**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF TENNESSEE**
**NASHVILLE DIVISION**

| | | |
|---|---|---|
| **L.E., by next friends and parents,<br>SHELLEY ESQUIVEL and<br>MARIO ESQUIVEL,** | ) | |
| **Plaintiff,** | ) | |
| | ) | **No. 3:21-cv-00835** |
| **v.** | ) | |
| | ) | **Chief Judge Crenshaw** |
| **BILL LEE, in his official capacity as<br>Governor of Tennessee; et al.,** | ) | **Magistrate Judge Newbern** |
| **KNOX COUNTY BOARD OF<br>EDUCATION a/k/a KNOX COUNTY<br>SCHOOL DISTRICT; et al.,** | ) | |
| **Defendants.** | ) | |

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## DECLARATION OF STEPHANIE BERGMEYER

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Pursuant to 28 U.S.C. § 1746, I, Stephanie Bergmeyer, hereby declare under penalty of perjury that the following is true and correct:

1. I am over the age of 18 and have direct knowledge of the mattes stated herein.

2. The State Defendants rely on the attached exhibits in support of their contemporaneously filed Response in Opposition to Plaintiff's Motion for Summary Judgment.

3. Exhibit 1 is a true and correct copy of the 2022-2023 Tennessee Secondary Schools Athletic Association Handbook, Golf Regulations (June 20, 2022), https://cms-files.tssaa.org/documents/tssaa/2022-23/sports-regulations/2022-23GolfRegulations.pdf.

4. Exhibit 2 is a true and correct copy of excerpts of the transcript and exhibit 3 of the Deposition of Farragut High School Golf Coach Jonathan Franklin Higgins, dated July 25, 2022.

5. Exhibit 3 is a true and correct copy of excerpts of the transcript of the Deposition of Melissa Cyperski, Ph.D., dated August 10, 2022.

6. Exhibit 4 is a true and correct copy of excerpts of the transcript of the Deposition of Helen Carroll., dated August 9, 2022.

7. Exhibit 5 is a true and correct copy of the FINA Policy on Eligibility for the Men's and Women's Competition Categories at 6-8 (June 19, 2022), https://resources.fina.org/fina/document/2022/06/19/525de003-51f4-47d3-8d5a-716dac5f77c7/FINA-INCLUSION-POLICY-AND-APPENDICES-FINAL-.pdf.

8. Exhibit 6 is a true and correct copy of the Expert Report of Stephen B. Levine, M.D.

9. I have personal knowledge of the facts in this declaration and if call upon to testify, could competently do so.

Dated this the 4th day of November, 2022.

s/Stephanie Bergmeyer
Stephanie Bergmeyer

# 2022-23 TSSAA Handbook

## GOLF REGULATIONS

### I. GENERAL REGULATIONS

In Division I, TSSAA schools shall be divided into eight regions in Class A and eight regions in Class AA for golf competition. In Division II, TSSAA schools shall be divided into three regions (East, Middle, and West) in Class A and three regions (East, Middle, and West) in Class AA.

### II. NUMBER THAT MAY ENTER

Four or five players will constitute a boys' team and two or three players a girls' team. A school may enter fewer than four boys in a competition or only one girl in a competition, but such players shall compete only as individuals. In boys' team competition, either four or five players would play and count the four lowest scores, and in the girls' competition either two or three players would play and count the two lowest scores for the team score. Players must be accompanied by a person meeting Article I, Section 9 of the TSSAA Bylaws.

### III. ON-COURSE COACHING REGULATIONS

Coaching is permitted on the course during the regular season and post season. Coaches and players must, however, adhere to the following criteria:

- The coach must be approved through his/her respective school, administration and/or district. The coach must also be registered through TSSAA as a Head or Assistant golf coach.
- Only one coach (Head or Assistant) may coach during TSSAA sanctioned events.
- A coach can give advice from Green to Tee. This is defined as the time when all players have completed a hole and before the first player tees off on the next hole. The coach may provide instruction, encouragement, and information to his/her golfer without interfering with the pace of play.
- IT IS IMPERATIVE THAT COACHES DO NOT SLOW THE PACE OF PLAY. SLOW PLAY WILL BE PENALIZED AS PER USGA RULES.
- If a coach violates any of these rules, he/she will be asked to immediately return and remain at the clubhouse. The school will then lose all coaching privileges for the remainder of the tournament.

### IV. TOURNAMENT PLAN AND SCORING (DISTRICT, REGIONAL, AND STATE)

Entry forms for the Division I and Division II Class A district championship must be submitted via the TSSAA Portal at least five days before the championship is to begin. Entry forms for the Division II Class AA region championship must be submitted via the TSSAA Portal at least five days before the championship is to begin. Schools that do not file a timely entry will be assessed a $25.00 penalty per day in order to compete in the championship.

All championships shall be played in accordance with the current USGA Rules of Golf Booklet and the TSSAA Local Rules & Terms of the Competition. All players must walk at all times and may not have a caddy. Pull carts are permitted provided they are pulled by the player. The only exception would be if the participant is permanently disabled. A written request, along with an accompanying statement, must be submitted to the TSSAA office at the time eligibility is filed for the individual in order to request the use of a golf cart. All other situations involved with handicapped golfers will be determined on an individual basis by TSSAA.

The approximate playing yardage for each championship should be 6,500 for boys and 5,500 for girls.

Golfers shall be placed in groupings at the discretion of the tournament director. No members of the same team shall play in the same grouping. In district and regional championships, adult scorers are required for each grouping (see Instructions for Scorers).

### V. SUBSTITUTIONS

Only four or five players (boys) and two or three players (girls) may participate as a team, but an alternate may be listed. Any of the players listed (players or alternates) may represent a team in any 18-hole round of the championship series (district, region, first day of state, second day of state). There shall be no substitution for an individual golfer that qualifies for the next higher championship.

## VI. DISTRICT COMPETITION – DI, DII-A; REGIONAL COMPETITION – DII-AA

In Division I district competition, schools in the district shall select the site of the district golf championships. These sites should be secured early in the year and the TSSAA office notified as soon as possible to properly plan for event.

In Division I district competition, the top three teams and the top five individuals not on one of the three teams with the best scores shall advance to the regional championship. The regional champion team and the top three individuals not on the team shall advance to the state championships.

In Division II Class A district competition, schools in the district shall select the site of the district golf championships. These sites should be secured early in the year and the TSSAA office notified as soon as possible to properly plan for the event.

In Division II, Class A, district competition, the top three teams and the top five individuals not on one of the three teams with the best scores shall advance to the regional championship. The regional champion team, the regional runner-up team, and the top two individuals not on one of the qualifying teams shall advance to the state championships.

In Division II Class AA regional competition, the schools in each Region shall select the site for the regional championship. These sites should be secured early in the year and the TSSAA office notified as soon as possible to properly plan for the event.

In Division II Class AA, regional competition, all players on the regional champion team, the regional runner-up team, and the top two individuals not on one of the qualifying teams shall advance to the state championships.

## VII. REGIONAL CHAMPIONSHIP SITES – DIVISION I & DIVISION II-A

The even-numbered district in the Division I Class A will set the region site in even-numbered years, and the odd-numbered district in Division I Class AA will set the region site in even-numbered years. The process will be reversed in odd-numbered years.

In Division II Class A, the even-numbered district will set the region site in even-numbered years, in odd-numbered years the odd-numbered district will set the region site.

District, regional, and state championships shall be played at stroke play. The district and regional championships shall be 18 holes and the state championship 36 holes. (The director of the state championship and the TSSAA at their discretion, because of bad weather, may revert back to the last completed 18-hole round as per the Rules of Golf.)

## VIII. TIES

In case there is a tie for any team position or individual position qualifying for the next higher championship, there shall be a sudden death playoff and the team or player with the best score, after playing the number of holes necessary to break the tie, shall advance to the next higher tournament. In the state tournament, there shall be a sudden death playoff for first place only in either team play or individual play.

Sudden death playoff procedure – Teams will draw for positions. The winner of the draw shall have the option of positions (A, B,…) as set forth below:

| | |
|---|---|
| Two Teams: | #5A, #5B, #4A, #4B, #3A<br>#3B, #2A, #2B, #1A, #1B |
| Three Teams: | #5A, #5B, #5C, #4A, #4B<br>#4C, #3A, #3B, #3C, #2A<br>#2B, #2C, #1A, #1B, #1C |

If more than three, follow the same pattern.

## IX. AWARDS

In Division I, TSSAA will award team plaques and medals to the champion and runner-up, and five medals for the top five individuals in the district championships. TSSAA will award team plaques and medals to the champion and runner-up, and four medals for the top four individual players in the regional championships. In the state championship, TSSAA will award trophies to the team champion and runner-up, medals to members of the championship and runner-up teams, medals to the top four finishers, and a plaque to the medalist.

In Division II Class A, TSSAA will award team plaques and medals to the champion and runner-up, and five medals for the top five individuals in the district championships. TSSAA will award team plaques and medals to the champion and runner-up, and four medals for the top four individual players in the regional championships. In the state championship, TSSAA will award trophies to the team champion and runner-up, medals to members of the championship and runner-up teams, medals to the top four finishers, and a plaque to the medalist.

In Division II Class AA, TSSAA will award team plaques and medals to the champion and runner-up, and five medals for the top five individuals in the region championships. In the state championships, TSSAA will award trophies to the team champion and runner-up, medals to members of the championship and runner-up teams, medals to the top four finishers, and a plaque to the medalist.

## X. ATTIRE

At the state championships, proper attire shall be worn. Examples of proper attire are collared shirts, walking shorts, slacks, etc. Examples of improper attire are blue jeans, tee shirts, etc.

## XI. PRACTICE ROUND – STATE CHAMPIONSHIP

One 18-hole practice round will be scheduled before the Division I state championships only.

In an effort to maintain conditions of the course and speed of play, each player may play only one ball, except each player may putt more than one ball on the putting green. Violation of this policy will result in the player and/or team being removed from the golf course and could result in further disciplinary action.

All players shall walk and carry their bags or use a pull cart during the official practice round provided they are pulled by the player.

Groups of six are not allowed. If a team has an alternate, the alternate will play with the group following them. Coaches are not permitted to play during the practice round and it is strongly recommended that the coach accompany their team during the entire practice round. Coaches should be responsible for monitoring pace of play, misconduct, and the enforcement of one practice ball rule.

If a team or player chooses not to play in the official practice round, the coach should contact the golf course.

## XII. STATE CHAMPIONSHIP INFORMATION

Spectators – There will be no carts provided for spectators. The viewing areas for persons with disabilities will be set up at the course and identified with signage.

Spectator Rules – Spectators must remain approximately 15 yards from players at all times. There may be no communication between players and spectators that could be deemed advice of any nature during any part of the stipulated round. (This applies to both regular season play and championship play.)

## INSTRUCTIONS FOR SCORERS

The purpose of a scorer is to help set the proper atmosphere for the group as they compete. Your presence should set the proper tone for the way the game should be played. You should introduce yourself to all players, learn and call them by name, and make the round of play a positive experience for everyone.

It is not your responsibility to be a rules official. You should keep each player’s score, but your card is unofficial.

You are keeping the scores so that information can be given to media, spectators, coaches, etc. As per the rules, each competitor is responsible for the correctness of their scorecard upon being returned to the committee. The scorer should be available until each competitor's scorecard has been returned to the committee.

The scorer can be of great assistance by:

1. Moving ahead to observe landing of tee shots.
2. Being in position to observe every stroke.
3. Locating a rules official when one is needed.
4. Helping to find lost balls.

## INSTRUCTIONS TO COACHES
## POINTS OF EMPHASIS

1. All play is governed by the current USGA Rules of Golf.

2. A coach should be present on the golf course at all times during the official practice round and rounds of competition.

3. A coach can observe play, carry equipment for the player other than clubs, look for lost balls, serve as a spotter where needed, etc.

4. Players can only receive advice and/or coaching during the stipulated round from the coach that has been designated to do so.

# POLICY ON ELIGIBILITY FOR THE MEN'S AND WOMEN'S COMPETITON CATEGORIES

## A. INTRODUCTION

FINA is the international federation recognised by the International Olympic Committee (**IOC**) for administering international competitions in Aquatics. Its primary mission is to promote and encourage the advancement of Aquatics in all possible aspects, throughout the world. It does this through the promotion of Aquatics health, education, and development, and the staging of FINA competitions, including the FINA World Championships, World Cups, Grand Prix, World Leagues, and World Series events and tournaments. FINA is responsible for promulgating appropriate rules and regulations for the disciplines of Swimming, Open Water Swimming, Diving, Water Polo, Artistic Swimming, and High Diving, as well as for Masters programme/activity.

As part of its mission, FINA is responsible for developing and administering eligibility criteria for its sport and competitions. In this respect, FINA is committed to providing safe, fair, inclusive, and non-discriminatory opportunities for all Aquatics athletes wishing to compete in FINA competitions.

Historically, Aquatics sport has been separated into men's and women's competition categories. The separation reflects the sport's commitment to: (1) ensuring equal opportunity for both male and female athletes to participate and succeed in the sport, including through the equal representation in its programs and competitions of athletes of both biological sexes; (2) ensuring competitive fairness and physical safety within its competition categories; and (3) developing the sport and promoting its popular appeal and commercial value. Because of the performance gap that emerges at puberty between biological males as a group and biological females as a group, separate sex competition is necessary for the attainment of these objectives. Without eligibility standards based on biological sex or sex-linked traits, we are very unlikely to see biological females in finals, on podiums, or in championship positions; and in sports and events involving collisions and projectiles, biological female athletes would be at greater risk of injury.

## B. BACKGROUND TO THE POLICY

In November 2021, the IOC issued its Framework on Fairness, Inclusion and Non-Discrimination on the Basis of Gender Identity and Sex Variations (**IOC Framework**), which encouraged all international federations to develop eligibility criteria for the women's competition category that reflect the specificities of their particular sports but that include to the maximum extent possible athletes who, without regard to their sex or sex-linked traits, identify as women.

Specifically, the IOC Framework rejects the presumption that the male sex confers an athletic advantage, and discourages continued reliance on a testosterone proxy as the exclusive basis for eligibility for the women's category. Where evidence-based concerns about safety or fairness mean it is not possible to include male-to-female transgender athletes (transgender women) and athletes with 46 XY differences of sex development (**46 XY DSD**) and a female legal gender and/or gender identity in the women's competition category, it encourages consideration of alternative opportunities within the sport, such as open events.

In January 2022, the International Federation of Sports Medicine and the European Federation of Sports Medicine Associations issued a joint position statement (**Joint Position Statement**) responding to what those organisations considered to be failures of the IOC process and recommendations. According to the Joint Position Statement, the IOC's focus on only one aspect of the human rights analysis meant that it failed to take proper account of "the scientific, biological or medical aspects," in particular that "high testosterone concentrations, either endogenous or exogenous, confer a baseline advantage for athletes in certain sports" such that "it is clear to uphold the integrity and fairness of sport that these baseline advantages of testosterone must be recognized and mitigated."

In response to the IOC Framework and the Joint Position Statement, FINA convened a working group to consider the best available statistical, scientific, and medical evidence concerning sex differences in sports performance, and any associated male sex-based advantage. Its charge was to use this evidence to establish eligibility criteria to regulate the participation of transgender and 46 XY DSD athletes in the men's and women's categories in Aquatic sports that are consistent with FINA's mission and core commitments. The working group included (a) an athlete group (**Athlete Group**), (b) a science and medicine group (**Science Group**), and (c) a legal and human rights group (**Legal and Human Rights Group**).

The Athlete Group was comprised of current and retired Aquatics athletes and coaches (including transgender athletes and coaches), who brought to account their views and the views of their broader communities. The view of the majority of the Athlete Group was that competitive fairness must remain the primary objective in the establishment of competition categories. Moreover, it was highlighted that by reason of their sex and sex-linked traits, females often enjoy fewer societal opportunities compared to males, including fewer sporting opportunities, and sex-separated competitions are necessary to help address this inequality. In the majority view, FINA should remain committed to the separation of athletes in sport into men's and women's categories based on biological sex and should allow male-to-female transgender athletes (transgender women) and athletes with 46 XY DSD with a female gender identity to compete in the women's category pursuant to eligibility criteria that are consistent with, and do not undermine, that commitment.

The Science Group was comprised of independent experts in the fields of physiology, endocrinology, and human performance, including specialists in sex differences in human performance and in transgender medicine. The task of the Science Group was to examine the most up-to-date scientific knowledge on (1) the impact of biological sex on athletic performance, and (2) the impact of gender-affirming medical transition on factors that influence athletic performance, and to produce a report setting out their findings.

The Science Group reported that biological sex is a key determinant of athletic performance, with males outperforming females in sports (including Aquatics sports) that are primarily determined by neuromuscular, cardiovascular, and respiratory function, and anthropometrics including body and limb size. The extent of the male/female performance gap varies by sport and competition, but the gap universally emerges starting from the onset of puberty. The group reported that there are sex-linked biological differences in Aquatics, especially among elite athletes, that are largely the result of the substantially higher levels of testosterone to which males are exposed from puberty onwards. Prior to puberty, testosterone levels are similar in females and males. During puberty, however, testes-derived testosterone concentrations increase 20-fold in males, while testosterone concentrations remain low in females so that post-pubescent males have circulating testosterone concentrations at least 15 times higher than post-pubescent females (15-20 nmol/L in adult males versus c.1 nmol/L in typical females of any age). High testosterone levels generate not only anatomical divergence in the reproductive system but also measurably different body types/compositions between sexes.

According to the Science Group, if gender-affirming male-to-female transition consistent with the medical standard of care is initiated after the onset of puberty, it will blunt some, but not all, of the effects of testosterone on body structure, muscle function, and other determinants of performance, but there will be persistent legacy effects that will give male-to-female transgender athletes (transgender women) a relative performance advantage over biological females. A biological female athlete cannot overcome that advantage through training or nutrition. Nor can they take additional testosterone to obtain the same advantage, because testosterone is a prohibited substance under the World Anti-Doping Code.

The Legal and Human Rights Group was comprised of legal experts in sex discrimination, human rights, and international sports law, including the jurisprudence of the Court of Arbitration for Sport (**CAS**). This group accepted the lawfulness of FINA’s mission, authority and responsibility, and FINA’s core commitment to equality of opportunity for both male and female athletes, all as summarised above. It was informed of the views of the Athlete Group and the scientific evidence produced by, and conclusions of, the Science Group. Thus, its task was to reflect FINA’s commitment to a sex-based women’s category as necessary to ensure that FINA does not discriminate against—and is able to empower—female athletes, and that Aquatics is able to promote male and female athletes and male and female sport equally. It is also understood that, as with any form of affirmative action, FINA’s effort not to discriminate against female athletes and thus to ensure a sex-based women’s category itself has exclusionary effects. In this instance, those effects are on male-to-female transgender athletes (transgender women) and athletes with 46 XY DSD whose gender identity is female. The Legal Group has tailored FINA’s eligibility rule narrowly, so that (a) it is neither under- nor over-inclusive, and (b) it includes provisions throughout that are designed to ensure that the requirements and restrictions for transgender women and 46 XY DSD athletes with a female gender identity to compete in the women's competition category are limited to what is necessary and proportionate to achieve FINA's overarching objectives.

## C. THE POLICY

Taking into account all of the matters outlined above, FINA issues this policy (the **Policy**) establishing the criteria for eligibility (a) to compete in the men's category or in the women's category in the FINA World Championships, World Cups, Grand Prix, World Leagues, and World Series events and tournaments, and other international competitions events (**FINA competitions**), and (b) to set FINA World Records in the men's category or in the women's category in FINA competitions and in other events recognised by FINA, wherever they are held.

## D. POLICY DEFINITIONS

FINA recognises that some individuals and groups may be uncomfortable with the use of medical and scientific terminology related to sex and sex-linked traits. FINA respects all Aquatics athletes and has sought to avoid sensitive terminology that may cause offense. Nevertheless, some use of sensitive terminology is needed to be precise about the sex characteristics that justify separate competition categories and to ensure that the Policy's terms are understood by all Aquatics stakeholders. Some of those terms are explained in this section.

For purposes of this Policy:

"Differences of sexual development" (**DSD**) are a group of conditions where external genital appearance is discordant with internal sex organs (testes and ovaries). This Policy is only concerned with 46 XY DSD, i.e., DSD affecting athletes with testes (males as defined below).

The word "female" means possession of XX chromosomes and (in the absence of medical intervention) ovaries and increased circulating oestrogen and progesterone starting at puberty.

The word "male" means possession of XY chromosomes and (in the absence of medical intervention) testes and increased circulating testosterone starting at puberty.

The word "sex" denotes natural biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. This Policy uses the word "sex" and the term "biological sex" interchangeably.

The term "Tanner Stages" denotes the five stages of puberty during which individuals develop secondary sex characteristics. Tanner Stage 2 denotes the onset of puberty. The normal time of onset of puberty ranges from 8 to 13 years old in females, and from 9 to 14 years old in males.

The term "transgender" refers to individuals whose gender identity and/or expression differs from what is typically associated with their sex.

## E. THE POLICY OBJECTIVES

FINA is committed to the inclusion of all Aquatics athletes from all countries in the sport, subject to the eligibility requirements set out in this Policy

It is committed to the separation of Aquatics sports into men's and women's categories according to sex, as this is necessary for the attainment of the goals for that category that are set out in the Introduction to this Policy. It is also committed to providing the opportunity for transgender and 46 XY DSD athletes to compete in Aquatics competitions pursuant to eligibility criteria that are consistent with and do not undermine those goals.

In light of these commitments, the objectives of this Policy are:

- to maintain the separation of Aquatic sports into men's and women's categories according to scientifically-grounded, sex-based criteria;

- to provide opportunities for transgender and 46 XY DSD athletes to compete in FINA competitions in the competition category that reflects their gender identity based on eligibility criteria that are consistent with and do not undermine FINA's goals for the women's category; and

- to provide a clear, fair, respectful, and confidential process by which athletes may establish their eligibility for FINA competitions.

## F. THE ELIGIBILITY REQUIREMENTS FOR COMPETITION AND FOR SETTING FINA RECORDS IN THE MEN'S AND WOMEN'S CATEGORIES

1. Eligibility

    a. Subject to the requirements set forth below, all Aquatics athletes are eligible to compete in the men's category or in the women's category in FINA competitions and to set FINA World Records in FINA competitions and other events recognised by FINA, whatever their legal gender, gender identity, or gender expression. No athlete is excluded from a FINA competition or from setting FINA World Records based on their legal gender, gender identity, or gender expression.

    b. All issues relating to the eligibility of an athlete under this Policy to compete in a particular sex category will be determined by FINA following consultation, as necessary, with one or more independent scientific and medical experts appointed by the FINA Executive. It is an important part of this Policy that the experts can assess whether a given athlete meets the eligibility criteria set out below. To that end, FINA may ask the athlete to provide further information and documents and/or to submit to one or more medical examinations. All costs associated with this assessment will be borne by FINA.

2. Certification

    a. All athletes must certify their chromosomal sex with their Member Federation in order to be eligible for FINA competitions. Failure to do so, or provision of a false certification, will render the athlete ineligible.

    b. Member Federations must confirm their athletes' certifications of chromosomal sex when registering their athletes to compete in FINA competitions.

    c. FINA reserves the right to include a chromosomal sex screen in its anti-doping protocol to confirm such certification.

3. Eligibility for the Men's Category

    a. All male athletes, including athletes with 46 XY DSD, are eligible to compete in FINA competitions and to set FINA World Records in the men's category, regardless of their legal gender, gender identity, or gender expression.

    b. Female-to-male transgender athletes (transgender men) are eligible to compete in FINA competitions and to set FINA World Records in the men's category, except that:

        i. For the disciplines of Water Polo and High Diving, the athlete must provide to FINA an assumption of risk form (in the form set out in Appendix One to this Policy) signed and dated by the athlete or, if the athlete is a minor, by their legal proxy.

        *[Comment to Section F.3.b.i: It is strongly recommended that the athlete speaks with a qualified medical specialist prior to competition to ensure their physical ability to participate in the event in the men's category and to ensure that they understand the attendant risks.]*

        ii. All athletes who are undergoing treatment involving testosterone or other anabolic substances as part of female-to-male gender-affirming hormone treatment are required to obtain a Therapeutic Use Exemption (**TUE**) for that treatment in accordance with the FINA Doping Control Rules (**FINA DCR**).

4. Eligibility for the Women's Category

   a. All female athletes are eligible to compete in FINA competitions and set FINA World Records in the women's category, regardless of their legal gender, gender identity, or gender expression, under the following conditions:

      i. Athletes who have previously used testosterone as part of female-to-male gender-affirming hormone treatment (with or without a TUE) but are no longer following that treatment are eligible to compete in the women's category in FINA competitions and to set FINA World Records in the women's category in FINA competitions and in other events recognised by FINA if they can establish to FINA's comfortable satisfaction that (a) the testosterone use was for less than a year in total (i.e., from the date of first use to the date of last use) and did not take place during pubertal growth and development, and (b) their testosterone levels in serum (or plasma) are back to pre-treatment normal and any associated anabolic effects have been eliminated.

      ii. Female athletes who have used testosterone in violation of the World Anti-Doping Code or FINA DCR (or any other applicable anti-doping rules) may return to competition after they have served their period of ineligibility.

   b. Male-to-female transgender athletes (transgender women) and athletes with 46 XY DSD whose legal gender and/or gender identity is female are eligible to compete in the women's category in FINA competitions and to set FINA World Records in the women's category in FINA competitions and in other events recognised by FINA if they can establish to FINA's comfortable satisfaction that they have not experienced any part of male puberty beyond Tanner Stage 2 or before age 12, whichever is later. Specifically, the athlete must produce evidence establishing that:

      i. They have complete androgen insensitivity and therefore could not experience male puberty; or

      ii. They are androgen sensitive but had male puberty suppressed beginning at Tanner Stage 2 or before age 12, whichever is later, <u>and</u> they have since continuously maintained their testosterone levels in serum (or plasma) below 2.5 nmol/L.

iii. An unintentional deviation from the below 2.5 nmol/L requirement may result in retrospective disqualification of results and/or a prospective period of ineligibility.

iv. An intentional deviation from the below 2.5 nmol/L requirement may result in retrospective disqualification of results and a prospective period of ineligibility equal or commensurate in length to periods imposed under the FINA DRC for intentional anti-doping rule violations involving anabolic steroids.

*[Comment to Section F.4.b: For purposes of the Policy, all measurements of serum testosterone must be conducted by means of liquid chromatography coupled with mass spectrometry.]*

5. Process for Application

The process for applications for eligibility is set forth in the Operational Requirements (see Appendix Two to this Policy).

## G. COMPETITIVE OPPORTUNITIES WITHIN AND OUTSIDE OF THE MEN'S AND WOMEN'S CATEGORIES

1. Classifying athletes on the basis of sex is necessary to meet FINA's goals for female Aquatics athletes and the women's competition category. FINA's eligibility standards for the women's category are narrowly tailored so that they can achieve those goals without unnecessarily limiting participation by gender-diverse athletes.

2. Male-to-female transgender athletes (transgender women) and athletes who have a 46 XY DSD and a female legal gender and/or gender identity are eligible to compete in the women's category in FINA competitions and to set FINA World Records in the women's category at FINA competitions and other events recognised by FINA if they meet the applicable eligibility conditions.

3. Female-to-male transgender athletes (transgender men) are eligible to compete in the men's category at FINA competitions and to set FINA World Records in the women's category at FINA competitions and in other events recognized by FINA if they meet the applicable eligibility conditions.

4. Otherwise, everyone who qualifies according to the applicable eligibility conditions has a place in FINA's competition categories based on their sex.

5. Within those categories, gender diversity is welcome. For example, female-to-male transgender athletes (transgender men) who are not using exogenous androgens remain eligible for, and are welcome to compete in, the women's category; and male-to-

female transgender athletes (transgender women) remain eligible for, and are welcome to compete in, the men’s category whether or not they are suppressing their endogenous androgens.

6. Athletes who do not meet the applicable criteria for the men’s category or the women’s category may compete in any open events that FINA may develop in the future. FINA will begin work following the final promulgation of this Policy to determine the feasibility of establishing an open category in Aquatics sport disciplines, in which an athlete who meets the eligibility criteria for that event would be able to compete without regard to their sex, their legal gender, or their gender identity.

7. Athletes may also seek to qualify for and compete in events that are organised and sanctioned by bodies other than FINA. FINA does not seek to limit the development by others of opportunities to participate in different competitions.

8. FINA recommends that each Member Federation adopts its own sex and gender policy to determine eligibility to compete in events taking place under its jurisdiction. FINA recommends that Member Federations use that policy to create a safe environment for their athletes, transgender or otherwise, that respects the inclusion of all Aquatics athletes.

9. Member Federations may use this Policy as a guideline for national-level and age-group competition, to be tailored based on any relevant requirements within their jurisdiction. For the avoidance of doubt, however, any policy applied at a national level will not determine the eligibility of athletes to compete in FINA competitions or to set FINA World Records. Instead, that will be determined exclusively by reference to this Policy. In addition, any policy adopted and enforced by a Member Federation remains within the jurisdiction of the Member Federation. It follows that any decision taken by a Member Federation concerning the applicability of its policy, or this Policy, is not considered a FINA decision.

10. FINA recommends that organisers of recreational (non-competitive or non-elite) Aquatics events consider their local circumstances and goals in their determination of whether or not separate sex competition is also necessary for them.

## H. CONTINUED INVOLVEMENT

While all athletes have a place in Aquatic sports, FINA acknowledges that the application of this Policy means that certain individuals may not be able to compete in the category that best aligns with their legal gender, gender identity, or gender expression. Individuals who exercise the choice not to compete because of these eligibility standards are encouraged to consider coaching, officiating, administration, and/or other ways to stay involved with Aquatics.

For more information on how to become involved, please contact FINA or your Member Federation.

## I. APPLICATION

This Policy will come into effect on 20 June 2022. It governs eligibility to compete in FINA competitions and to set FINA World Records at FINA competitions and other events recognised by FINA, taking place from that date forward.

FINA is committed to reviewing this Policy periodically to take account of all relevant scientific and medical developments. It may be amended from time to time by FINA based on such developments.

## J. ASSISTANCE WITH THIS POLICY

FINA is committed to the inclusion of all Aquatics athletes in accordance with the eligibility requirements set out in this Policy. Any individual seeking information on the application of this Policy should contact FINA for assistance at *eligibility@fina.org*.

# Appendix One

## ASSUMPTION OF RISK FORM

I, …………………………………… [print name], wish to compete in the men's competition category in Water Polo and/or High Diving in accordance with FINA's Policy on Eligibility for the Men's and Women's Competition Categories.

I have read and understood and agree to comply with the Policy and the Operational Requirements appended to the Policy.

I acknowledge and accept the possible increased injury risk associated with transgender men competing in the men's competition category in Water Polo alongside males who are statistically likely to be stronger, faster, and heavier than transgender men.

AND/OR

I acknowledge and accept the possible increased injury risk associated with transgender men competing in the men's competition category in the High Diving given the demands of the discipline.

I acknowledge and agree that it is my sole personal responsibility to determine whether I have the physical abilities to safely participate in the men's competition category in Water Polo and/or High Diving.

I understand and acknowledge that FINA strongly recommends that I speak to a qualified medical specialist prior to competition to ensure my physical ability to participate in the men's category and to ensure that I understand the attendant risks.

I acknowledge and agree that I am voluntarily assuming the risk that I might suffer loss, injury, death, or other damage as a result of my participation in the men's competition category, including (without limitation) any possible increased risk due to my status as a female-to-male transgender athlete. I hereby waive and release FINA and all persons and entities involved in any way in FINA Competitions (including, without limitation, all of their respective members, directors, officers, employees, volunteers, contractors, and agents) from any claim of liability in respect of such loss, injury, death, or other damage.

Athlete name: ………………………………………

Athlete National Federation: ………………………………………

Athlete signature: ………………………………………

Date: ………………………………………

If the athlete is under the age of eighteen, this form must be signed on the athlete's behalf by the athlete's legal proxy.

Proxy name: ……………………………………

Proxy signature: ……………………………………

Proxy relationship to athlete: ……………………………………

Date: ……………………………………

Please complete this form and return it to *eligibility@fina.org.*

# Appendix Two

# OPERATIONAL REQUIREMENTS IN RELATION TO FINA'S POLICY ON ELIGIBILITY FOR THE MEN'S AND WOMEN'S COMPETITION CATEGORIES

*(Effective as from 20 June 2022)*

In the case of confidential queries concerning the Policy or these Operational Requirements, or for the establishment of eligibility thereunder, please contact: *eligibility@fina.org*

## A. INTRODUCTION

1. These Operational Requirements implement the Policy on Eligibility for the Men's and Women's Competition Categories that the FINA Bureau adopted on 18 June 2022 and that the FINA Congress ratified on 19 June 2022 (the **Policy**). They will come into effect on 20 June 2022, and from that date forward they will bind all Member Federations, athletes, and other natural and legal persons who are subject to FINA's jurisdiction, and will govern eligibility: (a) to compete in the FINA World Championships, World Cups, Grand Prix, World Leagues, and World Series events and tournaments, and other international events (**FINA Competitions**), and (b) to set FINA World Records in FINA Competitions and/or in other events recognised by FINA, wherever they are held.

2. The Policy and these Operational Requirements are intended to operate uniformly around the world, regulating the conditions to compete in FINA Competitions, and to set FINA World Records in FINA Competitions and other events recognised by FINA, wherever they are held. The Policy and these Operational Requirements are, therefore, to be interpreted and applied not by reference to national or local laws, but rather as an independent and autonomous text, and in a manner that protects and advances the objectives identified in the Policy.

3. Defined words and phrases used in these Operational Requirements have the meaning given to them in the FINA Constitution, or in the Policy, or in these Operational Requirements.

## B. ELIGIBILITY CONDITIONS AND APPLICATION

1. The eligibility conditions for competing in the men's and women's categories in FINA competitions and for setting FINA World Records in the men's and women's categories in FINA Competitions and in other events recognised by FINA are set out in the Policy (the **Eligibility Conditions**).

2. Any athlete (including any transgender or 46 XY DSD athlete) who wishes to be eligible to participate in a FINA Competition, or to set a FINA World Record in a FINA Competition or in another event recognised by FINA, agrees, as a condition to such eligibility, and subject always to the confidentiality provisions set out in Section G:

   a. To fully comply with the Policy and these Operational Requirements;

   b. To cooperate promptly and in good faith with FINA and one or more independent scientific and medical experts appointed by the FINA Executive (**Independent Expert**) in the discharge of their responsibilities under the Policy and these Operational Requirements, including to provide them with all of the information and evidence (including physical examinations) they request to enable them to assess compliance and/or monitor continuing compliance with the eligibility conditions set out in the Policy and these Operational Requirements;

c. To the fullest extent permitted and required under data protection and other laws of Switzerland and any other applicable jurisdictions) to the collection, processing, disclosure, and use of information (including their sensitive personal information) as required to implement and apply the Policy and these Operational Requirements effectively and efficiently; and

d. To follow the procedures set out in Section F to challenge the Policy and/or these Operational Requirements and/or to appeal decisions made under the Policy and/or these Operational Requirements, and not to bring any proceedings in any court or other forum that are inconsistent with that agreement.

3. An athlete may revoke at any time, with or without giving reasons, the consent that they have granted under Section B.2, in which case they will be deemed to have withdrawn any claim to satisfy the eligibility conditions set out in the Policy and these Operational Requirements.

4. Prior to competition, each Member Federation must register its athletes with the FINA General Management System (GMS). At registration, each Member Federation will be required to identify each athlete's chromosomal sex in accordance with Policy Section F.2 and either confirm compliance with the Policy and these Operational Requirements or identify that the matter requires further consideration under the Policy and these Operational Requirements. It remains the obligation of the National Federation to maintain an accurate record of their athletes' chromosomal sex and understanding of the application of the Policy and these Operational Requirements.

5. The performance in an event recognised by FINA of an athlete who has not been registered with FINA (i.e. a non-FINA event) in accordance with the foregoing requirements may be recognised as a FINA World Record if the athlete and/or their Member Federation satisfies FINA that the athlete met all of the relevant Eligibility Conditions of the Policy at the time of the event.

6. If, pursuant to Sections, B.4, B.9, C.4 or C.5, or otherwise in FINA's discretion, a case arises that requires further consideration under the Policy and these Operational Requirements, that matter will be dealt with in accordance with the Policy and these Operational Requirements.

7. Every Member Federation and every athlete and other natural or legal person who is subject to FINA's jurisdiction:

a. must cooperate promptly and in good faith with an Independent Expert in the discharge of their respective responsibilities under the Policy and these Operational Requirements; and

b. when providing information pursuant to the Policy and these Operational Requirements, must provide accurate and complete information, and must not provide any information in bad faith or for an improper purpose.

8. For the avoidance of doubt, FINA notes the following:

a. Neither legal recognition of an athlete's gender identity as the athlete's legal sex nor surgical anatomical changes are required in order for a transgender or 46 XY DSD athlete to be eligible to compete at a FINA Competition or to set a FINA World Record in the competition category that is consistent with their gender identity.

b. No athlete is required to undergo any medical assessment and/or treatment under the Policy or these Operational Requirements. It is the athlete's responsibility, in consultation with their medical team, to decide on the advisability of proceeding with any assessment and/or treatment.

c. The Eligibility Conditions operate without prejudice to the other eligibility requirements that are applicable to all athletes under the FINA Rules, which must also be satisfied at all relevant times. In particular, nothing in the Policy or these Operational Requirements is intended to undermine or affect in any way any of the requirements of the World Anti-Doping Code, of the WADA International Standards (including the International Standard for Therapeutic Use Exemptions), or of the FINA Doping Control Rules. Nothing in the Policy or these Operational Requirements permits, excuses, or justifies non-compliance with any of those requirements, including any requirement for an athlete to obtain a TUE for the use of substances on the WADA Prohibited List, such as testosterone, spironolactone, or GnRH agonists (see further the WADA Transgender Athletes TUE Physician Guidelines, available at www.wada-ama.org).

9. Any Masters athlete must register directly with FINA prior to participation in the event in question. At registration, each athlete will certify their chromosomal sex in accordance with Policy Section F.2 and either confirm compliance with the Policy and these Operational Requirements or identify that the matter requires further consideration under the Policy and these Operational Requirements.

## C. ASSESSMENT BY INDEPENDENT SCIENTIFIC AND/OR MEDICAL EXPERT(S)

1. A female-to-male transgender athlete (transgender man), or a male-to-female transgender athlete (transgender woman), or an athlete with a 46 XY DSD whose legal gender and/or gender identity is female, who wishes to establish their eligibility under the Policy (including, without limitation, resulting from an investigation conducted further to Section D.2) must file the following with the FINA Executive:

    a. A comprehensive medical history and such other evidence as is required to demonstrate their satisfaction of the Eligibility Conditions. The athlete (and their Member Federation, where applicable) is responsible for ensuring that the information provided is accurate and complete, and that nothing relevant is withheld.

    b. The consents and waivers necessary to allow the FINA Executive to provide the athlete's submission under Section C.1.a to an Independent Expert who will conduct the eligibility assessment detailed herein.

2. Upon the athlete's request for an eligibility determination under Section C.1.a, or pursuant to an investigation under Section D.2, an Independent Expert shall review the submission and make a determination of eligibility under the Policy.

3. The Independent Expert shall have the medical and/or scientific credentials and expertise necessary and relevant for the assessments at issue. In selecting an Independent Expert, the FINA Executive may, but need not, draw from experts in the athlete's region.

4. The Independent Expert will assess cases referred to them by the FINA Executive to determine whether the Eligibility Conditions have been met. The Independent Expert may make such enquiries or undertake such investigations or examinations as they consider necessary to carry out the required assessment effectively, including requesting further information from the athlete and/or the athlete's physician, and/or conducting an independent physical examination of the athlete, and/or obtaining opinions from other relevant experts.

5. In making an assessment, an Independent Expert will take into account all relevant and reliable evidence that goes to establishing whether or not the Eligibility Conditions are satisfied, including (without limitation):

    a. evidence as to whether or not an athlete wishing to compete in the women's category has complete androgen insensitivity;

    b. evidence as to whether or not an athlete wishing to compete in the women's category suppressed male puberty beginning at Tanner Stage Two or before age 12;

c. evidence as to whether or not an athlete wishing to compete in the women's category continuously maintained their testosterone levels in serum (or plasma) below 2.5 nmol/L beginning at Tanner Stage Two or before age 12;

d. evidence as to whether or not an athlete wishing to compete in the men's category obtained a TUE authorizing the use of exogenous androgens in accordance with Policy Section 3.b.ii; and

e. evidence as to whether or not an athlete wishing to return to competition in the women's category satisfies the conditions set out in Policy Section 4.a.i.

6. If an Independent Expert has any concerns about the adequacy of the evidence provided by the athlete on any particular point, they must give the athlete a fair opportunity to try to address those concerns before they come to their final decision.

7. The Independent Expert will complete their assessment as soon as is reasonably practicable given the circumstances of the case. However, there is no obligation to complete the assessment by any particular date, and in no circumstance will FINA or the Independent Expert be liable for any detriment allegedly suffered by the athlete or anyone else as a result of the length of time taken to complete the assessment.

8. Once they have completed their assessment, the Independent Expert will send their decision in writing to the FINA Executive and the athlete.

a. If the Independent Expert decides that the Eligibility Conditions have not been met, they must explain in writing the reasons for that decision. Where applicable, they should also specify what else the athlete may do in order to satisfy the Eligibility Conditions.

b. If an Independent Expert decides that the Eligibility Conditions have been met, they must explain in writing the reasons for that decision. The athlete will immediately be eligible to compete in the relevant competition category (men's or women's, as applicable) in FINA Competitions and to set FINA World Records in that competition category in FINA Competitions and other events recognised by FINA. That eligibility will be subject in every case to the athlete's continuing satisfaction of the Eligibility Conditions, including (where applicable) continuously maintaining their testosterone in serum (or plasma) at a concentration of less than 2.5 nmol/L. The Independent Expert may specify particular means of demonstrating such continuing compliance. In any event, the athlete must produce, on request, evidence satisfactory to an Independent Expert of such continuing compliance.

9. The Independent Expert's decision will be final and binding on all parties. It may only be challenged by way of appeal in accordance with Section F.2.C.

## D. COMPLIANCE

1. FINA may monitor an athlete's ongoing compliance with the Eligibility Conditions by any appropriate means, including (where relevant) random or targeted testing of the athlete's testosterone level in serum (or plasma) or further assessment by an Independent Expert. The athlete agrees to provide whereabouts information and blood samples for this purpose on request, and also agrees that any samples or whereabouts information that they provide for anti-doping purposes and/or any anti-doping data relating to them may also be used for this purpose.

2. In addition to the general power to monitor continuing compliance with the Eligibility Conditions, FINA may investigate, at any time:

   a. whether an athlete who has not filed a declaration under these Operational Requirements is a transgender athlete or 46 XY DSD athlete who needs to establish their eligibility to compete in a particular competition category in accordance with the Policy and these Operational Requirements; and/or

   b. any circumstances that indicate actual or potential non-compliance with the Policy and/or these Operational Requirements.

In such cases, if they wish to retain their eligibility to compete in FINA Competitions and to set FINA records in FINA Competitions and in other events recognised by FINA, the athlete in question and their Member Federation (and all other relevant persons who come under FINA's jurisdiction) must cooperate fully and in good faith with that investigation. Where necessary to safeguard the fairness and/or integrity of competition and/or the safety of the competitors, the FINA Executive may provisionally suspend the athlete from competing in FINA Competitions and from setting FINA World Records in FINA Competitions or in other events recognised by FINA pending resolution of the matter, provided that in such cases all reasonable endeavours will be used to complete the investigation as expeditiously as possible. Any such provisional suspension may be appealed in accordance with Section F.2.a.

3. Any investigation under Section D.2 must be initiated in good faith and on reasonable grounds based on information derived from reliable sources, such as (without limitation) information from the affected athlete or their Member Federation, results from a routine pre-participation health examination, or data as to testosterone levels and/or other data obtained from analysis of samples collected for anti-doping purposes.

4. Without prejudice to Section D.5, if it is determined that a male-to-female transgender athlete (transgender woman) or a 46 XY DSD athlete competed in the women's competition category at a FINA Competition while having testosterone levels in serum (or plasma) of 2.5 nmol/L or more, the results obtained by the athlete/team at that event will be disqualified, with all resulting consequences, including forfeiture of any medals, ranking points, prize money, or other rewards awarded to the athlete based on those results.

5. An unintentional deviation from the 2.5 nmol/L requirement may result in retrospective disqualification of results and/or a prospective period of ineligibility.

6. Without prejudice to Section D.7, if it is determined that a male-to-female transgender athlete (transgender woman) or a 46 XY DSD athlete competed in the women's category at an event recognised by FINA while having testosterone levels in serum (or plasma) of 2.5 nmol/L or more, the results obtained by the athlete/team at that event will not be recognised for purposes of determining FINA records.

7. An intentional deviation from the 2.5 nmol/L requirement may result in retrospective disqualification of results and a prospective period of ineligibility equal or commensurate in length to periods imposed under the FINA Doping Control Rules for intentional anti-doping rule violations involving anabolic agents.

8. Since athletes specifically agree to comply with the Policy and these Operational Requirements for eligibility purposes (and transgender women undergoing testosterone-suppression treatment will typically maintain serum testosterone levels

below 2.5 nmol/L), the burden is on the athlete to establish, to FINA's reasonable satisfaction, that any deviation above 2.5nmol/L was unintentional.

## E. DISCIPLINARY PROCEEDINGS AND SANCTIONS

1. Where:

   a. information that is provided pursuant to the Policy and/or these Operational Requirements is inaccurate or misleadingly incomplete;

   b. an athlete competes in a FINA Competition in a category of competition for which they have not satisfied the Eligibility Conditions;

   c. an athlete who has previously been determined to have satisfied the Eligibility Conditions fails to cooperate fully and in good faith with efforts to determine their continuing compliance with the Eligibility Conditions;

   d. there has been any other breach of or non-compliance by an athlete with the Policy and/or these Operational Requirements; or

   e. a coach, trainer, agent, or other person or entity has been complicit in an athlete's breach of or non-compliance with the Policy and/or these Operational Rules;

   FINA may take disciplinary action against the person(s) involved in accordance with FINA Rule C 23.

2. In such disciplinary proceedings, the person(s) charged may not challenge the validity of the Policy or these Operational Requirements, or of any decision made under the Policy or these Operational Requirements. Instead, such challenge may only be brought by way of challenge or appeal in accordance with Section F.

3. In such disciplinary proceedings, the sanctions to be imposed, depending on all of the circumstances of the case, may include (without limitation):

   a. a caution, reprimand and/or warning as to future conduct;

   b. the disqualification of individual and/or team results obtained in FINA Competitions, with all resulting consequences, including forfeiture of any medals, ranking points, prize money, or other rewards awarded to the athlete based on those results;

   c. the non-recognition as a FINA record of individual and/or team results obtained at an event recognised by FINA;

d. a specified period of ineligibility to participate in FINA Competitions and to set FINA records in other events recognised by FINA;

e. a fine; and/or

f. if the breach involves more than two members of a representative team of a Member Federation, or if there are multiple breaches involving such a team, appropriate sanctions on the team and/or the Member Federation (e.g., disqualification of team results; imposition of a period of future ineligibility to participate in FINA Competitions; a fine).

## F. DISPUTE RESOLUTION

1. The validity of the Policy and/or these Operational Requirements may only be challenged by way of ordinary proceedings filed before the Court of Arbitration for Sport in Lausanne, Switzerland (**CAS**) or as part of an appeal to the CAS made pursuant to Section F.2.

2. The following decisions (and only the following decisions) made under the Policy and these Operational Requirements may be appealed to the CAS:

   a. a decision to suspend an athlete provisionally from competition pursuant to Section D.2 may be appealed by the athlete, in which case FINA will be the respondent to the appeal;

   b. a decision that the athlete may not compete in FINA Competitions or set FINA records in the competition category that is consistent with their gender identity may be appealed by the athlete, in which case FINA will be the respondent to the appeal; and

   c. a decision by an Independent Expert that the athlete may compete in FINA Competitions in the competition category that is consistent with their gender identity may be appealed by FINA, in which case the athlete will be the respondent to the appeal.

3. Any such challenge or appeal will be conducted in the English language and will be governed by the FINA Constitution and other FINA Rules (in particular, the Policy and these Operational Requirements), with the laws of Switzerland applying subsidiarily. In the case of any conflict between any of the above instruments and the CAS Code of Sports-Related Arbitration in force at the relevant time, the above-instruments will take precedence.

4. The CAS will hear and determine the challenge/appeal in accordance with the CAS Code of Sports-Related Arbitration. Pending that determination, the matter under challenge and/or the decision under appeal (as applicable) will remain in full force and effect unless the CAS orders otherwise.

5. The decision of the CAS will be final and binding on all parties, and no right of appeal or other challenge will lie from that decision on any ground, except as set out in Chapter 12 of the Swiss Federal Code on Private International Law.

## G. CONFIDENTIALITY

1. All cases arising under the Policy and these Operational Requirements, and in particular all athlete information provided to FINA under the Policy and these Operational Requirements, and all results of examinations and assessments conducted under the Policy and these Operational Requirements, will be dealt with in strict confidence at all times. All medical information and data relating to an athlete will be treated as sensitive personal information and the Independent Expert will ensure at all times that it is processed as such in accordance with applicable data protection and privacy laws. The information covered by this paragraph will not be used for any purpose not contemplated in the Policy and these Operational Requirements, and will not be disclosed to any third party save as is strictly necessary for the effective application and enforcement of the Policy and these Operational Requirements, or otherwise as is required by law.

2. FINA will not comment publicly on the specific facts of a pending case (as opposed to general descriptions of the process and science involved) except in response to public comments attributed to the athlete involved or their representatives.

3. Each Independent Expert will be required to sign an appropriate conflict of interest declaration and confidentiality undertaking in relation to their work carried out pursuant to the Policy and these Operational Requirements.

## H. COSTS

1. Athletes are responsible for the costs associated with their initial application for eligibility under the Policy and Operational Requirements, including for obtaining and transmitting their medical files to FINA, and (where applicable) for continuing to satisfy the Eligibility Conditions. FINA is responsible for the costs associated with any required medical assessments and monitoring under the Policy and Operational Requirements.

2. FINA and an athlete whose case arises for investigation and/or assessment under the Policy and these Operational Requirements may agree on the appointment of an independent Ombudsman to assist the athlete in understanding and addressing the Policy and these Operational Requirements. FINA is responsible for the costs of the Ombudsman, if any.

## I. MISCELLANEOUS

1. In no circumstances will FINA, the Independent Expert, or any of FINA's employees, officers, agents, representatives, or other persons involved in the administration of the

Policy and these Operational Requirements be liable in any way for any acts done (or omitted to be done) in good faith in connection with the administration of the Policy and these Operational Requirements.

2. In the event an issue arises that is not foreseen in the Policy or these Operational Requirements, it will be addressed by FINA in a manner that protects and promotes the objectives identified in the Policy.

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE MIDDLE DISTRICT OF TENNESSEE**
**NASHVILLE DIVISION**

**L.E., by his next friends and parents,)**
**SHELLEY ESQUIVEL and** )
**MARIO ESQUIVEL,** )
)
**Plaintiff,** )
) **No. 3:21-cv-00835**
**v.** )
) **Chief Judge Crenshaw**
**BILL LEE, in his official capacity** )
**as Governor of Tennessee; et al.,** ) **Magistrate Judge Newbern**
)
**Defendants.** )

# DECLARATION OF STEPHEN B. LEVINE, M.D.

I, Dr. Stephen B. Levine, pursuant to 28 U.S. Code § 1746, declare under penalty of perjury under the laws of the United States of America that the facts contained in my Expert Report of Stephen B. Levine, M.D., in the Case of *L.E. v. Governor Lee*, *et al.*, attached hereto, are true and correct to the best of my knowledge and belief, and that the opinions expressed therein represent my own expert opinions.

Executed on May 20, 2022

Stephen B Levine MD
Stephen B. Levine, M.D.

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## I. CREDENTIALS & SUMMARY

1. I am Clinical Professor of Psychiatry at Case Western Reserve University School of Medicine, and maintain an active private clinical practice. I received my MD from Case Western Reserve University in 1967, and completed a psychiatric residency at the University Hospitals of Cleveland in 1973. I became an Assistant Professor of Psychiatry at Case Western in 1973, became a Full Professor in 1985, and in 2021 was honored to be inducted into the Department of Psychiatry's "Hall of Fame."

2. Since July 1973, my specialties have included psychological problems and conditions relating to individuals' sexuality and sexual relations, therapies for sexual problems, and the relationship between love, intimate relationships, and wider mental health. In 2005, I received the Masters and Johnson Lifetime Achievement Award from the Society of Sex Therapy and Research. I am a Distinguished Life Fellow of the American Psychiatric Association.

3. I have served as a book and manuscript reviewer for numerous professional publications. I have been the Senior Editor of the first (2003), second (2010), and third (2016) editions of the *Handbook of Clinical Sexuality for Mental Health Professionals*. In addition to five previously solo-authored books for professionals, I have recently published *Psychotherapeutic Approaches to Sexual Problems* (2020). The book has a chapter titled "The Gender Revolution."

4. In total I have authored or co-authored over 180 journal articles and book chapters, 20 of which deal with the issue of gender dysphoria. I am an invited member of a Cochrane Collaboration subcommittee that is currently preparing a review of the scientific literature on the effectiveness of puberty blocking hormones and of cross-sex hormones for gender dysphoria for adolescents. Cochrane Reviews are a well-respected cornerstone of evidence-based practice, comprising a systematic review that aims to identify, appraise, and synthesize all the empirical evidence that meets pre-specified eligibility criteria in response to a particular research question.

5. I first encountered a patient suffering what we would now call gender dysphoria in July 1973. In 1974, I founded the Case Western Reserve University Gender Identity Clinic, and have served as Co-Director of that clinic since that time. Across the years, our Clinic treated hundreds of patients who were experiencing a transgender identity. An occasional child was seen during this era. I was the primary psychiatric caregiver for several dozen of our patients and supervisor of the work of other therapists. I was an early member of the Harry Benjamin International Gender Dysphoria Association (later known as WPATH) and served as the Chairman of the committee that developed the 5th version of its Standards of Care. In 1993 the Gender Identity Clinic was renamed, moved to a new location, and became independent of Case Western Reserve University. I continue to serve as Co-Director.

6. In the course of my five decades of practice treating patients who suffered from gender dysphoria, I have at one time or another recommended or prescribed or supported social transition, cross-sex hormones, and surgery for particular patients, but only after extensive diagnostic and psychotherapeutic work.

7. In 2006, Judge Mark Wolf of the Eastern District of Massachusetts asked me to serve as an independent, court-appointed expert in a litigation involving the treatment of a transgender inmate within the Massachusetts prison system. In that litigation, the U.S. Court of Appeals for the First Circuit in a 2014 (En Banc) opinion cited and relied on my expert testimony. I have been retained by the Massachusetts Department of Corrections as a consultant on the treatment of transgender inmates since 2007.

8. In 2019, I was qualified as an expert and testified concerning the diagnosis, understanding, developmental paths and outcomes, and therapeutic treatment of transgenderism and gender dysphoria, particularly as it relates to children, in the matter of *In the Interest of J.A.D.Y. and J.U.D.Y.*, Case No. DF-15-09887-S, 255th Judicial District, Dallas County, TX (the "*Younger* litigation"). I have provided expert testimony in other litigation as listed in my curriculum vitae. In 2019, I provided written expert testimony in the landmark case in the United Kingdom; *Bell v. The Tavistock and Portman NHS Foundation Trust*.

9. I am regularly requested to speak on the topic of gender dysphoria and have given countless presentations to academic conferences and Departments of Psychiatry around the country. On May 24, 2022 I organized and co-presented a symposium on the management of adolescent-onset transgender identity: Is it time to question "best practices" at American Psychiatric Association's Annual Meeting.

10. A fuller review of my professional experience, publications, and awards is provided in my curriculum vitae, a copy of which is attached hereto as Exhibit A.

11. I am being compensated for my time spent in connection with this case at a rate of $400.00 per hour for consultation and $500.00 per hour for time spent testifying.

## Summary

12. I have reviewed the "Declaration and Expert Report of Melissa A. Cyperski, PhD," dated April 15, 2022. In that declaration Dr. Cyperski makes a variety of statements about gender dysphoria as a serious medical condition, its interventions involving social transition of children and hormone administration for pre- and early adolescents,

other approaches to the therapy for gender dysphoria ("so-labelled conversion therapy") which I believe to be fashionable beliefs held by a large numbers of "experts" following outdated WPATH standards, and justified by institutional endorsements. The basic problem is that these beliefs are unsupported by scientific evidence. I note with some concern that Dr. Cyperski makes a number of sweeping assertions but cites almost no peer-reviewed articles or studies that support her opinions.

13. Based on her declaration, her CV, and her 4 years of experience working at VPATH, her relevant practice is focused on children, adolescents, and their families. It does not appear that she has had substantial experience in working with adults or older young adults who are living in a transgender identity, or who suffer from the distress of ongoing gender dysphoria after medical interventions. She makes no mention of the known substance abuse, psychiatric symptoms, medical problems, and shortened life spans of adult trans communities. She appears to favor instituting affirmative unquestioning social, medical, and ultimately surgical support (note she refers to "chest surgery" rather than bilateral mastectomies) but does not mention the numerous cases

that perhaps give the multidisciplinary team at VPATH great concern (hopefully, at least). These would include those on the autism spectrum, those in foster care, the adopted, the traumatized, those with poor mental health and those with disrupted family bonds.  Moreover, the wider lifecycle view that derives from experience with these adults (and familiarity with the literature concerning them) provides an important cautionary perspective. The psychiatrist or psychologist treating a trans child or adolescent, of course, seeks to make the young patient happier, but the overriding consideration is the creation of a happy, highly functional, mentally healthy person for the next 50 to 70 years of life. I refer to treatment that keeps this goal in view as the "life course" perspective.

14. Like myself, Dr. Cyperski works as an educator of mental health professionals in training, a laudatory endeavor. The issue, however, is what is communicated during such processes.  Is it "how to take care of trans-identified children and adolescents" or is it "understanding the controversies, clinical and political, that surround the treatment of this group" or is it "what does science know about the

outcome of various treatment interventions?" To the extent that Dr. Cyperski believes that the **only** way to avoid harm is affirmative care, she is also likely to have other questionable assumptions that lack firm scientific foundation. Dr. Cyperski's use of "unethical" seems to include that which she does not agree with.  Here is a list of other assumptions that many who are certain that affirmative care is best share:

a. A trans identity is immutable;
b. Trans identities are primarily caused by biological forces;
c. Gender identity and orientation are distinct stable dimensions of identity;
d. Affirmative care lastingly improves mental health and social function;
e. Affirmative care reduces the rates of suicidal ideation and suicide;
f. Young teens can give informed consent for hormones because they know best what will make them happy now and, in the future;
g. De-transition of affirmed youth is rare;

h. Associated psychopathology during and after affirmative care is primarily due to minority stress;

i. There are no ethical concerns in affirmative care of children, these only exist with non-affirmative care.

These assertions are inaccurate or unsupported, for reasons that I explain in this Declaration. I will provide citations to published, peer-reviewed articles that inform my judgments.

15. A summary of the key points that I explain in this report is as follows:

a. Sex as defined by biology and reproductive function is clear, binary, and cannot be changed. While hormonal and surgical procedures may enable some individuals to "pass" as the opposite gender during some or all of their lives, such procedures carry with them physical, psychological, and social risks, and no procedures can enable an individual to perform the reproductive role of the opposite sex. (Section II.A.)

b. The diagnosis of "gender dysphoria" encompasses a diverse array of conditions, with widely differing pathways and characteristics depending on age of onset, biological sex, mental health, intelligence, motivations for gender transition, socioeconomic status, country of origin, etc. Data from one population (e.g., adults) cannot be assumed to be applicable to others (e.g., children). (Section II.B.)

c. Among practitioners in the field, there are currently widely varying views concerning both the causes of and appropriate therapeutic response to gender dysphoria in children or adolescents. There are no generally accepted "standards of care" (including WPATH's Standards of Care) and existing studies do not provide a basis for a scientific conclusion as to which therapeutic response results in the best long-term outcomes for affected individuals. (Section III.)

d. Transgender identity is not biologically based. Rather, gender dysphoria is a psychiatric condition that cannot be identified by any biological test or measurement. (Sections IV.A, IV.B.). It is not a medical disorder even though advocates treat it with medications and surgery.

e. Disorders of sexual development ("DSDs") are biological phenomena. It is an error to conflate and/or scientifically link DSDs with incidents of gender dysphoria. (Sections IV.C, IV.D.)

f. The large majority of children who are diagnosed with gender dysphoria "desist"—that is, their gender dysphoria does not persist—by puberty or adulthood. Desistence is also increasingly observed among teens and young adults who have experienced "rapid onset gender dysphoria" — first manifesting gender dysphoria during or shortly after adolescence. (Section V.A., V.B.)

g. "Social transition" —the active affirmation of transgender identity—in young children is a powerful psychotherapeutic intervention that will substantially reduce the number of children "desisting" from transgender identity. Therefore, the profound implications of "affirmative" treatment—which include taking puberty blockers,  cross-sex hormones, and mastectomies—must be taken into account where social transition is being considered. (Section VI.A,, VI.B.)

h. Administration of puberty blockers is not a benign "pause" of puberty, but rather a powerful medical and psychotherapeutic intervention that almost invariably leads to persistence in a transgender identity and, ultimately, to the administration of cross-sex hormones. (Section VI.C.)

i. The knowledge base concerning the "affirmative" treatment of gender dysphoria available today has very low scientific quality with many long-term implications remaining unknown. (Section VII.A)

j. There are no studies that show that affirmation of transgender identity in young children reduces suicide or suicidal ideation, or improves long-term outcomes, as compared to other therapeutic approaches. Meanwhile, multiple studies show that adult individuals living transgender lives suffer much higher rates of suicidal ideation, completed suicide, and negative physical and mental health conditions than does the general population. This is true before and after transition, hormones, and surgery. (Section VII.B., VII.C.)

k. In light of what is known and not known about the impact of affirmation on the incidence of suicide, suicidal ideation, and other indicators of mental and physical health, it is scientifically baseless, and therefore unethical, to assert that a child or adolescent who express an interest in a transgender identity will kill him- or herself unless adults and peers affirm that child in a transgender identity. (Section VIII.)

l. Hormonal interventions to treat gender dysphoria are experimental in nature and have not been shown to be safe, but rather put an individual at risk of a wide range of long-term and even life-long harms including: physical health risks; sterilization and the associated emotional response; impaired sexual response; surgical complications and life-long after-care; alienation of family and romantic relationships; elevated mental health risks of depression, anxiety, and substance abuse. (Section IX.)

## II. BACKGROUND ON THE FIELD

### A. The biological baseline of the binary sexes

16. Advocates of affirmative care of children of assert that "the terms biological sex and biological male or female are imprecise and should be avoided" or that the term biological sex "can cause confusion." Biological sex is very well defined in all biological sciences including medicine. It is pervasively important in human development throughout the lifecycle.

17. Sex is not merely "assigned at birth" by humans visualizing the genitals of a newborn, nor is it generally imprecise. Rather, it is clear, binary, and determined at conception. The sex of a human individual at its core structures the individual's biological reproductive capabilities—to produce ova and bear children as a mother, or to produce semen and beget children as a father. As physicians know, sex determination occurs at the instant of conception, depending on whether a sperm's X or Y chromosome fertilizes the egg. A publication of the federal government's National Institute of Health accurately summarizes the scientific facts:

> "Sex is a biological classification, encoded in our DNA. Males have XY chromosomes, and females have XX chromosomes. Sex makes us male or female. Every cell in your body has a sex—making up tissues and organs, like your skin, brain, heart, and stomach. Each cell is either male or female depending on whether you are a man or a woman." (NIH Graphic)

18. The binary of biological sex is so fundamental and wide-ranging in its effects on human (and mammal) development and physiology that since 2014 the NIH has required all funded research on

humans or vertebrate animals to include “sex as a biological variable” and give “adequate consideration of both sexes in experiments.” (NIH Policy and Guidelines). In 2021, the Endocrine Society issued a position paper elaborating on the application of the NIH requirement. The Endocrine Society correctly stated that “Sex is a biological concept . . . all mammals have 2 distinct sexes;” that “biological sex is . . . a fundamental source of intraspecific variation in anatomy and physiology;” and that “In mammals, numerous sexual traits (gonads, genitalia, etc.) that typically differ in males and females are tightly linked to each other because one characteristic leads to sex differences in other traits.” (Bhargava 2021.)

19. The Endocrine Society emphasized that “The terms sex and gender should not be used interchangeably,” and noted that even in the case of those “rare” individuals who suffer from some defect such that they “possess a combination of male- and female-typical characteristics, those clusters of traits are sufficient to classify most individuals as either biologically male or female.” They concluded, “Sex is <u>an essential part of vertebrate biology</u>, but gender is a human phenomenon. Sex often

influences gender, but <u>gender cannot influence sex</u>." (Bhargava 2021.) For purposes of this litigation, Dr. Bhargava's statement that gender cannot influence sex is of central importance.

20. As these statements and the NIH requirement suggest, biological sex pervasively influences human anatomy, its development and physiology. This includes, of course, the development of the human brain, in which many sexually dimorphic characteristics have now been identified. In particular, the Endocrine Society and countless other researchers have determined that human brains undergo particular sex-specific developmental stages during puberty. This predictable developmental process is a genetically controlled coordinated endocrine response that begins with pituitary influences leading to increases in circulating sex hormones. (Bhargava 2021 at 225, 229; Blakemore 2020 at 926, 929; NIH 2001.).

21. Humans have viewed themselves in terms of binary sexes since the earliest historical records. Recognizing a concept of "gender identity" as something distinct from sex is a rather recent innovation whose earliest manifestations likely increased (from its rare mention in

various literatures) in the late 1940s. Its usage became common in medicine in the 1980s and subsequently in the larger culture. Definitions of gender have been evolving and remain individual centric and subjective. In a statement on “Gender and Health,” the World Health Organization defines “gender” as “the characteristics of women, men, girls and boys that are socially constructed” and that “var[y] from society to society and can change over time,” and “gender identity” as referring to “a person’s deeply felt, internal and individual experience of gender.” (WHO Gender and Health) As these definitions indicate, a person’s “felt” “experience of gender” is inextricably bound up with and affected by societal gender roles and stereotypes—or, more precisely, by the affected individual’s *perception* of societal gender roles and stereotypes and their personal idiosyncratic meanings. Typically, gendered persons also have subtly different, often idiosyncratic, reactions to societal gender roles and stereotypes without preoccupation with changing their anatomy.

22. Thus, the self-perceived gender of a child begins to develop along with the early stages of identity formation generally, influenced in

part from how others label the infant: “I love you, son (daughter).” This designation occurs thousands of times in the first two years of life when a child begins to show awareness of the two possibilities. As acceptance of the designated gender corresponding to the child’s sex is the outcome in >99% of children everywhere, anomalous gender identity formation begs for understanding.

a. Is it biologically shaped?
b. Is it biologically determined?
c. Is it the product of how the child was privately regarded and treated?
d. Is it a product of the quality of early life caregiver attachments?
e. Does it stem from trauma-based rejection of maleness or femaleness, and if so, flowing from what trauma?
f. Does it derive from a tense, chaotic interpersonal parental relationship without physical or sexual abuse?

g. Is it a symptom of another, as of yet unrevealed, emotional disturbance or neuropsychiatric condition (autism)?

h. For adolescent onset gender dysphoria, has the immersion in trans social media Internet sites fostered the early pubertal child's new concept of belong to the transgender community

The answers to these relevant questions are not scientifically known but are not likely to be the same for every trans-identified child, adolescent, or adult. All therapy approaches need to keep these eight questions in mind for every trans-identified patients.

23. Under the influence of hormones secreted by the testes or ovaries, numerous additional sex-specific differences between male and female bodies continuously develop postnatally, culminating in the dramatic maturation of the primary and secondary sex characteristics with puberty. These include differences in hormone levels, height, weight, bone mass, shape, musculature, body fat levels and distribution, and hair patterns, as well as physiological differences such as

menstruation and ejaculation. These are genetically programmed biological consequences of sex—the actual meaning of sex over time. Among the consequences of sex is the consolidation of gender identity during and after puberty.

24. Despite the increasing ability of hormones and various surgical procedures to reconfigure some male bodies to visually pass as female, or vice versa, the biology of the person remains as defined by his (XY) or her (XX) chromosomes, including cellular, anatomic, and physiologic characteristics and the particular disease vulnerabilities associated with that chromosomally defined sex. For instance, the XX (genetically female) individual who takes testosterone to stimulate certain male secondary sex characteristics will nevertheless remain unable to produce sperm and father children. It is certainly true, hormone therapy and grooming-clothing changes can significantly change a person's physical appearance. But in critical respects this change can only be "skin deep." Contrary to assertions and hopes that medicine and society can fulfill the aspiration of the trans individual to become "a complete man" or "a complete woman," this is not

biologically attainable. (Levine 2018 at 6; Levine 2016 at 238.) It is possible for some adolescents and adults to pass unnoticed—that is, to be perceived by most individuals as a member of the gender that they aspire to be—but with limitations, costs, and risks, as I detail later.

### B. Definition and diagnosis of gender dysphoria

25. Specialists have used a variety of terms over time, with somewhat shifting definitions, to identify and speak about a distressing incongruence between an individual's genetically determined sex and the gender with which they identify or to which they aspire. Today's American Psychiatric Association *Diagnostic and Statistical Manual of Mental Disorders* ("DSM-5") employs the term Gender Dysphoria and defines it with separate sets of criteria for adolescents and adults on the one hand, and children on the other.

26. There are at least five distinct pathways to gender dysphoria: early childhood onset; onset near or after puberty with no prior cross-gender patterns; onset after defining oneself as gay for several or more years and participating in a homosexual lifestyle; adult onset after years of heterosexual transvestism; and onset in later adulthood with few or no

prior indications of cross-gender tendencies or identity. (Levine 2021) The early childhood onset pathway and the more recently observed onset around puberty pathway are most relevant to this matter.

27. Gender dysphoria has very different characteristics depending on age and sex at onset. Young children who are living a transgender identity commonly suffer materially fewer symptoms of concurrent mental distress than do older patients. (Zucker 2018.) The developmental and mental health patterns for each of these groups are sufficiently different that data developed in connection with one of these populations cannot be assumed to be applicable to another.

28. The criteria used in DSM-5 to identify Gender Dysphoria include a number of signs of discomfort with one’s sex and vary somewhat depending on the age of the patient, but in all cases require “clinically significant distress or impairment in . . . important areas of functioning” such as social, school, or occupational settings. The symptoms must persist for at least six months.

29. Children who conclude that they are transgender are often unaware of a vast array of adaptive possibilities for how to live life as a

man or a woman—possibilities that become increasingly apparent over time to both males and females. A boy or a girl who claims or expresses interest in pursuing a transgender identity often does so based on stereotypical notions of femaleness and maleness that reflect constrictive notions of what men and women can be. (Levine 2017 at 7.) A young child's—or even an adolescent's—understanding of this topic is quite limited. Nor can they grasp what it may mean for their future to be sterile. These children and adolescents consider themselves to be relatively unique; they do not realize that discomfort with the body and perceived social role is neither rare nor new to civilization. What is new is that such discomfort is thought to indicate that they must be a trans person.

### C. Impact of gender dysphoria on minority and vulnerable groups

30. Given that a diagnosis of gender dysphoria is now frequently putting even young children on a pathway that leads to irreversible physical changes and sterilization by young adulthood, it should be of serious concern to all practitioners that minority and vulnerable groups

are receiving this diagnosis at disproportionately high rates. These include: children of color (Rider 2018), children with mental developmental disabilities (Shumer 2015), children on the autistic spectrum (at a rate more than 7x the general population) (Shumer 2016; van der Miesen 2018), children with ADHD (Becerra-Culqui 2018), children residing in foster care homes, adopted children (at a rate more than 3x the general population) (Shumer 2017), victims of childhood sexual or physical abuse or other "adverse childhood events" (Thoma 2021; Newcomb 2020; Kozlowska 2021), children with a prior history of psychiatric illness (Edwards-Leeper 2017; Kaltiala-Heino 2015; Littman 2018), and more recently adolescent girls (in a large recent study, at a rate more than 2x that of boys) (Rider 2018 at 4).

### D. Three competing conceptual models of gender dysphoria and transgender identity

31. Discussions about appropriate responses by mental health professionals ("MHPs") to actual or sub-threshold gender dysphoria are complicated by the fact that various speakers and advocates (or a single speaker at different times) view transgenderism through at least three

very different paradigms, often without being aware of, or at least without acknowledging, the distinctions.

32. Gender dysphoria is conceptualized and described by some professionals and laypersons as though it were a serious, physical **medical illness** that causes suffering, comparable to diseases that are curable before it spreads, such as, melanoma or sepsis. Within this paradigm, whatever is causing distress associated with gender dysphoria—whether secondary sex characteristics such as facial hair, nose and jaw shape, presence or absence of breasts, or the primary anatomical sex organs of testes, ovaries, penis, or vagina—should be removed to alleviate the illness. The promise of these interventions is the cure of the gender dysphoria.

33. Dr. Cyperski appears to endorse this perspective, asserting that gender dysphoria is a "medical condition." It should be noted, however, that gender dysphoria is a psychiatric, not a medical, diagnosis. Since its inception in DSM-III in 1983, it has always been specified in the psychiatric DSM manuals and has not been specified in medical diagnostic manuals. Notably, gender dysphoria is the only

psychiatric condition to be treated by surgery, even though no endocrine or surgical intervention package corrects any identified biological abnormality. (Levine 2016 at 240.)

34. Gender dysphoria is alternatively **conceptualized in developmental terms**, as an adaptation to a psychological problem that may have been first manifested as a failure to establish a comfortable conventional sense of self in early childhood. This paradigm starts from the premise that all human lives are influenced by past processes and events. Trans' lives are not exceptions to this axiom. (Levine 2016 at 238.) MHPs who think of gender dysphoria through this paradigm may work both to identify and address causes of the basic problem of the deeply uncomfortable self or a sense of self impaired by later adversity or abuse. The purpose is to ameliorate suffering when the underlying problem cannot be solved. MHPs first work with the patient and (ideally) family to learn about the events and processes that may have led to the trans person repudiating the gender associated with his sex. The developmental paradigm is mindful of temperamental, parental bonding, psychological, sexual, and physical trauma influences, and the

fact that young children work out their psychological issues through fantasy and play and adolescents work out their issues by adopting various interests and identity labels. It is basic to the understanding of adolescent development from puberty to early adulthood that the three elements of sexual identity—gender identity, orientation, and intention—are being privately considered by the teenager and may have changeable forms before they become relatively stable.

35. There is evidence among adolescents that peer social influences through "friend groups" (Littman 2019) or through the internet can increase the incidence of gender dysphoria or claims of transgender identity. Responsible MHPs will want to probe these potential influences to better understand what is truly deeply tied to the psychology of the patient, and what may instead be being "tried on" by the youth as part of the adolescent process of self-exploration and self-definition.

36. In addition, the developmental paradigm recognizes that, with the important exception of genetic sex, essentially all aspects of an individual's identity evolve—often markedly—across the individual's

lifetime. This includes gender. Some advocates assert that a transgender identity is biologically caused, fixed from early life, and eternally present in an unchanging manner. However, this assertion is not supported by science.[1]

37. The third paradigm through which gender dysphoria is alternatively conceptualized is from **a sexual minority rights perspective**. Under this paradigm, any response other than medical and societal affirmation and implementation of a patient's claim to "be" the opposite gender is a violation of the individual's civil right to self-expression. Any effort to ask "why" questions about the patient's condition, or to address underlying influences in this patient, is viewed as a violation of autonomy and civil rights. In the last few years, this paradigm has been successful in influencing public policy and the education of pediatricians, endocrinologists, and many mental health professionals. Obviously, however, this is not a medical or psychiatric perspective. Unfortunately, it appears to be the most powerful

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[1] Even the advocacy organization The Human Rights Campaign asserts that a person can have "a fluid or unfixed gender identity." https://www.hrc.org/resources/glossary-of-terms.

perspective that exists in the public, non-scientific debate. Courts must separate arguments that are based on science from those bases on beliefs.

### E. Four Competing Models of Therapy

38. Few would disagree that the human psyche is complex. Few would disagree that children's and adolescents' developmental pathways typically have surprising twists and turns. The complexity and unpredictability of the childhood and adolescent development equally applies to trans-identifying youth. Because of past difficulties of running placebo-controlled clinical trials in the transgender treatment arena, substantial disagreements among professionals about the causes of trans identities and their ideal treatments exist. These current disagreements might have been minimized if trans treated persons were carefully followed up to determine long-term outcomes. They have not been. When we add to this to the very different current paradigms for understanding transgender phenomena, it is not scientifically surprising that disagreements are sharply drawn. It is with this in mind that I

summarize below the leading approaches. I also offer certain observations and opinions concerning them.

**The "watchful waiting" therapy models**

39. Below I review the uniform finding of eleven follow-up studies that the large majority of children who present with gender dysphoria will desist from desiring a transgender identity by adulthood left untreated by social transition approaches.

40. When a pre-adolescent child presents with gender dysphoria, a "watchful waiting" approach seeks to allow for the fluid nature of gender identity in children to naturally evolve—that is, take its course from forces within and surrounding the child. Watchful waiting has two versions:

> -Model One: Treating any other psychological co-morbidities—that is, other mental illnesses as defined by DSM-5 (separation anxiety disorder, attention deficit hyperactivity disorder, autism spectrum disorder, obsessive compulsive disorder, etc.), or subthreshold for diagnosis but behavioral problems that the child may exhibit (school

avoidance, bedwetting, inability to make friends, aggression/defiance) without a focus on gender

-Model Two: No treatment at all for anything but a regular follow-up appointment. This might be labeled a "hands off" approach.

### **The psychotherapy model:** Alleviate distress by identifying and addressing causes (Model Three)

41. One of the foundational principles of psychotherapy has long been to work with a patient to identify the causes of observed psychological distress and then to address those causes as a means of alleviating the distress. The National Institute of Mental Health has promulgated the idea that 75% of adult psychopathology has its origins in childhood experience. Many experienced practitioners in the field of gender dysphoria, including myself, have believed that it makes sense to employ these long-standing tools of psychotherapy for patients suffering gender dysphoria, asking the question as to what factors in the patient's life are the determinants of the patient's repudiation of his or her sex. (Levine 2017 at 8; Levine 2021.) I and others have reported success in

alleviating distress in this way for at least some patients, whether the patient's sense of discomfort or incongruence with his or her sex entirely disappeared or not. Relieving accompanying psychological co-morbidities leaves the patient freer to consider the pros and cons of transition as he or she matures.

42. Among other things, the psychotherapist who is applying traditional methods of psychotherapy may help—for example—the male patient appreciates the wide range of masculine emotional and behavioral patterns as he grows older. He may discuss with his patient, for example, that one does not have to become a "woman" in order to be kind, compassionate, caring, noncompetitive, to love the arts, and to be devoted to others' feelings and needs. (Levine 2017 at 7.) Many biologically male trans individuals, from childhood to older ages, speak of their perceptions of femaleness as enabling them to discuss their feelings openly, whereas they perceive boys and men to be constrained from emotional expression within the family and larger culture, and to be aggressive. Men, of course, can be emotionally expressive, just as

they can wear pink. Converse examples can be given for girls and women. These types of ideas regularly arise during psychotherapies.

43. As I note above, many gender-nonconforming children and adolescents in recent years derive from minority and vulnerable groups who have reasons to feel isolated and have an uncomfortable sense of self. A trans identity may be a hopeful attempt to redefine the self in a manner that increases their comfort and decreases their anxiety. The clinician who uses traditional methods of psychotherapy may not focus on their gender identity, but instead work to help them to address the actual sources of their discomfort. Success in this effort may remove or reduce the desire for a redefined identity. This often involves a focus on disruptions in their attachment to parents in vulnerable children, for instance, those in the foster care system.

44. Because "watchful waiting" can include treatment of accompanying psychological co-morbidities, and the psychotherapist who hopes to relieve gender dysphoria may focus on potentially causal sources of psychological distress rather than on the gender dysphoria

itself, there is no sharp line between “watchful waiting” and the psychotherapy model in the case of prepubescent children.

45. To my knowledge, there is no evidence beyond anecdotal reports that psychotherapy can enable a return to male identification for genetically male boys, adolescents, and men, or return to female identification for genetically female girls, adolescents, and women. On the other hand, anecdotal evidence of such outcomes does exist; I and other clinicians have witnessed reinvestment in the patient’s biological sex in some individual patients who are undergoing psychotherapy. The Internet contains many such reports, and I have published a paper on a patient who sought my therapeutic assistance to reclaim his male gender identity after 30 years living as a woman and is in fact living as a man today. (Levine 2019 at 1.) I have seen children desist even before puberty in response to thoughtful parental interactions and a few meetings of the child with a therapist. There are now a series of articles and at least one major book on the psychological treatment of adolescents. ( D’Angelo 2021 at 7-16; Evans 2021.)

**The affirmation therapy model** (Model Four)

46. While it is widely agreed that the therapist should not immediately directly challenge a claimed transgender identity in a child, some advocates and practitioners go much further, and promote and recommend that any expression of transgender identity should be immediately accepted as decisive, and thoroughly affirmed by means of consistent use of clothing, toys, pronouns, etc., associated with transgender identity. They argue that the child should be comprehensively re-socialized in grade school in their aspired to gender. As I understand it, this is asserted as a reason why male students who assert a female gender identity must be permitted to compete in girls' or women's athletic events and female students who assert a male gender identity must be permitted to participate in scholastically organized male athletic teams. These advocates treat any question about the causes of the child's transgender identification as inappropriate. They may not recognize the child's ambivalence. They assume that observed psychological co-morbidities in the children or their families are unrelated or will get better with transition, and need not be addressed by

the MHP who is providing supportive guidance concerning the child's gender identity. These advocates also do not consider the impact on teammates that may vary from acceptance through neutrality through objection. Each attitude on the spectrum having numerous evolving determinants.

47. Some advocates, indeed, assert that unquestioning affirmation of any claim of transgender identity in children is essential, and that the child will otherwise face a high risk of psychological damage. Dr. Cyperski correctly points out the advantages of participation in organized sports for adolescents and wants these potential benefits for her patients. She emphasizes the negative impact of playing on sports teams consonant with her patients' anatomic and physiologic sex such as stigmatization, increasing distress of gender dysphoria, and disrespecting their privacy but does not mention any potential harms. These might include increasing gender dysphoria because of the physiological differences that become apparent, having to dress in separate facilities, exposure to hostility and ridicule, and becoming the focus of community concern. Implied, however, in Dr.

Cyperski's account is the potential to harm the already vulnerable anxious young trans-identified person. As Dr. Cyperski is aware that gender dysphoria is often associated with ongoing social isolation, anxiety, depression, and suicidality, she appears to see athletic participation only as a positive process. If she is wrong in one or more of these individual circumstances or the child does not have the courage to join a team, more harm than good may eventuate.

48. Dr. Cyperski also asserts that fully supported social transition is the "only treatment for prepubertal children." This is not correct. This may be the only treatment that Dr. Cyperski considers, but my own conversations and contacts lead me to believe that Dr. James Cantor was correct when he wrote that "almost all clinics and professional associations in the world" do not use "gender affirmation" for prepubescent children and instead "delay any transitions after the onset of puberty." (Cantor 2019 at 1.)

I do not know what proportion of practitioners are using which model. However, in my opinion, in the case of young children, prompt and thorough affirmation of a transgender identity disregards the principles of child development and family dynamics and is not supported by science. Instead of science, this approach is currently being reinforced by an echo-chamber of approval from other like-minded child-oriented professionals who do not sufficiently consider the known negative medical and psychiatric outcomes of trans adults. Rather than recommend social transition in grade school, the MHP must focus attention on the child's underlying internal and familial issues. Ongoing relationships between the MHP and the parents, and the MHP and the child, are vital to help the parents, child, other family members, and the MHP to understand over time the issues that need to be dealt with over time by each of them.

Likewise, since the child's sense of gender develops in interaction with his parents and their own gender roles and relationships, the responsible MHP will almost certainly need to delve into family and marital dynamics.

## III. THERE IS NO CONSENSUS OR AGREED "STANDARD OF CARE" CONCERNING THERAPEUTIC APPROACHES TO CHILD OR ADOLESCENT GENDER DYSPHORIA.

49. As I review in separate sections later, there is far too little firm clinical evidence in this field to permit any evidence-based standard of care. Given the lack of scientific evidence, it is neither surprising nor improper that—as I detailed in Section II—there is a diversity of views among practitioners as to as to the best therapeutic response for the child, adolescent, or young adult who suffers from gender dysphoria. Dr. Cyperski is unwittingly confusing therapeutic precedent among those who educated her and agree with her views, armed with ideas promulgated by WPATH and a subcommittee of the American Academy of Pediatrics, with careful scientific primary documentation of her concepts. She presumes that her views have been scientifically established even though much has been published highlighting the lack of supportive definitive evidence.

50. Reviewing the state of opinion and practice in 2021, the Royal Australian and New Zealand College of Psychiatrists observed that "There are polarised views and mixed evidence regarding treatment

options for people presenting with gender identity concerns, especially children and young people." Similarly, a few years earlier prominent Dutch researchers noted: "[T]here is currently no general consensus about the best approach to dealing with the (uncertain) future development of children with GD, and making decisions that may influence the function and/or development of the child — such as social transition." (Ristori 2016 at 18.)[2] In this Section, I comment on some of the more important areas of disagreement within the field.

### A. Experts and organizations disagree as to whether "distress" is a necessary element for diagnoses that justifies treatment for gender identity issues.

51. As outlined in Section II.B above, "clinically significant distress" is one of the criteria used in DSM-5 to identify gender dysphoria. This indicates a heightened level of distress that rises beyond a threshold level of social awkwardness or discomfort with the changing body. It is known that many trans-identified youth with incongruence between their sexed bodies and their gender identity choose not to take

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[2] *See also* Zucker 2019 which questions the merit of social transition as a first-line treatment.

hormones; their incongruence is quite tolerable as they further clarify their sexual identity elements. This population raises the questions of what distress is being measured when DSM-5 criteria are met and what else might be done about it?

52. I note that there is no “clinically significant distress” requirement in World Health Organization’s International Classification of Diseases (ICD-11) criteria for gender incongruence, which rather indicates “a marked and persistent incongruence between an individual´s experienced gender and the assigned sex.” (World Health Organization 2019).

Therefore, even between these two committee-based authorities, there is a significant disagreement as to what constitutes a gender condition justifying life-changing interventions. To my knowledge, some American gender clinics and practitioners are essentially operating under the ICD-11 criteria rather than the APA’s DSM-5 criteria, prescribing transition for children, hormonal interventions for slightly older children, and different hormones for adolescents who assert a desire for a transgender identity, whether or not they are exhibiting "clinically significant distress." Others adhere to the DSM-5 diagnostic standard.

53. I will add that even from within one "school of thought," such as embodied by Dr. Cyperski, it is not responsible to make a single, categorical statement about the proper treatment of children or adolescents presenting with gender dysphoria or other gender-related issues. There is no single pathway to the development of a trans identity and no reasonably uniform short- or long-term outcome of medically treating it. As individuals grow physically, mature psychologically, and experience or fail to experience satisfying romantic relationships, their life course depends on their differing psychological, social, familial, and life experiences. There should be no trust in assertions that trans-identified youth must be treated in a particular manner to avoid harm for two reasons: first, there is no systematic data on the nature of, and the rate of harms of either affirmative treatment, no treatment, or psychological only treatment. Second, as in other youthful psychiatric and other challenges, outcomes vary.

### B. Opinions and practices vary widely about the utilization of social transition for children and adolescents.

54. Dr. Cyperski notes that she is a member of the World Professional Association for Transgender Health (WPATH), invokes a guidance document that that organization has chosen to publish under the title of a "standard of care," and asserts that the WPATH Standards of Care are "widely accepted." Below, I will provide some explanation of WPATH and its "Standards of Care," which are not the product of a strictly scientific organization, and are by no means accepted by all or even most practitioners as setting out best practices.

Here, however, I will note that WPATH does not take a position concerning whether or when social transition may be appropriate for pre-pubertal children. Instead, the WPATH "Standards of Care" states that the question of social transition for children is a "controversial issue" and calls for mental health professionals to support families in what it describes as "difficult decisions" concerning social transition.

Dr. Erica Anderson is a prominent practitioner in this area who identifies as a transgender woman, who was the first transgender president of USPATH, and who is a former board member of WPATH. Dr. Anderson recently resigned from those organizations and has condemned automatic approval of transition upon the request of a child or adolescent, noting that "adolescents . . . are notoriously susceptible to peer influence," that transition "doesn't cure depression, doesn't cure anxiety disorders, doesn't cure autism-spectrum disorder, doesn't cure ADHD," and instead that "a comprehensive biopsychosocial evaluation" should proceed allowing a child to transition. (Anderson 2022.) And as I have explained previously, my own view based on 50 years of experience in this area favors strong caution before approving life-altering interventions such as social transition, puberty blockers, or cross-sex hormones.

### C. The WPATH "Standards of Care" is not an impartial or evidence-based document.

Because WPATH is frequently cited by advocates of social, hormonal, and surgical transition, I provide some context concerning that private organization and its "Standards of Care."

55. I was a member of the Harry Benjamin International Gender Dysphoria Association from 1974 until 2001. From 1997 through 1998, I served as the Chairman of the eight-person International Standards of Care Committee that issued the fifth version of the Standards of Care. I resigned my membership in 2002 due to my regretful conclusion that the organization and its recommendations had become dominated by politics and ideology, rather than by scientific process, as it was years earlier. In approximately 2007, the Henry Benjamin International Gender Dysphoria Association changed its name to the World Professional Association for Transgender Health.

WPATH is a voluntary membership organization. Since at least 2002, attendance at its biennial meetings has been open to trans individuals who are not licensed professionals. While this ensures taking patients' needs into consideration, it limits the ability for honest and scientific debate, and means that WPATH can no longer be considered a purely professional organization.

WPATH takes a decided view on issues as to which there is a wide range of opinion among professionals. WPATH explicitly views itself as not merely a scientific organization, but also as an advocacy organization. (Levine 2016 at 240.) WPATH is supportive to those who want sex reassignment surgery ("SRS"). Skepticism as to the benefits of SRS to patients, and strong alternate views, are not well tolerated in discussions within the organization or their educational outreach programs. Such views have been known to be shouted down and effectively silenced by the large numbers of non-professional adults who attend the organization's biennial meetings. Two groups of individuals that I regularly work with have attended recent and separate WPATH continuing education sessions. There, questions about alternative approaches were quickly dismissed with "There are none. This is how it is done." Such a response does not accurately reflect what is known, what is unknown, and the diversity of clinical approaches in this complex field.

The Standards of Care ("SOC") document is the product of an effort to be balanced, but it is not politically neutral. WPATH aspires to be both a scientific organization and an advocacy group for the transgendered. These aspirations sometimes conflict. The limitations of the Standards of Care, however, are not primarily political. They are caused by the lack of rigorous research in the field, which allows room for passionate convictions on how to care for the transgendered. And, of course, once individuals have socially, medically, and surgically transitioned, WPATH members and the trans people themselves at the meetings are committed to supporting others in their transitions. Not only have some trans participants been distrustful or hostile to those who question the wisdom of these interventions, their presence makes it difficult for professionals to raise their concerns. Vocal trans rights advocates have a worrisome track record of attacking those who have alternative views. (Dreger/Siebold 2015 book citation - Galileo's Middle Finger.)

56. In recent years, WPATH has fully adopted some mix of the medical and civil rights paradigms. Its seventh version downgraded the role of counseling or psychotherapy as a requirement for these life-changing processes. WPATH no longer considers preoperative psychotherapy to be a requirement. It is important to WPATH that the person has gender dysphoria; the pathway to the development of this

state is not. (Levine 2016 at 240.) The trans person is assumed to have thoughtfully considered his or her options before seeking hormones, for instance.

Most psychiatrists and psychologists who treat patients suffering sufficiently severe distress from gender dysphoria to seek inpatient psychiatric care are not members of WPATH. Many psychiatrists, psychologists, and pediatricians who treat some patients suffering gender dysphoria on an outpatient basis are not members of WPATH. WPATH represents a self-selected subset of the profession along with its many non-professional members; it does not capture the clinical experiences of others. WPATH claims to speak for the medical profession; however, it does not welcome skepticism and therefore, deviates from the philosophical core of medical science. There are pediatricians, psychiatrists, endocrinologists, and surgeons who object strongly, on professional grounds, to transitioning children and providing affirmation in a transgender identity as the first treatment option. WPATH does not speak for all of the medical profession.

In 2010 the WPATH Board of Directors issued a statement advocating that incongruence between sex and felt gender identity should cease to be identified in the DSM as a pathology.[3] This position was debated but not adopted by the (much larger) American Psychiatric Association, which maintained the definitions and diagnoses of gender dysphoria as a pathology in the DSM-5 manual issued in 2013.

In my experience some current members of WPATH have little ongoing experience with the mentally ill, and many trans care facilities are staffed by MHPs who are not deeply experienced with recognizing and treating frequently associated psychiatric and sexual co-morbidities. Further, being a mental health professional, per se, does not guarantee experience and skill in recognizing and effectively intervening in serious or subtle patterns. Because the 7th version of the WPATH SOC deleted the requirement for therapy, trans care facilities that consider these Standards sufficient are permitting patients to be

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[3] WPATH *De-Psychopathologisation Statement* (May 26, 2010), available at wpath.org/policies (last accessed January 21, 2020).

counseled to transition by means of social presentation, hormones, and surgery by individuals with masters rather than medical degrees.

### D. Opinions and practices differ widely with respect to the proper role of psychological counseling before, as part of, or after a diagnosis of gender dysphoria.

57. In Version 7 of its Standards of Care, released in 2012, WPATH downgraded the role of counseling or psychotherapy, and the organization no longer sees psychotherapy without transition and hormonal interventions as a potential path to eliminate gender dysphoria by enabling a patient to return to or achieve comfort with the gender identity aligned with his or her biology.

Around the world, many prominent voices and practitioners disagree. For example, renowned gender therapists Dr. Laura Edwards-Leeper and Dr. Erica Anderson (who, as mentioned above, identifies as a transgender woman) have recently spoken out arguing that children and adolescents are being subjected to puberty blockers and hormonal intervention far too quickly, when careful and extended psychotherapy and investigation for potential causes of feelings of dysphoria (such as prior sexual abuse) should be the first port of call and might resolve the dysphoria. (Edwards-Leeper and Anderson 2021; Anderson 2022.)

In a recently published position statement on gender dysphoria, the Royal Australian and New Zealand College of Psychiatrists emphasized the critical nature of mental health treatment for gender dysphoric minors, stressing "the importance of the psychiatrist's role to undertake thorough assessment and evidence-based treatment ideally as part of a multidisciplinary team, especially highlighting co-existing issues which may need addressing and treating." The Royal College also emphasized the importance of assessing the "psychological state and context in which Gender Dysphoria has arisen," before any treatment decisions are made.

Dr. Paul Hruz of the University of Washington St. Louis Medical School has noted, "The WPATH has rejected psychological counseling as a viable means to address sex–gender discordance with the claim that this approach has been proven to be unsuccessful and is harmful (Coleman et al. 2012). Yet the evidence cited to support this assertion, mostly from case reports published over forty years ago, includes data showing patients who benefited from this approach (Cohen-Kettenis and Kuiper 1984).” (Hruz 2020.)

### E. Opinions and practices vary widely with respect to the administration of puberty blockers and cross-sex hormones.

58. There is likewise no broadly accepted standard of care with respect to use of puberty blockers. The WPATH Standard of Care explicitly recognizes the lack of any consensus on this important point, stating: “Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment—starting with GnRH analogues to suppress puberty in the first Tanner stages—differs among countries and centers. Not all clinics offer puberty suppression. . . The percentages of treated adolescents are likely influenced by the organization of health care, insurance aspects, cultural differences, opinions of health professionals, and diagnostic procedures offered in different settings.”

The use of puberty blockers as a therapeutic intervention for gender dysphoria is often justified by reference to the seminal work of a respected Dutch research team that developed a protocol that administered puberty blockers to children no younger than age 14. However, it is well known that many clinics in North America now administer puberty blockers to children at much younger ages than the "Dutch Protocol" allows. (Zucker 2019.) The Dutch protocol only treated children with these characteristics: a stable cross-gender identity from early childhood; whose dysphoria worsened with the onset of puberty; but were otherwise psychologically healthy; and had healthy families; who agreed to individual and family counselling throughout the protocol. But the experience and results of the Dutch model is being used as a justification for giving puberty blockers to children who differ considerably from these criteria. Its authors have also recently noted this fact. (de Vries 2020.)

As it relates to the administration of cross-sex hormones, Zucker notes that "it is well known" that clinicians are administering cross-sex hormones, and approving surgery, at ages lower than the minimum age thresholds set by the respected "Dutch Protocol." (Zucker 2019.)

Similarly, at least one prominent clinic—that of Dr. Safer at Columbia's Mt. Sinai Medical Center—is quite openly admitting patients for even *surgical* transition who are not eligible under the criteria set out in WPATH's standard of care. A recent study published by Dr. Safer and colleagues revealed that of a sample of 139 individuals, 45% were eligible for surgery "immediately" under the center's own criteria, while only 15% were eligible under WPATH's criteria. That is, *three times* as many patients immediately qualified for surgery under the center's loose standards than would have qualified under WPATH criteria. (Lichenstein 2020.)

59. Internationally, there has been a recent marked trend *against* use of puberty blockers, as a result of extensive evidence reviews by national medical bodies, which I discuss later. The main gender clinic in Sweden has declared that it will no longer authorize use of puberty blockers for minors below the age of 16. Finland has similarly reversed its course; issuing new guidelines that allow puberty blockers only on a case-by-case basis after an extensive psychiatric assessment. A landmark legal challenge against the UK's National Health Service in 2020 by

"detransitioner" Keira Bell led to the suspension of the use of puberty blockers and new procedures to ensure better psychological care, as well as prompting a thorough evidence review by the National Institute for Health and Care Excellence (NICE).[4] France changed its policy about puberty blockers and cross-sex hormones in 2022; urging psychotherapy to be the initial approach.

In this country, some voices in the field are now publicly arguing that *no* comprehensive mental health assessment at all should be required before putting teens on puberty blockers or cross-sex hormones (New York Times 2022), while Dr. Anderson and Dr. Edwards-Leeper argue that U.S. practitioners are already moving too quickly to hormonal interventions. (Edwards-Leeper and Anderson 2021; Anderson 2022.) It is evident that opinions and practices are all over the map.

It is true that a committee of the American Academy of Pediatricians has issued a statement supporting administration of puberty blockers to children diagnosed with gender dysphoria. It is also true that

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[4] The decision requiring court approval for administration of hormones to any person younger than age 16 was later reversed on procedural grounds by the Court of Appeal and is currently under consideration by the UK Supreme Court.

no other American medical association has endorsed the use of puberty blockers, and that pediatricians are neither endocrinologists nor psychiatrists. Dr. James Cantor published a peer-reviewed paper detailing that the Academy's statement is not evidence-based and misdescribed the few scientific sources it did reference. (Cantor 2019.) It has been well noted in the field that the AAP has declined invitations to publish any rebuttal to Dr. Cantor's analysis. But this is all part of ongoing debate, simply highlighting the absence of any generally agreed standard of care.

The Endocrine Society's 2017 Practice Guidelines on Treatment of Gender-Dysphoric/Gender-Incongruent Persons (Hembree 2017) is used to justify hormonal treatment even through their document emphasizes the very low and low quality of scientific evidence for their "strong recommendations" for puberty blockers and cross-sex hormones. Their Guidelines themselves expressly state that they are *not* "standards of care." "The guidelines cannot guarantee any specific outcome. This is the meaning of low quality evidence. The guidelines are not intended to dictate the treatment of a particular patient." (Hembree 2017 at 2895 (emphasis added).), nor do the Guidelines claim to be the result of a "rigorous scientific process." Notably, the Guidelines do not make any firm statement that use of puberty blockers for this purpose *is* safe, and the Guidelines go no further than "suggest[ing]" use of puberty blockers—language the Guidelines warn represents only a "weak recommendation." (Hembree 2017 at 3872.) The guidelines are inconsistent within the 32-page document. Several authors have pointed out that not only were the Endocrine Society suggestions regarding use of puberty blockers reached on the basis of "low quality" evidence, but its not-quite claims of 'safety' and 'efficacy' are starkly contradicted by several in-depth evidence reviews. (Laidlaw, 2019; Malone 2021.) I detail these contradictory findings in more detail in Section VII below.

60. While there is too little meaningful clinical data and no consensus concerning best practices or a "standard of care" this area, there are long-standing ethical principles that do or should bind all medical and mental health professionals as they work with, counsel, and prescribe for these individuals.

One of the oldest and most fundamental principles guiding medical and psychological care—part of the Hippocratic Oath—is that the physician must "do no harm." This states an ethical responsibility that cannot be delegated to the patient. Physicians themselves must weigh the risks of treatment against the harm of not treating. If the risks of treatment outweigh the benefits, ethics prohibit the treatment.

## IV. TRANSGENDER IDENTITY IS NOT BIOLOGICALLY BASED.

61. Many advocates of affirmative care assert this belief (Safer). Nonetheless, in an article, Dr. Safer referred to data that he asserted supports the existence of "a fixed, biologic basis for gender identity." (Saraswat 2015 at 199.) Saraswat, however, states that studies attempting to find an association between genetics and transgender identification "have been contradictory," and that "no statistically significant association between particular genes [and transgender identity] has been described." (Saraswat 2015 at 201.) There is no scientific consensus that transgender identity has any biological basis

even though few would assert that biology plays no role in a child's adolescent's, or adult's fate in life.

62. No theory of biological basis has been scientifically validated. At the outset, the attempt to identify a single "typically . . . biological" cause for psychiatric conditions (including gender dysphoria) has been strongly criticized as "out of step with the rest of medicine" and as a lingering "ghost" of an understanding of the nature of psychiatric conditions that is now broadly disproven. (Kendler 2019 at 1088-1089.) Gender dysphoria is defined and diagnosed only as a psychiatric, not a medical, condition.

Similarly, while some have pointed to very small brain scan studies as evidence of a biological basis, no studies of brain structure of individuals identifying as transgender have found any statistically significant correlation between any distinct structure or pattern and transgender identification, after controlling for sexual orientation and exposure to exogenous hormones. (Sarawat 2015 at 201; Frigerio 2021)

Indeed, the Endocrine Society 2017 Guidelines recognizes: "With current knowledge, we cannot predict the psychosexual outcome for any specific child" and "there are currently no criteria to identify the GD/gender-incongruent children to whom this applies. At the present time, clinical experience suggests that persistence of GD/gender incongruence can only be reliably assessed after the first signs of puberty."

In short, no biological test or measurement has been identified that provides any ability to predict which children will exhibit, and which children will persist in, gender dysphoria or a transgender identification. Unless and until such a test is identified, the theory of a biological basis is a hypothesis still searching for support. A hypothesis is not a fact, and responsible scientists will not confuse hypothesis with fact.

### A. Large changes across time and geography in the epidemiology of transgender identification are inconsistent with the hypothesis of a biological basis for transgender identity.

63. In fact, there is substantial evidence that the "biological basis" is incorrect, at least with respect to the large majority of patients presenting with gender dysphoria today.

**a. Vast changes in incidence:** Historically, there were very low reported rates of gender dysphoria or transgender identification. In 2013, the DSM-5 estimated the incidence of gender dysphoria in adults to be at 2-14 per 100,000, or between 0.002% and 0.014%. (APA 2013 at 454.) Recently however, these numbers have increased dramatically, particularly in adolescent populations. Recent surveys estimate that between 2-9% of high school students identified as transgender or "gender non-conforming." with a significantly large increase in adolescents claiming "nonbinary" gender identity as well. (Johns 2019; Kidd 2021.) Consistent with these surveys, gender clinics around the world have seen numbers of referrals increase rapidly in the last decade, with the Tavistock clinic in London seeing a 30-fold increase in the last decade (GIDS 2019), and similar increases being observed in Finland (Kaltiala-Heino 2018), the Netherlands (de Vries 2020), and Canada (Zucker 2019). The rapid change in the number of individuals experiencing gender dysphoria points to social and cultural, not biological, causes.

**b. Large change in sex ratio:** In recent years there has been a marked shift in the sex ratio of patients presenting with gender dysphoria or transgender identification. The Tavistock clinic in London saw a ratio of 4 biological females(F):5 biological males(M) shift to essentially 11F:4M in a decade. (GIDS 2019.) One researcher summarizing multiple sources documented a swing of 1F:2M or 1F:1.4M through 2005 to 2F:1M generally (but as high as 7F:1M) in more recent samples. (Zucker 2019.) This phenomenon has been noted by Dr. Erica Anderson, who said: "The data are very clear that adolescent girls are coming to gender clinics in greater proportion than adolescent boys. And this is a change in the last couple of years. And it's an open question: What do we make of that? We don't really know what's going on. And we should be concerned about it." (Anderson 2022.) Again, this large and rapid change in who is experiencing gender dysphoria points to social, not biological, causes.

**c. Clustering**: Dr. Littman's recent study documented "clustering" of new presentations of gender dysphoria among natal females in specific schools and among specific friend groups. This again points strongly to social causes for gender dysphoria at least among the adolescent female population. (Littman 2019.)

**d. Desistence:** As I discuss later, there are very high levels of desistence among children diagnosed with gender dysphoria, as well as increasing (or at least increasingly vocal) numbers of individuals who first asserted a transgender identity during or after adolescence, underwent substantial medical interventions to “affirm” that trans-identity, and then “desisted” and reverted to a gender identity congruent with their sex. (See Section V.B below.) These narratives, too, point to a social and/or psychological cause, rather than a biological one.

**e. “Fluid” gender identification:** Advocates and some practitioners assert that gender identity is not binary, but can span an almost endless range of gender identity self-labels, which a given individual may try on, inhabit, and often discard. (A recent article identifies 72.[5]) I have not heard any theory offered for how there is or

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[5] Allarakha, *What Are the 72 Other Genders?*, MedicineNet, available at: https://www.medicinenet.com/what_are_the_72_other_genders/article.htm

could be a biological basis for gender identity as now expansively defined.

64. I frequently read attempts to explain away these five points. They include: these problems always existed, but children are now learning that there are effective treatments for their dilemma and are simply seeking them. And, children have hidden their trans identity throughout childhood and now that trans people are recognized and accepted, they are presenting themselves. And, now pediatricians realize that girls can have gender dysphoria and are referring them to gender clinics. But these are all based on an idea that transgenderism is an entity that has always existed in culture, everywhere and modern people are simply discovering what previous generations could not discover about their true, genuine, non-sex-dictated gendered self. The increased incidence and prevalence are indisputable facts recorded all over the world. Thus, culture, fashion, and nonbiological factors must be at work. One set of unproven hypotheses cannot provide support for the unproven hypothesis of biological basis. And none of these hypotheses

could even potentially explain the failure of science thus far to identify any predictive biological marker of transgender identification.

65. **Therapies affect gender identity outcomes:** Finally, the evidence shows that therapeutic choices can have a powerful effect on whether and how gender identity does change, or gender dysphoria desists. Social transition of juveniles, for instance, strongly influences gender identity outcomes to such an extent that it has been described a "unique predictor of persistence." (See Section V.B below.) Again, this observation cuts against the hypothesis of biological origin.

### B. Disorders of sexual development (or DSDs) and gender identity are very different phenomena, and it is an error to conflate the two.

66. The many forms of DSDs are biological phenomena.. Every DSD reflects either a genetic enzymatic defect with negative anatomic and physiological consequences. As the Endocrine Society recognized in a 2021 statement: "Given the complexities of the biology of sexual determination and differentiation, it is not surprising that there are dozens of examples of variations or errors in these pathways associated with genetic mutations that are now well known to endocrinologists and

geneticists; in medicine, these situations are generally termed *disorders of sexual development* (DSD) or *differences in sexual development*." Gender Identity on the other hand is uniformly defined as a subjective "sense" of being, a feeling or state of mind. (Section II.C.)

The vast majority of those who experience gender dysphoria or a transgender identity do not suffer from any DSD, nor from any genetic enzymatic disorder at all. Conversely, many who suffer from a DSD do not experience a gender identity different from their chromosomal sex (although some may). In short, those who suffer from gender dysphoria are not a subset of those who suffer from a DSD, nor are those who suffer from a DSD a subset of those who suffer from gender dysphoria. The two are simply different phenomena, one physical, the other mental, defined only as a psychiatric condition. The issue here is not whether biological forces play a role in personality development; it is whether there is strong evidence that it is determinative. Science has come too far to revert to single explanations for gender dysphoria or any psychiatric diagnosis.

67. The importance of this distinction is evident from the scientific literature. For example, in a recent study of clinical outcomes for gender dysphoric patients, Tavistock Clinic researchers *excluded* from their analysis any patients who did not have “normal endocrine function and karyotype consistent with birth registered sex.” (Carmichael 2021 at 4.) In other words, the researchers specifically *excluded* from their study anyone who suffered from genetic-based DSD, or a DSD comprising any serious defect in hormonal use pathways, in order to ensure the study was focused only on individuals experiencing the psychological effects of what we might call “ordinary” gender dysphoria.

### C. Studies of individuals born with DSDs suggest that there may be a biological predisposition towards *typical* gender identifications, but provide no support for a biological basis for *trans*gender identification.

68. Studies of individuals born with serious DSDs have been pointed to as evidence of a biological basis for transgender identification. They provide no such support. Meyer-Bahlburg reviewed the case histories of a number of XY (i.e. biologically male) individuals

born with severe DSDs who were surgically "feminized" in infancy and raised as girls. (Meyer-Bahlburg 2005.) The majority of these individuals nevertheless later adopted male gender identity—suggesting a strong biological predisposition towards identification aligned with genetic sex, even in the face of feminized genitalia from earliest childhood, and parental "affirmation" in a transgender identity. But at the same time, the fact that some of these genetically male individuals did *not* later adopt male gender identity serves as evidence that medical and social influences can indeed encourage and sustain transgender identification.

Importantly, the Meyer-Bahlburg study did *not* include any individuals who were assigned a gender identity congruent with their genetic sex who subsequently adopted a *trans*gender identity. Therefore, the study can provide no evidence of any kind that supports the hypothesis of a biological basis for *trans*gender identity. A second study (Reiner 2004) of XY subjects similarly provides evidence only for a biological bias towards a gender identity congruent with one's genetic sex, even in the face of medical and social "transition" interventions.

None of this provides any evidence at all of a biological basis for transgender identity.

## V. GENDER IDENTITY IS EMPIRICALLY NOT FIXED FOR MANY INDIVIDUALS.

69. It is not uncommon to read papers by advocates and clinicians that a trans identity is "durable and cannot be changed by medical intervention"—that gender identity is immutable and impervious to medical, psychotherapeutic, or developmental processes. Let's look at the evidence.

### A. Most children who experience gender dysphoria ultimately "desist" and resolve to their original identification.

70. A distinctive and critical characteristic of juvenile gender dysphoria is that multiple studies from separate groups and at different times have reported that in the large majority of patients, absent a substantial intervention such as social transition or puberty blocking hormone therapy, it does *not* persist through puberty.

A recent article reviewed all existing follow-up studies that the author could identify of children diagnosed with gender dysphoria

(11 studies), and reported that "every follow-up study of GD children, without exception, found the same thing: By puberty, the majority of GD children ceased to want to transition." (Cantor 2019 at 1.) Another author reviewed the existing studies and reported that in "prepubertal boys with gender discordance . . . 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." (Singh 2021; see also Cohen-Kettinis 2008 at 1895.) The Endocrine Society recognized this important baseline fact in its 2017 Guidelines. (Hembree 2017 at 3879.) It should be noted that the reason that the Dutch Protocol waited until age 14 to initiate puberty blockers was that it was well known that most kids desisted by then (deVries et al, 2011).

Findings of high levels of desistance among children who experience gender dysphoria or incongruence have been reaffirmed in the face of critiques through thorough reanalysis of the underlying data. (Zucker 2019.). It is not yet known how to distinguish those children who will desist from that small minority whose trans identity will persist.

It does appear that prevailing circumstances during particularly formative years can have a significant impact on the outcome of a juvenile's gender dysphoria. A 2016 study reviewing the follow-up literature noted that "the period between 10 and 13 years" was "crucial" in that "both persisters and desisters stated that the changes in their social environment, the anticipated and actual feminization or masculinization of their bodies, and the first experiences of falling in love and sexual attraction in this period, contributed to an increase (in the persisters) or decrease (in the desisters) of their gender related interests, behaviors, and feelings of gender discomfort." (Ristori 2016 at 16.) There is considerable evidence that early transition and affirmation in a transgender child causes far more children to persist in a transgender identity.

### B. Desistence is increasingly observed among teens and young adults who first manifest GD during or after adolescence.

71. Desistance within a relatively short period may also be a common outcome for post-pubertal youths who exhibit recently described "rapid onset gender disorder." I have observed an increasingly

vocal online community of young women who have reclaimed a female identity after claiming a male gender identity at some point during their teen years, and young "detransitioners" (individuals in the process of reidentifying with their birth sex after having undergone a gender transition) are now receiving increasing attention in both clinical literature and social media channels. De-transitioned individuals organized an all day program on March 12, 2022, entitled Detransition Awareness Day.

Almost all scientific articles on this topic have appeared within the last few years. Perhaps this historic lack of coverage is not entirely surprising – one academic who undertook an extensive review of the available scientific literature in 2021 noted that the phenomenon was "socially controversial" in that it "poses significant professional and bioethical challenges for those clinicians working in the field of gender dysphoria." (Expósito Campos 2021 at 270.) This review reported on multifarious reasons for why individuals were motivated to detransition, which included coming to "understand[ ] how past trauma, internalized sexism, and other psychological difficulties influenced the experience of GD."

In 2021, Lisa Littman of Brown University conducted a ground-breaking study of 100 teenage and young adults who had transitioned and lived in a transgender identity for a number of years, and then "detransitioned" or changed back to a gender identity matching their sex. Littman noted that the "visibility of individuals who have detransitioned is new and may be rapidly growing." (Littman 2021 at 1.) Of the 100 detransitioners included in Littman's study, 60% reported that their decision to detransition was motivated (at least in part) by the fact that they had become more comfortable identifying as their sex, and 38% had concluded that their gender dysphoria was caused by something specific such as trauma, abuse, or a mental health condition. A significant majority (76%) did not inform their clinicians of their detransition. (Littman 2021.)

72. A similar study that recruited a sample of 237 detransitioners (the large majority of whom had initially transitioned in their teens or early twenties) similarly reported that a common reason for

detransitioning was the subject’s conclusion that his or her gender dysphoria was related to other issues (70% of the sample). (Vandenbussche 2021.)

The existence of increasing number youth or young adult detransitioners has also been recently noted by Dr. Edwards-Leeper and Dr. Anderson. (Edwards-Leeper and Anderson 2021.) Edwards-Leeper and Anderson noted “the rising number of detransitioners that clinicians report seeing (they are forming support groups online)” which are “typically youth who experienced gender dysphoria and other complex mental health issues, rushed to medicalize their bodies and regretted it.” Other clinicians working with detransitioners have also noted the recent phenomenon. (Marchiano 2020.)

73. A growing body of evidence suggests that for many teens and young adults, a post-pubertal onset of transgender identification can be a transient phase of identity exploration, rather than a permanent identity, as evidenced by a growing number of young detransitioners (Entwistle, 2020; Littman, 2021; Vandenbussche, 2021). Previously, the rate of detransition and regret was reported to be very low, although these

estimates suffered from significant limitations and were likely undercounting true regret (D'Angelo, 2018). As gender-affirmative care has become popularized, the rate of detransition appears to be accelerating.

74. Two recent studies have begun to generate data on detranstioning by defined durations. Data from an VIUK adult gender clinic, observed that 6.9% of those treated with gender-affirmative interventions detransitioned within 16 months, and another 3.4% had a pattern of care suggestive of detransition, yielding a rate of probable detransition in excess of 10%. Another 21.7%, however, disengaged from the clinic without completing their treatment plan. While some of these individuals later re-engaged with the gender service, the authors concluded, "detransitioning might be more frequent than previously reported." (Hall 2021).

Another study from a UK primary care practice found that 12.2% of those who had started hormonal treatments either detransitioned or documented regret, while the total of 20% stopped the treatments for a wider range of reasons. The mean age of their presentation with gender dysphoria was 20, and the patients had been taking gender-affirming hormones for the average 5 years (17 months-10 years) prior to discontinuing. Comparing these much higher rates of treatment discontinuation and detransition to the significantly lower rates reported by the older studies, the researchers noted: “Thus, the detransition rate found in this population is novel and questions may be raised about the phenomenon of overdiagnosis, overtreatment, or iatrogenic harm as found in other medical fields” (Boyd 2022 at 15). Indeed, given that regret may take up to 8-11 years to materialize (Dhejne et al., 2014; Wiepjes et al., 2018), many more detransitioners are likely to emerge in the coming years. Detransitioner research is still in its infancy, but the Littman and Vandenbussche studies in 2021 report that detransitioners from the recently transitioning cohorts feel they had been rushed to medical gender-affirmative interventions with irreversible effects, often without the benefit of appropriate, or in some instances any, psychologic exploration.

## VI. TRANSITION AND AFFIRMATION IS AN IMPORTANT PSYCHOLOGICAL AND MEDICAL INTERVENTION THAT CHANGES GENDER IDENTITY OUTCOMES

75. If both a typical gender or a transgender long-term gender identity outcome are possible for a particular patient, the alternatives are not medically neutral. Where a juvenile experiences gender dysphoria, the gender identity that is stabilized will have a significant impact on the course of their life. Living in a transgender identity for a time will make desistence, if it is ever considered, more difficult to accomplish. If the juvenile desists from the gender dysphoria and becomes reasonably comfortable with a gender identity congruent with their sex—the most likely outcome from a statistical perspective absent affirming intervention—the child will not require ongoing pharmaceutical maintenance and will not have their fertility destroyed post-puberty.

76. However, if the juvenile persists in a transgender identity, under current practices, the child is most likely to require regular administration of hormones for the rest of their lives, exposing them to significant physical, mental health, and relational risks (which I detail below), as well as being irreversibly sterilized chemically and/or

surgically. The child is therefore rendered a “patient for life” with complex medical implications further to a scientifically unproven course of treatment.

77. Social transition of young children is a powerful psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance.  Some child-focused medical and psychological professionals believe that social transition is a a critical part of the treatment of gender dysphoria of childhood. What has already been demonstrated is that, social transition has a critical *effect* on the persistence of gender dysphoria. It is evident from the scientific literature that engaging in therapy that encourages social transition before or during puberty is a psychotherapeutic intervention that dramatically changes outcomes. Such an early intervention would understandably lead to the wish for the young trans person to participation on athletic teams and all other scholastic activities designated for the opposite sex. A prominent group of authors has written that “The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood.” (Guss 2015

at 421.) Similarly, a comparison of recent and older studies suggests that when an “affirming” methodology is used with children, a substantial proportion of children who would otherwise have desisted by adolescence—that is, achieved comfort identifying with their sex—instead persist in a transgender identity. (Zucker 2018 at 7.)[6] This introduces us to an ethical question: If the majority of cross-gender identified children are know to desist, how can it be ethical to socialize them in the opposite gender when that “treatment” increases the likelihood of persistence, which in turns places them on a problematic pathway?

78. A review of multiple studies of children treated for gender dysphoria across the last three decades found that early social transition to living as the opposite sex severely reduces the likelihood that the child will revert to identifying with the child’s sex, at least in the case of boys. Studies conducted before the widespread use of social transition

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[6] One study found that social transition by the child was found to be strongly correlated with persistence for natal boys, but not for girls. (Zucker 2018 at 5.) One researcher observed that a partial or complete gender social transition prior to puberty “proved to be a unique predictor of persistence.” (Singh 2021 at 14.)

for young children reported desistance rates in the range of 80-98%, a more recent study reported that fewer than 20% of boys who engaged in a partial or complete social transition before puberty had desisted when surveyed at age 15 or older. (Zucker 2018 at 7; Steensma 2013.)[7] Another researcher observed that a partial or complete gender social transition prior to puberty "proved to be a unique predictor of persistence." (Singh 2021 at 14.)

Some vocal practitioners of prompt affirmation and social transition even proudly claim that essentially *no* children who come to their clinics exhibiting gender dysphoria or cross-gender identification desist in that identification and return to a gender identity consistent with their biological sex.[8] This is a very large change as compared to the desistance rates documented apart from social transition.

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[7] Only 2 (3.6%) of 56 of the male desisters observed by Steensma et al. had made a complete or partial transition prior to puberty, and of the twelve males who made a complete or partial transition prior to puberty, only two had desisted when surveyed at age 15 or older. Steensma 2013 at 584.

[8] *See, e.g.*, Ehrensaft 2015 at 34: "In my own clinical practice . . . of those children who are carefully assessed as transgender and who are allowed to transition to their affirmed gender, we have no documentation of a child who has 'desisted' and asked to return to his or her assigned gender."

Even voices generally supportive of prompt affirmation and social transition are acknowledging a causal connection between social transition and this change in outcomes. As the Endocrine Society recognized in its 2017 Guidelines: “If children have completely socially transitioned, they may have great difficulty in returning to the original gender role upon entering puberty. . . [S]ocial transition (in addition to GD/gender incongruence) has been found to contribute to the likelihood of persistence.” (Hembree 2017 at 3879.) A researcher writing in 2015 reported that “The gender identity affirmed during puberty appears to predict the gender identity that will persist into adulthood.” (Guss 2015 at 2.) The fact is that these unproven interventions with the lives of kids and their families have systematically documented outcomes. Given this observed phenomenon, I agree with Dr. Ken Zucker who has written that social transition in children must be considered “a form of psychosocial treatment.” (Zucker 2019 at 1.)

Moreover, as I review below, social transition cannot be considered or decided alone. Studies show that engaging in social transition starts a juvenile on a “conveyor belt” path that almost inevitably leads to the administration of puberty blockers, which in turn almost inevitably leads to the administration of cross-sex hormones. The emergence of this well-documented path means that the implications of taking puberty blockers *and* cross-sex hormones must be taken into account even where "only" social transition is being considered or requested by the child or family. As a result, there are a number of important "known risks" associated with social transition.

### A. Administration of puberty blockers is a powerful medical and psychotherapeutic intervention that radically changes outcomes, almost eliminating desistance on the historically observed timeline.

79. Advocates of puberty blocking hormones have long spoken of this intervention as merely a pause. While puberty reorganizes human development both biologically, socially, and psychologically, the idea of a pause without consequences is naïve at best. It should be understood that puberty blockers are usually administered to children as young as 8-9 now as part of a program path that includes social transition. Moreover, medicine does not know what the long-term health effects on bone, brain, and other organs are of a "pause" between ages 11-16.

Medicine also does not know if the long-term effects of these compounds are different in boys than in girls. The mental health professional establishment likewise does not know the long-term effects on coping skills, interpersonal comfort, and intimate relationships of this "pause" while one's peers are undergoing their maturational gains in these vital arenas of future mental health. Puberty blockade should not be simply viewed a medical intervention; it also in a psychosocial one with complex implications. Advocates don't have evidence that it is safe except in a short-term medical sense and that some form of puberty will resume if they are stopped without administering cross-sex hormones.

80. Multiple studies show that the large majority of children who begin puberty blockers go on to receive cross-sex hormones. (de Vries 2020 at 2.) A recent study by the Tavistock and Portman NHS Gender Identity Development Service (UK)—the world's largest gender clinic—

found that 98% of adolescents who underwent puberty suppression continued on to cross-sex hormones. (Carmichael 2021.)[9]

These studies demonstrate that going on puberty blockers virtually eliminates the possibility of desistance in juveniles. Puberty blockers appear to act as a psychosocial "switch," decisively shifting many children to a persistent transgender identity. Therefore, as a practical and ethical matter the decision to put a child on puberty blockers must be considered as the equivalent of a decision to put that child on cross-sex hormones, with all the considerations and informed consent obligations implicit in that decision.

## VII. TRANSITION AND AFFIRMATION ARE STILL EXPERIMENTAL THERAPIES BECAUSE THEY HAVE NOT BEEN CONVINCINGLY SHOWN TO IMPROVE MENTAL OR PHYSICAL HEALTH OUTCOMES BY YOUNG ADULTHOOD.

81. It is undisputed that children and adolescents who present with gender dysphoria exhibit a very high level of mental health comorbidities. (Thompson et al, 2022) It is highly disuted whether the

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[9] *See also* Brik 2020 where Dutch researchers found nearly 97% of adolescents who received puberty blockers proceeded to cross-sex hormones.

gender dysphoria is cause of these various mental illness symptom patterns, or the product of these underlying maladaptive patterns, or whether these are merely coincident comorbidities. But the basic fact of the high prevalence of these co-morbidities is not.  When one considers the many indicators of poor mental health among adult trans communities, it may be that hormonal and subsequent surgical affirmations actually don’t eradicate the earlier in life indicators of mental health problems.  They may only distract the patient and their caregivers from the significance of these co-morbidities. Many pediatric professionals assume from their brief short-term visits with their endocrine treated adolescent patients that the hormones improved their happiness, mental health, social function, and ameliorated their gender dysphoria. This is scientifically incorrect. It ignores both what is known from independent reviews and what is unknown from the lack of scientifically meaningful follow up.

### A. The knowledge base concerning therapies for gender dysphoria is "very low quality."

82. At the outset, it is important for all sides to admit that the knowledge base concerning the causes and treatment of gender dysphoria has low scientific quality.

83. In evaluating claims of scientific or medical knowledge, it is axiomatic in science that no knowledge is absolute, and to recognize the widely accepted hierarchy of reliability when it comes to "knowledge" about medical or psychiatric phenomena and treatments. Unfortunately, in this field opinion is too often confused with knowledge, rather than clearly locating what exactly is scientifically known. In order of increasing confidence, such "knowledge" may be based upon data comprising:

a. Expert opinion—it is perhaps surprising to educated laypersons that expert opinion standing alone is the lowest form of knowledge, the least likely to be proven correct in the future, and therefore does not garner as much respect from professionals as what follows;

b. A single case or series of cases (what could be called anecdotal evidence) (Levine, *Reflections*, at 239.);
c. A series of cases with a control group;
d. A cohort study;
e. A randomized double-blind clinical trial;
f. A review of multiple trials;
g. A meta-analysis of multiple trials that maximizes the number of patients treated despite their methodological differences to detect trends from larger data sets.

Prominent voices in the field have emphasized the severe lack of scientific knowledge in this field. The American Academy of Child and Adolescent Psychiatry has recognized that "Different clinical approaches have been advocated for childhood gender discordance. . . . There have been no randomized controlled trials of any treatment. . . . [T]he proposed benefits of treatment to eliminate gender discordance … must be carefully weighed against … possible deleterious effects." (Adelson et al., *Practice Parameter*, at 968–69.) Similarly, the American Psychological Association has stated, "because no approach to working with [transgender and gender nonconforming] children has been adequately, empirically validated, consensus does not exist regarding best practice with pre-pubertal children."[10]

84. Critically, "there are no randomized control trials with regard to treatment of children with gender dysphoria." (Zucker 2018 at 8.) On numerous critical questions relating to cause, developmental path if untreated, and the effect of alternative treatments, the knowledge base remains primarily at the level of the practitioner's exposure to individual cases, or multiple individual cases. As a result, claims to certainty are not justifiable. (Levine 2016 at 239.)

85. Within the last two years, at least three formal evidence reviews concerning hormonal interventions for gender dysphoria have been conducted. All three found all of the available clinical evidence to be very low quality.The British National Health Service (NHS) commissioned formal "evidence reviews" of all clinical papers concerning the efficacy and safety of puberty blockers and cross-sex

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[10] American Psychological Association, *Guidelines for Psychological Practice with Transgender & Gender Nonconforming People* (2015), AM. PSYCHOLOGIST 70(9) 832 at 842.

hormones as treatments for gender dysphoria. These evidence reviews were performed by the U.K. National Institute for Health and Care Excellence (NICE), applying the respected "GRADE" criteria for evaluating the strength of clinical evidence.

Both the review of evidence concerning puberty blockers and the review of evidence concerning cross-sex hormones were published in 2020, and both found that *all* available evidence as to both efficacy and safety was "very low quality" according to the GRADE criteria. (NICE 2020a; NICE 2020b.) "Very low quality" according to GRADE means there is a high likelihood that the patient *will not experience* the hypothesized benefits of the treatment. (Balshem 2011.)

Similarly, the highly respected Cochrane Library—the leading source of independent systematic evidence reviews in health care—commissioned an evidence review concerning the efficacy and safety of hormonal treatments now commonly administered to "transitioning transgender women" (i.e., testosterone suppression and estrogen administration to biological males). That review, also published in 2020, concluded that "We found insufficient evidence to determine the efficacy or safety of hormonal treatment approaches for transgender women in transition." (Haupt 2020.) It must be understood that both the NICE and the Cochrane reviews considered *all* published scientific studies concerning these treatments.

86. As to social transition, as I have noted above, considerable evidence suggests that socially transitioning a pre-pubertal child puts him or her on a path from which very few children escape—a path which includes puberty blockers and cross-sex hormones before age 18. As a practical matter, then, a decision about social transition for a child must be made in light of what is known and what is unknown about the effects of those expected hormonal interventions.

### B. Youth who adopt a transgender identity show no durable improvement in mental health after social, hormonal, or surgical transition and affirmation.

87. The evidence reviews for the efficacy and safety of hormonal interventions published in 2020 concluded that the supporting evidence is so poor that there is "a high likelihood that the patient will not experience the hypothesized benefits of the treatment." There is now

some concrete evidence that on average they do not experience those benefits.

An important paper published in 2021 by Tavistock clinic clinicians provided the results of the first longitudinal study that measured widely used metrics of general psychological function and suicidality before commencement of puberty blockers, and then at least annually after commencing puberty blockers. After up to three years, they "found no evidence of change in psychological function with GnRHa treatment as indicated by parent report (CBCL) or self-report (YSR) of overall problems, internalizing or externalizing problems or self-harm" as compared to the pre-puberty-blocker baseline evaluations. "Outcomes that were not formally tested also showed little change." (Carmichael 2021.) Similarly, a study by Branström and Pachankis of the case histories of a set of individuals diagnosed with GD in Sweden found no positive effect on mental health from hormonal treatment. (Landen 2020.)

A cohort study by authors from Harvard and Boston Children's Hospital found that youth and young adults (ages 12-29) who self-identified as transgender had an elevated risk of depression (50.6% vs. 20.6%) and anxiety (26.7% vs. 10.0%); a higher risk of suicidal ideation (31.1% vs. 11.1%), suicide attempts (17.2% vs. 6.1%), and self-harm without lethal intent (16.7% vs. 4.4%) relative to the matched controls; and a significantly greater proportion of transgender youth accessed inpatient mental health care (22.8% vs. 11.1%) and outpatient mental health care (45.6% vs. 16.1%) services. (Reisner 2015 at 6.) Similarly, a recent longitudinal study of transgender and gender diverse youth and young adults in Chicago found rates of alcohol and substance abuse "substantially higher than those reported by large population-based studies of youth and adults." (Newcomb 2020.) Members of the clinical and research team at the prominent Dutch VU University gender dysphoria center recently compared mental health metrics of two groups of subjects before (mean age 14.5) and after (mean age 16.8) puberty blockers. But they acknowledged that the structure of their study meant that it "can . . . not provide evidence about . . . long-term mental health outcomes," and that based on what continues to be extremely limited scientific data "Conclusions about the long-term benefits of puberty suppression should . . . be made with extreme caution." In other words, we just don't know.

Kiera Bell, who was diagnosed with gender dysphoria at the Tavistock Clinic, given cross-sex hormones, and subjected to mastectomies, before desisting and reclaiming her female gender identity, and a Swedish teen girl who appeared in a recent documentary after walking that same path, have both stated that they feel that they were treated "like guinea pigs," experimental subjects. They are not wrong.

### C. Long term mental health outcomes for individuals who persist in a transgender identity are poor.

88. The responsible MHP cannot focus narrowly on the short-term happiness of the young patient, but must instead consider the happiness and health of the patient from a "life course" perspective. When we look at the available studies of individuals who continue to inhabit a transgender identity across adult years, the results are strongly negative.

In the United States, the death rates of trans veterans are comparable to those with schizophrenia and bipolar diagnoses—20 years earlier than expected. These crude death rates include significantly elevated rates of substance abuse as well as suicide. (Levine 2017 at 10.) Similarly, researchers in Sweden and Denmark have reported on almost all individuals who underwent sex-reassignment surgery over a 30-year period. (Dhejne 2011; Simonsen 2016.) The Swedish follow-up study similarly found a suicide rate in the post-SRS population 19.1 times greater than that of the controls; both studies demonstrated elevated mortality rates from medical and psychiatric conditions. (Levine 2017 at 10.)

A recent study in the American Journal of Psychiatry reported high mental health utilization patterns of adults for ten years after surgery for approximately 35% of patients. (Bränström & Panchankis, 2020.) Indeed, earlier Swedish researchers in a long-term study of all patients provided with SRS over a 30-year period (median time since SRS of > 10 years) concluded that individuals who have SRS exhibit such poor mental health that they should be very long psychiatric care after surgery. Unfortunately, across the succeeding decade, in Sweden and elsewhere their suggestion has been ignored.

I will note that these studies do not tell us whether the subjects first experienced gender dysphoria as children, adolescents, or adults, so we cannot be certain how their findings apply to each of these subpopulations which represent quite different pathways. But in the absence of knowledge, we should be cautions.

Meanwhile, no studies show that affirmation of pre-pubescent children or adolescents leads to more positive outcomes (mental, physical, social, or romantic) by, e.g., age 25 or older than does “watchful waiting” or ordinary therapy.

The many studies that I have cited here warn us that as we look ahead to the patient’s life as a young adult and adult, the prognosis for the physical health, mental health, and social well-being of the child or adolescent who transitions to live in a transgender identity is not good. Gender dysphoria is not easily managed because prescribing hormones is easy for the physician,  when one understands the marginalized, vulnerable physical, social, and psychological status of adult trans populations.

## VIII. TRANSITION AND AFFIRMATION DO NOT DECREASE, AND MAY INCREASE, THE RISK OF SUICIDE.

### A. The risk of suicide among transgender youth is confused and exaggerated in the public mind.

89. While suicide is closely linked to poor mental health, I comment on it separately because rhetoric relating to suicide figures so prominently in debates about responses to gender dysphoria. Any discussion of suicide when considering younger children involves very long-range and very uncertain prediction. Suicide in pre-pubescent children is extremely rare, and the existing studies of gender identity issues in pre-pubescent children do not report significant incidents of suicide. Any suggestion otherwise is misinformed. Our focus for this topic, then, is on adolescents and adults.

90. Some authors have reported rates of suicidal thoughts and behaviors among trans-identifying teens or adults ranging from 25% as high as 52%, generally through non-longitudinal self-reports obtained from non-represented survey samples. (Toomey 2018.) No studies show

that affirmation of children (or anyone else) reduces suicide, prevents suicidal ideation, or improves long-term outcomes, as compared to either a "watchful waiting" or a psychotherapeutic model of response.

91. Rhetorical references to suicidality figures in as many of 40% of gender identity patients need the following clarification. Suicidality is an umbrella term that includes: suicidal thoughts, suicidal plans, manipulative suicide gestures, potentially lethal actual attempts, and completed suicide. Suicidal thoughts can be a personal reassurance that "I always have that option." Suicidal thoughts with a plan can be a cry for help, manipulation, or expression of rage with serious attempts to end life.

92. Too often, in public comment suicidal thoughts are blurred with suicide. Yet the available data tells us that suicide among children and youth suffering from gender dysphoria is extremely rare.

93. An important new analysis of data covering patients as well as those on the waiting list (and thus untreated) at the UK Tavistock gender clinic—the world's largest gender clinic—found a total of only four completed suicides across 11 years' worth of patient data, reflecting

an estimated cumulative 30,000 patient-years spent by patients under the clinic’s care or on its waiting list. This corresponded to an annual suicide rate of 0.013%. The proportion of individual patients who died by suicide was 0.03%, which is orders of magnitude smaller than trans adolescents who self-report suicidal behavior or thoughts on surveys. (Biggs 2022.)

94. Thus, only a minute fraction of trans-identifying adolescents who report thoughts or conduct considered to represent “suicidality” actually commit suicide. I agree with the statement by Dr. Zucker that the assertion by, for example, Karasic and Ehrensaft (2015) that completed suicides among transgender youth are “alarmingly high” “has no formal and systematic empirical basis.” (Zucker 2019.) Professor Biggs of Oxford, author of the study of incidence of suicide among Tavistock Clinic patients, rightly cautions that it is “irresponsible to exaggerate the prevalence of suicide.” (Biggs 2022.)

95. It is my opinion that telling parents—or even allowing them to believe from their internet reading—that they face a choice between “a live son or a dead daughter” is both factually wrong and unethical.

Informed consent requires clinicians to tell the truth and ensure that their patients understand the truth. To be kind, the clinicians who believe such figures represent high risk of ultimate suicide in adolescence simply are ill informed.

## B. Transition of any sort has not been shown to reduce levels of suicide.

96. Every suicide is a tragedy, and steps that reduce suicide should be adopted. I have noted above that suicidality (that is, suicidal thoughts or behaviors, rather than suicide) is common among transgender adolescents and young adults before, during, and after social and medical transition. If a medical or mental health professional believes that an individual he or she is diagnosing or treating for gender dysphoria presents a suicide risk, in my view it is unethical for that professional merely to proceed with treatment for gender dysphoria and hope that "solves the problem." Rather, that professional has an obligation to provide or refer the patient for evidence-based therapies for addressing depression and suicidal thoughts that are well-known to the profession. (Levine 2016 at 242.)

97. This is all the more true because there is in fact no evidence that social and/or medical transition reduces the risk or incidence of actual suicide. On the contrary, in his analysis of those who were patients of or on the waiting list of the Tavistock Clinic, Professor Biggs found that the suicide rate was not higher among those on the clinic's waiting list (and thus as-yet untreated), than for those who were patients under care. (Biggs 2022.) And as corrected, Bränström and Pachankis similarly acknowledge that their review of records of GD patients "demonstrated no advantage of surgery in relation to . . . hospitalizations following suicide attempts." (I assume for this purpose that attempts that result in hospitalization are judged to be so serious as to predict a high rate of future suicide if not successfully addressed.")[11]

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[11] Turban 2020 has been described in press reports as demonstrating that administration of puberty suppressing hormones to transgender adolescents reduces suicide or suicidal ideation. The paper itself does not make that claim, nor permit that conclusion.

### C. Long-term life in a transgender identity correlates with very high rates of completed suicide.

98. As with mental health generally, the patient, parent, or clinician fearing the risk of suicide must consider not just the next month or year, but a life course perspective.

There are now four long-term studies that analyze completed suicide among those living in transgender identities into adulthood. The results vary significantly, but are uniformly highly negative.

Dhejne reported a long-term follow-up study of subjects after sex reassignment surgery. Across the multi-year study, subjects who had undergone SRS committed suicide at 19.1X the expected rate compared to general population controls matched by age and both sexes. MtF subjects committed suicide at 13.9X the expected rate, and FtM subjects committed suicide at 40.0X the expected rate. (Dhejne 2011 Supplemental Table S1.)

Asscheman, also writing in 2011, reported results of a long-term follow-up of all transexual subjects of the Netherland's leading gender medicine clinic who started cross-sex hormones before July 1, 1997, a total of 1331 patients. Due to the Dutch system of medical and death records, extensive follow-up was achieved. Median follow-up period was 18.5 years. The mortality rate among MtF patients was 51% higher than among the age-matched general population; the rate of completed suicide among MtF patients was six times that of the age-matched general population. (Asscheman 2011.)

Importantly, Asscheman found that “No suicides occurred within the first 2 years of hormone treatment, while there were six suicides after 2-5 years, seven after 5-10 years, and four after more than 10 years of CSH treatment at a mean age of 41.5 years." (Asscheman 2011 at 637-638.) This suggests that studies that follow patients for only a year or two after treatment are insufficient. Asscheman et al’s data suggests that such short-term follow-up is engaging only with an initial period of optimism, and will simply miss the feelings of disillusion and the increase in completed suicide that follows in later years.

A retrospective, long-term study published in 2020 of a very large cohort (8263) of patients referred to the Amsterdam University gender clinic between 1972 and 2017 found that the annual rate of completed suicides among the transgender subjects was “three to four times higher than the general Dutch population.” “[T]he incidence of observed suicide deaths was almost equally distributed over the different stages of treatment.” The authors concluded that “vulnerability for suicide occurs similarly in the different stages of transition.” (Wiepjes 2020.) In other words, neither social nor medical transition reduced the rate of suicide.

As with Asscheman (2011), Wiepjes found that the median time between start of hormones and suicide (when suicide occurred) was 6.1 years for natal males, and 6.9 years for natal females. Again, short- or even medium-term studies will miss this suicide phenomenon.

A 2021 study analyzed the case histories of a cohort of 175 gender dysphoria patients treated at one of the seven UK adult gender clinics who were “discharged” (discontinued as patients) within a selected one-year period. The authors reported the rather shocking result that 7.7% (3/39) of natal males who were diagnosed and admitted for treatment, and who were between 17 and 24 years old, were "discharged" because they committed suicide *during* treatment. (Hall 2021, Table 2.)

99. None of these studies demonstrate that the hormonal or surgical intervention *caused* suicide. That is possible, but as we have seen, the population that identifies as transgender suffers from a high incidence of comorbidities that correlate with suicide. What these studies demonstrate—at the least—is that this remains a troubled population in need of extensive and careful psychological care that they generally do not receive, and that neither hormonal nor surgical transition and "affirmation" resolve their underlying problems and put them on the path to a stable and healthy life.

100. In sum, claims that affirmation will reduce the risk of suicide for children and adolescents are not based on science. Instead, transition of any sort must be justified, if at all, as a life-enhancing measure, not a lifesaving measure. (Levine 2016 at 242.) In my opinion, this is an important fact that patients, parents, and even many MHPs fail to understand.

## IX. HORMONAL INTERVENTIONS ARE EXPERIMENTAL PROCEDURES THAT HAVE NOT BEEN PROVEN SAFE.

101. Given the widespread use of hormones for gender dysphoria it is not surprising that physicians consider their use safe, at least in the short term. I have already discussed the known and unknown dangers of puberty blocking agents for youthful gender dysphoria. On the contrary, no studies have been done that meaningfully demonstrate that either puberty blockers or cross-sex hormones are safe in the long run, for instance after five and 10 years.  No studies have attempted to determine whether the effects of puberty blockers, are fully reversible.

102. In fact, there are substantial reasons for concern that these hormonal interventions are not safe. Multiple researchers have expressed that concern that the full range of possible harms have not even been correctly conceptualized. Because evidence demonstrates that pre-pubertal social transition almost always leads to progression on to puberty blockers which in turn almost always leads to the use of cross-sex hormones, physicians bear the ethical responsibility for a thorough informed consent process for parents and patients that includes this fact

and its full implications. Informed consent does not mean sharing with the parents and patients what the doctor believes: it means sharing what is known and what is not known about the intervention. So much of what doctors believe is based on mere trust in what they have been taught. Neither they themselves nor their teachers may be aware of the scientific foundation and scientific limitations of what they are recommending.

### A. Use of puberty blockers has not been shown to be safe or reversible for gender dysphoria.

103. As I noted above, the recent very thorough literature review performed for the British NHS concluded that *all* available clinical evidence relating to "safety outcomes" from administration of puberty blockers for gender dysphoria is of "very low certainty." (NHS 2020a at 6.) In its 2017 Guidelines, the Endocrine Society cautioned that "in the future we need more rigorous evaluations of the effectiveness and safety of endocrine and surgical protocols" including "careful assessment of . . . the effects of prolonged delay of puberty in adolescents on bone health, gonadal function, and the brain (including effects on cognitive,

emotional, social, and sexual development).” (Hembree 2017 at 6.) No such “careful” or “rigorous” evaluation of these very serious safety questions has yet been done.

104. Some advocates argue that puberty blockers are “safe” because they have been approved by the Food and Drug Administration (FDA) for use to treat precocious puberty—a rare condition in which the puberty process may start at eight or younger. No such conclusion can be drawn. As the in-package label for Lupron (one of the most widely prescribed puberty blockers) explains, the FDA approved the drug only *until* the “age was appropriate for entry into puberty.” The label provides no information as to the safety or reversibility of *blocking* healthy, normally-timed puberty’s beginning, and *throughout* the years that body-wide continuing changes normally occur. Given the physical, social, and psychological dangers to the child with precocious puberty, drugs like Lupron are effective in returning the child to a puerile state without a high incidence of significant side effects—that is, they are “safe” to reverse the condition. But use of drugs to suppress normal

puberty have multiple organ system effects whose long-term consequences have not been investigated.

105. **Fertility**: The Endocrine Society Guidelines rightly say that research is needed into the effect of puberty blockade on "gonadal function" and "sexual development." The core purpose and function of puberty blockers is to prevent the maturation of the ovaries or testes, the sources of female hormones and male hormones when stimulated by the pituitary gland. From this predictable process fertility is accomplished within a few years. Despite widespread assertions that puberty blockers are "fully reversible," there has been no study published on the critical question of whether patients ever develop normal levels of fertility if puberty blockers are terminated after a "prolonged delay of puberty." The 2017 Endocrine Society Guidelines are correct that are no data on achievement of fertility "following prolonged gonadotropin suppression" (that is, puberty blockade). (Hembree 2017 at 12.)

106. **Bone strength**: Multiple studies have documented adverse effects from puberty blockers on bone density. (Klink 2015; Vlot 2017; Joseph 2019.) The most recent found that after two years on puberty

blockers, the bone density measurements for a significant minority of the children had declined to clinically concerning levels. Density in the spines of some subjects fell to a level found in only 0.13% of the population. (Biggs 2021 at 937-939.) Some other studies have found less concerning effects on bone density. While the available evidence remains limited and conflicting, it is not possible to conclude that the treatment is "safe."

107. **Brain development:** Important neurological growth and development in the brain occurs across puberty. The anatomic and functional effect on brain development of blocking the natural puberty process has not been well studied. A prominent Australian clinical team recently expressed concern that "no data were (or are) available on whether delaying the exposure of the brain to a sex steroid affects psychosexual, cognitive, emotional, or other neuropsychological maturation. (Kozlowska 2021 at 89.) In my opinion, given the observed correlation between puberty and brain development, the default hypothesis must be that there *would* be a negative impact. For the purpose of protecting patients all over the world, the burden of proof

should be on advocates to first demonstrate to a reasonable degree of certainty that brain structure and its measurable cognitive and affect processing are not negatively affective. This recalls the ethical principle: Above All Do No Harm.

The Endocrine Society Guidelines acknowledge as much, stating that side effects of pubertal suppression "may include . . . unknown effects on brain development," that "we need more rigorous evaluations of . . . the effects of prolonged delay of puberty in adolescents on . . . the brain (including effects on cognitive, emotional, social, and sexual development)," and stating that "animal data suggests there may be an effect of GnRH analogs [puberty blockers] on cognitive function." (Hembree 2017 at 6, 14, 15.) Given this concern, one can only wonder why this relevant question has not been scientifically investigated in a large group of natal males and females.

108. There has been a longitudinal study of one natal male child, assessed before, and again 20 months after, puberty suppression was commenced. It reported a reduction in the patient's "global IQ," measured an anomalous absence of certain structural brain development

expected during normal male puberty, and hypothesized that "a plausible explanation for the G[lobal] IQ decrease should consider a disruption of the synchronic [i.e., appropriately timed] development of brain areas by pubertal suppression." (Schneider 2017 at 7.) This should cause parents and practitioners serious concern.

109. Whether any impairment of brain development is "reversed" upon later termination of puberty blockade has, to my knowledge, not been studied at all. As a result, assertions by medical or mental health professionals that puberty blockade is "fully reversible" are unjustified and based on hope rather than science. Without a number of additional case studies—or preferably statistically significant clinical studies—two questions remain unanswered: 1). Are there brain anatomic or functional impairments from puberty blockers? 2). Are the documented changes reversed over time when puberty blockers are stopped? With these questions unanswered, it is impossible to assert with certainty that the effects of this class of medications are "fully reversible." Such an assertion is another example of ideas based on beliefs rather than on documentation, on hope not science.

110. **Psycho-social harm**: Puberty is a time of stress, anxiety, bodily discomfort during physical development, and identity formation for *all* humans. No careful study has been done of the long-term impact on the young person's coping skills, interpersonal comfort, and intimate relationships from remaining puerile for, e.g., two to five years while one's peers are undergoing pubertal transformations, and of then undergoing an artificial puberty at an older age. However, pediatricians and mental health professionals hear of distress, concern, and social awkwardness in those who naturally have a delayed onset of puberty. In my opinion, individuals in whom puberty is delayed multiple years are likely to suffer at least subtle negative psychosocial and self-confidence effects as they stand on the sidelines witnessing their peers developing the social relationships (and attendant painful social learning experiences) that come with adolescence. (Levine 2018 at 9.) Social anxiety and social avoidance are common findings in the evaluation of trans-identified children and teens. Are we expected to believe that creating years of being further different than their peers has no lasting

internal consequences? Do we ignore Adolescent Psychiatry's knowledge of the importance of peer groups among adolescents?

111. We simply do not know what all the psychological impacts of NOT grappling with puberty at the ordinary time may be, because it has not been studied. And we have no information as to whether that impact is "fully reversible." In addition, since the overwhelming proportion of children who begin puberty blockers continue on to cross-sex hormones, it appears that there is an important element of "psychological irreversibility" in play. The question of to what extent the physical and developmental impacts of puberty blockers might be reversible is an academic one, if psycho-social realities mean that very few patients well ever be able to make that choice once they have started down the road of social transition and puberty blockers.

### B. Use of cross-sex hormones in adolescents for gender dysphoria has not been shown to be medically safe except in the short term.

112. As with puberty blockers, all evidence concerning the safety of extended use of cross-sex hormones is of "very low quality." The U.K. NIH evidence review cautioned that "the safety profiles" of cross-

sex hormone treatments are "largely unknown," and that several of the limited studies that do exist reported high numbers of subjects "lost to follow-up," without explanation—a worrying indicator. (NIH 2020b.)

The 2020 Cochrane Review reported that: "We found insufficient evidence to determine the . . . safety of hormonal treatment approaches for transgender women in transition." (Haupt 2020.) Even the Endocrine Society tagged all its recommendations for the administration of cross-sex hormones as based on "low quality evidence." (Hembree 2017, at 3.)

113. **Sterilization**: It is undisputed, however, that harm to the gonads is an expected effect, to the extent that it must be assumed that cross-sex hormones will sterilize the patient. Thus, the Endocrine Society 2017 Guidelines caution that "[p]rolonged exposure of the testes to estrogen has been associated with testicular damage," that "[r]estoration of spermatogenesis after prolonged estrogen treatment has not been studied," and that "[i]n biological females, the effect of prolonged treatment with exogenous testosterone upon ovarian function

is uncertain." [12] The Guidelines go on to recommend that the practitioner counsel the patient about the (problematic and uncertain) options available to collect and preserve fertile sperm or ova before beginning cross-sex hormones. The life-long negative emotional impact of infertility on both men and women has been well studied. While this impact has not been studied specifically within the transgender population, the opportunity to be a parent is likely a human, emotional need, and so should be considered an important risk factor when considering gender transition for any patient.

114. **Sexual response**: Puberty blockers prevent maturation of the sexual organs and response. Some, and perhaps many, transgender individuals who did not go through puberty consistent with their sex and are then put on cross-sex hormones face significantly diminished sexual response as they enter adulthood and are unable ever to experience orgasm. In the case of males, the cross-sex administration of estrogen limits penile genital growth and function. In the case of females,

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[12] *See also* Guss 2015 at 4 ("a side effect [of cross-sex hormones] may be infertility") and at 5 ("cross-sex hormones . . . may have irreversible effects"); Tishelman 2015 at 8 (Cross-sex hormones are "irreversible interventions" with "significant ramifications for fertility").

prolonged exposure to exogenous testosterone impairs vaginal function. Much has been written about the negative psychological and relational consequences of anorgasmia among non-transgender individuals that is ultimately applicable to the transgendered. (Levine 2018 at 6.) At the same time, prolonged exposure of females to exogenous testosterone often increases sexual drive to a distracting degree. It is likely that parents and physicians are uncomfortable discussing any aspects of genital sexual activity with patients.

115. **Cardiovascular harm**: Several researchers have reported that cross-sex hormones increase the occurrence of various types of cardiovascular disease, including strokes, blood clots, and other acute cardiovascular events. (Getahun 2018; Guss 2015; Asscheman 2011.) With that said, I agree with the conclusion of the Endocrine Society committee (like that of the NIH Evidence Review) that: “A systematic review of the literature found that data were insufficient (due to very low–quality evidence) to allow a meaningful assessment of patient-important outcomes, such as death, stroke, myocardial infarction, or venous thromboembolism in transgender males. Future research is

needed to ascertain the potential harm of hormonal therapies." (Hembree 2017 at 23.) Future research questions concerning long-term harms need to be far more precisely defined. The concerns that cross-sex hormones are safe for adolescents and young adults cannot be answered by analogies to hormone replacement therapy in menopausal women (which is not a cross-sex usage). Medicine has answered safety questions for menopausal women in terms of cancer and cardiovascular safety: at what dose, for what duration, and at what age range. The science of endocrine treatment of gender dysphoric youth is being bypassed by short-term clinical impressions of safety even though physicians know that cardiovascular and cancer processes often develop over many years.

Further, in contrast to administration for menopausal women, hormones begun in adolescence are likely to be administered for four to six decades. The published evidence of adverse impact, coupled with the lack of data sufficient to reach a firm conclusion, make it irresponsible to assert that cross-sex hormones "are safe."

116. **Harm to family and friendship relationships:** As a psychiatrist, I recognize that mental health is a critical part of health generally, and that relationships cannot be separated from and profoundly impact mental health. Gender transition routinely leads to isolation from at least a significant portion of one's family in adulthood. In the case of a juvenile transition, this will be less dramatic while the child is young, but commonly increases over time as siblings who marry and have children of their own do not wish the transgender individual to be in contact with those children. By adulthood, the friendships of transgender individuals tend to be confined to other transgender individuals (often "virtual" friends known only online) and the generally limited set of others who are comfortable interacting with transgender individuals. (Levine 2017 at 5.) My concerns about this are based on decades of observations in my professional work with patients.

117. **Sexual-romantic harms associated with transition:** After adolescence, transgender individuals find the pool of individuals willing to develop a romantic and intimate relationship with them to be greatly diminished. When a trans person who passes well reveals his or her

anatomsex, many potential mates lose interest. When a trans person does not pass well, options are likely further diminished. But regardless of a person's appearance, these adults soon learn that many of their dates are looking for exotic sexual experiences rather than genuinely loving relationships. (Levine 2017 at 5, 13; Levine 2013 at 40; Anzani et al, 2021)

### C. The timing of harms.

118. The multi-year delay between start of hormones and the spike in completed suicide observed by Professor Biggs in the Tavistock data warn us that the safety and beneficence of these treatments cannot be judged based on short-term studies, or studies that do not continue into adulthood. Similarly, several of the harms that I discuss above would not be expected to manifest until the patients reaches at least middle-age. For example, stroke or other serious cardiovascular event is a complication that is unlikely to manifest during teen years even if its likelihood over the patient's lifetime has been materially increased via obesity, lipid abnormalities, and smoking (Jacobs et al, 2022). Regret over sterilization or over an inability to form a stable romantic

relationship may occur sooner. Psychological challenges of being a trans adult may become manifest after the medical profession is only doing routine follow up care—or, in many cases, has lost contact with the patient altogether. Because few, if any, clinics in this country are conducting systematic long-term follow-up with their child and adolescent patients, the doctors who counsel, prescribe, or perform hormonal and surgical therapies are unlikely ever to become aware of the later negative life impacts, however severe. These concerns are compounded by the findings in the recent "detranistioner" research that 76% did not inform their clinicians of their detransition. (Littman 2021.)

119. The possibility that steps along the transition and affirmation pathway, while lessening the pain of gender dysphoria in the short term, could lead to additional sources of crippling emotional and psychological pain, are too often not considered by advocates of social transition and not considered at all by the trans child. (Levine 2016 at 243.) Clinicians must distinguish the apparent short-term safety of hormones from likely or possible long-term consequences, and help the patient or parents understand these implications as well. The young

patient may feel, "I don't care if I die young, just as long I get to live as a woman." The mature adult may take a different view. Hopefully, so will the child's physician.

120. Individual patients often pin excessive hope in transition, believing that transition will solve what are in fact ordinary social stresses associated with maturation, or mental health co-morbidities. In this way, transition can prevent them from mastering personal challenges at the appropriate time or directly addressing conditions that require treatment. When the hoped-for "vanishing" of other mental health or social difficulties does not occur, disappointment, distress, and depression may ensue. It is noteworthy that half of the respondents to the larger "detransitioner" survey reported that their transition had not helped the gender dysphoria, and 70% had concluded that their gender dysphoria was related to other issues. (Vandenbussche 2021.) Without the clinical experience of monitoring the psychosocial outcomes of these young patients as they age into adulthood, many such professionals experience no challenge to their affirmative beliefs. But medical and mental health professionals who deliver trans affirmative care for those

with previous and co-existing mental health problems have an ethical obligation to inform themselves, and to inform patients and parents, that these dramatic treatments are not a panacea.

121. Whether we consider physical or mental health, science does not permit us to unequivably declare that puberty blockers or cross-sex hormones are "safe." Worrisome effects of endocrine treatment for the young include: increasing hemoglobin and red cell counts, asymptomatic abnormal lipid profiles, increasing weight, short stature, increased blood pressure, and decreasing bone calcium density. Ideally physicians will carefully monitor these parameters at regular intervals, which is the beginning of what will be the need for lifelong medical monitoring. Significant disease outcomes are not expected to frequently occur in the early years of endocrine treatment. Thus, parents and patients may be reassured, in this limited sense, that these endocrine interventions are "safe." Medicine is aware, however, about the higher mortality from physical disease that some of these parameters facilitate. While it is difficult to discuss sterility and sexual dysfunction with parents, these

down-the-road implications of affirmative care are easier to consider than the evidence of a shortened life span for their child.

122. Compassionate gender specialists who trust what they may have been taught also assume they are improving mental health because patients seem happy to receive the treatments and eager for the bodily changes. They presume this happiness will increase their chances for personal scholastic, social, romantic, and vocational successes. But while masculinizing or feminizing the young body is easily managed in a limited medical sense, what is not easy is managed is living one's life as.a trans person. This involves school and learning, new relationships with others who are not transgendered, and behaving in ways that facilitate vocational success. These matters are shaped by personal capacities and limitations. The underlying coping capacities, as reflected in the well-known array of psychiatric co-morbidities, are not simply ameliorated because of the hormones. For some, the continuing symptoms pose an existential crisis. They seek psychiatric care, often unbeknownst to their hormone providing physician. Regardless of one or a different physician's experiences with patients' mental health,

however, it is science that must answer the question. The data on the mental health of patients before, during, and after such treatments strongly contradict the assertion that gender dysphoria is cured, significantly ameliorated, or stabilized.

123. Gender change and its endocrine treatment of older children and early adolescents is a stunning process that raises vital philosophical and ethical questions. In answering these questions, passionate positions should be interrogated by the established facts. Science cannot be expected to provide all the answers. It is to be greatly respected, however. Three facts should remain foremost in mind when evaluating the ethics of affirmative care for minors:

a. The history of treating older children and adolescents with hormones prior to establishing their biopsychosocial short and long-terms effects;
b. The continued absence of long-term follow-ups despite the long existent need for them;
c. The vulnerable marginalized status of trans adult communities.

124. Much of this comes together when professionals examine how we execute our informed consent ethical obligation to parents and the young patient (Levine et al, 2022) Informed consent obligations cannot be ethically accomplished in one efficient perfunctory meeting. Each element of treatment requires a somewhat separate process. Given the age of the patient and family circumstances, these elements may include watchful waiting, psychotherapy for the patient or the parents, socialization in the opposite gender, puberty blockers, cross-sex hormones, mastectomies, orchiectomies or vaginoplasties. Any first step in affirmative care needs to be understood as setting the patient and family on a pathway through the life cycle which is fraught with many dangers. The immediate and long-term implications for the patient and entire family need to be carefully discussed. The professional needs to lead discussions on the family's hoped for benefits versus clinically recognized benefits, physical changes expected and their limitations, risks, alternate approaches available, and what science does not know. Professionals may ethically state what they believe will be the benefit of the intervention but must clarify the controversies within medicine.

Parents need to be told of the lack of controlled studies, inadequate follow-up studies, and the highly contentious political environment into which their child will be entering.

125. In committing ourselves to honestly portray the state of knowledge, professionals must be aware that some families will simply trust what the doctor recommends because they find the uncertainty overwhelming. There, of course, is danger in this. Caveat emptor—buyer beware—applies both to the patient, parents, and the physician. With today's knowledge base, we are scientifically uncertain whether we are harming or helping the patient. And this is a considerable ethical problem!

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