, and evidence is only now beginning to accumulate. Recently, many new studies of detransition have appeared in the peer-reviewed literature:

- Littman, L., O'Malley, S., Kerschner, H., & Bailey, J. M. (2023). Detransition and desistance among previously trans-identified young adults. *Archives of Sexual Behavior*. doi: 10.1007/s10508-023-02716-1
- MacKinnon, K. R., Gould, W. A., Enxuga, G., Kia, H., Abramovich, A., Lam, J. S. H., & Ross, L. E. (2023). Exploring the gender care experiences and perspectives of individuals who discontinued their transition or detransitioned in Canada. *PlosONE*. doi: 10.1371/journal.pone.0293868
- MacKinnon, K. R., Kia, H., Gould, W. A., Ross, L. E., Abramovich, A., Enxuga, G., & Lam, J. S. H. (in press). A typology of pathways to detransition: Considerations for care practice with transgender and gender diverse people who stop or reverse their gender transition. *Psychology of Sexual Orientation and Gender Diversity*. doi: 10.1037/sgd0000678
- Sanders, T., du Plessis, C., Mullens, A. B., & Brömdal, A. (2023). Navigating detransition borders: An exploration of social media narratives. *Archives of Sexual Behavior*, 52, 1061–1072.
- Sansfaçon, A. P., Gelly, M. A., Gravel, R., Medico, D., Baril, A., Susset, F., & Paradis, A. (2023). A nuanced look into youth journeys of gender transition and detransition. *Infant and Child Development*, 32, e2402.
- Sansfaçon, A. P., Gravel, É., Gelly, M., Planchat, T., Paradis, A., & Medico, D. (in press) A retrospective analysis of the gender trajectories of youth who have discontinued

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a transition. *International Journal of Transgender Health*. doi: 10.1080/26895269.2023.2279272

These empirical studies have employed a range of techniques to examine detransitioners' characteristics, including semi-structured interviews, thematic analysis of social media sites, and quantitative surveys using independently validated instruments.

177. The most scientifically rigorous of these is Littman et al. (2023). To recruit detransitioners to participate in this peer-reviewed study, the researchers noted that "Efforts were made to reach communities with differing perspectives about gender dysphoria, desistance, transition, and detransition" (at 60.). The study's sample consisted of individuals 91% of whom were biologically female, ranging in age from 18 to 33 years (mean of 24.9 years), and 81% white. The majority of participants described themselves as politically liberal (68%), non-religious (82%), and supportive of gay marriage rights (86%) and transgender rights (91%).

178. The results of this quantitative, peer-reviewed study confirmed the conclusions of the qualitative studies interviewing detransitioners and prior survey studies: The majority of the detransitioners reported that the phenomenon referred to as rapid onset gender dysphoria (ROGD) correctly describe their experience (53%), with 23% indicating they did not know, and 24% reporting it did not. Co-morbid psychiatric diagnoses were acknowledged by the majority, consistent with prior studies. Self-harm was extremely prevalent in the sample before and during their period of transgender identification, 71% and 64% respectively. Interestingly (and urgently calling for further research), self-reported self harm dropped radically to 23% among this sample after they detransitioned and returned to a gender identify aligned with their biological sex.

179. The study results also supported the social contagion hypothesis of ROGD:

Participants in the current study were asked if, at the time of transgender identification, they belonged to a friendship group where one or more members of the group became transgender-identified around the same time. The majority (60.3%) answered in the affirmative (with 24.4% referring to offline friendship)

groups, 14.1% referring to online friendship groups, and 21.8% referring to both). More than a third of participants responded that the majority of their offline and online friends became transgender-identified (34.6% and 38.5%, respectively) and participants acknowledged that their offline and online friendship groups engaged in mocking people who were not transgender-identified (42.3% and 41.0%, respectively). (Littman et al. 2023 at 68.)

It bears emphasizing this finding that more than a third of these (overwhelmingly female) respondents reported that "the *majority*" of their friends at some point became transgender-identified. In my opinion, this finding is entirely inconsistent with claims that transgender identity is innate and immutable, like sexual orientation, rather than influenced by social and psychological factors.

180. Importantly, study participants were asked about the informed consent procedures

they received from the clinicians providing the medicalized transition services. The majority

(61.5%) reported receiving hormonal treatments from clinicians using only the informed consent,

rather than a gate-keeping model, and, although they received some information, the results

indicated that:

66.7% felt they were inadequately informed about risks and 31.3% felt this about benefits. Only one participant (2.1%) reported that a clinician provided information about treatment alternatives to cross-sex hormones . . . 75.0% of participants reported that they received inadequate information about these alternatives, [and fewer than] one-tenth (8.3%) of participants indicated that they were informed by their clinician about the lack of long-term studies about natal females with late-onset gender dysphoria. Similarly, only 12.5% were informed that the risks, benefits, and outcomes for medical transition of late-onset gender dysphoric youth have not been well studied. (Littman et al. 2023, at 70–71.)

X. Suicide and suicidality are distinct phenomena representing different mental health issues and indicating different clinical needs.

181. *Suicide* refers to completed suicides and the sincere intent to die. It is substantially associated with impulsivity, using more lethal means, and being a biological male. (Freeman 2017.) *Suicidality* refers to *para*-suicidal behaviors, including suicidal ideation, threats, and gestures.

A. Rates of suicidality among all adolescents have skyrocketed with the advent of social media.

182. The CDC's 2019 Youth Risk Behavior Survey found that 24.1% of female and 13.3% of male high school students reported "seriously considering attempting suicide." (Ivey-Stephenson 2020 at 48.)

183. The CDC survey reported not only that these already alarming rates of suicide attempt were still increasing (by 8.1%–11.0% per year), but also that this increase was occurring only among female students. No such trend was observed among male students. That is, the demographic increasingly reporting suicidality is the same demographic increasingly reporting gender dysphoria. (Ivey-Stephenson 2020 at 51.)

184. The U.S. Substance Abuse and Mental Health Services Administration (SAMHSA) produces a series of evidence-based resource guides which includes their Treatment for Suicidal Ideation, Self-Harm, and Suicide Attempts Among Youth. It noted (italics added):

[F]rom 1999 through 2018, the suicide death rate doubled for females aged 15 to 19 and 20 to 24. For youth aged 10 to 14, the suicide death rate more than tripled from 2001 to 2018. Explanations for the increase in suicide may include bullying, social isolation, increase in technology and *social media*, increase in *mental illnesses*, and economic recession. (SAMHSA 2020 at 5.)

The danger potentially posed by social media follows from suicidality spreading as a social contagion, as suicidality increases after media reports, occurs in clusters of social groups, and in

adolescents after the death of a peer. (Gould & Lake 2013.)

185. Social media voices today loudly advocate "hormones-on-demand" while issuing hyperbolic warnings that teens will commit suicide unless this is not granted. Both adolescents and parents are exposed to the widely circulated slogan that "I'd rather have a living son than a dead daughter," and such baseless threats or fears are treated as a justification for referring to affirming gender transitions as 'life-saving' or 'medically necessary'. Such claims grossly misrepresent the research literature, however. Indeed, they are unethical: Suicide prevention research and public health campaigns repeatedly warn against circulating messages that can be taken to publicize or even glorify suicide, due to the risk of copy-cat behavior they encourage. (Gould & Lake 2013.)

186. A systematic review of 44 studies of suicidal thoughts and behaviors in LGBTQ youth and suicidality found only a small association between suicidality and sexual minority stress. (Hatchel 2021.) The quantitative summary of the studies (an especially powerful type of systematic review called *meta-analysis*) found no statistically significant association between suicidality and any of having an unsupportive school climate, stigma and discrimination, or outness/openness. There were, however, significant associations between suicidality and indicators of social functioning problems, including violence from intimate partners, victimization from LGBT peers and from non-LGBT peers, and sexual risk taking.

B. *Suicidality* is substantially more common among females, and *suicide*, among males. Sexual orientation is strongly associated with suicidality, but much less associated with suicide.

187. Notwithstanding public misconceptions about the frequency of suicide and related behaviors, the highest rates of death by suicide are among middle-aged and elderly men in high income countries. (Turecki & Brent 2016 at 3.) Males are at three times greater risk of death by

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suicide than are females, whereas suicidal ideation, plans, and attempts are three times more common among females. (Klonsky 2016; Turecki & Brent 2016.) In contrast with completed suicides, the frequency of suicidal ideation, plans, and attempts is highest during adolescence and young adulthood, with reported ideation rates spanning 12.1–33%. (Borges 2010; Nock 2008.) Relative to other countries, Americans report elevated rates of each of suicidal ideation (15.6%), plans (5.4%), and attempts (5.0%). (Klonsky 2016.) Suicide attempts occur up to 30 times more frequently than completed suicides. (Bachmann 2018.) The rate of completed suicides in the U.S. population is 14.5 per 100,000 people. (WHO 2022.)

188. There is substantial research associating sexual orientation with suicidality, but much less so with completed suicide. (Haas 2014.) More specifically, there is some evidence suggesting gay adult men are more likely to die by suicide than are heterosexual men, but there is less evidence of an analogous pattern among lesbian women. Regarding suicidality, surveys of self-identified LGB Americans repeatedly report rates of suicidal ideation and suicide attempts 2–7 times higher than their heterosexual counterparts. Because of this association of suicidality with sexual orientation, one must apply caution in interpreting findings allegedly about gender identity: because of the overlap between people who self-identify as non-heterosexual and as transgender or gender diverse, correlations detected between suicidality and gender dysphoria may instead reflect (be confounded by) sexual orientation. Indeed, other authors have made explicit their surprise that so many studies, purportedly of gender identity, entirely omitted measurement or consideration of sexual orientation, creating the situation where features that seem to be associated with gender identity instead reflect the sexual orientation of the members of the sample. (McNeil 2017.)

C. There is no evidence that medicalized transition reduces rates either of suicide or of suicidality.

189. It is repeatedly asserted that despite the known risks and despite the lack of research into the reality or severity of unquantified risks, it is essential and "the only ethical response" to provide medical transition to minors because medical transition is known to reduce the likelihood of suicide among minors who suffer from gender dysphoria. This is simply untrue. *No studies* have documented any reduction in suicide rates in minors (or any population) as a result of medical transition. No methodologically sound studies have provided meaningful evidence that medical transition reduces suicidality in minors. Instead, multiple studies show tragically high rates of suicide after medical transition, with that rate beginning to spike several years after medical transition.

190. Among post-transition adults, completed suicide rates remain elevated. (Wiepjes 2020.) Among post-operative transsexual adults in Sweden's highly tolerant society, death by suicide is 19 times higher than among the cisgendered. (Dhejne 2011.) Systematic review of 17 studies of suicidality in transsexual adults confirmed suicide rates remain elevated even after complete transition. (McNeil 2017.) Among post-operative patients in the Netherlands, long-term suicide rates of six times to eight times that of the general population were observed depending on age group. (Asscheman 2011 at 638.) Also studying patients in the Netherlands, Wiepjes et al. (2020) reported the "important finding" that "suicide occurs similarly" before and after medical transition. (Wiepjes 2020 at 490.) In other words, *transition did not reduce suicide*. A very large dataset from the U.K. GIDS clinic showed that those referred to the GIDS clinic for evaluation and treatment for gender dysphoria committed suicide at a rate five times that of the general population, both before and after commencement of medical transition (Biggs 2022). Finally, in a still-ongoing longitudinal study of U.S. patients, Chen *et al.* have reported a

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shockingly high rate of completed suicide among adolescent subjects in the first two years *after* hormonal transition, although they provide no pre-treatment data for this population to compare against. (Chen 2023 at 245.)

191. WPATH's systematic review of the effectiveness of puberty blockers and cross-sex hormones on suicide in minors concluded that "It was impossible to draw conclusions about the effects of [either] hormone therapy on death by suicide." (Baker 2021 at 12.) In short, I am aware of no respected voice that asserts that medical transition reduces suicide among minors who suffer from gender dysphoria.

192. As to the separate and far more common phenomenon of suicidality, of course, that claim is widely made. McNeil's systematic review revealed, however, a complicated set of interrelated factors rather than supporting the common hypothesis that rates of suicidal ideation and suicidal attempts would decrease upon transition. Rates of suicidal ideation did not show the same pattern as suicide attempts, male-to-female transitioners did not show the same patterns as female-to-male transitioners, and social transition did not show the same patterns as medical transition. Importantly, the review included one study that reported "a positive relationship between higher levels of social support from leaders (e.g., employers or teachers) and increased suicide attempt, which they suggested may be due to attempts instigating increased support from those around the person, rather than causing it." (McNeil 2017 at 348.)

193. Moreover, the 2020 Kuper, *et al.* cohort study of minors receiving hormone treatment found *increases* in each of suicidal ideation (from 25% to 38%), attempts (from 2% to 5%), and non-suicidal self-injury (10% to 17%). (Kuper 2020 at Table 5.) Research has found social support to be associated with *increased* suicide attempts, suggesting the reported suicidality may represent attempts to evoke more support. (Bauer 2015; Canetto 2021.)

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194. Overall, the research evidence is only minimally consistent with the hypothesis that an absence of transition causes mental health issues and suicide, but very strongly consistent with the hypothesis that mental health issues, such as *Borderline Personality Disorder* (BPD), cause both suicidality and unstable identity formation (including gender identity confusion). (See section XI.) BPD is repeatedly documented to be greatly elevated among sexuality minorities (Reuter 2016; Rodriguez-Seiljas 2021; Zanarini 2021), and both suicidality and identity confusion are symptoms of that disorder. Thus, diverting distressed youth towards transition necessarily diverts youth away from receiving the psychotherapies designed for treating the issues actually causing their distress.

195. Despite the fact that mental health issues, including suicidality, are repeatedly required by clinical standards of care to be resolved before transition, threats of suicide are instead oftentimes used as the very justification for labelling transition a "medical necessity". However plausible it might seem that failing to affirm transition causes suicidality, the epidemiological evidence does not support that hypothesis.

XI. Mental health profiles differ across adult-, adolescent-, and childhoodonset gender dysphoria.

A. Mental health issues in Adult-Onset Gender Dysphoria.

196. Systematic review of all studies examining mental health issues in transgender adults identified 38 such studies. (Dhejne 2016.) The review indicated that many studies were methodologically weak, but nonetheless consistently found (1) that the average rate of mental health issues among adults is highly elevated both before *and after* transition, (2) but that the average was less elevated among adults who completed transition. It could not be concluded that transition improves mental health, however. Patients were commonly receiving concurrent psychotherapy, introducing a confound (meaning, again, that it cannot be determined whether the change was caused by the transitioning or the mental health treatment). Further, several studies showed more than 40% of patients to become "lost to follow-up." It remains unknowable to what extent the information from the remaining participants accurately reflects the whole population.

B. Mental health issues in Childhood-Onset Gender Dysphoria.

197. Elevated rates of multiple mental health issues among gender dysphoric children are reported throughout the research literature. A formal analysis of children (ages 4–11) undergoing assessment at the Dutch child gender clinic showed that 52% fulfilled criteria for a formal DSM diagnosis of a clinical mental health condition other than Gender Dysphoria. (Wallien 2007 at 1307.) A comparison of the children attending the Canadian versus Dutch child gender dysphoria clinic showed only few differences between them, and a large proportion in both groups were diagnosable with clinically significant mental health issues. Results of standard assessment instruments (Child Behavior Check List, or CBCL) demonstrated that among 6–11-year-olds, 61.7% of the Canadian and 62.1% of the Dutch sample satisfied the diagnostic criteria for one or more mental health conditions other than gender dysphoria. (Cohen-Kettenis 2003 at 46-47.)

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198. A systematic review of all studies of Autism Spectrum Disorders (ASDs) and Attention-Deficit Hyperactivity Disorder (ADHD) among children diagnosed with gender dysphoria was recently conducted. (Thrower 2020.) It was able to identify a total of 22 studies examining the prevalence of ASD or ADHD youth with gender dysphoria. Studies reviewing medical records of children and adolescents referred to gender clinics showed 6–26% to have been diagnosed with ASD. (Thrower 2020 at 695.) Moreover, those authors gave specific caution on the "considerable overlap between symptoms of ASD and symptoms of gender variance, exemplified by the subthreshold group which may display symptoms which could be interpreted as either ASD or gender variance. Overlap between symptoms of ASD and symptoms of GD may well confound results." (Thrower 2020 at 703.) The rate of ADHD among children with GD was 8.3–11%. Conversely, data from children (ages 6–18) with Autism Spectrum Disorders (ASDs) show they are more than seven times more likely to have parent-reported "gender variance." (Janssen 2016 at 63.)

199. As shown by the outcomes studies (see Section XIII), there is little reliable evidence that transition improves the mental well-being of children. As shown repeatedly by clinical guidelines from multiple professional associations, mental health issues are expected or required to be resolved *before* undergoing transition. The reasoning behind these conclusions is that children may be expressing gender dysphoria, not because they are experiencing what gender dysphoric adults report, but because they mistake what their experiences indicate or to what they might lead. For example, a child experiencing depression from social isolation might develop the hope—and the unrealistic expectation—that transition will help them fit in, as a member of the other sex.

200. In cases where gender dysphoria is secondary to a different issue, efforts at transition

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are aiming at the wrong target and leave the primary issue(s) unaddressed. Given the highly reliable, repeatedly replicated finding that childhood-onset gender dysphoria resolves with puberty for the large majority of children, the evidence indicates that blocking a child's puberty blocks the child's natural maturation that itself would resolve the dysphoria.

C. Mental health issues in Adolescent-Onset Gender Dysphoria (ROGD).

201. The literature varies in the range of gender dysphoric adolescents with co-occurring disorders. In addition to self-reported rates of suicidality (see Section X), clinical assessments reveal elevated rates not only of depression (Holt 2016; Skagerberg 2013; Wallien 2007), but also anxiety disorders, disruptive behavior difficulties, Attention Deficit/Hyperactivity Disorder, Autism Spectrum Disorder, and personality disorders, especially Borderline Personality Disorder (BPD). (Anzani 2020; de Vries 2010; Jacobs 2014; Janssen 2016; May 2016; Strang 2014, 2016; Swedish Socialstyrelsen, Evolution 2020.)

202. Of particular concern in the context of adolescent-onset gender dysphoria is Borderline Personality Disorder (BPD; diagnostic criteria in Table 4 below). Symptoms of BPD overlap in important respects with symptoms commonly interpreted as signs of gender dysphoria, and it is increasingly hypothesized that very many cases appearing to be adolescentonset gender dysphoria actually represent cases of BPD. (E.g. Anzani 2020; Zucker 2019.) That is, some people may be misinterpreting their experiencing of the broader "identity disturbance" of symptom Criterion 3 to represent a gender identity issue specifically. Like adolescent-onset gender dysphoria, BPD begins to manifest in adolescence, is three times more common in biological females than males, and occurs in 2–3% of the population, rather than 1-in-5,000 people. (Thus, if even only a portion of people with BPD experienced an identity disturbance, and focused that disturbance on gender identity resulting in transgender identification, they could

easily overwhelm the number of genuine cases of gender dysphoria.)

Table 4. DSM-5-TR Diagnostic Criteria for Borderline Personality Disorder.

A pervasive pattern of instability of interpersonal relationships, self-image, and affects, and marked impulsivity beginning by early adulthood and present in a variety of contexts, as indicated by five (or more) of the following:

- 1. Frantic efforts to avoid real or imagined abandonment. (Note: Do not include suicidal or self-mutilating behaviour covered in Criterion 5.)
- 2. A pattern of unstable and intense interpersonal relationship characterized by alternating between extremes of idealization and devaluation.
- 3. Identity disturbance: markedly and persistently unstable self-image or sense of self.
- 4. Impulsivity in at least two areas that are potentially self-damaging (e.g., spending, sex, substance abuse, reckless driving, binge eating). (Note: Do not include suicidal or self-mutilating behavior covered in Criterion 5.)
- 5. Recurrent suicidal behaviour, gestures, or threats, or self-mutilating behavior.
- 6. Affective instability due to a marked reactivity of mood (e.g., intense episodic dysphoria, irritability, or anxiety usually lasting a few hours and only rarely more than a few days).
- 7. Chronic feelings of emptiness.
- 8. Inappropriate, intense anger or difficulty controlling anger (e.g., frequent displays of temper, constant anger, recurrent physical fights).
- 9. Transient, stress-related paranoid ideation or severe dissociative symptoms. (Italics added.)

(American Psychiatric Association 2022 at 752-753.)

203. Mistaking cases of BPD for cases of Gender Dysphoria may prevent such youth from receiving the correct mental health services for their condition. A primary cause for concern is symptom Criterion 5: *recurrent suicidality*. (See Section X on suicide and suicidality.) Regarding the provision of mental health care, the distinction between these conditions is crucial: A person with BPD going undiagnosed will not receive the appropriate treatments (the currently most effective of which is Dialectical Behavior Therapy). The problem was not about *gender* identity, but about having an *unstable* identity.

204. Regarding research, there have now been several attempts to document rates of

suicidality among gender dysphoric adolescents. The scientific concern presented by BPD is that

it poses a potential confound: samples of gender dysphoric adolescents could appear to have elevated rates of suicidality, not because of the gender dysphoria (or transphobia in society), but because of the number of people with BPD in the sample.

D. Neuroimaging studies have associated brain features with sex and with sexual orientation, but not gender identity.

205. Claims that transgender identity is an innate property resulting from brain structure remain unproven. Neuroimaging and other studies of brain anatomy repeatedly identify patterns distinguishing male from female brains, but when analyses search for those patterns among transgender individuals, "gender identity and gender incongruence could not be reliably identified." (Baldinger-Melich 2020 at 1345.) Although much smaller than male/female differences, statistically significant neurological differences are repeatedly associated with sexual orientation (termed "homosexual" vs "nonhomosexual" in the research literature). Importantly, despite the powerful associations between transsexuality and homosexuality, as explicated by Blanchard, many studies analyzing gender identity failed to control for sexual orientation, representing a problematic and centrally important confound. I myself pointed this out in the research literature, noting that neuroanatomical differences attributed to gender dysphoria should instead be attributed to sexual orientation. (Cantor 2011, Cantor 2012.) A more recent review of the science, by Guillamon, et al. (2016), agreed, stating:

Following this line of thought, Cantor (2011, 2012, but also see Italiano, 2012) has recently suggested that Blanchard's predictions have been fulfilled in two independent structural neuroimaging studies. Specifically, Savic and Arver (2011) using VBM on the cortex of untreated nonhomosexual MtFs and another study using DTI in homosexual MtFs (Rametti et al., 2011b) illustrate the predictions. *Cantor seems to be right*". (Guillamon 2016 at 1634, italics added; see also Italiano 2012.)

In addition to this confound, because snapshot neurobiological studies can provide only correlational data, it would not be possible for such studies to distinguish whether brain

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differences cause gender identity or if gender atypical behavior modifies the brain over time, such as through neuroplasticity. As noted by one team of neuroscientists, "[I]t remains unclear if the differences in brain phenotype of transgender people may be the result of a sex-atypical neural development or of a lifelong experience of gender non-conformity." (Fisher 2020 at 1731.) In sum, at present assertions that transgender identity is caused by neurology represent faith, not science.

XII. Medicalized transition of gender remains *experimental,* lacking causal evidence of mental health improvement.

A. Criteria distinguishing 'experimental' from 'established'.

206. In science, the term "experimental" has a specific technical meaning. Within the scientific method, research studies can be *observational* or *experimental*. Among observational studies, such as surveys, the researchers do not administer any treatment and instead only describe the features of the group observed. Among experimental studies, treatments are actively administered by the researchers, who then compare the treated and untreated groups (or compare a group to itself, before versus after treatment). Also, within a given treatment study, the term "experimental treatment" would be used to distinguish it from the "control treatment" or "treatment-as-usual" being provided to the control group.

207. Outside research studies and within public and legal contexts, the term 'experimental' typically denotes '*unverified by experimental evidence*'. A treatment would continue to be experimental until the demonstration of (1) reliable, clinically meaningful improvement and (2) the reliable estimation of safety risks in randomized, controlled trials (RCTs) or research of equivalent level of evidence. A treatment would remain experimental while its effects, including side effects, remain uninvestigated.

208. Being long-standing, popular, or familiar do not, of themselves, impact whether a treatment is experimental—they suggest opportunities for the experiments to have been done. Clinicians' feelings of self-confidence do not impact status as experimental.

B. International consensus explicitly regards gender transition to be experimental.

209. In England, after a thorough review of the literature and the current practice, Dr. Cass stated that the critical and currently unanswered question "is whether the evidence for the use

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and safety of the medication is strong enough as judged by reasonable clinical standards." She recognized that these treatments cannot formally be called "experimental," not because they are proven, but because the experiments needed to test their efficacy and safety remain no only undone, but are not even being attempted. (Cass 2022 at 37.) To address this, Dr. Cass called for "the rapid establishment of the necessary research infrastructure to prospectively enrol young people being considered for hormone treatment into a formal research programme." (Cass Review Letter 2022). In response, in its interim service specification, NHS England stated that it "will only commission GnRHa [i.e., puberty blockers] in the context of a formal research protocol." (NHS 2022 at 12.)

210. The final report of The Cass Review reiterated this, calling for "a full programme of research" including a "puberty blocker trial." (Cass 2024 at 35.) As of April 1, 2024, NHS England no longer "routinely available" in clinical practice. (NHS 2024.) The NHS England website makes explicit that puberty blockers "are not available to children and young people for gender incongruence or gender dysphoria *because there is not enough evidence of safety and clinical effectiveness*." (https://www.nhs.uk/conditions/gender-dysphoria/treatment/ italics added)

211. Finland, by law, restricts all assessment and treatment activities for gender dysphoric minors to its two research clinics, Helsinki University Central Hospital and Tampere University Hospital. (COHERE Summary.) Further, after conducting a systematic review of the research, the council responsible for the assessment of public health care services in Finland (COHERE Finland) concluded, "In light of available evidence, gender reassignment of minors is *an experimental practice.*" (COHERE Summary, italics added.)

212. Sweden's research on gender transition is conducted at the Karolinska Institutet in
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Stockholm. In 2015, that facility registered its research on medicalized transition with the U.S. National Institutes for Health (NIH), noting "[H]ormonal treatment includes inhibition of one's own sex hormone production followed by treatment with testosterone or estrogen levels that are normal for the opposite sex. *Seen as experimental model*, this is a process that provides an opportunity to study the sex hormone dependent influences." (Clinicaltrials.gov.) In its policy updates in 2021, Sweden limited medicalized treatments for gender dysphoria in minors to clinical research studies approved by the Swedish national research ethics board ("EPM"). (Medscape Psychiatry 2021.)

213. Norway reviewed its own national policy on transition in minors in 2023, explicitly concluding such medical procedures to be experimental. (Ukom 2023.)

214. The widely cited Dutch studies were co-conducted by Dr. Thomas Steensma. Despite being an originator and international leader of medicalized transition of gender dysphoric minors, Dr. Steensma stated in an interview in 2021 that he still considers it to be experimental: "Little research has yet been done on the treatment with puberty inhibitors and hormones in young people. That is why it is also *seen as experimental*." Dr. Steensma decried other clinics for "blindly adopting our research" despite the indications that those results may not actually apply: "We don't know whether studies we have done in the past are still applicable to today. Many more children are registering, and also a different type." Steensma opined that "every doctor or psychologist who is involved in transgender care should feel the obligation to do a good pre- and post-test." (Tetelepta 2021.) But few if any are doing so.

C. Claims that medical transition is "medically necessary" are undefined, unsupported, and self-interested.

215. While European health authorities have examined the science and concluded that medical transition for minors remains "experimental" and of unproven benefit, terminology has

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been distorted in the U.S. because the U.S. lacks a public health care system and the terms "medically necessary" and "experimental" impact health insurance coverage. "Medically necessary" justifies coverage for these procedures; advocates know or fear that the term "experimental" will preclude coverage.

216. WPATH's 2016 statement asserting "medical necessity" was explicitly made in order to facilitate insurance claims, as is clear in their document entitled, "Position Statement on Medical Necessity of Treatment, Sex Reassignment, and Insurance Coverage in the U.S.A." (WPATH Position Statement.) The AMA released a similar statement supporting insurance coverage for medical transition as a result of being assertedly medically necessary.⁹ U.S. medical associations' advocacy corresponds to the financial interests of their members.

217. Moreover, there do not exist a scientific definition or objective criteria of "medically necessary." An analysis published in the *Canadian Medical Association Journal*, however (not pertaining to gender dysphoria or transition), attempted to define 'medically necessary.' (Caulfield 2012.) The article quoted Timothy Caulfield, Research Chair in Health, Law, and Policy at the University of Alberta (Edmonton), Canada: "As for putting great effort into coming up with a tidy, all-encompassing definition of 'medically necessary'—it's probably a waste of time...Given the history of the concept of 'medically necessary' and the numerous failed attempts to define it, a practical, operational and meaningful definition is likely unattainable." (Caulfield at 1771–1772.) According to Mark Stabile, director of the School of Public Policy and Governance and professor of economics and public policy at the Rotman School of Management at the University of Toronto, "Providers of those services will naturally be critical of the decision if they feel that the demand for their services will decline as a result." (Caulfield at 1772.)

⁹ Available from https://www.ama-assn.org/system/files/2019-03/transgender-coverage-talking-points.pdf

D. WPATH repeatedly warns of untested hypotheses, continuing unknowns, and lack of research.

218. The latest (2022) WPATH Standards of Care v8 document avoided the word

"experimental" in its guidelines, but instead repeatedly deployed terms and phrases that are

synonymous with being experimental: "The criteria in this chapter [on assessment of adults]

have been significantly revised from SOC-7 to reduce requirements and unnecessary barriers to

care. It is hoped that future research will explore the effectiveness of this model." (Coleman

2022 at S33, italics added.)

219. The WPATH Standards of Care v8 (Coleman 2022) indicates the lack of

experimental evidence available again and again (italics added):

- "It primarily includes an assessment approach that uses specific criteria that are examined by [a Health Care Provider, or] HCP in close cooperation with a TGD adult and does not include randomized controlled trials or long-term longitudinal research" (at S33.)
- "While there was *limited supportive research*, this recommendation was considered to be good clinical practice as it allows a more reversible experience prior to the irreversible experience of surgery" (at S40.)
- "Due to *the limited research in this area,* clinical guidance is based primarily on individual case studies and the expert opinion of HCPs" (at S41.)
- "While available research shows consistent positive outcomes for the majority of TGD adults who choose to transition...some TGD adults may decompensate or experience a worsened condition following transition. *Little research has been conducted to systematically examine variables that correlate with poor or worsened biological, psychological, or social conditions following transition*" (at S42.)
- "Future research would shed more light on gender identity development if conducted over long periods of time with diverse cohort groups" (at S45.)
- "In addition, elevated scrotal temperatures can be associated with poor sperm characteristics, and genital tucking could theoretically affect spermatogenesis and fertility (Marsh 2019) although *there are no definitive studies evaluating these adverse outcomes*. Further *research is needed to determine the specific benefits and risks* of tucking in youth" (at S54.)
- *"There is no formal research evaluating* how menstrual suppression may impact gender incongruence and/or dysphoria" (at S54-55.)
- "Currently, there are only preliminary results from retrospective studies evaluating

transgender adults and the decisions they made when they were young regarding the consequences of medical-affirming treatment on reproductive capacity. It is important not to make assumptions about what future adult goals an adolescent may have" (at S57.)

- *"Only limited empirical research exists* to evaluate such interventions" (at S75.)
- *"Research has not been conclusive* about when in the life span such detransition is most likely to occur, or what percentage of youth will eventually experience gender fluidity and/or a desire to detransition" (at S77.)
- "Research on pitch-lowering surgeries is limited" (at S139.)
- "The number and quality of research studies evaluating pitch-lowering surgeries are currently insufficient" (at \$141.)
- "To date, research on the long-term impact of [Gender Affirming Hormone Treatment or] GAHT on cancer risk is limited...We have insufficient evidence to estimate the prevalence of cancer of the breast or reproductive organs among TGD populations (Joint et al., 2018.)" (at S144.)
- "Contraceptive *research gaps within this population are profound. No studies have examined* how the use of exogenous androgens (e.g., testosterone) may modify the efficacy or safety profile of hormonal contraceptive methods (e.g., combined estrogen and progestin hormonal contraceptives, progestin-only based contraceptives) or non-hormonal and barrier contraceptive methods" (at S162.)
- "TGD individuals AFAB undergoing abortion still represents a critical gap in research" (at S162.)
- "The effects of current TGD-related medical treatments on sexuality are heterogeneous (Ozer et al., 2022; T'Sjoen et al., 2020), and *there has been little research on the sexuality of TGD adolescents*" (at S163.)
- "While sex-positive approaches to counseling and treatment for sexual difficulties experienced by TGD individuals have been proposed (Fielding, 2021; Jacobson et al., 2019; Richards, 2021), to date *there is insufficient research on the effectiveness of such interventions*" (at S163.)

XIII. There have been 18 cohort studies of puberty blockers and cross-sex hormones in minors. They provide no reliable evidence of effectiveness for improving mental health relative to mental health treatments that lack medical risk.

220. There are studies claimed to show that medical transition in minors improves mental health beyond the issues of suicide and suicidality that I have already addressed. In fact, there is no reliable evidence of any such benefit.

221. In this section, I summarize the results of all cohort studies investigating the mental health outcomes of puberty blockers and cross-sex hormones on minors. These include all such studies identified by any of the systematic reviews of effectiveness from England, Sweden, Finland, and WPATH. (Listed in Table 1, *Cohort studies of effectiveness and safety of puberty blockers and cross-sex hormones in minors.*)

222. As enumerated in the following section, all of these studies that reported improved mental health among transitioners were also providing psychotherapy at the same time. (See Section VI on confounding.) None of these studies was able to differentiate which of them was contributing to the improvement.

223. The problem imposed by confounding medicalized transition with psychotherapy is widely recognized. As explicated in the NICE review from England:

[V]ery little data are reported on how many children and adolescents needed additional mental health support, and for what reasons, or whether additional interventions, and what form and duration (for example drug treatment or counselling) that took. This is a possible confounder for the treatment outcomes in the studies because *changes in critical and important outcomes may be attributable to external care rather than the psychological support or GnRH analogues used in the studies*. (NICE 2020a at 41, italics added.)

Similarly, WPATH's own systematic review noted that "[T]his conclusion is limited by high risk of bias in study designs, small sample sizes, and *confounding with other interventions*." (Baker 2021 at 1, italics added.)

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224. The need to disentangle the roles of these two treatments has been largely ignored despite that several issues depend upon them. If medicalized transition does not show mental health improvement superior to that of mental health treatment, it cannot readily be called "medically necessary" for insurance purposes or other institutional needs. Clinicians may be subjecting minors to known and potential (but unstudied) harms without any scientific justification.

225. Moreover, without a control group for comparison (i.e., another group of similar age, sex, and mental health status), these studies are also unable to identify when and if any changes are due to regression to the mean or maturation over time.

A. Of the cohort studies, seven found little to no improvement in mental health.

226. Cantu, *et al.* (2020) studied 80 youth, 11–18 years of age (average of 15.1 years), measuring patients' levels of anxiety, depression, and suicidality. This sample was 18.75% maleto-female, 72.5% female-to-male, and 8.75% nonbinary, but the report did not include the patients' ages of onset. The study authors compared youth according to those receiving puberty blockers only, cross-sex hormones only, both treatments, or neither. No significant differences in mental health were detected on any of these variables. Of the 27 youth reporting suicidality before medicalized treatment, 81% continued to report suicidality after medicalized treatment. Remarkably, although the authors reported that "the results of this study suggest that no clinically significant changes in mood symptoms occur" (Cantu 2020 at 199), they did not convey the logical interpretation that transition failed to help these youth. Instead, they emphasized that "findings suggest changes may actually take longer to occur." (Cantu 2020 at 196.)

227. Kaltiala, et al. (2020) similarly reported that after cross-sex hormone treatment,

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"Those who had psychiatric treatment needs or problems in school, peer relationships and managing everyday matters outside of home continued to have problems during real-life." (Kaltiala 2020 at 213.) They concluded:

Medical gender reassignment is not enough to improve functioning and relieve psychiatric comorbidities among adolescents with gender dysphoria. Appropriate interventions are warranted for psychiatric comorbidities and problems in adolescent development. (Kaltiala 2020 at 213.)

228. Carmichael, *et al.* (2021) released their findings from the Tavistock and Portman clinic in the U.K. (Carmichael 2021.) Study participants were ages 12–15 (Tanner stage 3 and above for natal males, Tanner stage 2 and above for natal females) and were repeatedly tested before beginning puberty-blocking medications and then every six months thereafter. Cases exhibiting serious mental illnesses (*e.g.*, psychosis, bipolar disorder, anorexia nervosa, severe body-dysmorphic disorder unrelated to gender dysphoria) were excluded. Relative to the time point before beginning puberty suppression, there were *no* significant changes in any psychological measure, from either the patients' or their parents' perspective.

229. Hisle-Gorman, *et al.* (2021) analyzed military families' healthcare data to compare 963 transgender and gender-diverse youth before versus after hormonal treatment, using their non-gender dysphoric siblings as a control group. The study participants included youth undergoing puberty-blocking as well as those undergoing cross-sex hormone treatment, but these subgroups did not differ from each other. Study participants had a mean age of 18 years when beginning hormonal treatments, but their initial clinical contacts and diagnoses occurred at a mean age of 10 years. According to the study, "mental health care visits overall did not significantly change following gender-affirming pharmaceutical care" (Hisle-Gorman 2021 at 1448), yet, "psychotropic medication use *increased*," (Hisle-Gorman 2021 at 1448, italics added) indicating *deteriorating* mental health.

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Tordoff, et al. (2022) reported on the mental health of youth (mean age 15.8) as they 230. underwent their first year of puberty blocker or cross-sex hormone treatment. The study began with 104 youth, 39 of whom dropped out by the end of the study. Of the initial 104, 62.5% were receiving psychotherapy at the same time. (Tordoff 2022 at 5 Table 1.) Tordoff did not separate participants into an experimental group and control group. Rather, the study began with the youth as non-medicated and then shifted them from the non-medicated to the medicated group when eligible. (Tordoff 2022 suppl eFigure 1.) At the beginning of the study, seven of the 104 initial participants were already receiving medication (6.7%). By the end of the study, 57 of the remaining 65 participants were receiving medication (i.e., 87.7%). At the beginning of the study, 59.0% of the youth were experiencing moderate to severe depression, and at the end, 58.5% were. At the beginning, 52.0% were experiencing moderate to severe anxiety, and at the end, 51.5%. At the beginning, 45% were experiencing suicidality or thoughts of self-harm, and at the end, 42.2%. Importantly, the report failed to indicate its procedures for assessing the mental health readiness of prospective transitioners, and the results are highly susceptible to selection bias between those deemed eligible for hormones or puberty blockers, and those who were not.

231. In 2023, two very large cohort studies were able to apply population-wide statistical techniques and appeared in the peer-reviewed literature, one out of Denmark (Glintborg et al. 2023), and the other out of Finland (Kaltiala et al. 2023). Both studies examined the medical and mental health records of *all* patients within their respective countries who were diagnosed with Gender Identity Disorder (Denmark) or referred to the centralized national gender identity clinics (Finland) across a large number of years (3812 patients across 21 years in Denmark, in Glintborg et al., and 3665 patients across 28 years in Finland in Kaltiala et al.). This method avoided the severe limitations caused by selection bias, as well as the small samples sizes of many studies in

this field.

232. Both studies measured mental health of subjects and controls across time based on clinical records. Because of the centralized administration of the Danish and Finnish public healthcare systems, the researchers had a relatively complete medical database available for analysis. This method avoided the limitations associated with self-reports and memory already detailed herein (Section IV.).

233. In both studies, before beginning medicalized transition (with cross-sex hormones) people diagnosed with or referred for gender dysphoria exhibited extremely elevated levels of other mental health issues, consistent with prior studies. Overall, Glintborg et al. found that "[Metrics of poor mental health] were stable after initiation of gender-affirming hormone treatment, without sign of decrease after date of first prescription of gender-affirming hormone." (at 342:2.) Kaltiala et al. similarly found that "the proportion requiring specialist-level psychiatric treatment actually increased more among those who underwent medical GR [gender reassignment]" as compared to otherwise comparable patients who did not, and reported that their "findings . . . do not suggest that medical GR interventions resolve psychiatric morbidity among people experiencing gender distress." (at 6:1.)

234. In Glintborg et al., analyses of the rates of psychiatric diagnoses before versus after medicalized transition revealed: At year one, post-transition rates of psychiatric illness greatly increased beyond their already elevated levels, relative to the non-transsexual control groups. By year five, psychiatric illness rates remained highly elevated, but approximating the level of elevation from before medicalized transition, relative to the control groups. Analyses of the rates of psychiatric medication use found that the gender dysphoric subjects exhibited greater use of psychiatric medication before transition relative to controls, and that this higher reliance on

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psychiatric medication had increased further one year after transition, and further still by year five.

235. In Glintborg et al., the people undergoing medicalized transition were age 15 and older (1,142 people under age 18, and 2,670 people age 18 or older). The researchers noted that they conducted their analysis both with and without people under 18, and they found the results not to differ.

236. These data reconfirm that (1) people with gender dysphoria have extremely elevated rates of other mental health issues, (2) medicalized transition is not followed by improvement in mental health, and (3) in the year after transition, mental health *worsened*. Glintborg et al. noted the possibility that undergoing the mental health assessments required before medicalized transition is what caused the apparent increase in rates of psychiatric illnesses recorded. They did not, however, include the alternative possibility that the increase followed from transitioners' realization that the interventions were not resolving their mental health issues and that the subsequent improvements (when observed at all) followed from the increased use of psychiatric medication they were also receiving to address the psychiatric issues directly.¹⁰

B. Seven of the cohort studies confounded medical treatment with mental health services.

237. The initial enthusiasm for medical blocking of puberty followed largely from early reports from the Dutch clinical research team suggesting at least some mental health improvement. (de Vries 2011, 2014.)

238. The Dutch clinical research team followed up a cohort of youth at their clinic undergoing puberty suppression (de Vries 2011), and later cross-sex hormone treatment and

¹⁰ I also observe a continuing drumbeat of anecdotal reports by detransitioners that medicalized transition did not improve their preexisting mental health problems. See, e.g. the several detransitioners' narratives reported in Pamela Paul, *As kids, they thought they were trans. They no longer do.*, New York Times, February 2, 2022.

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surgical sex reassignment (de Vries 2014). The youth improved on several variables upon follow-up as compared to pre-suppression measurement, including depressive symptoms and general functioning. No changes were detected in feelings of anxiety, or anger, or in gender dysphoria itself as a result of puberty suppression. Moreover, natal females suffered *increased* body dissatisfaction both with their secondary sex characteristics and with nonsexual characteristics. (Biggs 2020.)

239. The reports' own authors noted that while it remains possible that the improvement on some variables was due to the puberty blockers, it was also possible that the improvement was due to the mental health support or to natural maturation. The study authors noted this explicitly: "All these factors may have contributed to the psychological well-being of these gender dysphoric adolescents." (de Vries 2011 at 2281.)

240. van der Miesen, et al. (2020) provided an update of the Dutch clinic's sample, reporting continued improvement in transitioners' psychological functioning, but the medical and psychological treatments remained confounded. Also, the authors indicate that the changing demographic and other features among gender dysphoric youth might have caused the treated group to differ from the control group in unknown ways. The study authors expressly noted, "The present study can, therefore, not provide evidence about the direct benefits of puberty suppression over time and long-term mental health outcomes." (van der Miesen 2020 at 703.)

241. Allen, *et al.* (2019) reported on a sample of 47 youth, ages 13–20, undergoing crosssex hormone treatment. They reported observing increases in measures of well-being and decreases in measures of suicidality; however, as the authors also noted, "whether a patient is actively receiving psychotherapy" may have been a confounding variable. (Allen 2019.)

242. Becker-Hebly, et al. (2021) assessed the quality of life and overall functioning of a

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sample of German youth both before and after undergoing treatment with GnRHa, CSHT, or both. Excluded from participating were youth with severe psychiatric issues, including suicidality. Of the sample, 79% of the sample participated in psychotherapy at the same time. As the study authors were careful to indicate, "Because this study did not test for statistically significant differences between the four intervention groups or before and after treatment, the findings cannot be generalized to other samples of transgender adolescents." (Becker-Hebly 2021 at 1755.)

243. In Kuper, *et al.* (2020), a multidisciplinary team from Dallas used a battery of mental health tests to assess 148 youth undergoing either puberty-blocking or cross-sex hormone treatment. The tests revealed highly inconsistent results: Most revealed no significant change, some indicated improvement, and some indicated deterioration. Because 144 of the 148 participants were also in treatment with a therapist or counselor (Kuper at 7, Table 4), no conclusions can be drawn regarding the cause of the improvements. Similarly, 47% of the sample were receiving psychiatric medication at the time of their initial assessments, but it was 61% of the sample at the follow-up time: It cannot be known to what extent mental health improvement was associated with transition-related or with psychiatric medication. Importantly, the variables demonstrating deterioration included each of the ones indicating suicidality and self-harm: At follow-up time, the sample showed *higher* levels of suicidal ideation (from 25% to 38%), suicide attempts (from 2% to 5%), and "non-suicidal self-injury" (from 10% to 17%) (Kuper at 8, Table 5).

244. This evidence of worsening mental health was highly obscured in the Kuper report, however. Rather than provide the standard comparison of pre- and post-treatment rates, Kuper instead listed the post-treatment rates alongside the full *lifetime* rates: "Lifetime and follow-up

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rates were 81% and 39% for suicidal ideation, 16% and 4% for suicide attempt, and 52% and 18% for NSSI, respectively" (p. 1). Rates from over a lifetime are necessarily higher numbers, and putting them where pre-treatment rates normally appear conveys the statistical illusion of a decrease, exactly opposite to the actual pattern.

245. One recent study (McGregor et al., 2024) purports to show that medicalized transition is associated with better mental health scores. The study identified itself, correctly, as a "retrospective cohort" study. *Retrospective* cohort studies are faster and less expensive to conduct than *prospective* cohort studies, but provide less conclusive and more ambiguous results. Prospective studies identify a sample and follow them up again later to analyze what features changed among the participants, whereas retrospective studies select the participants at the end point and then go back to examine hospital or other records to explore what features differed at the beginning.

246. The McGregor study was conducted at the Gender Multispecialty Service (GeMS) program of Boston Children's Hospital. As noted in the study, the GeMS program assesses the mental health of children twice: once, prior to approving them for puberty-blocking medication, and a second time, prior to approving them for cross-sex hormone treatment. Also as noted in the study, adolescents already too old for puberty-blocking medication (i.e., past Tanner Stage 3) receive only the latter assessment.

247. Unfortunately, the analysis conducted and reported by the McGregor team has so profound a selection bias as to be meaningless (Section IV.E.): They compared the 40 children who sought and received puberty-blockers and are now seeking cross-sex hormone treatment (i.e., children who were assessed *and passed* the mental health screening) with the roughly 400 adolescents seeking cross-sex hormones who had not yet been screened for mental health at all.

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As a result, one cannot validly conclude that the greater mental health scores of the children receiving puberty-blockers were caused by the puberty-blockers. This retrospective study has no means of ruling out the much more logical conclusion that the children who received puberty-blockers only seem mentally healthier because the less healthy ones had already been screened out of that group.

248. Another fatal error of McGregor et al. is that they compared *childhood-onset* gender dysphoria with *adolescent-onset* gender dysphoria. As noted already herein, these represent distinct patient populations with distinct features, which McGregor neglected to discuss despite reporting the same distinctions. (Section IX.C.) As summarized by the McGregor authors:

These two groups were significantly different across all assessed demographic domains. The blocker population was significantly younger, more likely to be assigned male at birth, more likely to affirm a female gender, and more likely to identify as white. (McGregor et al. (2024) at 3.)

A comparison across two groups that already differ in so many potentially important ways is necessarily uninformative: As the authors correctly emphasized about their own results, "causation [of the differences in mental health between the two groups] cannot and should not be assumed." (at 5.) Indeed, the authors reported that once they controlled for age, the correlation they report between receiving puberty blockers and lower levels of suicidal thoughts *disappeared* (at 6.). In sum, that the adolescent-onset group showed poorer mental health than the childhood-onset group is consistent with the conclusion that gender dysphoria is a result of unresolved mental health issues, rather than poor mental health being a result of unresolved gender dysphoria.

249. I note that the McGregor et al. authors agree with a critical risk of harm detailed in my initial report—that puberty blockers alone may permanently sterilize a child, stating that "blockade impairs hormone-driven development of the ovaries or testes, and this may

substantially reduce *or eliminate* future fertility potential in the absence of experimental options" (at 5, emphasis added.). The reference to "experimental options" is an oblique way of indicating that reliable restoration of fertility after prolonged puberty blockade has not been demonstrated.

C. Two found no advantage of medicalization over psychotherapy.

Costa, et al. (2015) provided preliminary outcomes from a small study conducted 250. with patients of the GIDS clinic in the UK. They compared the psychological functioning of one group of youth receiving psychological support with a second group receiving both psychological support as well as puberty blocking medication (representing an "active comparator" group. See Section III.C.2). The "untreated" group, however, was different from the treated group in another important respect, in that these were the patients who began with such severe psychiatric co-morbidities that they were deemed ineligible to begin puberty blockers until mental health improved. Further, the study suffered a dramatic loss-to-follow-up, with almost two thirds of participants dropping out across just 18 months. (Biggs 2019.) In this preliminary report, both groups improved in psychological functioning over the course of the study, but no statistically significant difference between the groups was detected at any point. (Costa 2015 at 2212, Table 2.) In any event, all these findings have been superseded, however, and are moot. The final outcomes report for this cohort was subsequently published (as Carmichael 2021, above), finding that neither group actually had experienced any significant improvement at all. (Carmichael 2021.)

251. Achille, *et al.* (2020) at Stony Brook Children's Hospital in New York studied a sample of 95 youth with gender dysphoria, but 45 were lost-to-follow-up within just 12 months, failing to complete follow-up surveys at 6 month and or 1 year. That is, outcomes were available only for the 50 who remained in the study. As well as receiving puberty blocking medications,

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"Most subjects were followed by mental health professionals. Those that were not were encouraged to see a mental health professional." (Achille 2020 at 2.) Upon follow-up, some incremental improvements were noted; however, after statistically adjusting for psychiatric medication and engagement in counselling, "*most predictors did not reach statistical significance*." (Achille 2020 at 3, italics added.) That is, puberty blockers did not improve mental health any more than did mental health care on its own. More specifically, only one of the 12 predictors reached statistical significance. (Achille 2020 at Table 4.) That is, medicalized transition was not associated with improved mental health beyond improvement associated with the mental health care received. Moreover, the single predictor reaching the threshold for statistical significance is not reliable: the study authors made a methodological error by failing to account for the multiple comparisons it conducted. Had the study applied the standard adjustment for correcting for multiple comparisons, that remaining predictor would also have ceased to be statistically significant.

D. Two failed to report whether psychotherapy was provided.

252. Chen, *et al.* (2023) reported finding some improvement in some mental health variables associated with the cosmetic changes after two years of cross-sex hormone treatment in a sample of 315 youth (mean age, 16 years). Unlike the other studies, Chen et al. did not report how many participants were receiving psychotherapy or psychiatric medication at the same time as the hormone treatments. It is therefore not possible to assess to what extent any changes were due to hormone treatment versus the potential confounds. Because the study did not include a control group, it is not possible to assert that changes were due to hormone treatment rather than representing regression to the mean (see Section III.C.1. *Biases representing 'regression to the mean* '). Potential conclusions are also hampered by the large proportion of mental health data

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that were missing: Of the 315 youth in the sample, analyses could be conducted with only 208–217 (Chen 2023, supp. Material at 12, Table S5). The purported changes in mental health variables were statistically significant, but not clinically meaningful. The depression test used by Chen et al consisted of 21 items, with each item contributing up to 3-points to the total score. For example:

0 I do not feel sad.

1 I feel sad.

2 I am sad all the time and I can't snap out of it.

3 I am so sad and unhappy that I can't stand it.

Thus, the total scores range from 0 to 63. Scores 0–13 represent minimal difficulty; 14–19 represent mild depression; 20–28, moderate; and 29–63, severe. The change that Chen et al. found after two years of hormone treatment was from 16.39 to 13.95 (at Table S5). Changes of this size are unlikely to be associated with patients reporting they feel better. Such scores are below the "minimum clinically important difference." (Button 2015.) Although the report did not include data on co-morbid mental health diagnoses, it noted that two patients receiving cross-hormone treatment died by suicide (representing 0.6% mortality within just two years). (Chen 2023 at 240.)

253. In addition to the incomplete reporting of key aspects of the project and large proportion of missing data, Chen et al appears to have provided only a selected subportion of the information it collected. A knowledgeable journalist investigating transgender issues, Jesse Singal, identified documentation representing the full set of information the Chen et al team planned to collect. I have verified that documentation and have come to the same conclusion. As described by Singal:

In their study protocol, including a version that they submitted into a preregistration database, the researchers hypothesized that members of this cohort would experience improvement on eight measures, including ones that are just about universally recognized by youth gender researchers as important outcomes, such as

gender dysphoria, suicidality, and self-harm. Then, in the published *NEJM* paper, the researchers changed their hypothesis and six of those variables were nowhere to be found. The two remaining—anxiety and depression—moved in a positive direction for trans boys (natal females) but not trans girls (natal males). The researchers reported on three other variables, too, without explaining how they picked them (two improved for trans girls and boys, and one just for trans boys). (Singal 2023.)

254. This appears to represent "cherry-picking" of the findings being reported, rather than a comprehensive reporting on the complete set of evidence. Further, Chen et al. failed to balance the concrete and strikingly high rate of *completed* suicide among their sample against the very incremental mental health changes they claim, even though the ethical and clinical importance of those suicides is obvious.

255. In 2024, the Kuper team in Dallas released a study of 12–18 year old's receiving cross-sex hormones, puberty-blockers or both. (Chelliah et al., 2024.) The youth in the prior outcomes study from this team (Kuper et al., 2020, summarized in the preceding section) entered treatment between August 2014 and March 2018, the youth in this study enrolled between October 2017 and March 2020.¹¹ A total of 156 minors began the study, but only 115 were participating at follow-up, 11–18 months later. Chelliah et al. report that the youth showed moderately better scores at follow-up time on the three self-reported mental health variables, representing depression, anxiety, and quality of life. As discussed already, in the prior study from this team 97% of the sample were undergoing psychotherapy at the same time as their medicalized transitions, and a greater number of participants were receiving psychiatric medication at the end of the study, leaving it unknowable to what extent it was the medicalized transitions that was associated with changes in mental health. In this study, not only did the

¹¹ Fourteen people appear in both studies: Although the researchers reported that "analyses were re-run excluding these participants, and results were similar," p. 2, they did not provide a justification for permitting the overlap and foregoing the opportunity of an independent replication.

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Kuper team report no attempt to resolve that question, but it failed to report any information at all about patients receiving psychotherapy or psychiatric medication. It concluded that "results from the present study speak to the broad, short-term benefits of gender-affirming hormone therapy for TGD youth," but only because it failed to consider even the most obvious of alternative explanations. (Chelliah, 2024, at 5.)

XIV. Known and potential harms associated with administration of puberty blockers and cross-sex hormones to children and adolescents.

256. As I have explained, any conclusion about safety requires knowledge about and balancing of both risks and benefits.

257. In concluding that safety has not been established (see Section V above), national health authorities, authors of systematic reviews, and researchers have identified a number of harms which are either known to result from administration of puberty blockers and cross-sex hormones to children and adolescents, or can be reasonably anticipated but have not been sufficiently studied to reach any conclusion as to the likelihood or severity of harm.

258. When applying research regarding harms to clinical policy, several considerations need to be included: (1) The harms of medicalized transition of gender does or may differ between male-to-female and female-to-male cases, differ between ages of transition, and differ according to age-of-onset of the gender dysphoria. Evidence and conclusions about harms (and safety) cannot be generalized or extrapolated across such cases. (2) The evidence has strongly shown that after social transition of gender, minors are much more likely than otherwise to undergo medicalized transition of gender. Thus, the appropriate assessment of the risk:benefit ratio for social transition must include the increased risks posed by the medicalized path to which it is likely to lead. (3) The evidence has shown strongly that youth who undergo puberty blocking are highly likely to undergo cross-sex hormone treatment. Thus, the appropriate risk:benefit evaluation must also consider its potential implications over the full lifespan.

259. Systematic reviews of the evidence have identified fewer than 10 studies investigating potential harms of medicalized transition of minors at all, (NICE 2020a at 6) and most of these have been limited to bone and skeletal health. As concluded by the NICE systematic review, "A key limitation to identifying the effectiveness and safety of GnRH

analogues for children and adolescents with gender dysphoria is the lack of reliable comparative studies." (NICE 2020a at 40.) With that said, numerous harms are either known, or reasonably anticipated by respected health authorities but thus far unmeasured.

A. Sterilization without proven fertility preservation options.

260. Clinical guidelines for the medical transition of gender among children include the need to caution and counsel patients and parents about what are euphemistically called "options for fertility preservation." (e.g., Endocrine Society Guidelines, Hembree 2017 at 3872.) For children who are placed on puberty blockers at Tanner Stage 2, however, because most continue onto cross-sex hormones once they begin a medicalized approach to their dysphoria, no viable fertility preservation options exist. The decision to undergo medicalized transition also represents the decision never to have biological children of one's own.

261. For the large new population of young people who are first being put on puberty blockers and/or cross-sex hormones at a somewhat later stage of puberty, no studies at all have been done of when, whether, or with what probability either males or females can achieve healthy fertility if they later regret their transition decision and cease taking puberty blockers and/or cross-sex hormones. Much less has this been studied as a function of the stage of development at which they began puberty blockers and/or cross-sex hormones, and how long their gonads were subjected to cross-sex hormones.

262. Risk:benefit analysis requires information relevant to the possibility that medical transition will become perceived by the patient as having inflicted severe harm, and the potential impact and import of future parenting cannot be underestimated. Multiple studies have investigated the desires of transgender individuals to become biological parents, and a systematic review of this research has recently been completed and published: Stolk et al. (2023) reviewed

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of a total of 76 individual studies. The review found that that the majority of adults undergoing medicalized transition desired to become parents in the future; however, fertility preservation utilization rates were nonetheless low. That disconnect obviously leaves large room for future regret and harm.

263. Stolk et al. found that, unlike transgender adults, only a minority transgender adolescents stated a desire to become biological parents in the future. Stolk et al. did not however, find any study that measured by how such desires *change* over time, once those who transition as adolescents mature into adult life. The much greater levels of desire to become a parent reported by transgender adults suggests the hypothesis that this desire increases as one enters and lives adult life, although a longitudinal study would be necessary to conclude this with confidence. Also absent from Stolk et al. was information comparing levels of asserted desire to be a parent in the future among *non*-transgender adolescents with asserted desire on the part of non-transgender adults. Such a comparison that might give critical insight into the general stability (or lack of stability) of such desires across time and maturation.

264. Notably, Stolk et al. recognized that cross-sex hormone treatment beginning at Tanner Stage 2 ends the possibility of future fertility. The review noted also that WPATH guidelines include no procedures that would prevent this effective sterilization. Rather, WPATH guidelines include only the recommendation that individuals undergoing medicalized transition receive counseling about that loss of capacity for biological children. Neither the review nor WPATH provides any indication of how effective such counseling can be with, for example, a 10-year-old or prepubescent child making the irreversible decision never to become a biological parent. No evidence or methodology exists for validating whether any consent or assent obtained from such a child could be meaningfully informed.

B. Permanent loss of capacity for breast-feeding in adulthood.

265. While the removal of the breasts of a biological female adolescent or young adult may be cosmetically revised, it is functionally irreversible; even if the person later regrets and detransitions before or during adulthood, breast-feeding a child will never be possible. To the adolescent determined to transition, this may seem no cost at all. To the future adult mother, it may be a very severe harm indeed.

C. Lifetime lack of orgasm and sexual function.

266. There has not been systematic investigation of the effects on adult sexuality among people medically transitioned at an early stage of puberty. Notably, Dr. Marci Bowers, current President of WPATH, and surgeon with substantial experience conducting penis-to-vagina operations, opined, "If you've never had an orgasm pre-surgery, and then your puberty's blocked, it's very difficult to achieve that afterwards....I consider that a big problem, actually. It's kind of an overlooked problem that in our 'informed consent' of children undergoing puberty blockers, we've in some respects overlooked that a little bit." (Shrier 2021.) In my opinion as a psychologist and sex and couple's therapist, this represents a large potential harm to future relationships and mental health to "overlook," and must be taken into consideration in any serious risk:benefit analysis of "safety."

D. Hormonal treatments during puberty interfere with neurodevelopment and cognitive development.

267. It is well known that pubertal hormone levels drive important stages of neural development and resulting capabilities, although the mechanisms are not yet well understood. Dr. John Strang (Research Director of the Gender Development Program at Children's National Hospital in Washington, D.C.) (Terhune 2022), the Cass Review from England, and the systematic review from Finland all reiterated the central importance and unknown effects of

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GnRH-agonists on windows, or "sensitive periods," in brain development, notably including adolescence. As Dr. Cass put it:

A further concern, already shared with NHS England (July 2022) (Appendix 6), is that adolescent sex hormone surges may trigger the opening of a critical period for experience-dependent rewiring of neural circuits underlying executive function (i.e. maturation of the part of the brain concerned with planning, decision making and judgement). If this is the case, brain maturation may be temporarily or permanently disrupted by the use of puberty blockers, which could have a significant impact on the young person's ability to make complex risk-laden decisions, as well as having possible longer-term neuropsychological consequences. (Cass 2024 at 178.)

268. In a meta-analysis (a highly rigorous type of systematic review) of studies of neuropsychological performance, non-transsexual males undergoing puberty earlier show a different cognitive profile than those underdoing puberty later. The association of brain development with age of pubertal onset exists in humans as well as non-human animals. (Shirazi 2022.)

269. Even in adults, neuroscience studies employing MRI and other methods have shown that the blockade of normal levels of hormones associated with puberty and adulthood degrade brain performance. Thus, when GnRH-agonists are administered to adult biological women, several brain networks decrease in activity, and cognitive performance, such as working memory, declines. (Craig 2007; Grigorova 2006.)

270. In light of this science, multiple voices have expressed concern that blocking the process of puberty during its natural time could have a negative and potentially permanent impact on brain development (Cass 2022 at 38–39; Chen 2020; Hembree 2017 at 3874; Cass 2024 at 178.) As Chen *et al.* (2020) observed:

[I]t is possible these effects are temporary, with youth 'catching up'...However, pubertal suppression may prevent key aspects of development during a sensitive period of brain organization. Neurodevelopmental impacts might emerge over time, akin to the 'late effects' cognitive findings associated with certain [other] oncology treatments. (Chen 2020 at 249.)

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Chen et al. (2020) noted that no substantial studies have been conducted to identify such impacts outside "two small studies" (at 248) with conflicting results. I have not identified any systematic review of neurodevelopment or cognitive capacity.

271. Such a systematic review was attempted by University College London Professor Sallie Baxendale, about whether puberty-blockers' supposed reversibility includes brain development: Unlike the visible features of growth of the body, brain development in mammals is characterized by critical periods and windows of plasticity. The sequential, time-limited sensitivities to imprinting among these features during pubertal development predict the outcomes of altering the timing among them would not be reversible analogous to catch-up growth of the body. After finding that there existed insufficient studies of puberty-blockers on the neurodevelopment among gender dysphoric youth, she reviewed the analogous research on laboratory animals (11 studies) and the few neuropsychological studies of puberty-blockers on the children with precocious puberty (five studies). (Baxendale, 2023.) In the animal research:

The results from these studies indicate that treatment with a GnRH antagonist/agonist has a detrimental impact on learning and the development of social behaviours and responses to stress in mammals....There is no evidence in the animal literature that these effects are reversible following discontinuation of treatment. (Baxendale 2023 at 1159–1160.)

Studies of human children with central precocious puberty showed lower scores on IQ testing, with an effect sizes of d = -0.5 ("moderate") or more in some single case studies; however, the small samples and large proportions of people dropping out the studies hamper reliable estimates.

272. A related concern is that by slowing or preventing stages of neural development, puberty blockers may impair precisely the mature cognitive capabilities that would be necessary to evaluation of, and meaningful informed consent to, the type of life-changing impacts that accompany cross-sex hormones. (See Section XV.)

273. In sum, as the Cass Final Report put it, administering puberty blockers "could have a range of unintended and as yet unidentified consequences." (Cass 2024 at 178.)

E. Substantially delayed puberty is associated with medical harms.

274. The research cited by the WPATH Standards of Care includes the evidence that children whose natural puberty started very late (top 2.3% in age) have elevated risks of multiple health issues in adulthood. (Zhu & Chan 2017.) These include elevations in metabolic and cardiovascular disease, lower height, and decreased bone mineral density. It has not been studied whether these correlations also occur in children whose puberty is chemically delayed. Undergoing puberty much later than one's peers is also associated with poorer psychosocial functioning and lesser educational achievement. (Koerselman & Pekkarinen 2018.)

F. Elevated risk of Parkinsonism in adult females.

275. Epidemiological research has shown adult women without gender dysphoria, undergoing surgical removal of both ovaries for other reasons, to have substantially elevated odds of developing parkinsonism, including Parkinson's Disease, relative to age-matched women randomly selected from the local population in an on-going epidemiological study. (Rocca 2022.) The effect was greater among younger women, showing 7–8 times greater odds among women under 43. The observed delay between removal of ovaries and the onset of parkinsonism was 26.5 years. Whether chemically suppressing the ovaries of a biological female via puberty blockers during adolescence followed by cross-sex hormones will cause a similar increase in parkinsonism, or when, remains unknown.

G. Reduced bone density.

276. The systematic reviews by Sweden, Finland, and England all included bone health as an outcome. *The New York Times* also recently commissioned its own independent review of the

available studies. (Twohey & Jewett 2022.) These reviews all identified subsets of the same group of eight studies of bone health. (Carmichael 2021; Joseph 2019; Klink 2015; Navabi 2021; Schagen 2020; Stoffers 2019; van der Loos 2021; Vlot 2017.) These studies repeatedly arrived at the same conclusion. As described by *The New York Times* review:

[I]t'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.¹² (Twohey & Jewett 2022.)

277. There is some evidence that some of these losses of bone health are regained in some of these youth when cross-sex hormones are later administered. The rebounding appears to be limited to female-to-male cases, while bone development remains deficient among male-to-female cases.

278. The long-term effects of the deficient bone growth of people who undergo hormonal interventions at puberty remain unstudied. The trajectory of bone quality over the human lifetime includes decreases during aging in later adulthood. Because these individuals may enter their senior years with already deficient bone health, greater risks of fracture and other issues are expectable in the long term. As the *New York Times* ' analysts summarized, "That could lead to heightened risk of debilitating fractures earlier than would be expected from normal aging—in their 50s instead of 60s." Such harms, should they occur, would not be manifest during the youth and younger adulthood of these individuals. This distinction also represents one of the differences between adult transitioners and childhood transitioners and why their experiences cannot be extrapolated between them.

¹² The eighth study was Lee, et al., 2020, which reported the same deficient bone development.

279. There does not exist an evidence-based method demonstrated to prevent these

outcomes. The recommendations offered by groups endorsing puberty blockers are quite limited.

As summarized by The 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. (Twohey & Jewett 2022.)

H. Short-term/Immediate side-effects of puberty blockers include sterile abscesses, leg pain, headache, mood swings, and weight gain.

280. The interim report of The Cass Review summarized that "In the short-term, puberty blockers may have a range of side effects such as headaches, hot flushes, weight gain, tiredness, low mood and anxiety, all of which may make day-to-day functioning more difficult for a child or young person who is already experiencing distress." (Cass 2022 at 38.)

281. In 2016, the U.S. FDA began requiring drug manufacturers to add a warning about the psychiatric side effects, after reports of suicidal ideation and a suicide attempt began to emerge among children prescribed GnRH-agonists (for precocious puberty).¹³ The warning label on Lupron reads that "Psychiatric events have been reported in patients…such as crying, irritability, impatience, anger and aggression."

282. Other than the suicide attempt, such adverse effects may seem minor relative to the major health and developmental risks I have reviewed above, and they may be dismissed by children and by parents confronted by fears of suicidality and an urgent hope that transition will resolve the child's unhappiness and mental health issues. However, when assessing risk:benefit

¹³ Reuters Special Report; 2022, Oct. 6. Retrieved from https://www.reuters.com/investigates/special-report/usa-transyouth-care/

ratio for "safety" against the undemonstrated benefits claimed for hormonal interventions, these observed harms should not be ignored.

I. Long-term use of cross-sex hormones in adults with gender dysphoria is associated with unfavorable lipid profiles (cholesterol and triglycerides) and other issues.

283. As the interim report of The Cass Review correctly and succinctly indicated, "Sex hormones have been prescribed for transgender adults for several decades, and the long-term risks and side effects are well understood. These include increased cardiovascular risk, osteoporosis, and hormone-dependent cancers." (Cass 2022 at 36.)

284. Minors who begin puberty blockers and proceed to cross-sex hormones—as almost all do—will require continuing treatment with cross-sex hormones for life, unless they go through the very difficult process of detransition. Because a lifetime dependence on cross-sex hormones is the expected course, the known adverse effects of cross-sex hormones on adults must also be part of the risk:benefit analysis of the "safety" of putting a minor on cross-sex hormones (and indeed, of the initial decision to put a child on puberty blockers).

285. Systematic review identified 29 studies of the effects of cross-sex hormone treatment on cardiovascular health in adults. (Maraka 2017.) By the two-year follow-up mark among female-to-male transitioners, hormone administration was associated with increased serum triglycerides (indicating poorer health), increased low-density-lipid (LDL) cholesterol (indicating poorer health), and decreased high-density-lipid (HDL) cholesterol (indicating poorer health). Among male-to-female transitioners at the two-year mark, cross-sex hormone treatment was associated with increased serum triglycerides (indicating poorer health).

XV. Assertions that puberty blockers act only as a "fully reversible" "pause button" are not supported by scientific evidence.

286. Many advocates and organizations, have boldly asserted that the administration of puberty blockers to adolescents is "fully reversible." The assertion is not consistent with or supported by any objective assessment of the existing science. Although withdrawal of the medication will allow the pubertal process to resume, that is very far from establishing that the impact of that interruption of natural development is "fully reversible." The evidence is not that the person's life will proceed as if the medical intervention never happened, as the popularized phrase suggests. Rather, the evidence repeatedly indicates that stopping a healthy child's natural onset of puberty imposes multiple substantial harms, risks, or opportunity costs.

287. First, as I have previously mentioned (Section IV.D), it is scientifically invalid to extrapolate results from using puberty blockers to prevent precocious puberty by delaying the pubertal process to its normal age range, to using them to *prevent* normally occurring healthy puberty, merely assuming the effects and side-effects will be the same. The two are very different populations and very different uses.

288. Second, not all the effects of GnRHa's in otherwise healthy children are known: It is therefore not possible to assess whether all effects are reversed or to what extent. Indeed, within the scientific method, it is never possible to demonstrate that any intervention is "fully reversible." In science, it always remains possible for future evidence to identify an effect that does not reverse. To assert that all the effects of GnRHa's are fully reversible is to assert that all the effects of GnRHa's are fully reversible is to assert that all its effects have been investigated and checked for reversibility, which is false.

289. Third, and more concretely, I have reviewed above a large number of medical and developmental risks which multiple responsible voices have associated with administration of puberty blockers to adolescents, and which are either established by studies or have not been

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shown not to exist. In the face of this knowledge and lack of knowledge, it is scientifically unsupported and irresponsible to assert that this use of puberty blockers is "fully reversible" and "just a pause."

290. Here, I identify additional psycho-social developmental impacts of delaying healthy, naturally-occurring puberty which are likely to be irreversible, but have not been meaningfully studied.

A. Stopping puberty does not stop time: Patients' peers continue to develop and mature, with patients falling increasingly behind.

291. Initiating puberty blockers at Tanner Stage 2 (at the very first signs of puberty, typically ages 9 or 10) holds the child in a prepubescent state, while their peer group and classmates continue to grow. By the time many patients begin cross-sex hormone treatment, their peers will have completed puberty and progressed far into adolescence. Puberty may become unblocked, but these children have irreversibly lost the opportunity and experience of developing with their peers and must instead do so alone.

292. Being a "late bloomer," indeed among the latest possible bloomers, has psychological consequences of its own. Having the body and mind of a prepubescent child while one's friends have grown into physically mature sixteen-year-olds is extreme. Despite being a teenager chronologically, remaining prepubescent both physically and mentally while the lives of one's peers have advanced to teenagers' interests only increases the isolation of children already reporting social distress. There does not exist a means of distinguishing how much of any improvement in mental health that might be observed across these years in a particular study is simply the result of finally undergoing at least some pubertal development and finally catching up with one's peers in at least some parameters.

293. Concretely, undergoing puberty much later than one's peers (as a result of naturally

occurring rather than medically induced conditions) has been associated with poorer psychosocial functioning and lesser educational achievement. (Koerselman & Pekkarinen 2018.) Whether this holds true when the late puberty is the result of puberty blockers has not been studied.

B. Blocking puberty blocks the awareness of sexuality and sexual orientation that can play an important role in the individual's understanding of gender identity.

294. As demonstrated unanimously by the cohort studies of prepubescent children with gender dysphoria, the great majority cease to feel gender dysphoric during the course of puberty. (Section IX.B.) Studies also find that many such children subsequently identify as gay or lesbian, providing a potential alternative source and understanding of their atypical childhood gender interests. Blocking puberty, however, necessarily blocks for all children the onset of adult sexual interest, sexual arousal, and sexual response which are part of "the usual process of sexual orientation and gender identity development." (Cass 2022 at 38.) That is, blocking the experience of sexual feelings and development blocks the very phenomena that enable young people to understand sexuality and sexual orientation, and its distinction from gender identity. As Dr. Cass summarized:

Adolescence is a time of overall identity development, sexual development, sexual fluidity and experimentation. ... Blocking this experience means that young people have to understand their identity and sexuality based only on their discomfort about puberty and a sense of their gender identity developed at an early stage of the pubertal process. Therefore, there is no way of knowing whether the normal trajectory of the sexual and gender identity may be permanently altered. (Cass 2024 at 178.)

Thus, contrary to the hypothesis that providing time might permit more considered understanding and decision-making, the prevention of puberty blocks the awareness of a central factor that may well influence that understanding.

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295. Because puberty blockers prevent prepubescent children from developing any understanding of sexual arousal and sexual relationships they would otherwise gain with maturation, such children are necessarily incapable of providing informed consent. There does not exist—indeed, there cannot exist—an age-appropriate way to equip a child who has not gone through puberty to make an informed decision about age-inappropriate issues, such as their future sex life, choices of sexual partners, sex-bonded relationships including marriage, and sacrificing ever experiencing orgasm.

C. Blocking puberty may block development of adult decision-making capacity.

As I have explained above, there are reasons to fear that use of puberty blockers may 296. have permanent negative effects on brain development. That long-term risk aside, blocking puberty nevertheless threatens to prevent the child from growing towards adult decision-making capability during precisely the years in which he or she is being asked to make life-altering decisions about gender identity, gender presentation and cross-sex hormones. Pubertal brain development includes pervasive change in structural and functional connectivity (Chen 2020), re-balancing its capabilities between the acquisition of skills and knowledge and their application. Foremost among these are acquiring the abilities to control impulsivity and engage in rational and long-term decision-making (Crone & Steinbeis 2017), in association with development of a brain region called the "prefrontal cortex," and similarly acquiring the capacity to process adult social interaction, in association with the development of a network of brain areas (Kilford 2016), collectively called the "social brain." To understand medicalized transition of gender and its known and unknown consequences is one of the most complicated questions that a young person today could face, and a prepubescent brain is not equipped to process that information rationally, objectively, and with a whole lifetime rather than immediate desires and

social pressures in mind.

D. Time spent on puberty blockers poses significant opportunity costs.

297. One of the primary, if not the foremost, justifications for medically transitioning children and adolescents is to reduce the psychological distress they report. That hypothesis interprets these children's psychological concerns (e.g., anxiety and depression) to gender dysphoria and/or external sources (e.g., transphobia). As I have noted here previously, however, many gender dysphoric children and adolescents suffer from multiple other mental health issues. In several studies of minors on puberty blockers, a substantial portion of the subjects do not report ongoing psychological care. If years spent on puberty blockers in the hopes that that will relieve distress distract from systematic efforts to directly address comorbidities through psychotherapy, then it diverts the minors from treatment which exhibits substantial evidence of effectiveness for improving mental health and lacks the multiple and significant side-effects of puberty blockers.

XVI. Assessments of clinical guidelines, standards, and position statements.

298. Several sets of recommendations have been offered regarding the clinical treatment of people with gender dysphoria. In this section, I comment on these protocols or recommendations individually.

A. The Dutch Protocol (aka Dutch Approach).

299. The Netherlands' child gender identity clinic in Amsterdam associated with the Vrije University (VU) was one of the international leaders in the use of hormonal interventions to treat gender dysphoria in minors. Researchers associated with that clinic have generated a large portion of the seminal research literature in the field. Key early publications from that group spelled out criteria and procedures that are collectively referred to as the "Dutch Protocol," and this approach has been widely influential internationally.

300. The purpose of the protocol was to compromise conflicting desires and considerations including: clients' initial wishes upon assessment; the long-established and repeated observation that those wishes will change in the majority of (but not in all) childhood cases; and that cosmetic aspects of medical transition are perceived to be better when they occur earlier rather than later in pubertal development.

301. The VU team summarized and explicated their approach in their paper, *Clinical management of gender dysphoria in children and adolescents: The Dutch Approach.* (de Vries & Cohen-Kettenis 2012.) Key components of the Dutch Approach are:

- no social transition at all considered before age 12 (watchful waiting period),
- no puberty blockers considered before age 12,
- cross-sex hormones considered only after age 16, and
- resolution of mental health issues before any transition.

302. For youth under age 12, "the general recommendation is watchful waiting and

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carefully observing how gender dysphoria develops in the first stages of puberty." (de Vries & Cohen-Kettenis 2012 at 301.)

303. The age cut-offs of the Dutch Approach were not based on any research demonstrating their superiority over other potential age cut-offs. Rather, they were chosen to correspond to the ages of consent to medical procedures under Dutch law. Nevertheless, whatever the original rationale, the data from this clinic simply contain no information about the safety or efficacy of employing these measures at younger ages.

304. The authors of the Dutch Approach repeatedly and consistently emphasize the need for extensive mental health assessment, including clinical interviews, formal psychological testing with validated psychometric instruments, and multiple sessions with the child and the child's parents.

305. Within the Dutch Approach, there is no social transition before age twelve. That is, social affirmation of the new gender may not begin until age 12—as desistance is less likely to occur past that age. "Watchful Waiting" refers to a child's developmental period up to that age. Watchful waiting does not mean do nothing but passively observe the child. Rather, such children and families typically present with substantial distress involving both gender and non-gender issues, and it is during the watchful waiting other issues which may be exacerbating psychological stress or dysphoria. As noted by the Dutch clinic, "[T]he adolescents in this study received extensive family or other social support [and they] were all regularly seen by one of the clinic's psychologists or psychiatrists." (de Vries 2011 at 2281.) One is actively treating the person, while carefully "watching" the dysphoria.

306. The use of hormonal interventions described in the Dutch Protocol, while markedly
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more conservative than today's practice in many U.S. clinics, has recently been criticized in detail in a peer-reviewed article as unjustified by reliable evidence (Biggs 2022; Levine 2023; Levine 2022). Certainly, the published research evidence base concerning safety and efficacy available to the VU clinicians is and was no greater than the global evidence base that the NICE review recently labelled as uniformly of "very low quality."

307. Because clinical practices are often justified by alluding to the Dutch Protocol, however, it is important to be aware of the limitations on the use of hormones and puberty blockers specified by the Dutch Protocol and listed above (and thus the limits of the clinical evidence published out of the VU clinic) which are regularly ignored by clinicians in the U.S.

B. World Professional Association for Transgender Health (WPATH).

308. The WPATH standards of care have been lauded as long-established and high quality procedures. This does not reflect any objective assessment, however. The previous WPATH standards (version 7) were subjected to standardized evaluation, the Appraisal of Guidelines for Research and Evaluation ("AGREE II") method. (Dahlen 2021.) That assessment concluded "[t]ransition-related [clinical practice guidelines] tended to lack methodological rigour and rely on patchier, lower-quality primary research." (Dahlen 2021 at 6.) The WPATH guidelines were not merely given low scores, but received unanimous ratings of "Do not recommend." (Dahlen 2021 at 7.)

309. Immediately after the release of the current (2023) version of WPATH's standards (version 8), WPATH fundamentally altered it by removing from it minimum ages previously required for undergoing social or medical transition of gender. (WPATH Correction 2022.) This is despite the fact that age is the central component to young people's emerging understanding of their sexual identities through social identity formation, pubertal development, and the onset of

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sexual interest. The removal of age restrictions was not based on any research evidence at all— WPATH provided no reference to any study as justification, and the WPATH leadership have been explicit in indicating that the change was intended to prevent clinical care providers from legal liability for physicians rejecting those minimums. The implementation of such fundamental and dramatic changes, in the complete absence of any supporting science whatsoever, negates entirely any claim that WPATH represents evidence-based or empirically-supported treatment. As explicated herein, on Table 1, the systematic review on which WPATH based its standards for minors included exactly one study on puberty blockers and three studies on cross-sex hormones. All other references represent cherry-picked citations of studies rejected by its own systematic process. Moreover, even among the four studies in WPATH's review, three were rejected by the Swedish review, due to the low quality of the science they contained.

1. WPATH extensively violated international conflict of interest standards in the course of developing SOC-8, while claiming to comply with them.

310. In addition to these issues, WPATH was possessed of extensive conflicts of interest throughout the production of Version 8 of its Standards of Care (SOC-8), while making false representations that it was complying with accepted conflict of interest principles for that process.

311. For reference, the following section refers to these documents for its analysis:

Sharma et al. (2018).

WPATH's pre-registration in the PROSPERO database of the systematic review it planned, identifying each of the specific research questions it would examine.

Baker et al. (2021).

WPATH's systematic review of studies on the mental health of hormone therapy on transgender people, three of which were on minors.

WPATH (2022) aka Coleman et al. (2022). WPATH's completed *Standards of Care*, version 8 (SOC-8). WHO (2019) aka WHO (2019a).

The *International Classification of Diseases*, version 11 (ICD-11) of the World Health Organization.

WHO (2014).

The *WHO Handbook for Guideline Development* (2nd edition) of the World Health Organization. Chapter 6 pertains to the management of conflicts of interest. Chapter 14 pertains to the issuing of strong recommendations on the basis of low quality evidence.

IoM (2011).

Institute of Medicine. (2011). *Clinical Practice Guidelines We Can Trust.* Washington, DC: The National Academies Press.

312. SOC-8 indicates its guideline development methods in its appendix, on page S247:¹⁴

The process for development of the SOC-8 incorporated recommendations on clinical practice guideline development from the National Academies of Medicine and The World Health Organization that addressed transparency, the conflict-of-interest policy, committee composition and group process. (Institute of Medicine Committee on Standards for Developing Trustworthy Clinical Practice, 2011; World Health Organization, 2019a).

An attempt to verify the claim of reliance on those documents leads to dead ends, however.

313. The entry in WPATH's reference list for WHO (2019a) is to:

World Health Organization. (2019a). *International Statistical Classification of Diseases and Related Health Problems (11th ed.)*. World Health Organization. https://icd.who.int/browse11/lm/en#/http://id.who.int/icd/entity/90875286" (SOC-8 at p. S244.)

That document, however (the ICD-11, WHO 2019a), is not a methods manual at all. It does not

provide procedures for developing clinical guidelines, for conflict of interest or any other issue.

314. The other document that WPATH cited as its source, "IoM (2011)," does not appear

on WPATH's reference list at all, but it appears to refer to the Institute of Medicine's Clinical

Practice Guidelines We Can Trust (2011). The actual WHO manual for clinical guidelines

¹⁴ SOC-8 also indicates its methods on page S8 providing the text below, with no citation, and noting that "SOC-8 incorporated *the* recommendations" (emphasis added) rather than "SOC-8 incorporated recommendations."

[&]quot;The process for development of the SOC-8 incorporated *the* recommendations on clinical practice guideline development set forth by the National Academies of Medicine and the World Health Organization, which addressed transparency, conflict-of-interest policy, committee composition, and group process."

development is WHO (2014), the *WHO Handbook for Guideline Development*, referenced as above. This handbook is missing altogether from WPATH's reference list.

315. Both IoM (2011) and WHO (2014)¹⁵ provide conflict of interest guidelines, and they detail procedures that WPATH clearly violated: WPATH's SOC-8 were produced entirely by an association and a group of individuals whom both sets of international standards instruct should be excluded or whose role and influence should be strongly limited.

2. WPATH itself suffers a strong "associational conflict of interest" in producing clinical practice guidelines for treatment of gender dysphoria.

316. IoM (2011) and WHO (2014) describe and seek to prevent conflicts of interest pertaining both to individuals developing clinical practice guidelines (CPGs) *and* to the professional associations of those individuals. On the associational level, the international standard (as indicated by the very sources upon which WPATH claimed to have relied) is for such assessments to be conducted by experts at arm's length from those services—sufficiently familiar with topic but *not* professionally engaged in performing the clinical practices under review. IoM (2011) notes:

Many guidelines developed by medical societies and other private organizations are self-funded, through membership dues, donations, or other means. CPGs funded by medical societies dependent on membership dues may be cause for concern regarding conflict of interest if their recommendations would likely affect their members' income. (IoM 2011 at 47.)

317. This conflict of interest is strongly present in the case of WPATH and its development of SOC-8. WPATH's financial well-being depends upon the number of its dues-paying members which, in turn, depends upon WPATH acting in its members' financial interests: The more people who undergo transition, the greater the market available to

¹⁵ Even though WPATH does not cite WHO (2014), for the purposes of this report I reference this document as it is the relevant, and current, World Health Organization guidance on conflict of interest.

WPATH's dues-paying members.

318. Additionally, it is strongly in the financial interest of WPATH members, and thus of WPATH, that medicalized transition be deemed eligible for medical insurance as broadly as possible. For example, because medical insurance does not cover "experimental" treatments, WPATH's claims that medicalized transition of minors is *not* experimental represents a very direct conflict between expanding its members' potential market and protecting minors from undergoing experimental treatments unknowingly.

319. This association-level conflict of interest pertains not only to WPATH, but also to the other associations producing guidelines in the U.S., including the Endocrine Society and the American Academy of Pediatrics (AAP)—organizations whose policies are assessed herein (Sections VI & XVI.). By contrast, examples of health care authorities that are not afflicted with a conflict between the interests of service providers and the interests of patients are the national health care systems, such as those of England, Sweden, and Finland. (Examined in Sections II & V.) Because their health care systems are *publicly* funded, they are not susceptible to the same association-level conflicts.

320. In direct opposition with IoM's caution to *avoid* association-level conflict of interest, WPATH essentially *required* this conflict, by making membership in WPATH a requirement of professionals for appointment to the guideline development team:

Except for the Chair (Eli Coleman) who was appointed by the WPATH board to maintain a continuity from previous SOC editions, members of the Guideline Steering Committee were selected by the WPATH Board *from WPATH members* applying for these positions...Chapter Leads and Members were *required to be WPATH Full Members* in good standing. ...¹⁶ (SOC-8 at S248, emphasis added.)

¹⁶ Only members of the public, such as parents of gender dysphoric children participating as "stakeholders," were not required to be WPATH members.

3. WPATH did not screen for or disclose the personal financial and intellectual conflicts of interest of those who participated in developing SOC-8.

321. With respect to individuals who participate in creating a clinical guideline, IoM (2011) and WHO (2014) emphasize the importance of avoiding both *financial* conflicts of interest (direct and indirect), and *intellectual* conflicts of interest. These documents corroborate and detail the accepted methods to avoid conflict of interest and ensure objective assessment of any particular topic. These widely accepted principles and methods match the summary I set out herein (Section I.C.). Most importantly, these respected documents agree that the experts best equipped for assessing clinical practice guidelines are *not* the people whose livelihood, prestige, and/or ideological commitments are tied to providing the clinical services under review. Such people have both financial and professional incentives and thus a natural bias towards declaring their services to be effective and safe. IoM (2011) cites peer-reviewed studies that document the real-world effect of this conflict of interest can have:

Hutchings [& Raine (2006)] identified 22 studies examining the impact of individual participant specialty or profession. Overall, the authors observed that those who performed a procedure, versus those who did not, were more likely to rate more indications as appropriate for that procedure. [...] Murphy and colleagues (1998) offer other relevant findings in a systematic review in which they compared guideline recommendations produced by groups of varying composition. The authors concluded that differences in group composition may lead to contrasting recommendations; more specifically, members of a clinical specialty are more likely to promote interventions in which their specialty plays a part. (IoM 2011 at 84.)

322. Instead of complying with recognized conflict of interest principles, WPATH: gathered a team of individuals all or most of whom stood to benefit financially from expanding the number of youth approved to obtain medical transition services and expanding the availability of insurance to cover such services; neglected to assess or disclose direct financial benefits to those individuals; publicly (but falsely) declared that none of these individuals had

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any conflict of interest; claimed it followed established procedures to limit conflicts of interest that it did not follow; and excluded the sources of its procedures from its references.

323. The team of individuals whom WPATH gathered did not represent the range of opinions among topic experts and did not reflect the diversity of relevant stakeholders. On the contrary, WPATH limited membership on its team to individuals who paid dues to WPATH and excluded from participation any professional with a point of view which would have kept such a professional from joining WPATH. As a result, WPATH's process excluded the input of detransitioners, as well as of the practitioners, researchers, and prominent voices within European health authorities who are expressing scepticism and concern about performing medical transition procedures on minors.

324. Instead, the committee consisted of individuals whose academic and scholarly standing stood to benefit from WPATH's product. As I detail below, the WPATH procedure consisted of exactly the biased and one-sided methods that the IoM and WHO procedures are designed to prevent.

4. WPATH disregarded and failed to disclose extensive direct *financial* conflicts of interest.

325. As noted, both IoM (2011) and WHO (2014) indicate that receiving income from providing the clinical practices being evaluated by the guidelines represents a direct financial conflict of interest. The WPATH policy and disclosure forms, however, did not actually ask participants to disclose (and therefore WPATH did not disclose to the public) participants' *direct* financial interests and thus conflicts of interest. Instead, WPATH asked only about the rare and relatively minor instances of *indirect* financial conflicts of interest.

326. WHO (2014) describes financial conflicts of interest as:

A financial conflict of interest arises when an individual or organization receives income or monetary support that is related to, or could be affected by, the outcome of the WHO meeting or activity in which they are involved....Financial interests include, for example: *personal financial gain such as paid work*, consulting income or honoraria and travel stipends.... (WHO 2014 at 63, emphasis added.)

IoM (2011) provides similar language, dividing financial conflicts of interest into direct,

commercial conflicts and non-commercial conflicts:

Direct financial commercial activities include *clinical services from which a committee member derives a substantial proportion of his or her income;* consulting; board membership for which compensation of any type is received. . . (IoM 2011 at 79, emphasis added.)

and

Examples of noncommercial financial activities include research grants and other types of support from governments, foundations, or other nonprofit organizations. (IoM 2011 at 79.)

Physicians and therapists in private practice or clinics treating people with gender dysphoria very

clearly meet these criteria.

327. Despite ignoring the very clear and explicit indications from both IoM (2011) and

WHO (2014) as to what constitutes conflicts of interest, WPATH declared to the public in

SOC-8:

Conflict of interests were reviewed as part of the selection process for committee members and at the end of the process before publication. No conflicts of interest were deemed significant or consequential. (SOC-8 at 177.)

Contrary to this public representation, most or all WPATH committee members possess conflicts

of interest that WPATH denied.

328. Widely accepted conflict of interest guidelines recognize that the clinical experiences

of individuals who receive income from pertinent clinical activities can have information helpful

to guideline developers-indeed the IoM and WHO procedures permit such individuals to

function as consultants or stakeholders rather than bar them altogether from participation.

WPATH did not use such methods for managing conflicts of interest, however. Instead,

WPATH simply denied such conflicts existed.

329. The importance of the contradiction between WPATH's failure to inquire about and prevent direct financial conflict of interest on the one hand, and what it assured the public on the other, cannot be exaggerated: The guidelines it published contained a list of what it claimed to have been improvements over prior guidelines, explicitly naming management of conflict of interest as such an improvement, noting:

The main differences in the methodology of the SOC-8 when compared with other versions of the SOC are: [...] Management of *conflicts of interest*. (SOC-8 at S247, emphasis added.)

5. WPATH disregarded and failed to disclose extensive *intellectual* conflicts of interest.

330. WHO (2014) defines intellectual conflicts of interest as roles or positions that might

interfere with the objective assessment of a body of evidence, providing the following as

examples:

- *prior publication of a study or systematic review* that is part of the evidence base under consideration in the guideline;
- prior public declaration of a firm opinion or position, as in public testimony during a regulatory or judicial process, or in an editorial in a journal; or
- professional or personal affiliation with an organization advocating for products or services related to the subject of the guideline.

(WHO 2014 at 63.)

WHO (2014) also emphasizes that:

The GDG [guideline development group] should be composed of individuals with diverse perspectives, training and experiences to keep the recommendations from reflecting a single viewpoint that was conceived before examining and discussing the systematic review of the evidence. (WHO 2014 at 71.)

IoM (2011) similarly defines intellectual conflicts of interest:

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A person whose work or professional group fundamentally is jeopardized, or enhanced, by a guideline recommendation is said to have intellectual COI. Intellectual COI includes authoring a publication or acting as an investigator on a peer-reviewed grant directly related to recommendations under consideration. (IoM 2011 at 79.)

Adopting language offered by Dr. Gordon Guyatt et al., this includes "academic activities that create the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation." (Guyatt et al. 2010 at 739.)

331. The importance of appropriate handling of conflicts of interest is not limited to influences on actual decision making. The IoM emphasizes also that "Regardless of the nature of COI or its effects on guideline development, perception of bias undermines guideline users' confidence in guideline trustworthiness as well as public trust in science" (IoM 2011 at 79.)

332. The publicly available list of authors of SOC-8 nonetheless reveals individuals wellknown for their many "public declarations," prior publications stating "firm opinions or positions" favoring what they label "gender affirming care," belittling potential risks and harms, and for their strongly expressed political views.

333. Moreover, WPATH itself as an organization has engaged in stridently worded political advocacy and endorsement of specific interpretations of research literature,¹⁷ including its urging that the services its members provide should be eligible for health care insurance coverage, which its members would then receive as income. Thus, WPATH itself and all of its members are necessarily affected by what WHO (2014) identifies as an intellectual conflict of interest resulting from "professional or personal affiliation with an organization advocating for . . . services related to the subject of the guideline."

334. Again, conflict of interest guidelines do recognize that topic experts who receive

¹⁷ See, for example, the press releases and political advocacy documents posted at <u>https://www.wpath.org/policies</u>, WPATH/USPATH Public Statements (last accessed February 2, 2024).

income from pertinent clinical activities can have valuable information for guidelines developers, and the recommendations allow for such individuals to function as consultants or stakeholders, rather than bar them altogether from participation. WPATH did not, however, practice methods for managing conflicts of interest. Instead, WPATH simply denied that such conflicts existed and provided no supervision, tracking, or management of undue influence.

C. Endocrine Society (ES).

335. As I have noted, in preparing its guidelines the Endocrine Society did not conduct systematic reviews of evidence relating to efficacy of any hormonal intervention in children or adolescents, and instead conducted reviews on only two safety-related endpoints.

336. Although outside the professional expertise of endocrinologists, mental health issues were also addressed by the Endocrine Society, repeating the need to handle such issues before engaging in transition, "In cases in which severe psychopathology, circumstances, or both seriously interfere with the diagnostic work or make satisfactory treatment unlikely, clinicians should assist the adolescent in managing these other issues." (Hembree 2017 at 3877.) This ordering—to address mental health issues before embarking on transition—avoids relying on the unproven belief that transition will solve such issues.

337. The Endocrine Society did not endorse any affirmation-only approach. The guidelines were neutral with regard to social transitions before puberty, instead advising that such decisions be made only under clinical supervision: "We advise that decisions regarding the social transition of prepubertal youth are made with the assistance of a mental health professional or similarly experienced professional." (Hembree 2017 at 3870.)

338. The Endocrine Society guidelines make explicit that, after gathering information from adolescent clients seeking medical interventions and their parents, the clinician "provides correct

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information to prevent unrealistically high expectations [and] assesses whether medical

interventions may result in unfavorable psychological and social outcomes." (Hembree 2017 at

3877.)

339. The 2017 update of the Endocrine Society's guidelines added a disclaimer not previously appearing:

The guidelines cannot guarantee any specific outcome, nor do they establish a standard of care....The Endocrine Society makes no warranty, express or implied, regarding the guidelines and specifically excludes any warranties of merchantability and fitness for a particular use or purpose. The Society shall not be liable for direct, indirect, special, incidental, or consequential damages related to the use of the information contained herein. (Hembree 2017 at 3895-3896.)

340. The Endocrine Society guidelines do not rely on any systematic review of evidence of *efficacy* of any form of treatment for gender dysphoria. The Dahlen et al. team also subjected these guidelines to review according to the AGREE II criteria, and two out of three independent reviewers concluded that they should *not* be used clinically. (Dahlen 2021 at 7.)

D. American Academy of Pediatrics (AAP).

341. A "Policy Statement" issued by the American Academy of Pediatrics (AAP) in 2018—which on its face declared to represent exclusively the work of one author who alone is "accountable for all aspects of the work"—is unique among the major medical associations in being the only one to endorse an affirmation-on-demand policy, including social transition before puberty without any watchful waiting period. (Rafferty 2018.) Although changes in recommendations can obviously be appropriate in response to new research evidence, the AAP identified no such new evidence to justify a radical departure from the "therapy first" approach of the Dutch Protocol. Rather, the research studies AAP cited in support of its policy simply did not say what AAP claimed they did. In fact, the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing watchful waiting. (Cantor

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2019.) Moreover, of all the outcomes research published, the AAP policy cited *one*, and that without mentioning the outcome data it contained. (Cantor 2019.)

342. Immediately following the publication of the AAP policy, I conducted a point-bypoint fact-check of the claims it asserted and the references it cited in support. I submitted that to the *Journal of Sex & Marital Therapy*, a well-known research journal of my field, where it underwent blind peer review and was published. I append that article as part of this report. *See* Appendix 2. A great deal of published attention ensued; however, the AAP has yet to respond to the errors I demonstrated its policy contained. Writing for *The Economist* about the use of puberty blockers, Helen Joyce asked AAP directly, "Has the AAP responded to Dr Cantor? If not, have you any response now?" The AAP Media Relations Manager, Lisa Black, responded: "We do not have anyone available for comment."

I declare under penalty of perjury of the laws of the United States of American that the foregoing is true and correct.

Executed on May 22, 2024 Toronto, Ontario, Canada

/James M. Cantor, Ph.D.

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List of Appendices

Appendix 1

Curriculum Vita

Appendix 2

Cantor, J. M. (2020). Transgender and gender diverse children and adolescents: Factchecking of AAP policy. *Journal of Sex & Marital Therapy, 46,* 307–313. doi: 10.1080/0092623X.2019.1698481

Appendix 1
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| Senior ScientistJan., 2012–May, | 2018 |
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PUBLICATIONS

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PUBLICATIONS

LETTERS AND COMMENTARIES

- Cantor, J. M. (2015). Research methods, statistical analysis, and the phallometric test for hebephilia: Response to Fedoroff [Editorial Commentary]. *Journal of Sexual Medicine*, *12*, 2499–2500. doi: 10.1111/jsm.13040
- 2. Cantor, J. M. (2015). In his own words: Response to Moser [Editorial Commentary]. *Journal of Sexual Medicine, 12,* 2502–2503. doi: 10.1111/jsm.13075
- Cantor, J. M. (2015). Purported changes in pedophilia as statistical artefacts: Comment on Müller et al. (2014). Archives of Sexual Behavior, 44, 253–254. doi: 10.1007/s10508-014-0343-x
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- 5. Soh, D. W., & Cantor, J. M. (2015). A peek inside a furry convention [Letter to the Editor]. *Archives of Sexual Behavior, 44,* 1–2. doi: 10.1007/s10508-014-0423-y
- Cantor, J. M. (2012). Reply to Italiano's (2012) comment on Cantor (2011) [Letter to the Editor]. Archives of Sexual Behavior, 41, 1081–1082. doi: 10.1007/s10508-012-0011y
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- Cantor, J. M., & Blanchard, R. (2012). White matter volumes in pedophiles, hebephiles, and teleiophiles [Letter to the Editor]. *Archives of Sexual Behavior*, 41, 749–752. doi: 10.1007/s10508-012-9954-2
- Cantor, J. M. (2011). New MRI studies support the Blanchard typology of male-to-female transsexualism [Letter to the Editor]. *Archives of Sexual Behavior*, 40, 863–864. doi: 10.1007/s10508-011-9805-6
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- Cantor, J. M. (2003, Summer). Review of the book *The Man Who Would Be Queen* by J. Michael Bailey. *Newsletter of Division 44 of the American Psychological Association*, 19(2), 6.
- 12. Cantor, J. M. (2003, Spring). What are the hot topics in LGBT research in psychology? Newsletter of Division 44 of the American Psychological Association, 19(1), 21–24.
- 13. Cantor, J. M. (2002, Fall). Male homosexuality, science, and pedophilia. *Newsletter of Division 44 of the American Psychological Association, 18*(3), 5–8.
- 14. Cantor, J. M. (2000). Review of the book Sexual Addiction: An Integrated Approach. Journal of Sex and Marital Therapy, 26, 107–109.

EDITORIALS

1. Cantor, J. M. (2012). Editorial. Sexual Abuse: A Journal of Research and Treatment, 24.

- 2. Cantor, J. M. (2011). Editorial note. *Sexual Abuse: A Journal of Research and Treatment,* 23, 414.
- Barbaree, H. E., & Cantor, J. M. (2010). Performance indicates for Sexual Abuse: A Journal of Research and Treatment (SAJRT) [Editorial]. Sexual Abuse: A Journal of Research and Treatment, 22, 371–373.
- Barbaree, H. E., & Cantor, J. M. (2009). Sexual Abuse: A Journal of Research and Treatment performance indicators for 2007 [Editorial]. Sexual Abuse: A Journal of Research and Treatment, 21, 3–5.
- 5. Zucker, K. J., & Cantor, J. M. (2009). Cruising: Impact factor data [Editorial]. Archives of Sexual Research, 38, 878–882.
- 6. Barbaree, H. E., & Cantor, J. M. (2008). Performance indicators for *Sexual Abuse: A Journal of Research and Treatment* [Editorial]. *Sexual Abuse: A Journal of Research and Treatment, 20*, 3–4.
- 7. Zucker, K. J., & Cantor, J. M. (2008). The *Archives* in the era of online first ahead of print[Editorial]. *Archives of Sexual Behavior*, *37*, 512–516.
- 8. Zucker, K. J., & Cantor, J. M. (2006). The impact factor: The *Archives* breaks from the pack [Editorial]. *Archives of Sexual Behavior*, *35*, 7–9.
- 9. Zucker, K. J., & Cantor, J. M. (2005). The impact factor: "Goin' up" [Editorial]. Archives of Sexual Behavior, 34, 7–9.
- 10. Zucker, K., & Cantor, J. M. (2003). The numbers game: The impact factor and all that jazz [Editorial]. *Archives of Sexual Behavior*, *32*, 3–5.

FUNDING HISTORY

| Principal Investigators: Co-Investigators: | Doug VanderLaan, Meng-Chuan Lai James M. Cantor, Megha Mallar Chakravarty, Nancy Lobaugh, M. Palmert, M. Skorska |
|---|--|
| Title: | Brain function and connectomics following sex hormone treatment in adolescents experience gender dysphoria |
| Agency: | Canadian Institutes of Health Research (CIHR), Behavioural Sciences-B-2 |
| Funds: | \$650,250 / 5 years (July, 2018) |
| Principal Investigator: Co-Investigators: Title: Agency: Funds: | Michael C. Seto Martin Lalumière , James M. Cantor <i>Are connectivity differences unique to pedophilia?</i> University Medical Research Fund, Royal Ottawa Hospital \$50,000 / 1 year (January, 2018) |
| Principal Investigator: Co-Investigators: Title: | Lori Brotto Anthony Bogaert, James M. Cantor, Gerulf Rieger Investigations into the neural underpinnings and biological correlates of asexuality |
| Agency: | Natural Sciences and Engineering Research Council (NSERC), Discovery Grants Program |
| Funds: | \$195,000 / 5 years (April, 2017) |
| Principal Investigator: Co-Investigators: | Doug VanderLaan Jerald Bain, James M. Cantor, Megha Mallar Chakravarty, Sofia Chayez, Nancy Lobaugh, and Kenneth J. Zucker |
| Title: | Effects of sex hormone treatment on brain development: A magnetic resonance imaging study of adolescents with gender dysphoria |
| Agency: | Canadian Institutes of Health Research (CIHR), Transitional Open Grant Program |
| Funds: | \$952,955 / 5 years (September, 2015) |
| Principal Investigator: Co-Investigators: | James M. Cantor Howard E. Barbaree, Ray Blanchard, Robert Dickey, Todd A. Girard, Phillip E. Klassen, and David J. Mikulis |
| Title: | Neuroanatomic features specific to pedophilia |
| Agency: Funds: | Canadian Institutes of Health Research (CIHR) \$1,071,920 / 5 years (October, 2008) |
| Principal Investigator: Title: Agency: Funds: | James M. Cantor A preliminary study of fMRI as a diagnostic test of pedophilia Dean of Medicine New Faculty Grant Competition, Univ. of Toronto \$10,000 (July, 2008) |

| Principal Investigator: | James M. Cantor |
|-------------------------|---|
| Co-Investigator: | Ray Blanchard |
| Title: | Morphological and neuropsychological correlates of pedophilia |
| Agency: | Canadian Institutes of Health Research (CIHR) |
| Funds: | \$196,902 / 3 years (April, 2006) |

KEYNOTE AND INVITED ADDRESSES

- Cantor, J. M. (2022, December 5). The science of gender dysphoria and transgenderism. Lund University, Latvia. <u>https://files.fm/f/4bzznufvb</u>
- Cantor, J. M. (2021, September 28). No topic too tough for this expert panel: A year in review. Plenary Session for the 40th Annual Research and Treatment Conference, Association for the Treatment of Sexual Abusers.
- 3. Cantor, J. M. (2019, May 1). *Introduction and Q&A for 'I, Pedophile.'* StopSO 2nd Annual Conference, London, UK.
- 4. Cantor, J. M. (2018, August 29). *Neurobiology of pedophilia or paraphilia? Towards a 'Grand Unified Theory' of sexual interests*. Keynote address to the International Association for the Treatment of Sexual Offenders, Vilnius, Lithuania.
- 5. Cantor, J. M. (2018, August 29). *Pedophilia and the brain: Three questions asked and answered*. Preconference training presented to the International Association for the Treatment of Sexual Offenders, Vilnius, Lithuania.
- 6. Cantor, J. M. (2018, April 13). *The responses to* I, Pedophile *from We, the people.* Keynote address to the Minnesota Association for the Treatment of Sexual Abusers, Minneapolis, Minnesota.
- Cantor, J. M. (2018, April 11). Studying atypical sexualities: From vanilla to I, Pedophile. Full day workshop at the Minnesota Association for the Treatment of Sexual Abusers, Minneapolis, Minnesota.
- 8. Cantor, J. M. (2018, January 20). *How much sex is enough for a happy life?* Invited lecture to the University of Toronto Division of Urology Men's Health Summit, Toronto, Canada.
- Cantor, J. M. (2017, November 2). Pedophilia as a phenomenon of the brain: Update of evidence and the public response. Invited presentation to the 7th annual SBC education event, Centre for Addiction and Mental Health, Toronto, Canada.
- 10. Cantor, J. M. (2017, June 9). Pedophilia being in the brain: The evidence and the public's reaction. Invited presentation to *SEXposium at the ROM: The science of love and sex*, Toronto, Canada.
- Cantor, J. M., & Campea, M. (2017, April 20). "*I, Pedophile*" showing and discussion. Invited presentation to the 42nd annual meeting of the Society for Sex Therapy and Research, Montréal, Canada.
- 12. Cantor, J. M. (2017, March 1). Functional and structural neuroimaging of pedophilia: Consistencies across methods and modalities. Invited lecture to the Brain Imaging Centre, Royal Ottawa Hospital, Ottawa, Canada.
- Cantor, J. M. (2017, January 26). Pedophilia being in the brain: The evidence and the public reaction. Inaugural keynote address to the University of Toronto Sexuality Interest Network, Toronto, Ontario, Canada.
- 14. Cantor, J. M. (2016, October 14). *Discussion of CBC's "I, Pedophile."* Office of the Children's Lawyer Educational Session, Toronto, Ontario, Canada.
- Cantor, J. M. (2016, September 15). Evaluating the risk to reoffend: What we know and what we don't. Invited lecture to the Association of Ontario Judges, Ontario Court of Justice Annual Family Law Program, Blue Mountains, Ontario, Canada. [Private link only: <u>https://vimeo.com/239131108/3387c80652</u>]
- 16. Cantor, J. M. (2016, April 8). Pedophilia and the brain: Conclusions from the second

generation of research. Invited lecture at the 10th annual Risk and Recovery Forensic Conference, Hamilton, Ontario.

- 17. Cantor, J. M. (2016, April 7). *Hypersexuality without the hyperbole*. Keynote address to the 10th annual Risk and Recovery Forensic Conference, Hamilton, Ontario.
- Cantor, J. M. (2015, November). No one asks to be sexually attracted to children: Living in Daniel's World. Grand Rounds, Centre for Addiction and Mental Health. Toronto, Canada.
- Cantor, J. M. (2015, August). *Hypersexuality: Getting past whether "it" is or "it" isn't.* Invited address at the 41st annual meeting of the International Academy of Sex Research. Toronto, Canada.
- 20. Cantor, J. M. (2015, July). A unified theory of typical and atypical sexual interest in men: Paraphilia, hypersexuality, asexuality, and vanilla as outcomes of a single, dual opponent process. Invited presentation to the 2015 Puzzles of Sexual Orientation conference, Lethbridge, AL, Canada.
- 21. Cantor, J. M. (2015, June). *Hypersexuality*. Keynote Address to the Ontario Problem Gambling Provincial Forum. Toronto, Canada.
- 22. Cantor, J. M. (2015, May). Assessment of pedophilia: Past, present, future. Keynote Address to the International Symposium on Neural Mechanisms Underlying Pedophilia and Child Sexual Abuse (NeMUP). Berlin, Germany.
- 23. Cantor, J. M. (2015, March). Prevention of sexual abuse by tackling the biggest stigma of them all: Making sex therapy available to pedophiles. Keynote address to the 40th annual meeting of the Society for Sex Therapy and Research, Boston, MA.
- 24. Cantor, J. M. (2015, March. *Pedophilia: Predisposition or perversion?* Panel discussion at Columbia University School of Journalism. New York, NY.
- 25. Cantor, J. M. (2015, February). *Hypersexuality*. Research Day Grand Rounds presentation to Ontario Shores Centre for Mental Health Sciences, Whitby, Ontario, Canada.
- 26. Cantor, J. M. (2015, January). *Brain research and pedophilia: What it means for assessment, research, and policy.* Keynote address to the inaugural meeting of the Netherlands Association for the Treatment of Sexual Abusers, Utrecht, Netherlands.
- 27. Cantor, J. M. (2014, December). Understanding pedophilia and the brain: Implications for safety and society. Keynote address for The Jewish Community Confronts Violence and Abuse: Crisis Centre for Religious Women, Jerusalem, Israel.
- 28. Cantor, J. M. (2014, October). *Understanding pedophilia & the brain*. Invited full-day workshop for the Sex Offender Assessment Board of Pennsylvania, Harrisburg, PA.
- 29. Cantor, J. M. (2014, September). *Understanding neuroimaging of pedophilia: Current status and implications*. Invited lecture presented to the Mental Health and Addition Rounds, St. Joseph's Healthcare, Hamilton, Ontario, Canada.
- Cantor, J. M. (2014, June). An evening with Dr. James Cantor. Invited lecture presented to the Ontario Medical Association, District 11 Doctors' Lounge Program, Toronto, Ontario, Canada.
- 31. Cantor, J. M. (2014, April). *Pedophilia and the brain*. Invited lecture presented to the University of Toronto Medical Students lunchtime lecture. Toronto, Ontario, Canada.
- 32. Cantor, J. M. (2014, February). *Pedophilia and the brain: Recap and update.* Workshop presented at the 2014 annual meeting of the Washington State Association for the Treatment of Sexual Abusers, Cle Elum, WA.

- Cantor, J. M., Lafaille, S., Hannah, J., Kucyi, A., Soh, D., Girard, T. A., & Mikulis, D. M. (2014, February). *Functional connectivity in pedophilia*. Neuropsychiatry Rounds, Toronto Western Hospital, Toronto, Ontario, Canada.
- Cantor, J. M. (2013, November). Understanding pedophilia and the brain: The basics, the current status, and their implications. Invited lecture to the Forensic Psychology Research Centre, Carleton University, Ottawa, Canada.
- Cantor, J. M. (2013, November). *Mistaking puberty, mistaking hebephilia*. Keynote address
 presented to the 32nd annual meeting of the Association for the Treatment of Sexual
 Abusers, Chicago, IL.
- 36. Cantor, J. M. (2013, October). *Understanding pedophilia and the brain: A recap and update*. Invited workshop presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago, IL.
- 37. Cantor, J. M. (2013, October). *Compulsive-hyper-sex-addiction: I don't care what we all it, what can we* do? Invited address presented to the Board of Examiners of Sex Therapists and Counselors of Ontario, Toronto, Ontario, Canada.
- Cantor, J. M. (2013, September). Neuroimaging of pedophilia: Current status and implications. McGill University Health Centre, Department of Psychiatry Grand Rounds presentation, Montréal, Québec, Canada.
- 39. Cantor, J. M. (2013, April). *Understanding pedophilia and the brain*. Invited workshop presented at the 2013 meeting of the Minnesota Association for the Treatment of Sexual Abusers, Minneapolis, MN.
- 40. Cantor, J. M. (2013, April). *The neurobiology of pedophilia and its implications for assessment, treatment, and public policy.* Invited lecture at the 38th annual meeting of the Society for Sex Therapy and Research, Baltimore, MD.
- 41. Cantor, J. M. (2013, April). *Sex offenders: Relating research to policy.* Invited roundtable presentation at the annual meeting of the Academy of Criminal Justice Sciences, Dallas, TX.
- 42. Cantor, J. M. (2013, March). *Pedophilia and brain research: From the basics to the stateof-the-art.* Invited workshop presented to the annual meeting of the Forensic Mental Health Association of California, Monterey, CA.
- 43. Cantor, J. M. (2013, January). *Pedophilia and child molestation*. Invited lecture presented to the Canadian Border Services Agency, Toronto, Ontario, Canada.
- 44. Cantor, J. M. (2012, November). Understanding pedophilia and sexual offenders against children: Neuroimaging and its implications for public safety. Invited guest lecture to University of New Mexico School of Medicine Health Sciences Center, Albuquerque, NM.
- 45. Cantor, J. M. (2012, November). *Pedophilia and brain research*. Invited guest lecture to the annual meeting of the Circles of Support and Accountability, Toronto, Ontario, Canada.
- 46. Cantor, J. M. (2012, January). *Current findings on pedophilia brain research*. Invited workshop at the San Diego International Conference on Child and Family Maltreatment, San Diego, CA.
- 47. Cantor, J. M. (2012, January). *Pedophilia and the risk to re-offend*. Invited lecture to the Ontario Court of Justice Judicial Development Institute, Toronto, Ontario, Canada.
- 48. Cantor, J. M. (2011, November). *Pedophilia and the brain: What it means for assessment, treatment, and policy.* Plenary Lecture presented at the Association for the Treatment of Sexual Abusers, Toronto, Ontario, Canada.

- 49. Cantor, J. M. (2011, July). *Towards understanding contradictory findings in the neuroimaging of pedophilic men.* Keynote address to 7th annual conference on Research in Forensic Psychiatry, Regensberg, Germany.
- 50. Cantor, J. M. (2011, March). *Understanding sexual offending and the brain: Brain basics to the state of the art*. Workshop presented at the winter conference of the Oregon Association for the Treatment of Sexual Abusers, Oregon City, OR.
- 51. Cantor, J. M. (2010, October). *Manuscript publishing for students*. Workshop presented at the 29th annual meeting of the Association for the Treatment of Sexual Abusers, Phoenix, AZ.
- 52. Cantor, J. M. (2010, August). *Is sexual orientation a paraphilia*? Invited lecture at the International Behavioral Development Symposium, Lethbridge, Alberta, Canada.
- 53. Cantor, J. M. (2010, March). *Understanding sexual offending and the brain: From the basics to the state of the art.* Workshop presented at the annual meeting of the Washington State Association for the Treatment of Sexual Abusers, Blaine, WA.
- 54. Cantor, J. M. (2009, January). *Brain structure and function of pedophilia men.* Neuropsychiatry Rounds, Toronto Western Hospital, Toronto, Ontario.
- 55. Cantor, J. M. (2008, April). *Is pedophilia caused by brain dysfunction?* Invited address to the University-wide Science Day Lecture Series, SUNY Oswego, Oswego, NY.
- Cantor, J. M., Kabani, N., Christensen, B. K., Zipursky, R. B., Barbaree, H. E., Dickey, R., Klassen, P. E., Mikulis, D. J., Kuban, M. E., Blak, T., Richards, B. A., Hanratty, M. K., & Blanchard, R. (2006, September). *MRIs of pedophilic men*. Invited presentation at the 25th annual meeting of the Association for the Treatment of Sexual Abusers, Chicago.
- 57. Cantor, J. M., Blanchard, R., & Christensen, B. K. (2003, March). *Findings in and implications of neuropsychology and epidemiology of pedophilia*. Invited lecture at the 28th annual meeting of the Society for Sex Therapy and Research, Miami.
- 58. Cantor, J. M., Christensen, B. K., Klassen, P. E., Dickey, R., & Blanchard, R. (2001, July). *Neuropsychological functioning in pedophiles*. Invited lecture presented at the 27th annual meeting of the International Academy of Sex Research, Bromont, Canada.
- 59. Cantor, J. M., Blanchard, R., Christensen, B., Klassen, P., & Dickey, R. (2001, February). *First glance at IQ, memory functioning and handedness in sex offenders.* Lecture presented at the Forensic Lecture Series, Centre for Addiction and Mental Health, Toronto, Ontario, Canada.
- 60. Cantor, J. M. (1999, November). *Reversal of SSRI-induced male sexual dysfunction: Suggestions from an animal model.* Grand Rounds presentation at the Allan Memorial Institute, Royal Victoria Hospital, Montréal, Canada.

PAPER PRESENTATIONS AND SYMPOSIA

- 1. Cantor, J. M. (2020, April). "I'd rather have a trans kid than a dead kid": Critical assessment of reported rates of suicidality in trans kids. *Paper presented at the annual meeting of the Society for the Sex Therapy and Research*. Online in lieu of in person meeting.
- Stephens, S., Lalumière, M., Seto, M. C., & Cantor, J. M. (2017, October). *The relationship* between sexual responsiveness and sexual exclusivity in phallometric profiles. Paper presented at the annual meeting of the Canadian Sex Research Forum, Fredericton, New Brunswick, Canada.
- Stephens, S., Cantor, J. M., & Seto, M. C. (2017, March). Can the SSPI-2 detect hebephilic sexual interest? Paper presented at the annual meeting of the American-Psychology Law Society Annual Meeting, Seattle, WA.
- Stephens, S., Seto, M. C., Goodwill, A. M., & Cantor, J. M. (2015, October). *Victim choice polymorphism and recidivism.* Symposium Presentation. Paper presented at the 34th annual meeting of the Association for the Treatment of Sexual Abusers, Montréal, Canada.
- McPhail, I. V., Hermann, C. A., Fernane, S. Fernandez, Y., Cantor, J. M., & Nunes, K. L. (2014, October). Sexual deviance in sexual offenders against children: A meta-analytic review of phallometric research. Paper presented at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
- Stephens, S., Seto, M. C., Cantor, J. M., & Goodwill, A. M. (2014, October). *Is hebephilic sexual interest a criminogenic need?: A large scale recidivism study*. Paper presented at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
- Stephens, S., Seto, M. C., Cantor, J. M., & Lalumière, M. (2014, October). *Development* and validation of the Revised Screening Scale for Pedophilic Interests (SSPI–2). Paper presented at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
- Cantor, J. M., Lafaille, S., Hannah, J., Kucyi, A., Soh, D., Girard, T. A., & Mikulis, D. M. (2014, September). *Pedophilia and the brain: White matter differences detected with DTI*. Paper presented at the 13th annual meeting of the International Association for the Treatment of Sexual Abusers, Porto, Portugal.
- 9. Stephens, S., Seto, M., Cantor, J. M., Goodwill, A. M., & Kuban, M. (2014, March). *The role of hebephilic sexual interests in sexual victim choice*. Paper presented at the annual meeting of the American Psychology and Law Society, New Orleans, LA.
- McPhail, I. V., Fernane, S. A., Hermann, C. A., Fernandez, Y. M., Nunes, K. L., & Cantor, J. M. (2013, November). Sexual deviance and sexual recidivism in sexual offenders against children: A meta-analysis. Paper presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago, IL.
- Cantor, J. M. (2013, September). *Pedophilia and the brain: Current MRI research and its implications*. Paper presented at the 21st annual World Congress for Sexual Health, Porto Alegre, Brazil. [Featured among Best Abstracts, top 10 of 500.]
- 12. Cantor, J. M. (Chair). (2012, March). *Innovations in sex research*. Symposium conducted at the 37th annual meeting of the Society for Sex Therapy and Research, Chicago.
- 13. Cantor, J. M., & Blanchard, R. (2011, August). fMRI versus phallometry in the diagnosis of pedophilia and hebephilia. In J. M. Cantor (Chair), *Neuroimaging of men's object*

preferences. Symposium presented at the 37th annual meeting of the International Academy of Sex Research, Los Angeles, USA.

- Cantor, J. M. (Chair). (2011, August). Neuroimaging of men's object preferences. Symposium conducted at the 37th annual meeting of the International Academy of Sex Research, Los Angeles.
- 15. Cantor, J. M. (2010, October). A meta-analysis of neuroimaging studies of male sexual arousal. In S. Stolerú (Chair), *Brain processing of sexual stimuli in pedophilia: An application of functional neuroimaging*. Symposium presented at the 29th annual meeting of the Association for the Treatment of Sexual Abusers, Phoenix, AZ.
- Chivers, M. L., Seto, M. C., Cantor, J. C., Grimbos, T., & Roy, C. (April, 2010). *Psychophysiological assessment of sexual activity preferences in women.* Paper presented at the 35th annual meeting of the Society for Sex Therapy and Research, Boston, USA.
- Cantor, J. M., Girard, T. A., & Lovett-Barron, M. (2008, November). *The brain regions that respond to erotica: Sexual neuroscience for dummies*. Paper presented at the 51st annual meeting of the Society for the Scientific Study of Sexuality, San Juan, Puerto Rico.
- Barbaree, H., Langton, C., Blanchard, R., & Cantor, J. M. (2007, October). *The role of ageat-release in the evaluation of recidivism risk of sexual offenders*. Paper presented at the 26th annual meetingof the Association for the Treatment of Sexual Abusers, San Diego.
- Cantor, J. M., Kabani, N., Christensen, B. K., Zipursky, R. B., Barbaree, H. E., Dickey, R., Klassen, P. E., Mikulis, D. J., Kuban, M. E., Blak, T., Richards, B. A., Hanratty, M. K., & Blanchard, R. (2006, July). *Pedophilia and brain morphology*. Abstract and paper presented at the 32nd annual meeting of the International Academy of Sex Research, Amsterdam, Netherlands.
- 20. Seto, M. C., Cantor, J. M., & Blanchard, R. (2006, March). *Child pornography offending is a diagnostic indicator of pedophilia*. Paper presented at the 2006 annual meeting of the American Psychology-Law Society Conference, St. Petersburg, Florida.
- 21. Blanchard, R., Cantor, J. M., Bogaert, A. F., Breedlove, S. M., & Ellis, L. (2005, August). Interaction of fraternal birth order and handedness in the development of male homosexuality. Abstract and paper presented at the International Behavioral Development Symposium, Minot, North Dakota.
- Cantor, J. M., & Blanchard, R. (2005, July). *Quantitative reanalysis of aggregate data on IQ in sexual offenders*. Abstract and poster presented at the 31st annual meeting of the International Academy of Sex Research, Ottawa, Canada.
- Cantor, J. M. (2003, August). Sex reassignment on demand: The clinician's dilemma. Paper presented at the 111th annual meeting of the American Psychological Association, Toronto, Canada.
- 24. Cantor, J. M. (2003, June). *Meta-analysis of VIQ–PIQ differences in male sex offenders*. Paper presented at the Harvey Stancer Research Day, Toronto, Ontario, Canada.
- 25. Cantor, J. M. (2002, August). *Gender role in autogynephilic transsexuals: The more things change*... Paper presented at the 110th annual meeting of the American Psychological Association, Chicago.

- 26. Cantor, J. M., Christensen, B. K., Klassen, P. E., Dickey, R., & Blanchard, R. (2001, June). *IQ, memory functioning, and handedness in male sex offenders.* Paper presented at the Harvey Stancer Research Day, Toronto, Ontario, Canada.
- 27. Cantor, J. M. (1998, August). *Convention orientation for lesbian, gay, and bisexual students*. Papers presented at the 106th annual meeting of the American Psychological Association.
- 28. Cantor, J. M. (1997, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 105th annual meeting of the American Psychological Association.
- 29. Cantor, J. M. (1997, August). *Convention orientation for lesbian, gay, and bisexual students*. Paper presented at the 105th annual meeting of the American Psychological Association.
- 30. Cantor, J. M. (1996, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 104th annual meeting of the American Psychological Association.
- Cantor, J. M. (1996, August). Symposium: Question of inclusion: Lesbian and gay psychologists and accreditation. Paper presented at the 104th annual meeting of the American Psychological Association, Toronto.
- Cantor, J. M. (1996, August). Convention orientation for lesbian, gay, and bisexual students. Papers presented at the 104th annual meeting of the American Psychological Association.
- 33. Cantor, J. M. (1995, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 103rd annual meeting of the American Psychological Association.
- Cantor, J. M. (1995, August). Convention orientation for lesbian, gay, and bisexual students. Papers presented at the 103rd annual meeting of the American Psychological Association.
- 35. Cantor, J. M. (1994, August). *Discussion hour for lesbian, gay, and bisexual students*. Presented at the 102nd annual meeting of the American Psychological Association.
- Cantor, J. M. (1994, August). Convention orientation for lesbian, gay, and bisexual students. Papers presented at the 102nd annual meeting of the American Psychological Association.
- Cantor, J. M., & Pilkington, N. W. (1992, August). *Homophobia in psychology programs: A* survey of graduate students. Paper presented at the Centennial Convention of the American Psychological Association, Washington, DC. (ERIC Document Reproduction Service No. ED 351 618)
- Cantor, J. M. (1991, August). Being gay and being a graduate student: Double the memberships, four times the problems. Paper presented at the 99th annual meeting of the American Psychological Association, San Francisco.

POSTER PRESENTATIONS

- Klein, L., Stephens, S., Goodwill, A. M., Cantor, J. M., & Seto, M. C. (2015, October). *The* psychological propensities of risk in undetected sexual offenders. Poster presented at the 34th annual meeting of the Association for the Treatment of Sexual Abusers, Montréal, Canada.
- Pullman, L. E., Stephens, S., Seto, M. C., Goodwill, A. M., & Cantor, J. M. (2015, October). *Why are incest offenders less likely to recidivate?* Poster presented at the 34th annual meeting of the Association for the Treatment of Sexual Abusers, Montréal, Canada.
- Seto, M. C., Stephens, S. M., Cantor, J. M., Lalumiere, M. L., Sandler, J. C., & Freeman, N. A. (2015, August). *The development and validation of the Revised Screening Scale for Pedophilic Interests (SSPI-2)*. Poster presentation at the 41st annual meeting of the International Academy of Sex Research. Toronto, Canada.
- Soh, D. W., & Cantor, J. M. (2015, August). A peek inside a furry convention. Poster presentation at the 41st annual meeting of the International Academy of Sex Research. Toronto, Canada.
- VanderLaan, D. P., Lobaugh, N. J., Chakravarty, M. M., Patel, R., Chavez, S. Stojanovski, S. O., Takagi, A., Hughes, S. K., Wasserman, L., Bain, J., Cantor, J. M., & Zucker, K. J. (2015, August). *The neurohormonal hypothesis of gender dysphoria: Preliminary evidence of cortical surface area differences in adolescent natal females*. Poster presentation at the 31st annual meeting of the International Academy of Sex Research. Toronto, Canada.
- 6. Cantor, J. M., Lafaille, S. J., Moayedi, M., Mikulis, D. M., & Girard, T. A. (2015, June). *Diffusion tensor imaging (DTI) of the brain in pedohebephilic men: Preliminary analyses.* Harvey Stancer Research Day, Toronto, Ontario Canada.
- Newman, J. E., Stephens, S., Seto, M. C., & Cantor, J. M. (2014, October). *The validity of the Static-99 in sexual offenders with low intellectual abilities*. Poster presentation at the 33rd annual meeting of the Association for the Treatment of Sexual Abusers, San Diego, CA.
- Lykins, A. D., Walton, M. T., & Cantor, J. M. (2014, June). An online assessment of personality, psychological, and sexuality trait variables associated with self-reported hypersexual behavior. Poster presentation at the 30th annual meeting of the International Academy of Sex Research, Dubrovnik, Croatia.
- Stephens, S., Seto, M. C., Cantor, J. M., Goodwill, A. M., & Kuban, M. (2013, November). *The utility of phallometry in the assessment of hebephilia*. Poster presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago.
- Stephens, S., Seto, M. C., Cantor, J. M., Goodwill, A. M., & Kuban, M. (2013, October). *The role of hebephilic sexual interests in sexual victim choice*. Poster presented at the 32nd annual meeting of the Association for the Treatment of Sexual Abusers, Chicago.
- Fazio, R. L., & Cantor, J. M. (2013, October). Analysis of the Fazio Laterality Inventory (FLI) in a population with established atypical handedness. Poster presented at the 33rd annual meeting of the National Academy of Neuropsychology, San Diego.
- Lafaille, S., Hannah, J., Soh, D., Kucyi, A., Girard, T. A., Mikulis, D. M., & Cantor, J. M. (2013, August). *Investigating resting state networks in pedohebephiles*. Poster presented at the 29th annual meeting of the International Academy of Sex Research, Chicago.

- McPhail, I. V., Lykins, A. D., Robinson, J. J., LeBlanc, S., & Cantor, J. M. (2013, August). *Effects of prescription medication on volumetric phallometry output.* Poster presented at the 29th annual meeting of the International Academy of Sex Research, Chicago.
- Murray, M. E., Dyshniku, F., Fazio, R. L., & Cantor, J. M. (2013, August). *Minor physical anomalies as a window into the prenatal origins of pedophilia*. Poster presented at the 29th annual meeting of the International Academy of Sex Research, Chicago.
- Sutton, K. S., Stephens, S., Dyshniku, F., Tulloch, T., & Cantor, J. M. (2013, August). *Pilot group treatment for "procrasturbation."* Poster presented at 39th annual meeting of the International Academy of Sex Research, Chicago.
- Sutton, K. S., Pytyck, J., Stratton, N., Sylva, D., Kolla, N., & Cantor, J. M. (2013, August). *Client characteristics by type of hypersexuality referral: A quantitative chart review.* Poster presented at the 39th annual meeting of the International Academy of Sex Research, Chicago.
- Fazio, R. L., & Cantor, J. M. (2013, June). A replication and extension of the psychometric properties of the Digit Vigilance Test. Poster presented at the 11th annual meeting of the American Academy of Clinical Neuropsychology, Chicago.
- Lafaille, S., Moayedi, M., Mikulis, D. M., Girard, T. A., Kuban, M., Blak, T., & Cantor, J. M. (2012, July). *Diffusion Tensor Imaging (DTI) of the brain in pedohebephilic men: Preliminary analyses.* Poster presented at the 38th annual meeting of the International Academy of Sex Research, Lisbon, Portugal.
- Lykins, A. D., Cantor, J. M., Kuban, M. E., Blak, T., Dickey, R., Klassen, P. E., & Blanchard, R. (2010, July). *Sexual arousal to female children in gynephilic men.* Poster presented at the 38th annual meeting of the International Academy of Sex Research, Prague, Czech Republic.
- 20. Cantor, J. M., Girard, T. A., Lovett-Barron, M., & Blak, T. (2008, July). Brain regions responding to visual sexual stimuli: Meta-analysis of PET and fMRI studies. Abstract and poster presented at the 34th annual meeting of the International Academy of Sex Research, Leuven, Belgium.
- Lykins, A. D., Blanchard, R., Cantor, J. M., Blak, T., & Kuban, M. E. (2008, July). *Diagnosing sexual attraction to children: Considerations for DSM-V*. Poster presented at the 34th annual meeting of the International Academy of Sex Research, Leuven, Belgium.
- Cantor, J. M., Blak, T., Kuban, M. E., Klassen, P. E., Dickey, R. and Blanchard, R. (2007, October). *Physical height in pedophilia and hebephilia*. Poster presented at the 26th annual meeting of the Association for the Treatment of Sexual Abusers, San Diego.
- 23. Cantor, J. M., Blak, T., Kuban, M. E., Klassen, P. E., Dickey, R. and Blanchard, R. (2007, August). *Physical height in pedophilia and hebephilia*. Abstract and poster presented at the 33rd annual meeting of the International Academy of Sex Research, Vancouver, Canada.
- 24. Puts, D. A., Blanchard, R., Cardenas, R., Cantor, J., Jordan, C. L., & Breedlove, S. M. (2007, August). *Earlier puberty predicts superior performance on male-biased* visuospatial tasks in men but not women. Abstract and poster presented at the 33rd annual meeting of the International Academy of Sex Research, Vancouver, Canada.
- 25. Seto, M. C., Cantor, J. M., & Blanchard, R. (2005, November). *Possession of child pornography is a diagnostic indicator of pedophilia*. Poster presented at the 24th annual meeting of the Association for the Treatment of Sexual Abusers, New Orleans.

- 26. Blanchard, R., Cantor, J. M., Bogaert, A. F., Breedlove. S. M., & Ellis, L. (2005, July). Interaction of fraternal birth order and handedness in the development of male homosexuality. Abstract and poster presented at the 31st annual meeting of the International Academy of Sex Research, Ottawa, Canada.
- 27. Cantor, J. M., & Blanchard, R. (2003, July). *The reported VIQ–PIQ differences in male sex offenders are artifactual?* Abstract and poster presented at the 29th annual meeting of the International Academy of Sex Research, Bloomington, Indiana.
- Christensen, B. K., Cantor, J. M., Millikin, C., & Blanchard, R. (2002, February). Factor analysis of two brief memory tests: Preliminary evidence for modality-specific measurement. Poster presented at the 30th annual meeting of the International Neuropsychological Society, Toronto, Ontario, Canada.
- 29. Cantor, J. M., Blanchard, R., Paterson, A., Bogaert, A. (2000, June). *How many gay men owe their sexual orientation to fraternal birth order?* Abstract and poster presented at the International Behavioral Development Symposium, Minot, North Dakota.
- Cantor, J. M., Binik, Y., & Pfaus, J. G. (1996, November). *Fluoxetine inhibition of male rat sexual behavior: Reversal by oxytocin*. Poster presented at the 26th annual meeting of the Society for Neurosciences, Washington, DC.
- Cantor, J. M., Binik, Y., & Pfaus, J. G. (1996, June). An animal model of fluoxetine-induced sexual dysfunction: Dose dependence and time course. Poster presented at the 28th annual Conference on Reproductive Behavior, Montréal, Canada.
- 32. Cantor, J. M., O'Connor, M. G., Kaplan, B., & Cermak, L. S. (1993, June). Transient events test of retrograde memory: Performance of amnestic and unimpaired populations. Poster presented at the 2nd annual science symposium of the Massachusetts Neuropsychological Society, Cambridge, MA.

EDITORIAL AND PEER-REVIEWING ACTIVITIES

Editor-in-Chief

Sexual Abuse: A Journal of Research and Treatment

Jan., 2010–Dec., 2014

Editorial Board Memberships

Journal of Sexual Aggression Journal of Sex Research, The Sexual Abuse: A Journal of Research and Treatment Archives of Sexual Behavior The Clinical Psychologist

Jan., 2010–Dec., 2021 Jan., 2008–Aug., 2020 Jan., 2006–Dec., 2019 Jan., 2004–Present Jan., 2004–Dec., 2005

Ad hoc Journal Reviewer Activity

American Journal of Psychiatry Annual Review of Sex Research Archives of General Psychiatry Assessment Biological Psychiatry BMC Psychiatry Brain Structure and Function British Journal of Psychiatry British Medical Journal Canadian Journal of Behavioural Science Canadian Journal of Psychiatry Cerebral Cortex Clinical Case Studies *Comprehensive Psychiatry* Developmental Psychology European Psychologist Frontiers in Human Neuroscience Human Brain Mapping International Journal of Epidemiology International Journal of Impotence Research International Journal of Sexual Health International Journal of Transgenderism Journal of Abnormal Psychology Journal of Clinical Psychology

Journal of Consulting and Clinical Psychology Journal of Forensic Psychology Practice Journal for the Scientific Study of Religion Journal of Sexual Aggression Journal of Sexual Medicine Journal of Psychiatric Research Nature Neuroscience Neurobiology Reviews Neuroscience & Biobehavioral Reviews *Neuroscience Letters* Proceedings of the Royal Society B (Biological Sciences) Psychological Assessment Psychological Medicine Psychological Science Psychology of Men & Masculinity Sex Roles Sexual and Marital Therapy Sexual and Relationship Therapy Sexuality & Culture Sexuality Research and Social Policy The Clinical Psychologist Traumatology World Journal of Biological Psychiatry

GRANT REVIEW PANELS

| 2017–2021 | Member, College of Reviewers, Canadian Institutes of Health Research, Canada. |
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| 2017 | Committee Member, Peer Review Committee—Doctoral Research Awards A. Canadian Institutes of Health Research, Canada. |
| 2017 | Member, International Review Board, Research collaborations on behavioural disorders related to violence, neglect, maltreatment and abuse in childhood and adolescence. <i>Bundesministerium für Bildung und Forschung [Ministry of Education and Research]</i> , Germany. |
| 2016 | Reviewer. National Science Center [Narodowe Centrum Nauki], Poland. |
| 2016 | Committee Member, Peer Review Committee—Doctoral Research Awards A. Canadian Institutes of Health Research, Canada. |
| 2015 | Assessor (Peer Reviewer). Discovery Grants Program. Australian Research Council, Australia. |
| 2015 | Reviewer. Czech Science Foundation, Czech Republic. |
| 2015 | Reviewer, "Off the beaten track" grant scheme. <i>Volkswagen Foundation,</i> Germany. |
| 2015 | External Reviewer, Discovery Grants program—Biological Systems and Functions. <i>National Sciences and Engineering Research Council of Canada</i> , Canada |
| 2015 | Committee Member, Peer Review Committee—Doctoral Research Awards A. Canadian Institutes of Health Research, Canada. |
| 2014 | Assessor (Peer Reviewer). Discovery Grants Program. Australian Research Council, Australia. |
| 2014 | External Reviewer, Discovery Grants program—Biological Systems and Functions. <i>National Sciences and Engineering Research Council of Canada</i> , Canada. |
| 2014 | Panel Member, Dean's Fund—Clinical Science Panel. University of Toronto Faculty of Medicine, Canada. |
| 2014 | Committee Member, Peer Review Committee—Doctoral Research Awards A. Canadian Institutes of Health Research, Canada. |
| 2013 | Panel Member, Grant Miller Cancer Research Grant Panel. University of Toronto Faculty of Medicine, Canada. |

- 2013 Panel Member, Dean of Medicine Fund New Faculty Grant Clinical Science Panel. *University of Toronto Faculty of Medicine*, Canada.
- 2012 Board Member, International Review Board, Research collaborations on behavioural disorders related to violence, neglect, maltreatment and abuse in childhood and adolescence (2nd round). *Bundesministerium für Bildung und Forschung [Ministry of Education and Research]*, Germany.
- 2012 External Reviewer, University of Ottawa Medical Research Fund. University of Ottawa Department of Psychiatry, Canada.
- 2012 External Reviewer, Behavioural Sciences—B. *Canadian Institutes of Health Research*, Canada.
- 2011 Board Member, International Review Board, Research collaborations on behavioural disorders related to violence, neglect, maltreatment and abuse in childhood and adolescence. *Bundesministerium für Bildung und Forschung [Ministry of Education and Research]*, Germany.

TEACHING AND TRAINING

| PostDoctoral Research Supervision | alth Toronto Canada |
|---|------------------------|
| Dr. Katherine S. Sutton | Sept. 2012–Dec. 2013 |
| Dr. Rachel Fazio | Sept. 2012 Dec., 2013 |
| Dr. Amy Lykins | Sept., 2008–Nov., 2009 |
| Doctoral Research Supervision Centre for Addiction and Mental Health. Toronto. Canada | |
| Michael Walton • University of New England, Australia | Sept., 2017–Aug., 2018 |
| Debra Soh • York University | May, 2013–Aug, 2017 |
| Skye Stephens • Ryerson University | April, 2012–June, 2016 |
| Masters Research Supervision Centre for Addiction and Mental Health, Toronto, Canada | |
| Nicole Cormier • Ryerson University | June, 2012–present |
| Debra Soh • Ryerson University | May, 2009–April, 2010 |
| Undergraduate Research Supervision Centre for Addiction and Mental Health. Toronto. Canada | |
| Kylie Reale • Ryerson University | Spring, 2014 |
| Jarrett Hannah • University of Rochester | Summer, 2013 |
| Michael Humeniuk • University of Toronto | Summer, 2012 |
| Clinical Supervision (Doctoral Internship) Clinical Internship Program, Centre for Addiction and Mental Heal | lth, Toronto, Canada |
| Katherine S. Sutton • Queen's University | 2011–2012 |
| David Sylva • Northwestern University | 2011–2012 |
| Jordan Rullo • University of Utah | 2010-2011 |

| 2010–2011 |
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| 2010–2011 |
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TEACHING AND TRAINING

Clinical Supervision (Doctoral- and Masters- level practica) Centre for Addiction and Mental Health, Toronto, Canada

| Tyler Tulloch • Ryerson University | 2013-2014 |
|--|--------------|
| Natalie Stratton • Ryerson University | Summer, 2013 |
| Fiona Dyshniku • University of Windsor | Summer, 2013 |
| Mackenzie Becker • McMaster University | Summer, 2013 |
| Skye Stephens • Ryerson University | 2012-2013 |
| Vivian Nyantakyi • Capella University | 2010-2011 |
| Cailey Hartwick • University of Guelph | Fall, 2010 |
| Tricia Teeft • Humber College | Summer, 2010 |
| Allison Reeves • Ontario Institute for Studies in Education/Univ. of Toronto | 2009–2010 |
| Helen Bailey • Ryerson University | Summer, 2009 |
| Edna Aryee • Ontario Institute for Studies in Education/Univ. of Toronto | 2008–2009 |
| Iryna Ivanova • Ontario Institute for Studies in Education/Univ. of Toronto | 2008–2009 |
| Jennifer Robinson • Ontario Institute for Studies in Education/Univ. of Toronto | 2008-2009 |
| Zoë Laksman • Adler School of Professional Psychology | 2005-2006 |
| Diana Mandelew • Adler School of Professional Psychology | 2005–2006 |
| Susan Wnuk • York University | 2004–2005 |
| Hiten Lad • Adler School of Professional Psychology | 2004–2005 |
| Natasha Williams • Adler School of Professional Psychology | 2003-2004 |
| Lisa Couperthwaite • Ontario Institute for Studies in Education/Univ. of Toronto | 2003-2004 |
| Lori Gray, née Robichaud • University of Windsor | Summer, 2003 |
| Sandra Belfry • Ontario Institute for Studies in Education/Univ. of Toronto | 2002-2003 |
| Althea Monteiro • York University | Summer, 2002 |
| Samantha Dworsky • York University | 2001-2002 |
| Kerry Collins • University of Windsor | Summer, 2001 |
| Jennifer Fogarty • Waterloo University | 2000-2001 |
| Emily Cripps • Waterloo University | Summer, 2000 |
| Lee Beckstead • University of Utah | 2000 |

PROFESSIONAL SOCIETY ACTIVITIES

OFFICES HELD

| 2018–2019 | Local Host. Society for Sex Therapy and Research. |
|------------|--|
| 2015 | Member, International Scientific Committee, World Association for Sexual Health. |
| 2015 | Member, Program Planning and Conference Committee, Association for the Treatment of Sexual Abusers |
| 2012–2013 | Chair, Student Research Awards Committee, Society for Sex Therapy & Research |
| 2012–2013 | Member, Program Planning and Conference Committee, Association for the Treatment of Sexual Abusers |
| 2011–2012 | Chair, Student Research Awards Committee, Society for Sex Therapy & Research |
| 2010–2011 | Scientific Program Committee, International Academy of Sex Research |
| 2002–2004 | Membership Committee • APA Division 12 (Clinical Psychology) |
| 2002–2003 | Chair, Committee on Science Issues, APA Division 44 |
| 2002 | Observer, Grant Review Committee • Canadian Institutes of Health Research Behavioural Sciences (B) |
| 2001–2009 | Reviewer • APA Division 44 Convention Program Committee |
| 2001, 2002 | Reviewer • APA Malyon-Smith Scholarship Committee |
| 2000–2005 | Task Force on Transgender Issues, APA Division 44 |
| 1998–1999 | Consultant, APA Board of Directors Working Group on Psychology Marketplace |
| 1997 | Student Representative • APA Board of Professional Affairs' Institute on TeleHealth |
| 1997–1998 | Founder and Chair • APA/APAGS Task Force on New Psychologists' Concerns |
| 1997–1999 | Student Representative • APA/CAPP Sub-Committee for a National Strategy for Prescription Privileges |
| 1997–1999 | Liaison • APA Committee for the Advancement of Professional Practice |
| 1997–1998 | Liaison • APA Board of Professional Affairs |
| 1993–1997 | Founder and Chair • APA/APAGS Committee on LGB Concerns |

PROFESSIONAL SOCIETY ACTIVITIES

MEMBERSHIPS

- 2022-Present Consultant Society for the Advancement of Actuarial Risk Needs Assessment
- 2017–2021 Member Canadian Sex Research Forum
- 2009–Present Member Society for Sex Therapy and Research
- 2007–Present Fellow Association for the Treatment and Prevention of Sexual Abuse
- 2006-Present Full Member (elected) International Academy of Sex Research
- 2006–Present Research and Clinical Member Association for the Treatment and Prevention of Sexual Abuse
- 2003–2006 Associate Member (elected) International Academy of Sex Research
- 2002 Founding Member CPA Section on Sexual Orientation and Gender Identity
- 2001–2013 Member Canadian Psychological Association (CPA)
- 2000–2015 Member American Association for the Advancement of Science
- 2000–2015 Member American Psychological Association (APA) APA Division 12 (Clinical Psychology)

APA Division 44 (Society for the Psychological Study of LGB Issues)

- 2000–2020 Member Society for the Scientific Study of Sexuality
- 1995–2000 Student Member Society for the Scientific Study of Sexuality
- 1993–2000 Student Affiliate American Psychological Association
- 1990–1999 Member, American Psychological Association of Graduate Students (APAGS)

CLINICAL LICENSURE/REGISTRATION

Certificate of Registration, Number 3793 College of Psychologists of Ontario, Ontario, Canada

AWARDS AND HONORS

2022 Distinguished Contribution Award

Association for the Treatment and Prevention of Sexual Abuse (ATSA)

2011 Howard E. Barbaree Award for Excellence in Research

Centre for Addiction and Mental Health, Law and Mental Health Program

2004 fMRI Visiting Fellowship Program at Massachusetts General Hospital

American Psychological Association Advanced Training Institute and NIH

1999–2001 CAMH Post-Doctoral Research Fellowship

Centre for Addiction and Mental Health Foundation and Ontario Ministry of Health

1998 Award for Distinguished Contribution by a Student

American Psychological Association, Division 44

1995 Dissertation Research Grant

Society for the Scientific Study of Sexuality

1994–1996 McGill University Doctoral Scholarship

1994 Award for Outstanding Contribution to Undergraduate Teaching

"TA of the Year Award," from the McGill Psychology Undergraduate Student Association

MAJOR MEDIA

(Complete list available upon request.)

Feature-length Documentaries

Vice Canada Reports. *Age of Consent.* 14 Jan 2017. Canadian Broadcasting Company. *I, Pedophile*. Firsthand documentaries. 10 Mar 2016.

Appearances and Interviews

- 11 Mar 2020. Ibbitson, John. <u>It is crucial that Parliament gets the conversion-therapy ban right.</u> *The Globe & Mail.*
- 25 Jan 2020. Ook de hulpvaardige buurman kan verzamelaar van kinderporno zin. De Morgen.
- 3 Nov 2019. Village of the damned. 60 Minutes Australia.
- 1 Nov 2019. HÅKON F. HØYDAL. <u>Norsk nettovergriper: Jeg hater meg selv: Nordmannen</u> <u>laster ned overgrepsmateriale fra nettet – og oppfordrer politiet til å gi amnesti for slike</u> <u>som ham</u>.
- 10 Oct 2019. Smith, T. <u>Growing efforts are looking at how—or if—#MeToo offenders can be</u> reformed. *National Public Radio*.
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- 29 Apr 2019. Mathieu, Isabelle. La poupée qui a troublé les Terre-Neuviens. La Tribune.
- 21 Mar 2019. Pope Francis wants psychological testing to prevent problem priests. But can it really do that? The Washington Post.
- 12 Dec 2018. <u>Child sex dolls: Illegal in Canada, and dozens seized at the border.</u> Ontario Today with Rita Celli. *CBC*.
- 12 Dec 2018. Celli, R. & Harris, K. Dozens of child sex dolls seized by Canadian border agents. *CBC News*.
- 27 Apr 2018. Rogers, Brook A. The online 'incel' culture is real-and dangerous. New York Post.
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- 24 Ap 2018 Understanding 'incel'. CTV News.
- 27 Nov 2017. Carey, B. <u>Therapy for Sexual Misconduct? It's Mostly Unproven.</u> New York *Times.*
- 14 Nov 2017. Tremonti, A. M. The Current. CBC.
- 9 Nov2017. Christensen, J. Why men use masturbation to harass women. *CNN*. <u>http://www.cnn.com/2017/11/09/health/masturbation-sexual-harassment/index.html</u>
- 7 Nov 2017. Nazaryan, A. Why is the alt-right obsessed with pedophilia? Newsweek.
- 15 Oct 2017. Ouatik, B. Déscouvre. Pédophilie et science. CBC Radio Canada.
- 12 Oct 2017. Ouatik, B. Peut-on guérir la pédophilie? CBC Radio Canada.
- 11 Sep 2017. Burns, C. The young paedophiles who say they don't abuse children. BBC News.
- 18 Aug 2017. Interview. National Post Radio. Sirius XM Canada.
- 16 Aug 2017. Blackwell, Tom. <u>Man says he was cured of pedophilia at Ottawa clinic: 'It's like a</u> weight that's been lifted': But skeptics worry about the impact of sending pedophiles into the world convinced their curse has been vanquished. *National Post*.
- 26 Apr 2017. Zalkind, S. Prep schools hid sex abuse just like the catholic church. VICE.
- 24 Apr 2017. Sastre, P. Pédophilie: une panique morale jamais n'abolira un crime. Slate France.
- 12 Feb 2017. Payette, G. Child sex doll trial opens Pandora's box of questions. CBC News.
- 26 Nov 2016. Det morke uvettet ["The unknown darkness]". Fedrelandsvennen.
- 13 July 2016. Paedophilia: Shedding light on the dark field. The Economist.

- 1 Jul 2016. Debusschere, B. <u>Niet iedereen die kinderporno kijkt, is een pedofiel: De mythes rond</u> <u>pedofilie ontkracht</u>. *De Morgen*.
- 12 Apr 2016. O'Connor, R. <u>Terence Martin: The Tasmanian MP whose medication 'turned him</u> <u>into a paedophile</u>'. *The Independent*.
- 8 Mar 2016. Bielski, Z. <u>'The most viscerally hated group on earth': Documentary explores how</u> intervention can stop pedophiles. *The Globe and Mail*.
- 1 Mar 2016. Elmhirst, S. What should we do about paedophiles? The Guardian.
- 24 Feb 2016. The man whose brain tumour 'turned him into a paedophile'. The Independent.
- 24 Nov 2015. Byron, T. The truth about child sex abuse. BBC Two.
- 20 Aug 2015. The Jared Fogle case: Why we understand so little about abuse. Washington Post.
- 19 Aug 2015. Blackwell, T. <u>Treat sex offenders for impotence—to keep them out of trouble</u>, <u>Canadian psychiatrist says</u>. *National Post*.
- 2 Aug 2015. Menendez, J. BBC News Hour. BBC World Service.
- 13 Jul 2015. The nature of pedophilia. BBC Radio 4.
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- 10 Apr 2015. NWT failed to prevent sex offender from abusing stepdaughter again. CBC News.
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- 9 Dec 2014. Carey, B. When a rapist's weapon is a pill. New York Times.
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- 17 Nov2014. Say pedófile, busco aydua. El Pais.
- 4 Sep 2014. Born that way? Ideas, with Paul Kennedy. CBC Radio One.
- 27 Aug 2014. Interrogating the statistics for the prevalence of paedophilia. BBC.
- 25 Jul 2014. Stephenson, W. The prevalence of paedophilia. BBC World Service.
- 21 Jul 2014. Hildebrandt, A. Virtuous Pedophiles group gives support therapy cannot. CBC.
- 26 Jan 2014. Paedophilia a result of faulty wiring, scientists suggest. Daily Mail.
- 22 Dec 2013. Kane, L. Is pedophilia a sexual orientation? Toronto Star.
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- 1 Jul 2013. Morin, H. Pédophilie: la difficile quête d'une origine biologique. Le Monde.
- 2 Jun 2013. Malcolm, L. The psychology of paedophilia. Australian National Radio.
- 1 Mar 2013. Kay, J. The mobbing of Tom Flanagan is unwarranted and cruel. National Post.
- 6 Feb 2013. Boy Scouts board delays vote on lifting ban on gays. L.A. Times.
- 31 Aug 2012. CNN Newsroom interview with Ashleigh Banfield. CNN.
- 24 Jun 2012. CNN Newsroom interview with Don Lemon. CNN.

EXPERT WITNESS TESTIMONY

<u>2010</u>

In Re the detention of William G. Dutcher Case No 08-2-38259-1 SEA Superior Court, King County, Seattle, WA

<u>2015</u>

State of Florida vs Jon Herb Case No 11-2013-CF-001958-AXXX-XX

<u>2017</u>

In re Commitment of Nicholas Bauer (Frye Hearing) Case No. 2-18-0905; Appeal No. 2009-MR-64 Appellate Court of Illinois, Lee County, Second District

U.S. vs. William Hutcheson Leford (Presentencing Hearing) Case No. 3:16-CR-00012-1 Southern District of Georgia, Dublin Division

<u>2018</u>

NY State Office Mental Health/Dept. of Corrections & Comm Superv vs. Fernando Little Index# CA2016-002179; RJI No 32-16-7108; Consec No. 290430 Application for discharge from Central NY Psychiatric Center Utica, New York

<u>2019</u>

John Fitzpatrick v Her Majesty the Queen Ontario Superior Court of Justice, Canada

Re Commitment of Steven Casper (Frye Hearing) Case No. 09 MR 135, IDOC No. B23461; DHS No. 887057 Kendall County, Illinois

Re Commitment of Ian Inger (Frye Hearing) Poughkeepsie, NY

Helen Spiegel v. Keeley Savoie Docket No HS14D0435 DR Probate & Family Court, Hampshire Division, Massachusetts

Southern District of New York vs. Peter Bright Case No. 1:19 Cr -00521 PKC U.S. District Court, New York, Southern District

<u>2021</u>

State of Arizona vs Franklin Arnett Clifton IR# JWID 14-70629; Cr2017-150114-001 Maricopa County, Arizona

B.P.J. v West Virginia Civil Action No. 2:21-cv-00316 US District Court, Southern District, Charleston Division

Cross, et al. v Loudoun School Board Case No. CL21-3254 Circuit Court, County of Loudoun, VA

Re Commitment of Michael Hughes (Frye Hearing) Case No. 10-CR-80013 Circuit Court, Cook County, Chicago, Illinois

In the Matter of Alexander Aurora Cox Cause number 48C02-215-JC-000143 Madison Circuit Court 2, Indiana

Josephson v University of Kentucky Case No: 3:19-cv-00230-RGJ Kentucky Western District, Louisville Division

<u>2022</u>

A.M. v. Indianapolis Public Schools, et al. Cause No. 1:22-cv-01705-JMS-DLP U.S. District Court, Southern District of Indiana

Boe et al, USA v Marshall Civil Action No. 2:22-cv-00184- LCB U.S. District Court, Middle District of Alabama, Northern Div

Bridge, et al. v Oklahoma State Department of Education, et al. Case No. CIV-22-787-JD Oklahoma, Western District Court

Dekker, et al. v Florida Agency for Health Care Admin. Case 4:22-cv-00325-RH-MAF Florida, Northern District Court

Doe, et al. v Abbott, et al. Case No. D-1-GN-22-000977 Texas, Travis County

Xavier Hersom and John Doe v West Virginia

Civil Action No. 2:21-cv-00450 US District Court, Southern District, Charleston Division

NY v Frederick B. (Re: Commitment of Frederick B.) Index No. 001141/2022 New York Supreme Court

Pamela Ricard v USD 475 Geary County School Board Case No. 5:22-cv-04015 US District Court, District of Kansas

Roe, et al. v. Utah High School Activities Association, et al. Case No. 220903262 Salt Lake County, Utah Third Judicial District Court

Voe, PFLAG, et al. v Abbott NO. D-1-GN-22-002569 Texas, Travis County District Court

<u>2023</u>

Doe, et al. v. Thornbury, et al. Civil No. 3:23CV-230-RGJ U.S. District Court, Western District of Kentucky

Doe, et al. v. Horne, et al. Case No. 4:23-cv-00185-JGZ District of Arizona, Tucson Division

K.C., et al. v. Medical Licensing Board of Indiana, et al. Case No. 1:23-CV-595 Southern District of Indiana, Indianapolis Division

L.W., et al. v. Skrmetti, et al. Case No. 3:23-cv-00376 Middle District of Tennessee, Nashville Division

Poe, et al., v. Drummond, et al. Case No. 23-CV-00177-JFH-SH Northern District of Oklahoma

Koe, et al., v. Noggle, et al. Civil Action No. 1:23-cv-02904-SEG U.S. District Court, Northern District of Georgia, Atlanta Div

Poe, et al., v. Labrador Case No. 1:23-cv-00269-CWD U.S. District Court, District of Idaho, Southern Division Roe, et al., v. Critchfield, et al. Case No. 1:23-cv-00315-DCN U.S. District Court, District of Idaho

Lazaro Loe v Texas Cause No. D-1-GN-23-003616 201st Judicial District, Travis County, Texas

Noe, et al., v. Parson, et al. Case No 23AC-CC04530 Circuit Court of Cole County, State of Missouri

Van Garderen, et al. v. Montana, et al. Cause No. DV 2023–0541 Montana Fourth Judicial District Court, Missoula County

B.C. College of Nurses and Midwives v Amy HAMM Citation issued under Health Professional Act

Voe, et al. v Mansfield, et al. Civil No. 1:23-cv-864 U.S. District Court, North Carolina, Middle District, Durham Div.

TD, et al. v Wrigley, et al. Case No. 08-2023-CV-2189 District Court, South Central Judicial District, North Dakota

<u>2024</u>

Moe, et al. v Yost, et al. Case No. 24-cv-002481 Court of Common Pleas, Franklin County, Ohio

McComb Children's Clinic v Xavier Becerra (HHS) Case No. 5:24-cv-48-KS-LGI U.S. District Court, Southern District of Mississippi, Western Division

Appendix 2




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Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy

James M. Cantor

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Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy

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ABSTRACT

The American Academy of Pediatrics (AAP) recently published a policy statement: *Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents*. Although almost all clinics and professional associations in the world use what's called the *watchful waiting* approach to helping gender diverse (GD) children, the AAP statement instead rejected that consensus, endorsing *gender affirmation* as the only acceptable approach. Remarkably, not only did the AAP statement fail to include any of the actual outcomes literature on such cases, but it also misrepresented the contents of its citations, which repeatedly said the very opposite of what AAP attributed to them.

The American Academy of Pediatrics (AAP) recently published a policy statement entitled, Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents (Rafferty, AAP Committee on Psychosocial Aspects of Child and Family Health, AAP Committee on Adolescence, AAP Section on Lesbian, Gay, Bisexual, and Transgender Health and Wellness, 2018). These are children who manifest discontent with the sex they were born as and desire to live as the other sex (or as some alternative gender role). The policy was quite a remarkable document: Although almost all clinics and professional associations in the world use what's called the watchful waiting approach to helping transgender and gender diverse (GD) children, the AAP statement rejected that consensus, endorsing only gender affirmation. That is, where the consensus is to delay any transitions after the onset of puberty, AAP instead rejected waiting before transition. With AAP taking such a dramatic departure from other professional associations, I was immediately curious about what evidence led them to that conclusion. As I read the works on which they based their policy, however, I was pretty surprised—rather alarmed, actually: These documents simply did not say what AAP claimed they did. In fact, the references that AAP cited as the basis of their policy instead outright contradicted that policy, repeatedly endorsing watchful waiting.

The AAP statement was also remarkable in what it left out—namely, the actual outcomes research on GD children. In total, there have been 11 follow-up studies of GD children, of which AAP cited one (Wallien & Cohen-Kettenis, 2008), doing so without actually mentioning the outcome data it contained. The literature on outcomes was neither reviewed, summarized, nor subjected to meta-analysis to be considered in the aggregate—It was merely disappeared. (The list of all existing studies appears in the appendix.) As they make clear, *every* follow-up study of GD children, without exception, found the same thing: Over puberty, the majority of GD children cease to want to transition. AAP is, of course, free to establish whatever policy it likes on

whatever basis it likes. But any assertion that their policy is based on evidence is demonstrably false, as detailed below.

AAP divided clinical approaches into three types—conversion therapy, watchful waiting, and gender affirmation. It rejected the first two and endorsed *gender affirmation* as the only acceptable alternative. Most readers will likely be familiar already with attempts to use conversion therapy to change sexual orientation. With regard to gender identity, AAP wrote:

"[C]onversion" or "reparative" treatment models are used to prevent children and adolescents from identifying as transgender or to dissuade them from exhibiting gender-diverse expressions.... Reparative approaches have been proven to be not only unsuccessful³⁸ but also deleterious and are considered outside the mainstream of traditional medical practice.^{29,39-42}

The citations were:

- 38. Haldeman DC. The practice and ethics of sexual orientation conversion therapy. J Consult Clin Psychol. 1994;62(2):221–227.
- 29. Adelson SL; American Academy of Child and Adolescent Psychiatry (AACAP) Committee on Quality Issues (CQI). Practice parameter on gay, lesbian, or bisexual sexual orientation, gender nonconformity, and gender discordance in children and adolescents. J Am Acad Child Adolesc Psychiatry. 2012;51(9):957–974.
- 39. Byne W. Regulations restrict practice of conversion therapy. LGBT Health. 2016;3(2):97-99.
- 40. Cohen-Kettenis PT, Delemarrevan de Waal HA, Gooren LJ. The treatment of adolescent transsexuals: changing insights. *J Sex Med.* 2008;5(8):1892–1897.
- 41. Bryant K. Making gender identity disorder of childhood: historical lessons for contemporary debates. Sex Res Soc Policy. 2006;3(3):23–39.
- 42. World Professional Association for Transgender Health. *WPATH De-Psychopathologisation Statement*. Minneapolis, MN: World Professional Association for Transgender Health; 2010.

AAP's claims struck me as odd because *there are no studies of conversion therapy for gender identity*. Studies of conversion therapy have been limited to *sexual orientation*, and, moreover, to the sexual orientation *of adults*, not to gender identity and not of children in any case. The article AAP cited to support their claim (reference number 38) is indeed a classic and well-known review, but it is a review of sexual orientation research *only*. Neither gender identity, nor even children, received a single mention in it. Indeed, the narrower scope of that article should be clear to anyone reading even just its title: "The practice and ethics of *sexual orientation* conversion therapy" [italics added].

AAP continued, saying that conversion approaches for GD children have already been rejected by medical consensus, citing five sources. This claim struck me as just as odd, however—I recalled associations banning conversion therapy for sexual orientation, but not for gender identity, exactly because there is no evidence for generalizing from adult sexual orientation to childhood gender identity. So, I started checking AAP's citations for that, and these sources too pertained only to sexual orientation, not gender identity (specifics below). What AAP's sources *did* repeatedly emphasize was that:

- A. Sexual orientation of adults is unaffected by conversion therapy and any other [known] intervention;
- B. Gender dysphoria in childhood before puberty desists in the majority of cases, becoming (cis-gendered) homosexuality in adulthood, again regardless of any [known] intervention; and
- C. Gender dysphoria in childhood persisting after puberty tends to persist entirely.

That is, in the context of GD children, it simply makes no sense to refer to externally induced "conversion": The majority of children "convert" to cisgender or "desist" from transgender *regardless* of any attempt to change them. "Conversion" only makes sense with regard to adult sexual orientation because (unlike childhood gender identity), adult homosexuality never or nearly never spontaneously changes to heterosexuality. Although gender identity and sexual orientation may often be analogous and discussed together with regard to social or political values and to civil rights, they are nonetheless distinct—with distinct origins, needs, and responses to medical and mental health care choices. Although AAP emphasized to the reader that "gender identity is not synonymous with 'sexual orientation" (Rafferty et al., 2018, p. 3), they went ahead to treat them as such nonetheless.

To return to checking AAP's fidelity to its sources: Reference 29 was a practice guideline from the Committee on Quality Issues of the American Academy of Child and Adolescent Psychiatry (AACAP). Despite AAP applying this source to *gender identity*, AACAP was quite unambiguous regarding their intent to speak to sexual orientation and *only* to sexual orientation: "Principle 6. Clinicians should be aware that there is no evidence that *sexual orientation* can be altered through therapy, and that attempts to do so may be harmful. There is no established evidence that change in a predominant, enduring *homosexual* pattern of development is possible. Although sexual fantasies can, to some degree, be suppressed or repressed by those who are ashamed of or in conflict about them, sexual desire is not a choice. However, behavior, social role, and—to a degree—identity and self-acceptance are. Although operant conditioning modifies sexual fetishes, it does not alter *homosexuality*. Psychiatric efforts to alter *sexual orientation* through 'reparative therapy' *in adults* have found little or no change in *sexual orientation*, while causing significant risk of harm to self-esteem" (AACAP, 2012, p. 967, italics added).

Whereas AAP cites AACAP to support gender affirmation as the only alternative for treating GD children, AACAP's actual view was decidedly neutral, noting the lack of evidence: "Given the lack of empirical evidence from randomized, controlled trials of the efficacy of treatment aimed at eliminating gender discordance, the potential risks of treatment, and longitudinal evidence that gender discordance persists in only a small minority of untreated cases arising in childhood, further research is needed on predictors of persistence and desistence of childhood gender discordance as well as the long-term risks and benefits of intervention before any treatment to eliminate gender discordance can be endorsed" (AACAP, 2012, p. 969). Moreover, whereas AAP rejected watchful waiting, what AACAP recommended was: "In general, it is desirable to help adolescents who may be experiencing gender distress and dysphoria to defer sex reassignment until adulthood" (AACAP, 2012, p. 969). So, not only did AAP attribute to AACAP something AACAP never said, but also AAP withheld from readers AACAP's actual view.

Next, in reference 39, Byne (2016) also addressed only sexual orientation, doing so very clearly: "Reparative therapy is a subset of conversion therapies based on the premise that *same-sex attraction* are reparations for childhood trauma. Thus, practitioners of reparative therapy believe that exploring, isolating, and repairing these childhood emotional wounds will often result in reducing *same-sex attractions*" (Byne, 2016, p. 97). Byne does not say this of gender identity, as the AAP statement misrepresents.

In AAP reference 40, Cohen-Kettenis et al. (2008) did finally pertain to gender identity; however, this article never mentions conversion therapy. (!) Rather, in this study, the authors presented that clinic's lowering of their minimum age for cross-sex hormone treatment from age 18 to 16, which they did on the basis of a series of studies showing the high rates of success with this age group. Although it did strike me as odd that AAP picked as support against conversion therapy an article that did not mention conversion therapy, I could imagine AAP cited the article as an example of what the "mainstream of traditional medical practice" consists of (the logic being that conversion therapy falls outside what an 'ideal' clinic like this one provides). However, what this clinic provides is the very *watchful waiting* approach that AAP rejected. The approach espoused by Cohen-Kettenis (and the other clinics mentioned in the source—Gent, Boston, Oslo, and now formerly, Toronto) is to make puberty-halting interventions available at age 12 because: "[P]ubertal suppression may give adolescents, together with the attending health professional, more time to explore their gender identity, without the distress of the developing secondary sex characteristics. The precision of the diagnosis may thus be improved" (Cohen-Kettenis et al., 2008, p. 1894).

Reference 41 presented a very interesting history spanning the 1960s-1990s about how feminine boys and tomboyish girls came to be recognized as mostly pre-homosexual, and how that status came to be entered into the DSM at the same time as homosexuality was being *removed* from the DSM. Conversion therapy is never mentioned. Indeed, to the extent that Bryant mentions treatment at all, it is to say that treatment is entirely irrelevant to his analysis: "An important omission from the DSM is a discussion of the kinds of treatment that GIDC children should receive. (This omission is a general orientation of the DSM and not unique to GIDC)" (Bryant, 2006, p. 35). How this article supports AAP's claim is a mystery. Moreover, how AAP could cite a 2006 history discussing events of the 1990s and earlier to support a claim about the *current* consensus in this quickly evolving discussion remains all the more unfathomable.

Cited last in this section was a one-paragraph press release from the World Professional Association for Transgender Health. Written during the early stages of the American Psychiatric Association's (APA's) update of the DSM, the statement asserted simply that "The WPATH Board of Directors strongly urges the de-psychopathologisation of gender variance worldwide." Very reasonable debate can (and should) be had regarding whether gender dysphoria should be removed from the DSM as homosexuality was, and WPATH was well within its purview to assert that it should. Now that the DSM revision process is years completed however, history has seen that APA ultimately retained the diagnostic categories, rejecting WPATH's urging. This makes AAP's logic entirely backwards: That WPATH's request to depathologize gender dysphoria was *rejected* suggests that it is *WPATH's* view—and therefore the AAP policy—which fall "outside the mainstream of traditional medical practice." (!)

AAP based this entire line of reasoning on their belief that conversion therapy is being used "to prevent children and adolescents from identifying as transgender" (Rafferty et al., 2018, p. 4). That claim is left without citation or support. In contrast, what is said by AAP's sources is "delaying affirmation should *not* be construed as conversion therapy or an attempt to change gender identity" in the first place (Byne, 2016, p. 2). Nonetheless, AAP seems to be doing exactly that: simply relabeling any alternative approach as equivalent to conversion therapy.

Although AAP (and anyone else) may reject (what they label to be) conversion therapy purely on the basis of political or personal values, there is no evidence to back the AAP's stated claim about the existing science on gender identity at all, never mind gender identity of children.

AAP also dismissed the watchful waiting approach out of hand, not citing any evidence, but repeatedly calling it "outdated." The criticisms AAP provided, however, again defied the existing evidence, with even its own sources repeatedly calling watchful waiting the current standard. According to AAP:

[G]ender affirmation is in contrast to the outdated approach in which a child's gender-diverse assertions are held as "possibly true" until an arbitrary age (often after pubertal onset) when they can be considered valid, an approach that authors of the literature have termed "watchful waiting." This outdated approach does not serve the child because critical support is withheld. Watchful waiting is based on binary notions of gender in which gender diversity and fluidity is pathologized; in watchful waiting, it is also assumed that notions of gender identity become fixed at a certain age. The approach is also influenced by a group of early studies with validity concerns, methodologic flaws, and limited follow-up on children who identified as TGD and, by adolescence, did not seek further treatment ("desisters").^{45,47}

The citations from AAP's reference list are:

- 45. Ehrensaft D, Giammattei SV, Storck K, Tishelman AC, Keo-Meier C. Prepubertal social gender transitions: what we know; what we can learn—a view from a gender affirmative lens. *Int J Transgend*. 2018;19(2):251–268
- 47. Olson KR. Prepubescent transgender children: what we do and do not know. J Am Acad Child Adolesc Psychiatry. 2016;55(3):155–156.e3

I was surprised first by the AAP's claim that watchful waiting's delay to puberty was somehow "arbitrary." The literature, including AAP's sources, repeatedly indicated the pivotal importance of puberty, noting that outcomes strongly diverge at that point. According to AAP reference 29, in "prepubertal boys with gender discordance-including many without any mental health treatment-the cross gender wishes usually fade over time and do not persist into adulthood, with only 2.2% to 11.9% continuing to experience gender discordance" (Adelson & AACAP, 2012, p. 963, italics added), whereas "when gender variance with the desire to be the other sex is present in adolescence, this desire usually does persist through adulthood" (Adelson & AACAP, 2012, p. 964, italics added). Similarly, according to AAP reference 40, "Symptoms of GID at prepubertal ages decrease or even disappear in a considerable percentage of children (estimates range from 80-95%). Therefore, any intervention in childhood would seem premature and inappropriate. However, GID persisting into early puberty appears to be highly persistent" (Cohen-Kettenis et al., 2008, p. 1895, italics added). That follow-up studies of prepubertal transition differ from postpubertal transition is the very meaning of non-arbitrary. AAP gave readers exactly the reverse of what was contained in its own sources. If AAP were correct in saying that puberty is an arbitrarily selected age, then AAP will be able to offer another point to wait for with as much empirical backing as puberty has.

Next, it was not clear on what basis AAP could say that watchful waiting withholds support— AAP cited no support for its claim. The people in such programs often receive substantial support during this period. Also unclear is on what basis AAP could already know exactly which treatments are "critical" and which are not—Answering that question is the very purpose of this entire endeavor. Indeed, the logic of AAP's claim appears entirely circular: It is only if one were already pre-convinced that gender affirmation is the only acceptable alternative that would make watchful waiting seem to withhold critical support—What it delays is gender affirmation, the method one has already decided to be critical.

Although AAP's next claim did not have a citation appearing at the end of its sentence, binary notions of gender were mentioned both in references 45 and 47. Specifically, both pointed out that existing outcome studies have been about people transitioning from one sex to the other, rather than from one sex to an in-between status or a combination of masculine/feminine features. Neither reference presented this as a reason to reject the results from the existing studies of complete transition however (which is how AAP cast it). Although it is indeed true that the outcome data have been about complete transition, some future study showing that partial transition shows a different outcome would not invalidate what is known about complete transition. Indeed, data showing that partial transition gives better outcomes than complete transition would, once again, support the watchful waiting approach which AAP rejected.

Next was a vague reference alleging concerns and criticisms about early studies. Had AAP indicated what those alleged concerns and flaws were (or which studies they were), then it would be possible to evaluate or address them. Nonetheless, the argument is a red herring: Because all of the later studies showed the same result as did the early studies, any such allegation is necessarily moot.

Reference 47 was a one-and-a-half page commentary in which the author off-handedly mentions criticisms previously made of three of the eleven outcome studies of GD children, but does not provide any analysis or discussion. The only specific claim was that studies (whether early or late) had limited follow-up periods—the logic being that had outcome researchers lengthened the follow-up period, then people who seemed to have desisted might have returned to the clinic as

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cases of "persistence-after-interruption." Although one could debate the merits of that prediction, AAP instead simply withheld from the reader the result from the original researchers having tested that very prediction directly: Steensma and Cohen-Kettenis (2015) conducted another analysis of their cohort, by then ages 19–28 (mean age 25.9 years), and found that 3.3% (5 people of the sample of 150) later returned. That is, in long-term follow-up, the childhood sample showed 66.7% desistence instead of 70.0% desistance.

Reference 45 did not support the claim that watchful-waiting is "outdated" either. Indeed, that source said the very opposite, explicitly referring to watchful waiting as the *current* approach: "Put another way, if clinicians are straying from SOC 7 guidelines for social transitions, not abiding by the watchful waiting model *favored by the standards*, we will have adolescents who have been consistently living in their affirmed gender since age 3, 4, or 5" (Ehrensaft et al., 2018, p. 255). Moreover, Ehrensaft et al. said there are cases in which they too would still use watchful waiting: "When a child's gender identity is unclear, the watchful waiting approach can give the child and their family time to develop a clearer understanding and is not necessarily in contrast to the needs of the child" (p. 259). Ehrensaft et al. are indeed critical of the watchful waiting model (which they feel is applied too conservatively), but they do not come close to the position the AAP policy espouses. Where Ehrensaft summaries the potential benefits and potential risks both to transitioning and not transitioning, the AAP presents an ironically binary narrative.

In its policy statement, AAP told neither the truth nor the whole truth, committing sins both of commission and of omission, asserting claims easily falsified by anyone caring to do any fact-checking at all. AAP claimed, "This policy statement is focused specifically on children and youth that identify as TGD rather than the larger LGBTQ population"; however, much of that evidence was about sexual orientation, not gender identity. AAP claimed, "Current available research and expert opinion from clinical and research leaders ... will serve as the basis for recommendations" (pp. 1–2); however, they provided recommendations entirely unsupported and even in direct opposition to that research and opinion.

AAP is advocating for something far in excess of mainstream practice and medical consensus. In the presence of compelling evidence, that is just what is called for. The problems with Rafferty, however, do not constitute merely a misquote, a misinterpretation of an ambiguous statement, or a missing reference or two. Rather, AAP's statement is a systematic exclusion and misrepresentation of entire literatures. Not only did AAP fail to provide compelling evidence, it failed to provide the evidence at all. Indeed, AAP's recommendations are *despite* the existing evidence.

Disclosure statement

No potential conflict of interest was reported by the author.

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- Steensma, T. D., & Cohen-Kettenis, P. T. (2015). More than two developmental pathways in children with gender dysphoria? *Journal of the American Academy of Child and Adolescent Psychiatry*, 52, 147–148. doi:10.1016/j.jaac. 2014.10.016
- Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. Journal of the American Academy of Child and Adolescent Psychiatry, 47, 1413–1423. doi:10.1097/CHI.0b013e31818956b9

Appendix

| Count | Group | Study |
|------------------------------|--|---|
| 2/16 4/16 10/16 | gay* trans-/crossdress straight*/uncertain | Lebovitz, P. S. (1972). Feminine behavior in boys: Aspects of its outcome. American Journal of Psychiatry, 128, 1283–1289. |
| 2/16 2/16 12/16 | trans- uncertain gay | Zuger, B. (1978). Effeminate behavior present in boys from childhood: Ten additional years of follow-up. <i>Comprehensive Psychiatry, 19,</i> 363–369. |
| 0/9 9/9 | trans- gay | Money, J., & Russo, A. J. (1979). Homosexual outcome of discordant gender identity/role: Longitudinal follow-up. <i>Journal of Pediatric Psychology, 4,</i> 29–41. |
| 2/45 10/45 33/45 | trans-/crossdress uncertain gay | Zuger, B. (1984). Early effeminate behavior in boys: Outcome and significance for homosexuality. <i>Journal of Nervous and Mental Disease</i> , 172, 90–97. |
| 1/10 2/10 3/10 4/10 | trans- gay uncertain straight | Davenport, C. W. (1986). A follow-up study of 10 feminine boys. <i>Archives of Sexual Behavior, 15,</i> 511–517. |
| 1/44 43/44 | trans- cis- | Green, R. (1987). The "sissy boy syndrome" and the development of homosexuality. New Haven, CT: Yale University Press. |
| 0/8 8/8 | trans- cis- | Kosky, R. J. (1987). Gender-disordered children: Does inpatient treatment help? <i>Medical Journal of Australia, 146, 5</i> 65–569. |
| 21/54 33/54 | trans- cis- | Wallien, M. S. C., & Cohen-Kettenis, P. T. (2008). Psychosexual outcome of gender-dysphoric children. Journal of the American Academy of Child and Adolescent Psychiatry, 47, 1413–1423. |
| 3/25 6/25 16/25 | trans- lesbian/bi- straight | Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J. (2008). A follow-up study of girls with gender identity disorder. <i>Developmental Psychology</i> , 44, 34–45. |
| 17/139 122/139 | trans- cis- | Singh, D. (2012). A follow-up study of boys with gender identity disorder. Unpublished doctoral dissertation, University of Toronto. |
| 47/127 80/127 | trans- cis- | Steensma, T. D., McGuire, J. K., Kreukels, B. P. C., Beekman, A. J., & Cohen-Kettenis, P. T. (2013). Factors associated with desistence and persistence of childhood gender dysphoria: A quantitative follow-up study. <i>Journal of the American Academy of Child and Adolescent</i> <i>Psychiatry, 52</i> , 582–590. |

*For brevity, the list uses "gay" for "gay and cis-", "straight" for "straight and cis-", etc.

IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF MISSISSIPPI WESTERN DIVISION

| McComb Children's Clinic, LTD., |) |
|---------------------------------|---|
| |) |
| Plaintiff, |) |
| |) |
| V. |) |
| |) |
| Xavier Becerra, et al., | |
| |) |
| Defendants. |) |

Case No. 5:24-cv-48-KS-LGI

PLAINTIFF'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR A DELAY OF EFFECTIVE DATE AND FOR PRELIMINARY INJUNCTION

Federal officials seek to make medical clinics perform and promote harmful "gender-transition" procedures that block puberty and remove healthy body parts from children. McComb Children's Clinic, LTD. ("MCC") needs urgent judicial relief from that new rule issued by the U.S. Department of Health and Human Services ("HHS"). Without relief, MCC will lose the ability to continue treating underserved patients in the southwest Mississippi area, because the rule will eject MCC from Medicare, Medicaid, the Children's Health Insurance Program ("CHIP"), and other federally funded health programs. This rule violates the Administrative Procedure Act, federalism, and the First Amendment's Free Speech Clause. Its effective date and enforcement should be enjoined while the Court hears this case.

BACKGROUND

On May 6, 2024, HHS published a rule deeming it "gender-identity" discrimination when medical caregivers decline to provide or promote harmful "gender-transition" procedures. *See* Nondiscrimination in Health Programs and Activities, 89 Fed. Reg. 37522 (May 6, 2024). HHS issued this rule purporting to clarify Section 1557 of the Affordable Care Act ("ACA"), which incorporates Title IX

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of the Education Amendments of 1972. One week later, MCC challenged the rule under the Administrative Procedure Act, the structural principles of federalism, and the Free Speech Clause of the First Amendment. Compl. See Compl. [ECF 1] at ¶¶ 256–323. MCC is a pediatric practice that cares for patients in southwest Mississippi through programs such as Medicaid and CHIP. Artigues Decl. See Decl. of Michael Artigues, M.D., F.C.P. [ECF 1-2] at ¶¶ 3, 7, 61 ("Artigues Decl."). MCC provides excellent healthcare to all patients, including patients who identify contrary to their sex. Id. ¶¶ 10, 27–28. But the rule extends far beyond ensuring that kids with a cough or cold receive equal, compassionate care.

This new rule turns medicine upside down. Doctors who heal must also hurt. Caregivers committed to science must practice as if the basic biology of their patients is a mere mental construct. Because MCC provides or refers for certain treatments when medically indicated, the rule considers MCC as illegally "discriminating" if it does not also provide or refer kids for the same treatment when its sole purpose is to "transition" kids to the opposite sex — as if that were scientifically possible — setting kids on a life-long trajectory of pain, sorrow, and sterility. 89 Fed. Reg. at 37698–701 (to be codified at 45 C.F.R. §§ 92.101, 92.206); Compl. [ECF 1] at ¶¶ 93–96, 163; Artigues Decl. [ECF 1-2] at ¶¶ 25–26.

For example, since MCC refers kids for medication to treat early puberty, it must also refer kids for those hormones to "transition" their gender. Compl. [ECF 1] at ¶¶ 84–86, 163; Artigues Decl. [ECF 1-2] at ¶ 25. Since MCC offers lactation help for new mothers, it must also help men "chestfeed." Compl. [ECF 1] at ¶¶ 113, 169–70; Artigues Decl. [ECF 1-2] at ¶¶ 20–23. MCC must allow males use its "Breastfeeding Moms Only" rooms. 89 Fed. Reg. at 37698–701 (to be codified at 45 C.F.R. §§ 92.101, 92.206); *see also* HHS, Nondiscrimination in Health Programs and Activities, 87 Fed. Reg. 47824, 47866–867 (proposed Aug. 4, 2022); Compl. [ECF 1] at ¶¶ 169–70, 213; Artigues Decl. [ECF 1-2] at ¶¶ 20–21. The rule even purports to

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preempt state laws protecting children from gender-reassignment procedures. 89 Fed. Reg. at 37535; Compl. [ECF 1] at ¶¶ 94, 187, 314.

Equally egregious, the rule censors and compels speech. It deems it a "hostile environment" if MCC shares its medical judgment that gender-transition procedures are categorically harmful, experimental, and cosmetic. 89 Fed. Reg. at 37596, 37698– 701 (to be codified at 45 C.F.R. §§ 92.101, 92.206); Compl. [ECF 1] at ¶¶ 75, 93–96, 98–104. Instead MCC must affirm these efforts and use pronouns contrary to a patient's sex. Compl. [ECF 1] at ¶¶ 106–08, 166–68, 289; Artigues Decl. [ECF 1-2] at ¶¶ 17–18. Under the same provisions, MCC must be willing to say men can become pregnant and give birth. 87 Fed. Reg. 47824, 47865; Compl. [ECF 1] at ¶¶ 109–10.

The rule makes untold numbers of medical caregivers ineligible to help the most needy patients enrolled in Medicare, Medicaid, and CHIP. Compl. [ECF 1] at $\P\P$ 4, 130, 135, 194. By July 5, 2024, those caregivers must provide, refer for, and affirm gender-transition procedures within their scope of practice or be disqualified, and must submit assurances to the government that they comply. 89 Fed. Reg. at 37693 (to be codified at 45 C.F.R. § 92.1(b)). MCC must violate and remove its existing policy that categorically opposes providing, referring for, or affirming gender-transition efforts. Compl. [ECF 1] at $\P\P$ 119, 208–12; Artigues Decl. [ECF 1-2] at $\P\P$ 15, 34–35, 40, 53–54. MCC must instead start referring for gender-transition medical actions, start using patients' purported pronouns, and remove its "Breastfeeding Moms Only" signs so men can use MCC's lactation rooms. 89 Fed. Reg. at 37698–701 (to be codified at 45 C.F.R. §§ 92.101, 92.206); Compl. [ECF 1] at $\P\P$ 99, 106–08, 206, 213.

Then, within one year, medical caregivers must go further: they must affirmatively adopt, hand out to all patients, and prominently post on their office walls new HHS-approved gender-identity and abortion-nondiscrimination policies, plus they must reeducate all employees to comply with the rule. 89 Fed. Reg. at 37693

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(to be codified at 45 C.F.R. §§ 92.1(b), 92.8, 92.9). Under these policies, MCC would imply that it would perform, refer for, or affirm gender-transition procedures or elective abortions. This, again, would require repeal of MCC's existing policy. Compl. [ECF 1] at ¶¶ 159, 212; Artigues Decl. [ECF 1-2] at ¶¶ 15, 34–35, 40, 54.

To ensure patients can keep receiving healthcare, MCC seeks a delay of the rule's effective date and a preliminary injunction. About 75% of MCC's patients pay through Medicaid or CHIP — the clinic will not be financially viable if ejected from these programs. Artigues Decl. [ECF 1-2] at ¶¶ 7, 63. Without relief, MCC must harm patients and self-censor, or incur devastating penalties.

STANDARD FOR GRANTING THE MOTION

Under the Administrative Procedure Act, "to prevent irreparable injury," this Court may "issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings." 5 U.S.C. § 705; *see Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1143 (5th Cir. 2021).

A plaintiff seeking a delay or preliminary injunction under § 705 must show: (1) a substantial likelihood of success on the merits; (2) a substantial threat that the plaintiff will suffer irreparable harm without an injunction; (3) that the threatened injury outweighs any damage that the injunction might cause the defendants; and (4) that the injunction will not disserve the public interest. *All. for Hippocratic Med. v. U.S. Food & Drug Admin. (AHM v. FDA)*, 78 F.4th 210, 241 (5th Cir. 2023).

ARGUMENT

I. This Court has jurisdiction.

A. McComb Children's Clinic has standing as a regulated entity.

MCC has standing to challenge the rule. In a suit challenging government action, if a plaintiff like MCC is the object of such government action, "there is ordinarily little question" that the action or inaction has caused MCC injury and thus MCC has standing. *Texas v. EEOC*, 933 F.3d 433, 446 (5th Cir. 2019) (cleaned up). Entities are the object of a regulation when (1) "the regulation is directed at them"; (2) "it requires them to make significant changes in their everyday business practices"; and (3), "if they fail to observe" the regulation, they are "exposed to ... sanctions." *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 153–54 (1967). Each condition is met here.

First, the rule directs its requirements to all recipients of federal health programs such as Medicaid and CHIP, and MCC is such an entity. 89 Fed. Reg. at 37694 (to be codified at 45 C.F.R. § 92.4); Compl. [ECF 1] at ¶¶ 46–48, 183–84; Artigues Decl. [ECF 1-2] at ¶ 7. The rule not only imposes nondiscrimination requirements, it imposes procedural requirements that HHS admits will exert a financial burden on clinics like MCC. *See, e.g.*, 89 Fed. Reg. at 37677–85; Compl. [ECF 1] at ¶¶ 218, 220–36.

Second, the rule requires significant changes to MCC's everyday medical practices and speech. The rule forces MCC to either: (1) ignore sound medical judgment and applicable state law and comply, with all the burdens associated with compliance; (2) risk liability and devastating penalties; or (3) stop seeing Medicaid and CHIP patients, possibly closing the clinic. Compl. [ECF 1] at ¶ 193.

Third, the government's threatened sanctions are strong. MCC will lose eligibility for extensive funding and will risk liability if it fails to comply, exposing it

to investigations and lawsuits. *Id.* ¶¶ 57–66, 138–52. MCC's standing is also bolstered because HHS invites patients to file an administrative complaint against clinics like MCC if they do not comply. *Id.* ¶¶ 64–65 *Cf. Susan B. Anthony List v. Driehaus* (*SBA List*), 573 U.S. 149, 164 (2014).

B. The rule threatens serious and imminent injuries-in-fact.

MCC's injuries are moreover "concrete and particularized" and "actual or imminent, not conjectural or hypothetical"; its injuries are fairly traceable to the rule; and its injuries are likely to be redressed by relief. Lujan v. Defs. of Wildlife, 504 U.S. 555, 560–61 (1992) (cleaned up). The rule admits it imposes financial compliance costs, 89 Fed. Reg. at 37677–85, those costs have already begun, Artigues Decl. [ECF 1-2] at ¶¶ 31–50, and added injuries are more than "fairly likely[.]" Crawford v. Hinds Cnty. Bd. of Supervisors, 1 F.4th 371, 376 (5th Cir. 2021). The rule causes these injuries, and the Court must assume its illegality for standing purposes. FEC v. Cruz, 596 U.S. 289, 298 (2022). Delaying and enjoining the rule would remedy these injuries and maintain the status quo.

1. The rule causes MCC economic losses.

MCC faces irreparable financial harm from the rule in two forms. *First*, it faces the imminent loss of Medicaid and CHIP reimbursement unless it complies with the rule. Compl. [ECF 1] at ¶¶ 57–66, 138–52. Such "economic injury is a quintessential injury upon which to base standing." *Tex. Democratic Party v. Benkiser*, 459 F.3d 582, 586 (5th Cir. 2006). *Second*, the rule admits that it imposes financial compliance costs. 89 Fed. Reg. at 37677–85. MCC has already spent time preparing for compliance consistent with these estimates, and if judicial relief is not forthcoming it stands to lose even more. Artigues Decl. [ECF 1-2] at ¶¶ 31–50.

Activities the rule estimates will cost MCC, and that will actually cost it, include reading the rule, changing policies, providing notices, preparing and

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providing employee training, and keeping records of training and grievances. *Id.* MCC employees will be "forced to divert time and resources away from their regular patients," *AHM v. FDA*, 78 F.4th at 235. Such monetary harms "obvious" concrete harms, *TransUnion LLC v. Ramirez*, 594 U.S. 413, 425 (2021), and they are particularized because they affect MCC individually, *Spokeo, Inc. v. Robins*, 578 U.S. 330, 339–40 (2016).

2. The rule removes MCC's state-law protections.

Next, the rule seeks to preempt MCC's "state-created right[s]" not to perform, refer for, or affirm certain gender-transition procedures, which "alone creates Article III injury." *Deanda v. Becerra*, 96 F.4th 750, 753 (5th Cir. 2024). Mississippi has restrictions on gender-transition procedures, laws that protect MCC from having to perform, refer for, or affirm these procedures. Compl. [ECF 1] at ¶¶ 94, 187, 314. Mississippi also protects medical rights of conscience. Miss. Code § 41-107-1 to -13 (2004). But the rule sweeps these state-law rights aside. 89 Fed. Reg. at 37535.

3. The rule rewrites MCC's healthcare policies.

What is more, MCC faces injuries from the rule's unlawful "pressure" to act and speak differently in at least five ways. *Texas v. EEOC*, 933 F.3d at 449.

First, MCC can no longer publish or follow its policy that it categorically opposes providing, referring for, or affirming gender-transition efforts. 89 Fed. Reg. at 37693 (to be codified at 92 C.F.R. § 92.1(b)); Compl. [ECF 1] at ¶¶ 119, 208–12; Artigues Decl. [ECF 1-2] at ¶¶ 15, 34–35, 40, 54. The clinic must take down this policy or else it will be a lie or a liability. Artigues Decl. [ECF 1-2] at ¶ 42. The rule requires MCC to revise, publish, and train employees on new policies. 89 Fed. Reg. at 37696–98 (to be codified at 45 C.F.R. §§ 92.8, 92.9, 92.10); Compl. [ECF 1] at ¶ 119; Artigues Decl. [ECF 1-2] at ¶¶ 34, 54. By July 5, 2024, MCC must also submit assurances to the government that it complies with this rule. 89 Fed. Reg. at 37696 (to be codified

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at 92 C.F.R. § 92.5). When the government compels an American recipient of funds to abandon or adopt a position as a condition of funding, it "violates the First Amendment." *Agency for Int'l Dev. v. All. for Open Soc'y Int'l, Inc. ("AOSI")*, 570 U.S. 205, 221 (2013).

Second, MCC must start referring, for gender-transition, puberty blockers and cross-sex hormones, and lactation training for men, because the clinic refers for these drugs and services for legitimate medical reasons. 89 Fed. Reg. at 37698–701 (to be codified at 45 C.F.R. §§ 92.101, 92.206); Compl. [ECF 1] at ¶¶ 84–86, 93–96, 163; Artigues Decl. [ECF 1-2] at ¶¶ 20–21, 25–26. MCC cannot decline to provide these referrals based on its medical judgment that they are categorically harmful. Compl. [ECF 1] at ¶¶ 75, 93–96, 98–104. The rule "force[s MCC] to choose between following" its sound medical judgment "and providing care." AHM v. FDA, 78 F.4th at 236.

Third, the rule censors MCC from providing its complete medical opinion. 89 Fed. Reg. at 37596, 37698–701 (to be codified at 45 C.F.R. §§ 92.101, 92.206); Compl. [ECF 1] at ¶¶ 75, 93–96, 98–105. If patients ask, the rule forces MCC to withhold its true categorical opposition to "gender transitions" and give patients the false impression that such procedures are not harmful, experimental, or cosmetic. *Id*.

Fourth, in using a patient's pronouns MCC bases them on their biological and binary reality as a male or female. Artigues Decl. [ECF 1-2] at ¶¶ 17–18. But the rule forces the clinic to use self-selected pronouns contrary to sex according to biology. 89 Fed. Reg. at 37596, 37698–701 (to be codified at 45 C.F.R. §§ 92.101, 92.206); Compl. [ECF 1] at ¶¶ 106–108, 166–68, 289.

Fifth, MCC provides lactation training and lactation rooms by sex—not by "gender identity." Compl. [ECF 1] at ¶¶ 169–70, 213; Artigues Decl. [ECF 1-2] at ¶¶ 20–21. But the rule requires it treat some males as if they are female, and to remove its "Breastfeeding Moms Only" signs on July 5, 2024, even at the risk to

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women's privacy, dignity, and safety. 89 Fed. Reg. at 37698–701 (to be codified at 45 C.F.R. §§ 92.101, 92.206); *see also* 87 Fed. Reg. at 47866.

C. MCC's claims may proceed now.

MCC's case is thus ready for decision. HHS's rule is "by definition, a final agency action" subject to review under the APA. *Texas v. EEOC*, 933 F.3d at 441–42, 446. MCC is more than arguably "within the zone of interests" that Congress governed Section 1557 in the ACA, which regulates healthcare entities like MCC. *Texas v. United States*, 809 F.3d 134, 152 (5th Cir. 2015) (cleaned up); *see* 42 U.S.C. § 18114. And further factual development would not "significantly advance [the Court's] ability to deal with the legal issues." *Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 812 (2003) (citations omitted).

MCC need not wait for specific enforcement. *Texas v. EEOC*, 933 F.3d at 449. When an entity can "realistically expect[]" that its policies "will be perceived by the Department as a violation," it has shown "a sufficiently distinct and palpable injury." *Sabre, Inc. v. Dep't of Transp.*, 429 F.3d 1113, 1118 (D.C. Cir. 2005). MCC intends to engage in speech and activities more than "arguably affected with a constitutional interest," *infra* Pt.II.B–C, and its medical practices will be more than "arguably" proscribed. *SBA List*, 573 U.S. at 159–60. With no exemptions covering MCC, it may bring an "immediate challenge." *Franciscan All., Inc. v. Becerra*, 47 F.4th 368, 376– 77 (5th Cir. 2022) (cleaned up).

Indeed, the federal government previously lost its attempt to impose a similar mandate even when it alleged some exemptions might apply, which it does not do for MCC here. *See, e.g., Becerra*, 47 F.4th at 375–76, 379–80 (affirming grant of a permanent injunction against a prior HHS attempt to impose this Section 1557 mandate); *Religious Sisters of Mercy v. Becerra*, 55 F.4th 583, 602–06 (8th Cir. 2022) (same); *Christian Emps. All. v. EEOC*, No. 1:21-cv-195, 2024 WL 935591, at *5

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(D.N.D. Mar. 4, 2024) (granting similar injunction); *Texas v. EEOC*, No. 2:21-CV-194-Z, at 19–28 (N.D. Tex. May 26, 2022) (same); *Neese v. Becerra*, No. 2:21-CV-163-Z, 2022 WL 1265925, at *4–6 (N.D. Tex. Apr. 26, 2022) (same); *Franciscan All., Inc. v. Burwell*, 227 F. Supp. 3d 660, 678–79 (N.D. Tex. 2016) (same); cf. Tennessee v. U.S. *Dep't of Educ.*, 615 F. Supp. 3d 807, 820–28 (E.D. Tenn. 2022) (granting injunction against a prior Title IX gender-identity mandate); *Texas v. United States*, 201 F. Supp. 3d 810, 819–23 (N.D. Tex. 2016) (same). Finally, if the statutes underlying this rule were read to impose similar mandates (they do not), MCC's constitutional claims would still protect it against enforcement.

II. MCC has a substantial likelihood of success on the merits.

MCC has a substantial likelihood of success on the merits, for three reasons. *First*, Congress never included gender identity in Section 1557 or Title IX. *Second*, the rule violates the structural principles of federalism. *Third*, the rule coerces expression in violation of the First Amendment.

Under the APA, 5 U.S.C. § 706(2), a rule must be "set aside" when it is "(A) ... not in accordance with law; (B) contrary to constitutional right, power, privilege, or immunity; [or] (C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." Courts also have constitutional authority to enjoin *ultra vires* agency action. *See Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 689– 90, 693 (1949).

A. The rule lacks statutory authority.

Section 1557 does not address gender identity. It is a healthcare statute that acknowledges sex according to biology, and it is based on a 1972 educational statute that acknowledges sex according to biology.

1. Title IX prohibits treating one sex worse than the other.

As relevant to this case, section 1557 combines two statutes, and therefore the Court's statutory analysis should consider both: the ACA and Title IX. Section 1557 prohibits discrimination "on the ground prohibited under ... title IX of the Education Amendments of 1972." 42 U.S.C. § 18116(a).

Title IX is an equal-opportunity law that protects and sometimes requires sex distinctions. 20 U.S.C. § 1681(a). It does not cover gender identity. When Title IX was adopted in 1972, "on the basis of sex" was commonly understood to refer to biological differences between males and females. *Adams ex rel. Kasper v. Sch. Bd. of St. Johns Cnty.*, 57 F.4th 791, 812 (11th Cir. 2022). Sex was considered an "immutable" trait, "determined solely by the accident of birth." *Frontiero v. Richardson*, 411 U.S. 677, 686 (1973). Throughout Title IX, Congress used "sex" to denote the male-female biological binary. *Neese v. Becerra*, 640 F. Supp. 3d 668, 684 (N.D. Tex. 2022). For example, Title IX permits schools to go from admitting "only students of one sex" to admitting "students of both sexes." 20 U.S.C. § 1681(a)(2).

Congress spoke similarly in the ACA in 2010. It referenced "sex" in biological binary terms—not gender identity. It overwhelmingly refers to "women" and mothers separately from "men," and seeks to protect "women's unique health care needs." 42 U.S.C. §§ 1315a(b)(2)(B)(i); see also, e.g., 42 U.S.C. §§ 237a, 242s, 280g-12(a)(3)(B), 280k(b)(1), 300gg-13(a)(4), 711, 712 (note), 713(c)(1), 1396d(l)(3)(b)(2) & (bb)(1), 18201–03. For example, the ACA requires the provision of "information to women and health care providers on those areas in which differences between men and women exist." 21 U.S.C. § 399b (emphasis added). Reframing "sex" in the ACA to include men as women if they so identify negates the words of Congress. HHS cannot do this: "[a]gencies have only those powers given to them by Congress." W. Virginia v. Env't Prot. Agency, 597 U.S. 697, 723 (2022)

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Next, to "be subjected to discrimination" under Title IX, 20 U.S.C. § 1681(a), refers to an unjust distinction, or the "failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored." *CSX Transp., Inc. v. Ala. Dep't of Revenue*, 562 U.S. 277, 286 (2011) (cleaned up). Sex discrimination means more than treating males and females differently; it means subjecting someone to "differential" or "less favorable" treatment than similarly situated persons based on their biological status as male or female, *Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 174 (2005), where "there is no justification for the difference in treatment," *CSX*, 562 U.S. at 287.

Because Title IX applies to "any education program or activity receiving Federal financial assistance," 20 U.S.C. § 1681(a), what constitutes a reasonable distinction between men and women thus depends on whether the sexes are similarly situated in particular contexts, like intimate spaces, specific programs, and athletics. Title IX's well-established purpose was to promote opportunities for women. *McCormick ex rel. McCormick v. Sch. Dist. of Mamaroneck*, 370 F.3d 275, 286 (2d Cir. 2004). That allows and often requires sex distinctions. Statutory text "cannot be divorced from the circumstances existing at the time it was passed" or "from the evil which Congress sought to correct and prevent." United States v. Champlin Refin. Co., 341 U.S. 290, 297 (1951).

2. Title IX does not prohibit all sex distinctions.

Because men and women sometimes differ, not all sex distinctions constitute discrimination. That is why Title IX protects and even requires some sex distinctions. Congress said that "nothing contained herein shall be construed to prohibit ... separate living facilities for the different sexes." 20 U.S.C. § 1686. This is a rule of construction that shows "sex" refers only to biology, not gender identity. As Senator Birch Bayh (D-IN) explained, "I do not read [Title IX] as requiring integration of

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dormitories between the sexes, nor do I feel it mandates the desegregation of football fields. What we are trying to do is provide equal access for women and men students. ... We are not requiring that intercollegiate football be desegregated, nor that the men's locker room be desegregated." 117 Cong. Rec. S. 30407 (Aug. 6, 1971). This also explains why Title IX exempts "father-son or mother-daughter activities," 20 U.S.C. § 1681(a)(8); fraternities and sororities "limited to persons of one sex," *id*. § 1681(a)(6); and beauty pageants "limited to individuals of one sex only," *id*. § 1681(a)(9). Though fraternities and beauty pageants are not necessary for educational opportunities, Congress protected them anyway, recognizing that singlesex spaces are not necessarily discriminatory.

3. Title IX's postenactment history confirms that sex distinctions are sometimes necessary.

Longstanding Title IX regulations also recognize that Title IX allows and sometimes requires sex distinctions. These regulations protect (1) sex-education classes designated by sex, 34 C.F.R. § 106.34(a)(3); (2) comparable, "separate toilet, locker room, and shower facilities on the basis of sex," *id.* § 106.33; (3) separate "physical education classes or activities during participation in ... sports," *id.* § 106.34(a)(1); and (4) schools to "sponsor separate [sports] teams for members of each sex," *id.* § 106.41(b). The regulations require schools to provide "equal athletic opportunity for members of both sexes," in "the selection of sports and levels of competition" for "both sexes." *Id.* § 106.41(c). HHS's predecessor promulgated these rules (the Department of Health, Education and Welfare ("HEW")), and explained that a school must "provide separate teams for men and women."¹

¹ Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting from Federal Financial Assistance, 40 Fed. Reg. 24128, 24134 (June 4, 1975) (now codified at 34 C.F.R. pt. 106).

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Making these distinctions is critical to providing equal opportunities in areas like sports or private facilities. After all, "the great bulk of the females would quickly be eliminated from participation and denied any meaningful opportunity for athletic involvement" without sex-specific teams. *Cape v. Tenn. Secondary Sch. Athletic Ass'n*, 563 F.2d 793, 795 (6th Cir. 1977) (per curiam). And consider places like restrooms, showers, and locker rooms where students may appear in a state of undress. Sex determines whether persons are similarly situated "because biological sex is the sole characteristic on which [separate restrooms] are based." *Adams*, 57 F.4th at 803 n.6. But "if 'sex' were ambiguous enough to include 'gender identity' ... the various [Title IX] carveouts ... would be rendered meaningless." *Adams*, 57 F.4th at 813. For example, those who identify as transgender "would be able to live in both living facilities associated with their biological sex and living facilities associated with their biological sex and living facilities associated with their sex.

This "postenactment history" sheds strong light on Title IX's "intended scope." See N. Haven Bd. of Educ. v. Bell, 456 U.S. 512, 530 (1982). Shortly after Congress enacted Title IX it passed the Javits Amendment directing HEW to publish rules implementing Title IX and submit them to Congress for review. Pub. L. No. 93-380, § 844, 88 Stat. 484, 612 (1974); 40 Fed. Reg. 24128 (June 4, 1975). After "six days of hearings to determine whether the HEW regulations were consistent with the law and with the intent of the Congress in enacting the law," Congress allowed the regulations to take effect. N. Haven, 456 U.S. at 531–32 (cleaned up). This procedure "was designed to determine if the regulation writers have read [Title IX] and understood it the way the lawmakers intended it to be read and understood." Jocelyn Samuels & Kristen Galles, In Defense of Title IX: Why Current Policies Are Required to Ensure Equality of Opportunity, 14 Marq. Sports L. Rev. 11, 20 (2003) (cleaned up).

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All this is why agencies and courts have always understood Title IX to permit sex-conscious decisions by affirming the need for women's-only sports teams. *E.g.*, *Mansourian v. Regents of Univ. of Cal.*, 602 F.3d 957, 973 (9th Cir. 2010); *Pederson v. La. State Univ.*, 213 F.3d 858, 871, 878 (5th Cir. 2000); *Cohen v. Brown Univ.*, 101 F.3d 155, 177 (1st Cir. 1996); *Kelley v. Bd. of Trs.*, 35 F.3d 265, 269–70 (7th Cir. 1994); *Williams v. Sch. Dist. of Bethlehem*, 998 F.2d 168, 175 (3d Cir. 1993).

Congress moreover reaffirmed this construction when it amended Title IX in 1987 through the Civil Rights Restoration Act, Pub. L. 100–259; 102 Stat. 28 (Mar. 22, 1988) (codified at 20 U.S.C. § 1687). This Act dictated that Title IX's provisions applied to all education programs (including sports) at covered schools. In doing so, Congress "reaffirmed its prior positions on Title IX and its goal of achieving equity in all educational programs and activities, including athletics," and legislators "expressly cited the need to apply Title IX to athletics to remedy discrimination against female athletes" and to create "a more level playing field for female athletes." Samuels & Galles, *supra* at 23–24 (cleaned up). In the Act, Congress made an express finding in support of the "prior consistent and long-standing executive branch interpretation and broad, institution-wide application of" Title IX. § 2, 102 Stat. 28. No rule from HHS can achieve through "administrative fiat" what Congress has failed to do through legislation. *Franciscan All., Inc. v. Becerra*, 553 F. Supp. 3d 361, 372 (N.D. Tex. 2021).

4. Bostock does not encompass Title IX.

Because males and females are not always similarly situated in educational contexts, Title IX permits and sometimes requires sex distinctions. This differs starkly from Title VII's employment context narrowly addressed in *Bostock v. Clayton County*, 590 U.S. 644 (2020). While Title IX has extensive and unique language

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describing sex's biological binary, Title VII has a bare restriction on employment discrimination based on several traits, mentioning sex among others.

Title VII also prohibits discrimination in "employment practice[s]" "because of ... sex," 42 U.S.C. § 2000e-2(a), whereas Title IX applies "on the basis of sex," 20 U.S.C. § 1681(a). *Bostock* concluded that "because of ... sex" means but-for causation. *Bostock*, 590 U.S. at 656, 661. But "on the basis of sex" doesn't mean the same thing. *Neese*, 640 F. Supp. 3d at 679. Instead, "on the basis of sex" in Title IX means that biological sex must be the sole reason for action.

The statutes also have two different contexts, and, in "law as in life," context matters. *Yates v. United States*, 574 U.S. 528, 537 (2015). "[T]he same words, placed in different contexts, sometimes mean different things." *Id.* To comply with Title IX and give women equal opportunities, schools often "must consider sex." *Meriwether v. Hartop*, 992 F.3d 492, 510 n.4 (6th Cir. 2021). Not so in deciding whether to hire or fire. So "it does not follow that principles announced in the Title VII context automatically apply in the Title IX context," *id.*, especially where they would eviscerate the female educational opportunities the law was designed to promote.

In this rule, HHS wrongly invoked *Bostock* to find that Section 1557 (through Title IX) forbids gender-identity discrimination. This rendered HHS's rule contrary to law. *Bostock* expressly dealt only with hiring and firing in employment, 590 U.S. at 681, and *Bostock*'s "text-driven reasoning applies only to Title VII," *L.W. ex rel. Williams v. Skrmetti*, 83 F.4th 460, 484 (6th Cir. 2023). The decision did not "sweep beyond Title VII to other federal or state laws that prohibit sex discrimination." *Bostock*, 590 U.S. at 681. *Bostock* further explicitly declined to opine about "bathrooms, locker rooms, or anything else of the kind," where sex is relevant. *Id*. But healthcare involves exactly such settings: examination rooms, lactation rooms, patients in undress, and discussions of intimate biological functions. *Adams*, 57 F.4th at 808 (*Bostock* did not prohibit sex distinctions where sex is relevant). Several courts

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have thus noted that "the rule in *Bostock* extends no further than Title VII." *Pelcha* v. *MW Bancorp, Inc.*, 988 F.3d 318, 324 (6th Cir. 2021); e.g., *Adams*, 57 F.4th at 808, 818.

Title IX's rule of construction represents this same principle: "[N]othing in [Title IX] shall be construed to prohibit ... maintaining separate living facilities for the different sexes." 20 U.S.C. § 1686. Title IX is not violated every time "changing the [student's] sex would have yielded a different choice by the [school]." *Bostock*, 590 U.S. at 659–60. A dorm room assignment, or a doctor's judgment, legitimately considers sex. Title IX is not governed by *Bostock*.

Plenty of litigants have already tried, and failed, to show that Title IX prohibits schools from noticing sex. When some schools began cutting men's sports teams to bring themselves into compliance with Title IX, male athletes sued for sex discrimination—and lost. *E.g.*, *Miami Univ. Wrestling Club v. Miami Univ.*, 302 F.3d 608, 615 (6th Cir. 2002); *Chalenor v. Univ. of N.D.*, 291 F.3d 1042 (8th Cir. 2002); *see also Boulahanis v. Bd. of Regents*, 198 F.3d 633, 636 (7th Cir. 1999), *abrogated on other grounds by Fitzgerald v. Barnstable Sch. Comm.*, 555 U.S. 246, 259 (2009). Title IX allows considering sex. *See Boulahanis*, 198 F.3d at 639.

As with Title IX, so too it is with Section 1557. In choosing not to provide, refer for, or affirm gender-transition procedures, MCC takes into account the sex of the patient. Patients taking certain hormones to heal an ailment related to their sex, such as precocious puberty, allows them to be a healthy person of that sex. Patients taking hormones to purportedly change their sex is an action contrary to their health as a person of that sex. MCC affirms the former and rejects the latter. Referencing sex is inevitable when discussing procedures for "transition[ing] from one gender to another." *L.W.*, 83 F.4th at 482. "By the same token, the regulation of a course of treatment that only gender nonconforming individuals … undergo" is not unlawful

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discrimination based on sex. *Eknes-Tucker v. Governor of Ala.*, 80 F.4th 1205, 1229–30 (11th Cir. 2023).

Yet MCC's distinctions do not violate Title IX, because they are not discrimination on a ground prohibited by Title IX. Title IX allows distinctions based on legitimate sex differences. MCC "treat[s] similarly situated individuals evenhandedly." *L.W.*, 83 F.4th at 479. But by changing Section 1557 to a gender-identity nondiscrimination mandate in this new rule, HHS has rewritten Title IX and Section 1557 to ban MCC's ethical practice of medicine.

5. *Bostock* cannot apply to Title IX and Section 1557 without a clear congressional statement.

Title IX and Section 1557 do not include "gender identity" as a protected trait, but were there any doubt, the Constitution would require HHS to show a clearer statement from Congress before it could impose its mandates.

Congress must "enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power." *Sackett v. EPA*, 598 U.S. 651, 679 (2023). Even in interpreting "expansive language," courts "insist on a clear" statement before intruding on the state's traditional powers over health, medicine, and education. *Bond v. United States*, 572 U.S. 844, 860 (2014).

Moreover, "Title IX was enacted as an exercise of Congress' powers under the Spending Clause." Jackson, 544 U.S. at 181. So was Section 1557. Nat'l Fed'n of Indep. Bus. v. Sebelius ("NFIB"), 567 U.S. 519, 585 (2012) (plurality). Therefore Congress must "speak with a clear voice," Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 17 (1981), and give funding recipients unmistakably clear notice of their obligations, Cummings v. Premier Rehab Keller, PLLC, 596 U.S. 212, 219 (2022). Congress may not use "expansive language," Bond, 572 U.S. at 857–58, 860, or surprise recipients with "retroactive conditions," Pennhurst, 451 U.S. at 25 (cleaned up), nor impose "a burden of unspecified proportions and weight, to be

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revealed only through case-by-case adjudication," Bd. of Educ. of Hendrick Hudson Cent. Sch. Dist. v. Rowley, 458 U.S. 176, 190 n.11 (1982).

But Congress' "intention" to include gender-identity in Title IX or Section 1557 is not "unmistakably clear in the language of the statute[s]." *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991) (cleaned up). To the contrary, doing so goes against those statutes' text and purpose. There is no serious argument that in 2010, much less 1972, Congress unmistakably required anyone to provide, refer for, or affirm gendertransition procedures. And the last thing one can say of Section 1557 and Title IX is that they clearly mandate using pronouns contrary to sex or enable men to "chestfeed" in rooms marked "Breastfeeding Moms Only," when the ACA itself expressly references males and females.

Bostock did not consider the "particularly strict" effect of the clear-notice canon when it interpreted Title VII. But interpreting Title IX requires the Court to apply these canons because Title IX uses a "contractual framework" and Title VII does not: Title IX obtains compliance as a condition on federal funds. Gebser v. Lago Vista Indep. Sch. Dist., 524 U.S. 274, 286 (1998).

For the same reason, the major questions doctrine dooms this rule. Like HHS's nationwide ban on evictions, or the Labor Department's nationwide vaccine mandate, or the Education Department's nationwide student-loan forgiveness, or the EPA's nationwide restructuring of the energy industry, HHS's imposing of a gender-transition mandate on all medical caregivers in this rule is a matter of "staggering" "economic and political significance" — and Congress has given HHS no "clear" authority to impose this mandate. *See, e.g., Biden v. Nebraska*, 143 S. Ct. 2355, 2373

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(2023) (cleaned up). The political significance is transparent — and the economic significance is massive, covering over 1 trillion.^2

Finally, the rule's interpretation of Section 1557 and Title IX raises constitutional concerns that this Court should avoid by construing the rule according to its text's longstanding public meaning. *Infra* Pt.II.B–C. Under the constitutional-avoidance doctrine, if an act is subject to "competing plausible interpretations," *Clark v. Martinez*, 543 U.S. 371, 381 (2005), the statute must be construed "to avoid not only the conclusion that it is unconstitutional but also grave doubts upon that score," *Almendarez-Torres v. United States*, 523 U.S. 224, 237 (1998) (cleaned up).

B. The rule violates the structural principles of federalism.

In four key ways, the rule's reinterpretation of Section 1557 and Title IX transgresses the federal constitution's structural principles of federalism.

First, for a statute to preempt the historic police powers of the States, to abrogate state sovereign immunity, or to regulate a matter in areas of traditional state responsibility, the Constitution limits the States' and the public's obligations to those requirements "unambiguously" set out on the face of the statute. Pennhurst, 451 U.S. at 17. But no funding recipient could unmistakably know or clearly understand that Section 1557 or Title IX would impose the mandates created by the rule as a condition of accepting federal funds from HHS. The public thus lacked the constitutionally required clear notice that the statutes would apply in this way when Section 1557 or Title IX was passed or when funding grants were made. Bennett v. New Jersey, 470 U.S. 632, 638 (1985).

² Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., National Health Expenditures 2022 Highlights 3, https://www.cms.gov/files/document/highlights.pdf (Dec. 12, 2023).

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Second, HHS expressly and impliedly, but improperly, seeks to use a Spending Clause statute to preempt state laws. But Congress does not have that authority. An agency may not pay anyone to violate state law. Instead, if state law prevents the spending of federal funds in a certain way, the agency may only disallow funds. *Health & Hosp. Corp. v. Talevski*, 599 U.S. 166, 183 (2023).

Third, the rule is an unconstitutionally coercive use of the Spending Clause. The rule threatens to withhold billions of dollars in funding unless States and medical caregivers act as if Section 1557 and Title IX cover new bases. Compl. [ECF 1] at $\P\P$ 49–55. Federal Medicaid funding alone is about 27% of the average state budget. Id. \P 53. And any ineligibility for Medicare, Medicaid, or CHIP funding threatens to drive doctors out of the practice of medicine. Id. \P 194. The rule amounts to a "gun to the head" for the States and clinics. NFIB, 567 U.S. at 581 (plurality). Worse yet, the rule seeks to coerce States and medical caregivers to abandon their laws even though the federal government cannot try to force state governments to repeal their laws. Murphy v. NCAA 584 U.S. 453, 470–75 (2018).

C. The rule coerces speech in violation of the First Amendment.

The rule violates the First Amendment's Free Speech Clause. It censors and compels speech based on content and viewpoint, *Reed v. Town of Gilbert*, 576 U.S. 155, 163, 168 (2015), and it attaches unconstitutional conditions to grant funding, *AOSI*, 570 U.S. at 214. The rule forces MCC to adopt and speak government policy statements that violate its sound medical judgment and to assure compliance. Compl. [ECF 1] at ¶¶ 119, 208–12; Artigues Decl. [ECF 1-2] at ¶¶ 15, 34–35, 40, 53–54. In addition, to avoid what HHS considers discrimination, harassment, or a hostile environment, the rule makes MCC avoid speaking its views, such as by advising patients that gender-transition procedures are harmful, and to speak in ways contrary to biological fact, such as by using incorrect pronouns, and prohibits. Compl.

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[ECF 1] at ¶¶ 75, 93–96, 98–104, 106–08, 166–68, 289; Artigues Decl. [ECF 1-2] at ¶¶ 17–18. It forces MCC to remove its current policy from its website and requires the clinic to take down its signs saying "Breastfeeding Moms Only." 87 Fed. Reg. at 47866; Compl. [ECF 1] at ¶¶ 159, 169–70, 212–13; Artigues Decl. [ECF 1-2] at ¶¶ 15, 20–21, 34–35, 40, 53–54. This includes forcing MCC to say it does not discriminate based on abortion ("termination of pregnancy"). But performing, referring for, facilitating, or affirming abortion contradicts MCC's explicit pro-life policy and implies that MCC violates state law — so MCC cannot adopt such a misleading policy.

Because the rule coerces MCC's speech, the First Amendment triggers strict scrutiny. *E.g.*, *NIFLA v. Becerra*, 585 U.S. 755, 766 (2018); *Meriwether*, 992 F.3d at 508. But the government lacks any legitimate objective "to produce speakers free" from purported bias, *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 578–79 (1995). Far from being "always" a "compelling interest," this interest is "comparatively weak" in the context of pronouns. *Meriwether*, 992 F.3d at 510. Narrower approaches also exist, like letting patients go elsewhere.

III. MCC faces irreparable harm.

MCC and its patients are "likely to suffer irreparable harm in the absence of preliminary relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). Without a delay of the rule, MCC must risk financial penalties or take steps to stop seeing Medicaid and CHIP patients, or harm patients — pressure meant to force MCC to violate its medical judgment, ignore state law, and harm patients.

A plaintiff's "harm is irreparable where there is no adequate remedy at law," *Janvey v. Alguire*, 647 F.3d 585, 600 (5th Cir. 2011), and here there is no cause of action to recover damages from HHS. *AHM v. FDA*, 78 F.4th at 251. That means that the clinic's "economic injuries—the potential damage to [MCC's] medical practice, heightened exposure to malpractice liability, and increased ... costs—are

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irreparable." *Id.* And any "loss of freedoms guaranteed by the First Amendment ... constitute[s] per se irreparable harm." *Franciscan All., Inc.*, 47 F.4th at 380.

IV. The balance of equities and the public interest both favor relief.

For five reasons, the balance of the equities and the public interest strongly favor ensuring that no doctors must provide, refer for, or affirm transition efforts.

First, a delay would not harm HHS. HHS has "no public interest in the perpetuation of unlawful agency action." *Louisiana v. Biden*, 55 F.4th 1017, 1035 (5th Cir. 2022) (cleaned up). To preserve the status quo courts regularly prevent agencies from implementing unlawful rules during litigation challenging their validity. *E.g.*, *Texas v. United States*, 787 F.3d 733 (5th Cir. 2015). The status quo favors a delay order here. *Wages & White Lion*, 16 F.4th at 1143–44.

Second, in contrast, the imminent injury to MCC, patients, and medical caregivers outweighs any impact on HHS. A delay would ensure that no clinic like MCC is forced out of business, leaving underserved patients without care, and no clinic is liable for penalties simply for providing ethical medical care.

Third, the public interest is "served by maintaining our constitutional structure," giving state law its due. *BST Holdings*, *LLC v. OSHA*, 17 F.4th 604, 618–19 (5th Cir. 2021). The rule irreparably harms States' sovereign interests in enforcing their laws and protecting patients. *Abbott v. Perez*, 585 U.S. 579, 602 n.17 (2018).

Fourth, it is impossible to change a person's sex, and gender-transition procedures lack a sound scientific basis. Cantor Decl. ¶¶ 9–14, 38–75, 103–155, 298–342 (attached to the motion as Exhibit A). Medicalized transition of gender remains experimental and there is no evidence that gender-transition procedures improve mental health, *Id.* ¶¶ 206–55, or reduce suicide or suicidality, *Id.* ¶¶ 181–95. There is no reliable evidence of effectiveness on minors' mental health when weighed against less risky treatments, *Id.* ¶¶ 220–55, and "social transition" (such as using

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pronouns contrary to sex) is not associated with improvement in minors' mental health. *Id.* ¶¶ 124–29. In fact, multiple international healthcare systems that had expanded medicalized transition to include minors have reversed course based on systematic reviews concluding that the evidence on medicalized transition in minors is of poor quality. *Id.* ¶¶ 17–37, 76–101. Methodological defects limit or negate many such studies' evidentiary value. *Id.* ¶¶ 63–75.

But while the effectiveness of transition efforts is scientifically unknown and unproven, what is known is that gender-transition procedures are unsafe. *Id.* ¶¶ 256–97. The many harms associated with administering puberty blockers or cross-sex hormones to children and adolescents include: sterilization without proven fertility preservation options, permanent loss of capacity for breastfeeding, lifetime lack of orgasm and sexual function, interference with neurodevelopment and cognitive development, substantially delayed puberty associated with medical harms, elevated risk of Parkinsonism in adult females, reduced bone density, lifetime dependence on hormone treatments, increased cardiovascular risk, and hormone-dependent cancers, among other effects. *Id.* ¶¶ 256–85. In particular, assertions that puberty blockers act only as a "fully reversible" "pause button" lack scientific evidence. *Id.* ¶¶ 286–97.

Fifth and finally, delaying the rule as to its gender-identity requirements is fully appropriate under 5 U.S.C. § 705. When an agency rule of broad applicability is unlawful, "the ordinary result is that the rules are vacated—not that their application to the individual petitioners is proscribed." Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (cleaned up). "Vacatur is the only statutorily prescribed remedy for a successful APA challenge to a regulation." Franciscan All., Inc., 47 F.4th at 374–75. By extension, at the outset of a case, "a stay is the temporary form of vacatur." AHM v. FDA, 78 F.4th at 254. HHS in fact regularly consents to using 5 U.S.C. § 705 to delay its rules' effective dates. E.g., HHS, Grants Regulation, 87 Fed. Reg. 31432 (May 24, 2022) (delays over 15 months);

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HHS, Delay of SUNSET Rule, 87 Fed. Reg. 12399 (Mar. 4, 2022) (delay over 18 months). HHS has sometimes conceded that the proper remedy for an APA violation is to delay or vacate the agency action as a whole. *Tice-Harouff v. Johnson*, No. 6:22-cv-201, ECF No. 38 (E.D. Tex. Dec. 6, 2022); *Facing Foster Care in Alaska v. HHS*, No. 21-cv-00308, ECF No. 44 (D.D.C. June 29, 2022).

A delay is not only the well-established remedy to issue — it is the most effective remedy to stop this rule's coercion. Without relief, MCC is in danger, as the rule is easy to enforce. HHS invites patients who want to change MCC's medical practices and speech to file complaints against it at HHS for violating the rule precisely so HHS can impose draconian investigations and threats against MCC's funding unless it chooses to ignore biological science and begin harming children.

CONCLUSION

Therefore, the Court should grant this motion, delay the rule's effective date, and enjoin HHS from enforcing it pending the outcome of this case.³

Respectfully submitted this 3rd day of June, 2024.

/s/D. Michael Hurst, Jr.

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³ Because the injunctive relief requested would serve the public interest, MCC asks the Court to exercise its discretion to not require a security or bond under Fed. R. Civ. P. 65(c). *City of Atlanta v. Metro. Atlanta Rapid Transit Auth.*, 636 F.2d 1084, 1094 (5th Cir. 1981).

CERTIFICATE OF SERVICE

I hereby certify that on June 3, 2024, I electronically filed the foregoing and its attachments with the Clerk of the Court for the United States District Court Southern District of Mississippi by using the CM/ECF system. I further certify that I served Defendants by emailing the foregoing to counsel for Defendants, Liam C. Holland, Trial Attorney, Civil Division, Federal Programs Branch, U.S. Department of Justice, who represented to counsel for Plaintiff that Defendants would accept service of this memorandum and its accompanying papers by email to him.

/s/D. Michael Hurst, Jr.

Counsel for Plaintiff McComb Children's Clinic, LTD.