In the Matter Of:

K.C., ET AL

-v-

INDIVIDUAL MEMBERS OF MEDICAL LICENSING BOARD OF INDIANA, ET AL

Elaine Cox, M.D.

May 31, 2023

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

K.C., et al.,	)	
	)	
Plaintiffs,	)	
	)	
-v-	)	CASE NO.
	)	1:23-cv-00595-JPH-KMB
THE INDIVIDUAL MEMBERS OF THE MEDICAL LICENSING BOARD OF INDIANA, in their official capacities, et al.,	)	
	)	
Defendants.	)	

The 30(b)(6) deposition upon oral examination of RILEY CHILDREN'S HEALTH by ELAINE COX, M.D., a witness produced and remotely sworn before me, Debbi S. Austin, RMR, CRR, Notary Public in and for the County of Hendricks, State of Indiana, taken on behalf of the Defendants via Zoom videoconference on May 31, 2023, at 9:01 a.m., pursuant to the Federal Rules of Civil Procedure.

STEWART RICHARDSON & ASSOCIATES
Registered Professional Reporters
(800)869-0873

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(All participants via Zoom videoconference)

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Mylene Laughlin
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Shay Storz
John Vastag
Roarke Matchett

INDEX OF EXAMINATION

INDEX OF EXHIBITS

INDEX OF EXHIBITS (CONT'D.)

Fertility Preservation for Transgender and Gender-Nonbinary People

Riley Children's Gender Health Team

Why should transgender and gender-nonbinary people think about fertility preservation?

It is important to talk about fertility preservation (saving eggs or sperm to use in the future) before you make decisions about gender-affirming medical care. If you use hormones like estrogen or testosterone (gender-affirming hormone therapy) or have surgery to remove your testes or ovaries (gonadectomy), it can change your fertility. Fertility is the ability to create a baby with your egg or sperm.

Researchers have talked to transgender and nonbinary adults about creating families. Some transgender and nonbinary adults feel like they missed out on the chance to have children who are genetically related to them. Some of them would rather become parents by adopting. Many of them think we should discuss the different choices you have before you start medical treatments that could change your fertility.

You may not want to be a parent, or maybe right now it's hard to imagine being a parent. Your thoughts about this may change as you get older. It is important for you to know what can be done now and in the future.

Here are some things related to fertility preservation that you might want to talk about with us:

- ***Future desire to be a parent***. Before starting hormones, think about whether you want the option to have children who are genetically related to you in the future. Hormones and surgeries can decrease your fertility or cause you to become infertile. It is important to make decisions about fertility preservation now before you start those treatments.
- ***Understanding the process***. It's important to understand the options for fertility preservation that are available. It's also important to understand what your future reproductive options are. You may want to know about the success rates of procedures that use saved eggs/sperm/embryos.
- ***Cost.*** The costs of fertility preservation are not covered by most insurance plans. One cost is the retrieval and storage of eggs/sperm/embryos. Another cost is for future procedures, such as IVF (in vitro fertilization). IVF is a procedure where doctors help make an embryo (the first stage of fertilization) by mixing your unfrozen eggs or sperm with another person's eggs or sperm. The embryo can then be put into a uterus—either yours, if you have one, or another person's. This can also be done with unfrozen embryos.

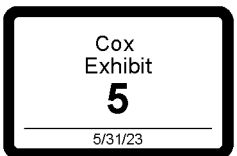
Parents/guardians are also very important when it comes to helping their child think about their options for fertility preservation. They usually have to give consent for any procedures. They also need to consider any effects on their child's mental and physical health. Our team members are available to discuss these issues or other concerns.

For people who have not started puberty:

You do not have to start puberty in order to do fertility preservation. You can have tissue from your ovaries or testes stored before you start or finish puberty. Doctors use anesthesia (giving you medicine so you don't feel pain) to do a small surgery to remove a piece of tissue from your ovaries or testes to save it. Right now, this is the only fertility preservation option for people who have not started puberty yet or who are in the earlier stages of puberty. It is considered experimental.

For people who have started puberty and are using (or thinking about using) puberty blockers:

If you are already on puberty blockers and want to do fertility preservation before you start hormone therapy, you can save eggs or sperm to use in the future. However, most people will need to stop the



puberty blocker and let their body to go through puberty for a while before their sperm or eggs can be collected. Sometimes adolescents can save tissue from their testes or ovaries for future use.

For people who have finished puberty and started hormones (or plan to start hormones or have surgery in the future):

If you have started gender-affirming hormones but still have your testes or ovaries, you usually need to stop taking your hormones for a while so that your fertility comes back. Then you can do fertility preservation. It may take 3-6 months for your fertility to come back after you stop the hormones. However, some people have permanent fertility loss after starting hormones. Some people will need to try one of the procedures that we talk about below. Once your testes or ovaries are removed, fertility preservation isn't an option anymore. It is important to think about fertility choices before you have that surgery.

If you were born with ovaries:

- **Retrieving and freezing ovarian tissue (ovarian tissue cryopreservation).** This is currently experimental. It has been performed successfully at centers with experts in this area. A doctor would take a piece of tissue from your ovaries and freeze it. Later on, the ovary tissue is unfrozen and matured in a laboratory to make eggs. Then doctors use those eggs to make an embryo that is put back into a uterus to make a pregnancy. Another option is that the unfrozen tissue could be put back into your body to let your body try to make eggs on its own.
- **Retrieving and freezing eggs (oocyte cryopreservation**). A doctor would remove the eggs from your body and then freeze them. Later on, the eggs can be unfrozen and fertilized with sperm from a donor or a partner to make an embryo. Then embryos can be put into a uterus to make a pregnancy. The uterus can belong to a surrogate (someone who is okay with carrying your embryo for you in their body until the baby is born), your partner (if they can experience pregnancy), or you (if you have not had surgery to remove your uterus and would like to experience the pregnancy yourself). If you are taking testosterone, you will have to stop taking the testosterone before the doctor removes your eggs (or before embryos are put into your uterus if you want to be pregnant).
- **Retrieving eggs to create embryos with sperm from a donor or partner (embryo cryopreservation).** If an embryo was made it can be frozen and then unfrozen later. Then the embryo can be carried by a surrogate or by you or your partner (if one of you has a uterus and wants to be pregnant). Remember that if you are taking testosterone, you will have to stop taking it before the doctor removes your eggs to make the embryo (or before embryos are put into your uterus if you want to be pregnant).

If you were born with testicles:

- **Retrieving and freezing sperm.** Sperm are removed from your body by masturbating, by vibration or electrical stimulation, or by surgery. Then the sperm are saved by freezing. Later on, the sperm can be unfrozen and fertilized with an egg (from a donor or your partner) to make an embryo. Then doctors can put the embryo inside your partner (if they can experience pregnancy) or a surrogate (someone who is okay with carrying your embryo for you in their body until the baby can be delivered). If you decide to remove the sperm from your body by masturbating, you can do this with an at-home kit, or you can do it in a doctor's office.
- **Testicular tissue preservation**. This is experimental. Doctors remove a small piece of your testicle tissue and send it to a center where it will be stored for you to use in the future.

You don't have to use your sperm or eggs to become a parent. You can adopt, be a foster parent, or have someone else carry the pregnancy with donated sperm, eggs, or embryos. You can also choose not to be a parent. We want everyone to know what their options are so that they can make the best decision about their own future.

Hormone therapy: Testosterone

What is the goal of testosterone therapy?

- Testosterone has two main jobs: 1) it causes masculinizing changes to occur throughout the body, and 2) it suppresses the production of estrogen. Some of the changes caused by testosterone are permanent (they would remain if testosterone was stopped), and other changes are reversible.

How is testosterone administered?

- Testosterone is available as injections, cream or gel. Injections are administered either every 2 weeks intramuscularly (into the muscle) or every week subcutaneously (under the skin). Nursing staff provides injection training here at clinic. Cream and gels are absorbed through the skin and are applied daily.

What are the irreversible effects of testosterone?

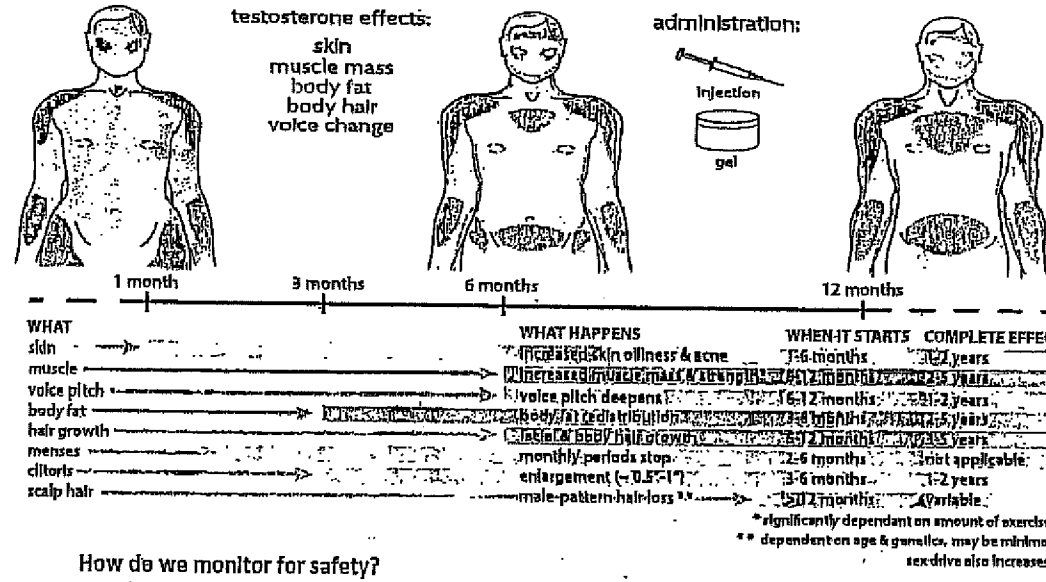
- Testosterone causes voice deepening, clitoral growth, body/facial hair growth, and sometimes male-pattern balding (also influenced by age, genetics). Testosterone may irreversibly affect fertility. Desires for fertility should be considered prior to starting hormones, and for those seeking fertility preservation (or education about fertility preservation), referrals can be made to Lurie's fertility preservation team.

What are some of the reversible effects of testosterone?

- Testosterone causes increased muscle tone, fat redistribution (hips → stomach area), skin oiliness and acne. Mood changes (often irritability, having a "shorter fuse") and heightened sex drive may occur. Menstrual cycles will change and eventually stop after some time. There may be genital changes caused by low estrogen levels.

What are some of the known side effects and risks of testosterone?

- Testosterone may increase your metabolic risk profile – that is, the risk for conditions such as heart disease, diabetes, high cholesterol or blood pressure. The risk for heart disease is higher for people who smoke cigarettes, are overweight or have a family history of heart disease.
- Testosterone causes hematocrit, the proportion of red blood cells in a volume of blood, to increase. This blood thickening, at high levels, can be life-threatening, causing stroke or a heart attack.
- Testosterone can also cause increased appetite, headaches and acne.



How do we monitor for safety?

- Labs (bloodwork) are collected prior to starting hormones and every 3 months for the first year of treatment. In the second year labs are checked every 6 months. Tests that are monitored include cholesterol, liver tests, hematocrit and hormone levels. These labs can be drawn at Lurie's or at a local facility.

How quickly will changes develop?

- Remember, it's normal to want to see changes occur rapidly, but (just like in puberty) these changes take time! Most changes start to begin ~3-6 months after starting testosterone and take years to fully develop.

Will I look like my friend ____??

- Remember, everyone experiences puberty differently. Factors other than testosterone (such as genes!) affect appearance. It's impossible to predict exactly what changes will develop.
- It's important to take the prescribed dose of testosterone. Taking more increases health risks.
- Always tell your health care provider if you have questions or concerns about your health.

Cox Exhibit 6 5/31/23

IUH00003893

ORAL CONTRACEPTION CONSENT

Place your initials before each statement to indicate that you have read, understand, and agree with the statement.

____ I have been given information on other forms of birth control and I have had all of my questions answered. I have voluntarily chosen the birth control pill as my method of birth control, if I need birth control.

____ I have been informed that I must take the birth control pills correctly in order to prevent pregnancy. The typical effectiveness of the pill is 97-98% protective, but skipping or missing pills puts me at risk for pregnancy.

____ I understand that birth control pills will not prevent infection. I need to have my partner use condoms to prevent possible infection with sexually transmitted diseases, including HIV.

____ Missing pills, and vomiting and/or diarrhea may decrease the pill's effectiveness. I understand that I should use a backup method of birth control (condoms) as discussed with my provider in these instances to decrease my risk of pregnancy.

____ I understand that it is important to discuss all other medications that I am taking as some prescriptions may interfere with the pill's effectiveness.

____ I understand it is common to experience breast tenderness, nausea, dizziness, and spotting during the first three months of pills use. By taking my pills every day at approximately the same time and with food, I may decrease some of these symptoms.

____ I understand that besides preventing pregnancy, the pills also have some health benefits as decreasing blood flow and menstrual cramps and helping to regulate my period. In addition, the use of pills may also improve acne.

____ I understand that by taking birth control pills, there is also a chance of decreased risk for ovarian cysts, ovarian and endometrial cancer, pelvic inflammatory disease, anemia, premenstrual syndrome, and mid-cycle pain.

____ I have been informed of the **possible side effects** of birth control pills:

- Nausea
- Headaches
- Spotting between periods
- Breast tenderness
- Mood changes-depression
- Weight gain or weight loss
- Worsening of acne

____ I understand that birth control pills may also be associated with **minimal risk** for:

- Increased cholesterol – but Usually HDL – the "good cholesterol"
- Increase in blood pressure
- Blood clots of the lungs or legs
- Gall bladder disease

____ I understand that **serious pill-related health problems** are rare, but may occur. Therefore, I agree that if I have any of the following danger signs, I will call the clinic, contact my health care provider, or go to the nearest emergency department or immediate care center:

- Severe abdominal pain
- Severe headache
- Severe leg pain
- Chest pain
- Visual changes
- One-sided body weakness and/or numbness
- Yellowing of the skin/eyes

____ I understand that the potential risk to life and health is greater from pregnancy than from pill use.

____ I have had the opportunity to read the Birth Control fact sheet, discuss the risks and benefits of taking "the pill", and review any questions or concerns I have with my health care provider.

____ I understand the importance of returning to the clinic for routine follow-up health care or at any time I am experiencing a problem. I am aware of the need for a yearly physical exam or check-up.

Patient's signature _____ / Date

Staff Signature _____ / Date

INDIANA UNIVERSITY
DEPARTMENT OF PEDIATRICS
School of Medicine

DEPO-PROVERA CONSENT

Place your initials before each statement to indicate that you have read, understand, and agree with the statement.

____ I am aware that there are many birth control methods to choose from. I have been told about the benefits, disadvantages, and known risks of using Depo-Provera.

____ I am aware that the typical effectiveness of Depo is 97-99.7%.

____ I understand that if I have the following health problems I should seek immediate care at the clinic or the emergency department:

- Sharp chest pain
- Coughing up blood or sudden shortness of breath
- Sudden severe headache or vomiting
- Dizziness or fainting
- Problems with my eyesight or speech
- Weakness or numbness in an arm or leg
- Severe pain or swelling in the lower leg
- Severe pain or tenderness in the lower abdominal area
- Heavy vaginal bleeding (1-2 pads every 1-2 hours for a few hours)
- Persistent pain, pus, or bleeding at the injection site

____ I understand that when I stop using Depo-Provera, it could take several months before my regular menstrual cycle resumes. Taking birth control pills or using the contraceptive patch for 3 months may help to regulate my periods more quickly.

____ I understand that it could take from a few weeks to as long as months after my last injection in order to become pregnant. If I DO NOT desire pregnancy, I must use another method of birth control immediately after stopping the Depo.

____ I understand that the following are the MOST COMMON side effects of Depo-Provera

- An increase in appetite that may lead to weight gain
- Irregular menstrual bleeding or spotting
- Menstrual like cramps
- Amenorrhea (no periods)

____ I understand that the following are the LEAST COMMON side effects of Depo-Provera and occur less frequently:

- Headaches
- Bloating
- Moodiness or Depression
- Acne
- Swelling of the hands or feet
- No hair growth or excessive hair loss
- Nausea
- Breast swelling and/or tenderness
- Nervousness
- Dizziness

____ I understand the BLACK BOX WARNING associated with Depo-Provera:

- Women who use Depo-Provera may lose significant bone mineral density. Bone loss is greater with increasing duration of use (e.g. longer than 2 years) and may not be completely reversible.
- It is unknown if use of Depo-Provera during adolescence or early adulthood will reduce peak bone mass and increase risk for osteoporotic fracture in later life.
- Depo-Provera should be used as a long-term birth control method only if other methods are inadequate

____ I understand the Depo-Provera does not protect me from the AIDS virus or other sexually transmitted infections. I need to use condoms for this protection.

____ I understand that I need to return every 11-13 weeks for another injection in order for this method to continue working. I am aware that I need to return for an annual physical exam.

____ I have had the opportunity to read the Depo-Provera Fact Sheet, review it with my nurse and have any questions I may have answered. I know I may call my nurse for future questions or concerns and if I am experiencing any side effects. I understand the importance of rescheduling a missed appointment as soon as possible.

Patient's Signature Date

Staff Signature Date

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CH-898 (MAY 16)
Page 1 of 1

Indiana University Health

CONSENT FOR INTRAUTERINE DEVICE PLACEMENT

Patient Sticker

By signing this form, I agree to the procedure(s) listed here. _____

Intrauterine Device Placement

☐ ParaGuard Intrauterine Device ☐ Mirena Intrauterine System

☐ Liletta

to be done by _____

members of Indiana University Health medical or other licensed personnel staff.

From this point on

- all procedures will be called the "procedure"; and
- the persons performing the procedure will be called "treating practitioner."

The exceptions to my consent are as follows:

_____

_____

I understand and agree to the following items.

- Residents and students may help with my care.
- Medical staff other than the treating practitioner may do part of my procedure.
- Industry representatives may be in the room to consult during my procedure.
- The treating practitioner may do other procedures not listed here if they are needed.
- A bad outcome may occur. A bad outcome does not mean care was not appropriate.
- The anesthesiologist or treating practitioner will give me an anesthetic. I have been told about the risks of anesthesia. These include death, injury to my teeth, throat and mouth, other injury and damage to my dentures.
- I agree to get blood and/or blood products any time during this hospital stay if the treating practitioner thinks I need it. I have been told about the risk of getting blood. I have been told if there are other choices. If I need blood or blood products, I agree to the risks that include allergic reactions, infections (hepatitis and AIDS), intravascular fluid overload, and chemical imbalances.
- Parts of my body taken out during surgery can be thrown away or used for research so long as my name is not used.
- Pictures may be taken and used for teaching as long as my name is not used.
- I have talked with the treating practitioner about the procedure, why I need it, the expected outcome, the risks, the chances of success, risks, benefits and results of other treatments, and what could happen if I do not have the procedure.
- I have been told about other choices, including not having the procedure, other procedures, medicine, and therapy.
  - Other choices: _____
- I have been told about the risk of the procedure, which include but are not limited to bleeding, infection, injury, scarring, damage to parts of my body, and death. Other risks: _____

RISKS: Unplanned pregnancy (chance of pregnancy is less than one in one hundred). Ectopic pregnancy (pregnancy in the tubes). If a pregnancy occurs with an IUD in place, it may result in miscarriage. Pelvic infection (may cause infertility, serious infection, need for surgery or even hysterectomy). Perforation (hole) in the uterus during placement of IUD (may require surgery to remove IUD). Expulsion of the IUD. I will have changes in my period while using the IUD.

_____
Signature of Patient / Surrogate

_____
Time Signed Date Signed

_____
If Signed by Surrogate, Relationship to Patient

OPTIONAL:

Additional Adult Witness Signature

Time Signed Date Signed

TREATING PRACTITIONER USE ONLY

I have discussed with the patient the nature of the proposed care, treatment, services, medications, interventions or procedures; the potential benefits, risks or side effects, including potential problems related to recuperation; the likelihood of achieving care, treatment and service goals; the reasonable alternatives to the proposed care, treatment and service; the relevant risks, benefits and side effects related to alternatives, including the possible results of not receiving care, treatment and services; and when indicated, any limitations on the confidentiality of information learned from or about the patient.

Signed: _____ **Date:** _____ **Time:** _____

DOCUMENTATION OF EMERGENT/URGENT PROCEDURE

This procedure was performed emergently.

Signed: **Date:** **Time:**

NEXPLANON® (etonogestrel implant)
Radiopaque
Subdermal Use Only

PATIENT CONSENT FORM

I understand that there are many birth control methods and that each has its own benefits, risks and potential side effects. The insertion of NEXPLANON requires a surgical procedure performed by a healthcare provider who is trained on the use of this product. Like all surgical procedures, the outcomes are best with healthcare providers who are experienced.

By completing this Patient Consent Form, I am consenting to the insertion of NEXPLANON and acknowledging that I have read and understand the following points and made an informed and careful decision to use NEXPLANON.

- NEXPLANON is an implant that releases a hormone (etonogestrel) to prevent pregnancy. It is inserted during a surgical procedure and it can be used for up to three years.
- NEXPLANON helps to keep me from getting pregnant but does not protect me against HIV infection (the virus that causes AIDS) or other sexually transmitted diseases.
- No contraceptive method is 100% effective, including NEXPLANON.
- It is important to have the NEXPLANON implant placed in my arm at the right time of my menstrual cycle in order to prevent pregnancy.
- NEXPLANON is placed just under my skin on the inside of my upper arm during a procedure done in my healthcare provider's office. There is a slight risk of getting a scar or an infection from this procedure.
- NEXPLANON should not be deeply inserted. An implant that is inserted deeply may have been placed in muscle tissue or, in rare instances, a blood vessel. A deep insertion may cause the implant to move beyond the implant site.
- After NEXPLANON is placed in my arm, both my healthcare provider and I should check that it is in place by gently pressing my fingertips over the skin where the implant was placed. I should be able to feel both ends of the implant. If I cannot feel the implant, it may not have been inserted or it may have been inserted deeply. In this case, I need to use a non-hormonal birth control method (such as condoms or barrier methods) until my healthcare provider confirms the implant is in place. I may need special tests to check that the implant is in place. Once my healthcare provider has located the implant, it should be removed.
- Incomplete insertions or infections may cause NEXPLANON to come partially or entirely out of my arm.
- Most women have changes in their menstrual bleeding patterns while using NEXPLANON. I also will likely have changes in my menstrual bleeding pattern while using NEXPLANON. My bleeding may be irregular, lighter or heavier, or my bleeding may completely stop. If I think I am pregnant, I should contact my healthcare provider as soon as possible.
- NEXPLANON must be removed at the end of three years, but it can be removed earlier if I want. I may become pregnant as early as the first week after removal of the implant.
- Removal is usually a minor procedure. If NEXPLANON was inserted deeply, the removal may be more difficult or, in rare cases, impossible. Special procedures, including imaging methods to locate the implant and surgery in the hospital, may be needed. Difficult removals may cause pain and scarring and may result in injury to nerves and blood vessels. If the implant is not removed, its effects will likely continue.
- I have read and understand all of the information in the Patient Labeling for NEXPLANON, including the risks of using NEXPLANON, possible side effects, and warning signs of medical problems. Any questions I have about the information in the Patient Labeling and about using NEXPLANON have been answered by my healthcare provider.
- I should tell all my healthcare providers that I am using NEXPLANON.
- I need to have a medical checkup regularly and at any time I am having problems.
- For additional information and full prescribing information, please call toll free 1-844-674-3200 or log on to www.nexplanon.com.

35258
CH-1096 (JAN 12)
Effective 2012

Indiana University Health

CONSENT FOR PROCEDURE

By signing this form, I agree to the procedure(s) listed here. _____

_____

_____

_____

to be done by _____, _____
members of Indiana University Health medical or other licensed personnel staff.

From this point on

- all procedures will be called the "procedure"; and
- the persons performing the procedure will be called "treating practitioner".

The exceptions to my consent are as follows:

_____

_____

I understand and agree to the following items.

- Residents and students may help with my care.
- Medical staff other than the treating practitioner may do part of my procedure.
- Industry representatives may be in the room to consult during my procedure.
- The treating practitioner may do other procedures not listed here if they are needed.
- A bad outcome may occur. A bad outcome does not mean care was not appropriate.
- The anesthesiologist or treating practitioner will give me an anesthetic. I have been told about the risks of anesthesia. These include death, injury to my teeth, throat and mouth, other injury and damage to my dentures.
- I agree to get blood and/or blood products any time during this hospital stay if the treating practitioner thinks I need it. I have been told about the risk of getting blood. I have been told if there are other choices. If I need blood or blood products, I agree to the risks that include allergic reactions, infections (hepatitis and AIDS), intravascular fluid overload, and chemical imbalances.
- Parts of my body taken out during surgery can be thrown away or used for research so long as my name is not used.
- Pictures may be taken and used for teaching as long as my name is not used.
- I have talked with the treating practitioner about the procedure, why I need it, the expected outcome, the risks, the chances of success, risks, benefits and results of other treatments, and what could happen if I do not have the procedure.
- I have been told about other choices, including not having the procedure, other procedures, medicine, and therapy.
  Other choices: _____
  _____
- I have been told about the risk of the procedure, which include but are not limited to bleeding, infection, injury, scarring, damage to parts of my body, and death. Other risks: _____
  _____
  _____

_____
Signature of Patient/Surrogate

_____
Time Signed Date Signed

_____
If Signed by Surrogate, Relationship to Patient

OPTIONAL

_____
Additional Adult Witness Signature

_____
Time Signed Date Signed

TREATING PRACTITIONER USE ONLY

I have discussed with the patient the nature of the proposed care, treatment, services, medications, interventions or procedures; the potential benefits, risks or side effects, including potential problems related to recuperation; the likelihood of achieving care, treatment and service goals; the reasonable alternatives to the proposed care, treatment and service; the relevant risks, benefits and side effects related to alternatives, including the possible results of not receiving care, treatment and services; and when indicated, any limitations on the confidentiality of information learned from or about the patient.

Signed: _____ Date: _____ Time: _____

DOCUMENTATION OF EMERGENT/URGENT PROCEDURE

This procedure was performed emergently.

Signed: _____ Date: _____ Time: _____

INDIANA UNIVERSITY
DEPARTMENT OF PEDIATRICS
School of Medicine

CONSENT FOR ORTHO EVRA

Instructions: Place your initials after each line to indicate that you have read, understood, and agree with the statement. If you have any questions as you read, we will be happy to answer them.

___ I have been given information on other forms of birth control and I have had all of my questions answered. I have voluntarily chosen the Ortho Evra contraceptive patch as my method of birth control.

___ I have been informed that I must use the contraceptive patch correctly in order to prevent pregnancy. It is 97- 99% protective. In other words, 1-3 women out of 100 will become pregnant after using the patch for one year. Incorrect use of "the patch" will increase the risk of pregnancy.

___ I understand that the contraceptive patch will not prevent infection. I need to have my partner(s) use condoms to prevent possible infection with sexually transmitted disease, include HIV/AIDs.

___ I understand that it is important to inform my health care provider and/or nurse of all medications I am taking. This includes prescription drugs and over the counter medications.

___ I understand it is common to experience breast tenderness, nausea, dizziness, and spotting during the first three (3) months of using the contraceptive patch. These possible side effects improve with time.

___ I understand that besides preventing pregnancy, the contraceptive patch also has such benefits as decreasing blood flow and cramps with my period, regulating my periods and may also improve acne.

___ I understand that by using the patch, there may be some protection from having difficult periods, ovarian cysts, ovarian and endometrial cancer, pelvic inflammatory disease, anemia, premenstrual syndrome, and mid-cycle pain.

___ I have been informed of the **possible** side effects of the contraceptive patch:

- Nausea
- Depression
- Skin irritation at the patch site
- Aggravation of acne
- Increase in yeast infections
- Breast tenderness
- Weight gain

___ I understand that the contraceptive patch may also be associated with **minimal** risk for:

- Increased cholesterol (HDL "good cholesterol")
- Gall bladder disease
- Blood clots of lungs or legs
- Liver Tumors
- Increase in blood pressure

___ I understand that if my weight is over 200 pounds the risk of pregnancy may be higher than in a woman who is less that 200 pounds.

___ I understand that serious health problems related to use of "the patch" are **rare** but may occur. Therefore, I agree that if I have any of the following danger signs, I will call the clinic, contact my health care provider, or go to the emergency room for **immediate** care:

- Severe abdominal pain
- Chest pain
- Severe headache
- Yellowing of skin/eyes
- Visual changes
- Severe leg pain
- One-sided body weakness and/or numbness

___ I understand that the risk to life and health is greater from pregnancy than from use of the contraceptive patch.

___ I have had the opportunity to read the Ortho Evra fact sheet, discuss the risks and benefits of using "the patch" and review any questions or concerns I have with my health provider. I understand the importance of routine follow-up care or any time I am experiencing a problem. I am aware of the need for an Annual Physical exam.

_____/_____ _____/_____
Patient Signature Date Staff Signature Date

Is Gender Affirming Care Safe & Effective

- Gender Affirming care is safe, effective, and important to the health and well-being of transgender people. This life-saving care encompasses both social affirmation (e.g., supporting a transgender person's chosen name, dress etc.) and medical affirmation, which allows transgender people to live in a body that matches the gender with which they identify.
- Expert medical standards of care on the provision of gender-affirming care have been continuously maintained and updated for more than 40 years. These standards require providers to carefully evaluate each patient and make decisions in the patient's best interest.
- Every major U.S medical and mental health organization, including the American Medical Association, American Academy of Pediatrics, Federation of Pediatric Organizations, and American Psychological Association, supports access to gender affirming support and care for transgender young people and adults.
- Researchers and health experts have studied the effects of gender-affirming care for decades. The scientific evidence shows that transgender people who have access to the care they need see a positive impact on their mental and physical health. (See further detail below.)

Standards of Care for Gender Affirming Care

- Every person has unique health needs, including transgender people. Health care providers follow well-established expert best practices to prescribe age-appropriate gender-affirming support and care.
    - For prepubertal children, the only intervention is social support, such as wearing different clothes or using a chosen name. Social support (sometimes called social transition) can help kids understand and explore their gender as they grow up and is endorsed by the American Academy of Pediatrics, which is the national expert medical society for pediatricians. Social transition is entirely reversible.
    - For adolescents with clinically recognized gender dysphoria who have just started or are well into puberty, the first step in medical gender affirmation is typically the use of medications that temporarily pause puberty, otherwise known as puberty blockers. These medications have been used to treat both transgender and non-transgender young people experiencing puberty at the wrong time for more than 30 years and have been shown to be safe and effective.[i]
    - Puberty delay medications can be stopped at any time, and puberty starts back up after being temporarily paused.
    - If an adolescent continues to experience gender dysphoria, gender-affirming hormones are often used to help bring the person's body into alignment with their gender. Gender-affirming hormone therapy has been safely and effectively used for both transgender and non-transgender people.

- It is recommended that genital surgeries (commonly referred to as "top" or "bottom" surgeries) should not be carried out until (i) patients reaches the legal age of majority, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity.[ii]
- Mental health professionals are an integral part of gender affirmation for transgender youth to make sure that young people and their families feel safe and supported.

Substantial Scientific Evidence Supports Access to Gender-Affirming Care

- Recent research found that 98% of transgender youth who begin gender affirming medical treatment in adolescence continue gender-affirming medical care into young adulthood.[iii] This adds to the vast body of scientific evidence demonstrating that gender-affirming care is essential for improving the mental health and overall well-being of transgender people.

- Other studies have found similar positive impacts[iv] on the mental health of transgender and nonbinary youth.
  - Example: A 2018 review of over 50 research studies indicated that gender-affirming health care services are associated with better mental health for transgender people, including reduced suicide attempts, less depression, and higher life satisfaction.
  - Example: A 2022 review of over 50 studies found reduced rates of suicide attempts, anxiety, depression, and symptoms of gender dysphoria along with higher levels of life satisfaction, happiness, and quality of life after gender affirming surgery among transgender adults.
  - Example: A 2022 peer-reviewed study found that receipt of gender affirming care among young people aged 13 to 20 was associated with 60% lower odds of depression and 73% lower odds of suicidality over a 12-month follow-up.
  - Example: A 2021 peer-reviewed study found that transgender and nonbinary adolescents (those that don't identify with one particular sex) with access to gender affirming hormone therapy treatments had nearly 40% lower odds of having had a suicide attempt in the past year, compared to peers who did not have access to affirming care.
  - Example: A 2022 review of 16 studies on gender affirming care for transgender youth found that this care results in favorable mental health outcomes.
  - Example: A 2016 peer-reviewed study showed that transgender youth who were socially supported in their gender identity had much better mental health than those who were not supported in their identity.

Gender Affirming Care Services at Riley Hospital for Children

- At Riley, all gender affirming Care interventions are done in consultation and with consent of parent(s) or legal guardian(s) when the patient is a minor.
    - All are done in consultation and review by a mental health professional, confirming the patient's diagnosis of gender dysphoria. (NOTE: Gender Dysphoria is defined as the distress and unease experienced if the gender identity and sex at birth are not completely congruent.)
    - All are done in alignment with national and international guidelines of care for children, adolescents, and adults who are transgender.
    - All include consistent appointments over time to follow a patient's mental and physical health throughout treatment.
- As discussed above, puberty (hormone) blockers, which have been around since the early 1990s, are very safe when appropriately used. At Riley, we typically stop hormone blockers between the ages of 14-16 years old to avoid any long term impacts to bone growth and development.
- Gender affirming hormones are largely reversible therapies. They can be initiated at the age of 14 or older, with a step-wise increase in doses over 12-24 months. When on gender affirming hormones, a patient typically has appointments every 3 months for the first 2-3 years, and then at least annually.
- Consistent with current standards of care in the U.S. , Riley does not conduct top or bottom surgeries on any patient before the age of 18. These guidelines exist to ensure that patients receive the individualized and age-appropriate care they need in consultation with their families and their doctors.

Gender Affirming Interventions for *Pediatric Patients* (less than 18yo) at Riley Hospital for Children

Services Provided	Services NOT Provided
Ambiguous genitalia surgery	Top Surgery
Treatment for menstrual suppression	Bottom Surgery
Gender-affirming hormone therapy	
Surgery consultation and coordination	

[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7430465/#CIT0061

[ii] SOC V7_English.pdf (wpath.org), see page 21

[iii] Van der Loos, M. A. T. C., Hannema, S. E., Klink, D. T., den Heijer, M., & Wiepjes, C. M. (2022). Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: A cohort study in the Netherlands. The Lancet Child & Adolescent Health, 6(12), 869–875. https://doi.org/10.1016/s2352-4642(22)00254-1

[iv] Ramos, G. G. F., Mengai, A. C. S., Daltro, C. A. T., Cutrim, P. T., Zlotnik, E., & Beck, A. P. A. (2021). Systematic Review: Puberty suppression with GnRH analogues in adolescents with gender incongruity. Journal of Endocrinological Investigation, 44(6):1151-1158. doi: 10.1007/s40618-020-01449-5

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Indiana University Health

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Gender Care Services

- Approximately 0.7% of adolescents (13-17) identify as transgender or gender fluid. This means they do not identify with the gender they were assigned at birth.[i]
- Transgender youth face marginalization and marked health disparities not due to their gender identities, but due to discrimination, societal stigma, lack of social support, and lack of access to gender-affirming care.[ii]
- Medical intervention for gender affirmation, when it is clinically and developmentally appropriate, is supported by solid medical evidence.[iii] These interventions can include:
    - Social Transitions: name change, change in dress, etc.
    - Medication (hormone blockers, menstrual regulation, or gender affirming hormones), and
    - Surgery [iv]
- Transgender youth have high rates of depression (12.4-64% range), self-harm (13-53%), and suicide attempts (9.3-30%). Transgender children who socially transition, and adolescents who receive medical treatment, return to the same risk of depression or anxiety as cisgender (non-transgender) children.[v]
- Not all adolescents desire gender affirming hormones, and only a small minority consider surgery of any kind in the future once they are adults.[vi]
- At Riley, all interventions are done in consultation and with consent of parent(s) or legal guardian(s) when the patient is a minor.
    - All are done in consultation and review by a mental health professional, confirming the patient's diagnosis of gender dysphoria.
    - All are done in alignment with national and international guidelines of care for children, adolescents, and adults who are transgender.
    - All include consistent appointments over time to follow a patient's mental and physical health throughout treatment.
- Puberty (hormone) blockers, which have been around since the early 1990s, are very safe when appropriately used. At Riley, we typically stop hormone blockers between the ages of 14-16 years old to avoid any long term impacts to bone growth and development.
- Gender affirming hormones are largely reversible therapies. They can be initiated at the age of 14 or older, with a step-wise increase in doses over 12-24 months. When on gender affirming hormones, a patient typically has appointments every 3 months for the first 2-3 years, and then at least annually.

Gender Care Interventions for Pediatric Patients (less than 18yo) & Riley Hospital for Children

Services Provided at Riley	Services NOT Provided at Riley
Ambiguous genitalia surgery	Top Surgery
Treatment for menstrual suppression	Bottom Surgery
Gender-affirming hormone therapy	
Surgery consultation and coordination	

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[ii] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4802845/

[iii] https://www.wpath.org/publications/soc

[iv] Wylie C Hembree, Peggy T Cohen-Kettenis, Louis Gooren, Sabine E Hannema, Walter J Meyer, M Hassan Murad, Stephen M Rosenthal, Joshua D Safer, Vin Tangpricha, Guy G T'Sjoen, Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline, *The Journal of Clinical Endocrinology & Metabolism*, Volume 102, Issue 11, 1 November 2017, Pages 3869–3903, https://doi.org/10.1210/jc.2017-01658

[v] https://www.sciencedirect.com/science/article/abs/pii/S1054139X1630146X#preview-section-snippets

[vi] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8754307/

Demographic and temporal trends in transgender identities and gender confirming surgery - PMC (nih.gov)

Gender Affirming Support and Education:

Community Organizations for Support:

1. Indiana Youth Group
2. GenderNexus
3. TransSolutions
4. GEKCO
5. Trans Parent USA
6. The Trevor Project
7. PFLAG
8. Gender Spectrum

Creating A Safe Folder/ Supporting Gender Expansive Loved Ones:

9. Safe Folder (imatyfa.org)
10. Our Trans Loved Ones: Questions and Answers for Parents, Families, and Friends of People who are Transgender and Gender Expansive

History of Gender Non Conformity across cultures:

11. https://historicengland.org.uk/research/inclusive-heritage/lgbtq-heritage-project/trans-and-gender-nonconforming-histories/
12. https://screenshot-media.com/politics/lgbtqi-rights/non-binary-cultures/
13. https://www.pbs.org/independentlens/content/two-spirits_map-html/
14. https://www.lgbthealth.org.uk/lgbt-health-blog/transgenderism-in-ancient-cultures/

Gender Affirming Legal Support:

Changing Name and Gender Markers:

15. https://www.indianalegalservices.org/LGBTVAP
16. Name change scholarship (Translifeline.org)

Gender Nonconforming Student Rights:

17. Transgender Students: Know Your Rights | ACLU of Indiana (aclu-in.org)

Gender Affirming Social Supports:

Binding:

18. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe3539.pdf
19. Binding: Resources & info about safer chest binding by Point of Pride
20. Safer Binding (callen-lorde.org)
21. Indiana Youth Group Binding Resources
22. Sizing for Binders
23. Chest binder donations

Packing:

24. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe3637.pdf
25. https://www.prideinpractice.org/articles/packers-stand-to-pee/

Gender Affirming Medical Care:

Puberty Blockers:

26. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe2572.pdf
27. Puberty Blockers at Seattle Children's - YouTube
28. Mary Bridge Puberty Blockers Handout

Hormone Replacement Therapy- Testosterone:

29. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe2707.pdf
30. Lurie Children's- Testosterone
31. Masculinizing Hormone Therapy at Seattle Children's - YouTube

Menstrual Suppression:

32. Seattle Children's- Menstrual Hygiene for Gender Diverse Youth
33. Seattle Children's- Menstrual Suppression

Fertility Preservation:

34. https://www.seattlechildrens.org/globalassets/documents/for-patients-and-families/pfe/pe3359.pdf
35. Fertility Preservation for Trans and Gender Non-Conforming People

A Guide to Feminizing Hormones

Gender Affirming Care

Hormone therapy is an option that can help transgender people feel more comfortable in their bodies. Like other medical treatments, there are benefits and risks. Knowing what to expect will help us partner to maximize the benefits and minimize the risks.

The binary term “male,” “female,” “masculine,” “feminine,” “masculinizing” and “feminizing” do not accurately reflect the diversity of people’s bodies or identities. To describe how hormones work, it is helpful to know how testosterone works in non-intersex, non-trans men’s bodies, and how estrogen and progesterone works in non-intersex, non-trans women’s bodies. We keep these binary terms in quotes to emphasize that they are artificial and imperfect concepts.

What are hormones?

Hormones are chemical messengers that tell tissues of the body how to function, when to grow, when to divide and when to die. They regulate many functions, including growth, sex drive, hunger, thirst, digestion, metabolism, fat burning and storage, blood sugar, cholesterol levels and reproduction.

What are sex hormones?

Sex hormones are involved in the development of the penis and testicles, or the vulva and clitoris (external genitals). Sex hormones also affect the secondary sex characteristics that typically develop at puberty (facial and body hair, bone growth, breast growth, voice changes, etc.). There are 3 categories of sex hormones in the body:

- **Androgens:** testosterone, dehydroepiandrosterone (DHEA), dihydrotestosterone (DHT)
- **Estrogens:** estradiol, estriol, estrone
- **Progestin:** progesterone

Generally, people with testicles tend to have higher androgen levels, and people with ovaries tend to have higher levels of estrogens and progestogens.

What is hormone therapy?

Hormone therapy is taking medicine to change the levels of sex hormones in your body. Changing these levels will affect your hair growth, voice pitch, fat distribution, muscle mass and other features that are associated with sex and gender. Feminizing hormone therapy can help make the body look and feel less “masculine” and more “feminine” — making your body more closely match your identity.

To Learn More

- Adolescent Medicine - 206-987-2028
- Gender Clinic Care Navigator 206-987-8319
- Ask your child’s healthcare provider
- seattlechildrens.org

Free Interpreter Services

- In the hospital, ask your nurse.
- From outside the hospital, call the toll-free Family Interpreting Line, 1-866-583-1527. Tell the interpreter the name or extension you need.

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What medicines are involved?

There are different kinds of medicines used to change the levels of sex hormones in your body. These medicines work by affecting:

- The part of your brain that stimulates sex hormone production
- Your testicles (which produce testosterone)
- The cells in your body that respond to sex hormones

Usually, feminizing hormone therapy involves:

- Estrogen
- A medicine to block testosterone
- A combination of estrogen and a medicine to block testosterone
- Sometimes a progestin is added

Estrogen

Estrogen is the main hormone responsible for promoting "feminine" physical traits. It works directly on tissues in your body (for example, makes breasts develop). Estrogen also indirectly reduces testosterone. Estrogen can be taken by:

- Pill (oral or under the tongue)
- Injection (intramuscular or subcutaneous)
- Skin patch or gel (transdermal)

There are different formulations of estrogen. Your healthcare provider will talk to you about the different kinds and what is right for you.

Androgen blockers

Androgen-blockers work by blocking testosterone. They are also known as anti-androgens or androgen antagonists. They reduce "masculine" physical traits and have a mildly "feminizing" effect. For example, they will help slow "male" pattern baldness, reduce growth of facial hair and stop spontaneous/morning erections.

There are different types of androgen blockers. The one most typically prescribed is spironolactone. Androgen blockers are often prescribed in addition to estrogen because they have effects that complement each other. Taking androgen blockers reduces the amount of estrogen you need to get the same effects, which minimizes the health risks associated with estrogen. Androgen blockers can be prescribed alone for people who want to reduce "masculine" characteristics for a more androgynous appearance because it is less "feminizing" than estrogen.

Progestins

There are mixed opinions about using progestins for feminizing hormone therapy. Some gender clinic programs choose not to use progestins due to the lack of clear evidence that they facilitate "feminization." Progestins also have known side effects (which include depression, weight gain and changes to blood fats).

However, progestins may be used by some gender care providers in the following situations:

- If estrogen alone is not working, even at the maximum dose.
- As a replacement for estrogen if there are concerns about the side effects or risks of estrogen.
- To promote nipple and breast development (but there is not strong evidence for this yet).

As with estrogen and androgen blockers, balancing possible risks and benefits of progestins is a decision between you and your healthcare providers.

What is a typical dose?

Feminizing hormone therapy varies greatly from person to person. There is no right hormone combination, type, or dose for everyone. Deciding what to take depends on your health because each hormone therapy has different risks and side effects. What your healthcare provider prescribes depends on what is available locally and what you can afford. It may also depend on insurance coverage.

It can change based on how your body reacts when you start taking hormones — everyone's body is different and sometimes people have a negative reaction to a specific kind of medicine.

The right dose or type of medicine for you might not be the same as for someone else. It is a good idea to discuss the advantages and disadvantages of different options with us. If you have any concerns about being able to take the medicines — or about the side effects, costs or health risks — let us know. We take your needs and concerns into account when planning your hormone therapy.

We will partner with you to explore your insurance coverage and any other resources to make sure you get the care you need.

In prescribing a specific medicine and dose, we consider your overall health, including any other medicines you are taking. Every person is different — each body absorbs, processes and responds to sex hormones differently. Some people show more changes than others. Changes happen more quickly for some than others.

Taking more hormones than the dose you were prescribed will not speed up changes. Taking more than your prescribed dose greatly increases your health risks.

If you think your dose is too low, talk with us to discuss your options. It might be better to try a different type of medicine or a combination of medicines, rather than increasing the dose.

If you have your testicles removed, your body will only produce a tiny amount of testosterone, so:

- The dose of estrogen can be reduced
- Androgen blockers can be reduced or stopped

You will need to stay on estrogen or another form of medicine for the rest of your life to keep your bones strong. We may also suggest you take low-dose testosterone to help your metabolism. Your provider may also suggest that you take calcium and vitamin D supplements to protect your bones.

What changes can I expect?

Feminizing hormone therapy has important physical and psychological benefits. Bringing mind and body closer together eases gender dysphoria and can help you feel better about your body. People who have had gender dysphoria often describe being less anxious, less depressed, calmer and happier when they start taking hormones. For some people, this psychological change happens as soon as they start taking hormones. For others, it happens a bit later as the physical changes appear more.

Each person changes differently. How quickly changes appear for you depend on:

- Your age
- The number of hormones receptors in your body
- The way your body responds to the medicine

There is no way to know how your body will respond before you start hormones.

Androgen blocker (spironolactone) without estrogen

Taking spironolactone (the most common androgen blocker) without estrogen has small effects. The changes are caused by the medicine blocking the effect of testosterone in your body. Most of the changes are reversible, which means if you stop taking it, your body will go back to how it was before you started taking the medicine. Androgen blockers affect the whole body. You cannot pick the changes you want.

Average timeline	Effect
After 1 to 3 months	• Decreased sex drive • Fewer instances of waking up with an erection or spontaneously having an erection. Some people also have difficulty getting an erection even when they are sexually aroused • Decreased ability to make sperm and ejaculatory fluid
Gradual changes (usually takes at least 2 years)	• Slower growth of facial or body hair • Slowed or stopped “male”-pattern balding • Slight breast growth (reversible in some cases, not in others)

Estrogen

Taking estrogen has stronger physical "feminizing" effects. These changes are caused by the estrogen's effect on cells in your body that have estrogen receptors. Taking estrogen also has an indirect effect of suppressing testosterone production. Like androgen blockers, estrogen affect the whole body. You cannot pick the changes you want.

Average timeline	Effect
After 1 to 6 months	• Softening of skin • Less muscle mass and more body fat • Redistribution of body fat to be more on breasts and hips • Possible decrease in sex drive • Fewer instances of waking up with an erection or spontaneously having an erection. Some people also have difficulty getting an erection even when they are sexually aroused. • Decreased ability to make sperm and ejaculatory fluid
Gradual changes (maximum changes after 2 to 3 years)	• Nipple and breast growth • Slower growth of facial and body hair • Slowed or stopped "male" pattern balding • Smaller testicles

Breast and nipple growth starts early but is usually gradual. It can take 2 years or more for breasts to reach their maximum size. As with all people, there is a range in how large breasts grow. In many cases, your breasts might not grow beyond an A or B cup size. If you are not happy with the size of your breasts after 18 to 24 months on estrogen, you can consider surgical augmentation. The implants will look most natural if you wait to get as much growth as you can from hormones.

Most of the effects of hormones happen in the first 2 years. During this time, the doctor who prescribes your hormones will usually want to see you every 3 months. This is to check if the hormones are working properly. After that, you will probably need an appointment every 6-12 months. At appointments in the first 2 years, your doctor will likely:

- Look at your facial and body hair. If you shave, the doctor will ask how quickly your hair grows back.
- Ask about changes to your sex drive, erections, or other sexual changes.
- Ask about breast growth or nipple changes
- Order blood test to see what your hormone levels are.
- Ask how your feel about the changes that have happened so far.

After 2 years, your doctor will monitor the effects by asking if you notice any more changes from the hormones.

When you are 21 years old, you will transition to a medical provider who can continue your treatments as an adult. For information about moving to an adult healthcare provider, visit seattlechildrens.org/TransitioningToAdultHealthcare.

Are the changes permanent?

Some of the changes you will notice from the feminizing hormone therapy are not permanent. If you stop taking the medicine, some of the changes will stop and your body will return to how it was before you started the hormones. There are 3 types of changes that may be permanent:

- Breast growth
- Fertility
- Fat distribution to hips

Breast growth

If you are taking the androgen blocker called spironolactone without estrogen because you do not want visible changes, you might see some breast growth. This growth happens slowly, so you can stop taking it if you do not want breast growth. Breast growth from spironolactone is usually small and reversible. But in some people, the breast tissue remains even after the spironolactone is stopped.

Estrogen causes permanent nipple development and breast growth. Even if you stop taking estrogen, the breast tissue will not go away and your nipples will not shrink.

Fertility

Both androgen blockers and estrogen affect your production of sperm, which means you may have trouble having biological children after taking them. It is also important to know that we do not yet fully understand the long-term effects feminizing medications have on fertility. If you stop taking feminizing hormones, your ability to make sperm may or may not return to what it was before you started. We strongly recommend that you talk about options for sperm banking before starting hormone therapy. If you have already started hormones, you can work with your doctor to stop the hormones, give sperm samples and store them if they are viable. Then you could go back on hormones.

Although androgen blockers and estrogen affect sperm production, there may still be a chance you could make someone pregnant after starting hormone therapy. **Depending on how you have sex, you may need to use birth control.**

Hormone therapy does not lower your risk of HIV and other sexually transmitted infections. Depending on how you have sex, you may need to use condoms, gloves or other latex barriers. Feminizing hormones can make erections less firm, increasing the risk of condom leakage. In this situation, your partner can use a special condom they put inside their anus or vagina. They are called “female condoms,” but can be used by people of any gender.

What are the risks?

The medical effects and safety of feminizing hormone therapy are not fully understood. Most of the studies on hormone therapy involve different doses than are used for gender affirming care. There may be long-term risks that are not known yet.

We can lower many of the known risks of feminizing hormone therapy by creating a hormone combination that is made just for you. There are also actions you can take to reduce the risks, including:

- Not smoking. This is the number one thing you can do to reduce your risk of blood clots and heart disease. Even the occasional smoker is at an increased risk. If you do not smoke it increases the amount of estrogen that we can prescribe safely.
- Having your blood tested as recommended by your doctor.

Social repercussions

Being a person in a transphobic society can have social risks. Some people experience violence, harassment and discrimination, while others have lost support of loved ones. If you are worried about how others might react to the changes that come with hormone therapy, counseling can be useful. If you are looking for a therapist, see "How to Find a Therapist." seattlechildrens.org/pdf/PE2195.pdf.

Blood clots

Taking estrogen increases the risk of blood clots. Blood clots can cause death, permanent lung damage (clot in the lungs), permanent brain damage (stroke), heart attack or chronic problems with veins in your legs. The risk of blood clots is much higher for if you smoke.

The danger is so high that some doctors will not prescribe estrogen if you smoke, even occasionally. Most healthcare providers will prescribe you only a low dose of estrogen until you fully stop smoking. The risk of blood clots can be made lower by:

- Taking estrogen by skin patch or gel (transdermal)
- Taking estrogen under the tongue (sublingual)
- Taking estrogen by injection (intramuscular or subcutaneous)
- Using a lower dose of estrogen

Taking estrogen changes the way your body uses and stores fat. Taking estrogen can increase deposits of fat around your internal organs. This type of fat is associated with an increased risk for diabetes and heart disease. Estrogen also increases the risk of gallstones, which can block your gallbladder. See a medical professional right away if you have these symptoms of gallstones:

- Chest, leg or abdominal pain
- Any swelling (edema) in your legs

If you have the following symptoms for more than a couple of days, call a healthcare professional:

- Nausea and vomiting (similar to morning sickness in pregnant women)
- Frequent headaches or migraines, if the pain is unusually bad or if you are vomiting

High blood pressure

Estrogen can also cause an increase in blood pressure. This can be avoided by taking estrogen with an androgen blocker medicine (spironolactone) that lowers blood pressure. If you cannot take spironolactone, you can make other changes to reduce your risk. This includes other types of medicine, exercise, not smoking and changes to your diet.

Galactorrhea and prolactinoma

With breast growth, there is often an increase in milky discharge from the nipples. This is called galactorrhea. This is caused by the estrogen stimulating the production of the hormone prolactin, which stimulates breast ducts to make milk. We do not know if milk production increases the risk of noncancerous tumors (prolactinoma) of the pituitary gland.

Although prolactinoma is not usually life-threatening, it can damage your vision and cause headaches. For this reason, your doctor will monitor for signs of prolactinoma regularly for at least 3 years after you start taking estrogen. More tests can be ordered if your prolactin level is high or if prolactinoma is suspected.

Breast cancer

It is not known if estrogen causes an increased risk of breast cancer. There have been cases of people who have developed breast cancer after hormone therapy for gender affirming care. Talk with your healthcare provider about screening tests that can be done to catch early signs of breast cancer. Your breast cancer risk is higher if you:

- Have a family history of breast cancer
- Have been taking estrogen or progestin for more than 5 years
- Are 50 years or older
- Are overweight

Kidney health

Spironolactone (the most common androgen blocker) affects the balance of water and salt in the kidneys. If the amount of water and salt gets out of balance, you can have problems with low blood pressure. Rarely, this imbalance can lead to high levels of potassium in your body, which can cause changes in heart rhythm that can be life-threatening. Your blood tests will check your potassium levels and kidney function on a regular basis. This is especially important if you:

- Have a history of kidney problems
- Are taking medicine that can raise blood potassium (ask your doctor or pharmacist)
- Are taking ACE-inhibitors (commonly prescribed for people with high blood pressure or heart problems).

If you receive care from another healthcare provider, tell them you are on hormone therapy, so you do not take these kinds of medicines unknowingly.

Migraine headaches

Migraine headaches may happen more often after starting estrogen. People with a history of migraines may want to begin therapy at lower estrogen doses and increase doses slowly. Please talk with your provider if you develop new or different migraines after starting estrogen.

Skin rash

The skin patch (transdermal application) of estrogen can sometimes cause a skin rash. The androgen blocker spironolactone can also cause a skin rash. If this happens, contact us.

How do I get the most benefit and minimize risks?

You can help make hormone therapy as effective and safe as possible. Here are steps you can take:

- **Be informed.** Understanding how hormones work, what to expect, and possible side effects and risks will give you the tools to be in charge of your health and make informed decisions. Do your own research and ask questions. To get started, see "Gender Clinic Booklist and Resources" seattlechildrens.org/pdf/PE2634.pdf.
- **If you smoke, stop or cut down.** Any smoking greatly increases the risks of hormone therapy. If you are a smoker, your estrogen level may be kept low. If you need help to quit smoking, we can help you develop a plan or direct you to resources. You can contact QuitNow quitnow.net/Program/ as a first step. If you are not quite ready to quit, consider cutting down. Every little bit helps.
- **Find a healthcare provider you trust and can be honest with.** To get the most from hormone therapy, you need to be able to talk openly about what you want, concerns you have, and problems you are experiencing. You should feel comfortable to talk openly with your healthcare provider about your health history, smoking, alcohol, street drugs, dietary supplements, herbs and any other medicines you are taking. Hormone therapy can be affected by all of these things. Being honest with your healthcare provider will help the provider to create a hormone plan that is right for you.
- **Deal with problems early on.** If caught early enough, most of the problems that can result from hormone therapy can be dealt with in a creative way that does not involve stopping hormone therapy. Waiting to talk with your provider can make the problem worse.
- **Do not change medicine on your own.** Check with your healthcare provider if you want to start, stop or change the dose of any of your medicines. Taking medicine more often or at a higher does than prescribed increases health risks and can slow down the changes you want. If you want to change your medicine, talk with your provider first.
- **Take a holistic approach to your health.** Health involves more than just hormone levels, and taking hormones is only one way for you to improve your quality of life. Building a circle of care that includes health professionals, friends, partners and other people who care about you will help you to deal with problems as they come up. This support will help you to heal from societal transphobia.
- **Know where to go for help.** The Seattle Children's Gender Clinic can help you find information on health and transition issues. We can also help you connect with support groups and community resources. We can help with referrals if you need assistance finding other medical providers, counselors or another type of health professional.

What will not change?

Body image

Many people experience an increase in self-esteem and confidence as their body changes with hormones. You might find that there are also unrealistic societal standards after hormone therapy. It can be hard to separate gender dysphoria from body image problems. Professional and peer counseling can help you sort through your expectations about your appearance and work toward self-acceptance.

Mental health

Many people experience positive emotional changes from hormone therapy, including decreased gender dysphoria. Hormone therapy might help you to become more accepting of yourself, but life can still present emotional and social challenges. Biological factors, stresses of transphobia and unresolved personal issues can also affect your mental health. It is important to continue to access counseling, medication and other supports as needed for your mental health.

Your community

Some people hope that they will find greater acceptance after they make physical changes. Seek support from people and communities who accept and respect you as your body, gender identity and expression evolve. It can be helpful to connect with other transgender people, while remembering that no one will exactly mirror your own experience, identity and beliefs. It can be common to feel lonely and alone after starting hormone therapy. Having a support network to turn to can help.

Your body

Hormone therapy does not affect some parts of the body. Some changes are very small. Parts of the body that will not change:

- Penis
- Vagina
- Sex chromosomes
- Adam's apple
- Bone structure
- Voice pitch
- Height

Hormone therapy can make facial and body hair grow more slowly and be less noticeable, but hair will not go away completely. Some people get laser treatment or electrolysis to get rid of facial hair. Laser hair removal works best if you have light skin and dark hair. Electrolysis destroys the follicle that the hair grows out of, so it is permanent hair removal. Electrolysis works for all people.

While "male" pattern baldness may slow down or stop, bald areas will not grow hair again. Some people use wigs or hairpieces, hair transplants or other medical treatments, like Minoxidil (Rogaine).

Feminizing hormone therapy does not change how high or low your voice is (pitch). Hormone therapy will not change your speech patterns. Speech

therapy can help change pitch and other aspects of speech associated with gender. Some people have surgery on their vocal cords or the surrounding cartilage to try to make their voice sound higher.

Once your bones have stopped growing after puberty, feminizing hormone therapy cannot change the size or shape of your bones. Some people use facial feminizing surgery to change the shape of the skull and facial features, and to reduce a prominent Adam's apple. After puberty, there are no treatments you can take to change your height or the size of your hands and feet.

How often do I need to come in for appointments?

You need regular physical exams and lab tests to monitor your overall health while you are on hormone therapy. The first year after starting hormones, this will be at least every 2 to 3 months.

What will happen at appointments?

At every appointment, we will:

- Ask questions about your overall health
- Check your blood pressure, check your weight and listen to your lungs
- Look at your arms, legs, hands and feet to check your overall circulation and look for any signs of swelling, fluid retention or pain
- Check for early warning signs of health problems that can be caused by hormone therapy (blood clots, heart disease, diabetes)
- Recommend blood tests
- Recommend other tests (such as bone scans, heart stress function tests) as needed, depending on your health history, age and any signs of possible health problems
- Starting at age 40, but also depending on your age, family history and other risks for breast cancer, you may need an examination of your breast tissue (mammogram). When you are over 50, your healthcare provider should discuss checking for prostate cancer.

While gender healthcare training for providers emphasizes the need to be creative and stopping hormones only as a last resort, there are some health problems that make it dangerous to take hormones, such as uncontrolled heart disease. If your healthcare provider suspects you have one of these health problems, we will try to control it through medical treatment and changes to your diet or exercise routine. If the condition cannot be controlled, your provider may switch you to another type of hormone or reduce or stop your dose until your other health problems can be controlled.

Resources

Feminizing Hormone Therapy at Seattle Children's (video, 3:12)
youtu.be/8_gdLCXKI5Y

Excellence for Transgender Health - transhealth.ucsf.edu

12/20
PE2706

A Guide to Masculinizing Hormones

Gender Affirming Care

Hormone therapy is an option that can help transgender people feel more comfortable in their bodies. Like other medical treatments, there are benefits and risks. Knowing what to expect will help us partner to maximize the benefits and minimize the risks.

The binary terms “male,” “female,” “masculine,” “feminine,” “masculinizing” and “feminizing” do not accurately reflect the diversity of people’s bodies or identities. To describe how hormones work, it is helpful to know how testosterone works in non-intersex, non-trans men’s bodies, and how estrogen and progesterone works in non-intersex, non-trans women’s bodies. We keep these binary terms in quotes to emphasize that they are artificial and imperfect concepts.

What are hormones?

Hormones are chemical messengers that tell tissues of the body how to function, when to grow. They regulate many functions, including growth, sex drive, hunger, thirst, digestion, metabolism, fat burning and storage, blood sugar, cholesterol levels and reproduction.

What are sex hormones?

Sex hormones are involved in the development of the vulva and clitoris, or the penis and testicles (external genitals). Sex hormones also affect the secondary sex characteristics that typically develop at puberty (facial and body hair, bone growth, breast growth, voice changes, etc.). There are 3 categories of sex hormones in the body:

- Androgens: testosterone, dehydroepiandrosterone (DHEA), dihydrotestosterone (DHT)
- Estrogens: estradiol, estriol, estrone
- Progestin: progesterone

Generally, people with testicles tend to have higher androgen levels, and people with ovaries tend to have higher levels of estrogens and progestogens.

What is hormone therapy?

Hormone therapy is taking medicine to change the levels of sex hormones in your body. Changing these levels will affect your hair growth, voice pitch, fat distribution, muscle mass and other features that are associated with sex and gender. Masculinizing hormone therapy can help make the body look and feel less “feminine” and more “masculine” — making your body more closely match your identity.

To Learn More

- Adolescent Medicine 206-987-2028
- Gender Clinic Care Navigator 206-987-8319
- Ask your child’s healthcare provider
- seattlechildrens.org

Free Interpreter Services

- In the hospital, ask your nurse.
- From outside the hospital, call the toll-free Family Interpreting Line, 1-866-583-1527. Tell the interpreter the name or extension you need.

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What medicines are involved?

Testosterone (sometimes called "T") is the main hormone responsible for promoting "masculine" physical traits and is usually used for hormonal "masculinization." Testosterone works on tissues in your body (such as stimulating growth of your clitoris). Testosterone alone will eventually stop menstrual cycles, but to stop menstrual cycles immediately, there are treatments that can be used to stop your period. Examples are injecting Depo-Provera (a type of progestin) every 3 months, Nexplanon (implant under the skin in the arm), an IUD (intrauterine device), daily pills with or without estrogen.

How do you take it?

Testosterone can be taken in different ways:

- Injection (subcutaneous application)
- Skin patch, cream or gel (transdermal application)

What are the differences in the ways to take it?

The way you take testosterone seems to affect how fast the changes happen. Using a patch, cream or gel takes slightly longer than injection to make menstrual periods stop and to make facial and body hair grow. Using a skin patch, cream or gel to take testosterone means a steady level in your blood. With injection, there is a peak right after injecting and a dip at the end of the injection cycle. This can increase side effects at both ends of the cycle (aggression/mood swings when testosterone peaks, and fatigue/irritability/mood swings when testosterone dips). This can be reduced by injecting once a week instead of every other week, or by switching to a skin patch, cream or gel.

What is a typical dose?

Testosterone therapy varies greatly. Deciding what to take depends on:

- Your health (each type of testosterone has different risks and side effects)
- What is available where you live
- What you can afford (what your insurance covers)
- How your body reacts when you start taking testosterone (every person is different, and some people have a negative reaction to a specific kind of brand or formulation)
- Your gender goals

We will partner with you to explore your insurance coverage and any other resources to make sure you get the care you need.

The right dose or type of testosterone for you may be different than for others. It is a good idea to talk about the different options with your Gender Clinic healthcare team. If you have any concerns about being able to take the testosterone, or about the side effects, costs or health risks, let us know. It is important that your needs and concerns be taken into account when planning your hormone therapy.

You may need to start on a lower dose if you have not experienced any puberty, have chronic health problems, are at risk for specific side effects or have had your ovaries removed. If you have questions about the reasons for your dose, talk with us.

Every person is different in terms of how their body absorbs, processes and responds to sex hormones. Some people have more changes than others.

Changes happen more quickly for some people than others. Taking more testosterone than the dose you were prescribed — or taking another kind of steroid as well as testosterone (sometimes called "stacking") — can greatly increase your health risks. Extra testosterone in your body can be converted to estrogen. If you think your dose is too low, talk with us to discuss your options.

If you have your ovaries removed in the future, you may need a different dose of testosterone. To maintain the full effects of testosterone, you will need to stay on testosterone or another form of medicine for the rest of your life (unless you choose to go off of it). Most people will stay on the medicine. In addition, to preserve bone strength, your doctor may also suggest you take calcium and Vitamin D supplements.

What changes can I expect?

Masculinizing hormone therapy has physical and psychological benefits. Bringing the mind and body closer together eases gender dysphoria and can help you feel better about your body. People who have had gender dysphoria often describe being less anxious, less depressed, calmer and happier when they start taking hormones. For some people, this psychological change happens as soon as they start taking hormones. For others, it happens a bit later as physical changes progress. Each person changes differently. How quickly changes appear for you depend on:

- Your age
- The number of hormone receptors in your body
- How sensitive your body is to testosterone

There is no way of knowing how your body will respond before you start hormones. You cannot pick the changes you want.

Average timeline	Effect
After 1 to 3 months	• Increased sex drive • Vaginal dryness • Growth of your clitoris (typically 1 to 3 cm) • Increased growth, coarseness and thickness of hairs on arms, legs, chest, back and abdomen • Oilier skin and increased acne • Increased muscle mass and upper body strength • Redistribution of body fat (more around waist and less around hips)
After 1 to 6 months	• Menstrual periods stop
After 3 to 6 months	• Voice starts to crack and drop (can take up to a year to finish changing fully)
Gradual changes (usually takes at least 1 year)	• Gradual growth of facial hair (usually takes 1 to 4 years to reach full growth) • Possible "male"-pattern balding

Most of the effects of hormones happen in the first 2 years. During this time, the doctor who prescribes your testosterone will want to see you every

2 to 3 months. This will continue until the dose that is best for you gets figured out and blood tests show you are at consistent level. After that, you will need an appointment once a year until you are 21 years old. When you are 21 years old or when you are at a stable maintenance dose and ready to switch to an adult provider, you will transition to a provider who can continue your treatments as an adult. For information about moving to an adult health care provider visit: seattlechildrens.org/TransitioningToAdultHealthcare.

- At appointments in the first 2 years, your doctor will likely:
- Look at your facial and body hair. If you shave, the doctor will ask how quickly your hair grows back.
- Ask about changes to your sex drive, clitoris or other sexual changes; menstrual period, skin and voice.
- Order blood tests check your hormone levels.
- Ask how your feel about the changes that have happened.

After 2 years have passed, you will likely just be asked if you notice any further changes from the hormones.

Are the changes permanent?

Most of the changes you will notice from the testosterone are not fully reversible, even if you stop taking testosterone.

- **Permanent (not reversible):** deeper voice, hair growth. "Male"-pattern baldness may or may not happen, based on your family history.
- **May or may not reverse:** clitoral growth, body and facial hair will decrease but usually does not completely disappear, the ability to get pregnant
- **Reversible:** menstrual periods will return and changes to fat, muscle and skin will reverse

Fertility

The long-term effects of testosterone on fertility are not fully understood. The ability to get pregnant **may not come back** even if you stop taking testosterone. Although testosterone can permanently affect your fertility, there may still be a chance you could get pregnant even after starting hormone therapy. **Depending on how you have sex, you may need to use birth control.**

What will not change?

Body image	Many people experience an increase in self-esteem and confidence as their body changes with hormones. You might find that there are also unrealistic societal standards after hormone therapy. It can be hard to separate gender dysphoria from body image problems. Professional and peer counseling can help you sort through your expectations about your appearance and work toward self-acceptance.
Mental health	Many people experience positive emotional changes from hormone therapy, including decreased gender dysphoria. Hormone therapy might help you to become more accepting of yourself, but life can still present emotional and social challenges. Biological factors, stresses of transphobia and unresolved personal issues can also affect your mental health. It is important to continue to access counseling, medication and other supports as needed for your mental health.
Your community	Some people hope that they will find greater acceptance after they make physical changes. Seek support from people and communities who accept and respect you as your body, gender identity and expression evolve. It can be helpful to connect with other transgender people, while remembering that no one will exactly mirror your own experience, identity and beliefs. It can be common to feel lonely and alone after starting hormone therapy. Having a support network to turn to can help.
Your body shape	Hormone therapy will not change some physical characteristics, and some are only slightly changed. These include aspects of your body that develop before birth (vagina, sex chromosomes, etc.) and also physical characteristics that developed from the increase in estrogen at puberty.
Your speech patterns	Although testosterone typically makes your voice pitch drop to deeper levels, it does not change intonation and other speech patterns that are associated with gender socialization. Some people find that speech therapy can help. Speech therapy can also be useful if your pitch does not drop as much as you wanted.
Breast tissue	Testosterone may slightly change the shape of your chest by increasing muscle mass and decreasing fat. However, it does not make breast tissue go away. Some people have “top surgery,” a surgery to remove breast tissue and reshape their chest.

Bone structure

Once your bones have stopped growing after puberty, testosterone cannot change the size or shapes of your bones. There are no treatments you can take to increase your height or the size of your hands and feet.

Pregnancy and sexually transmitted infections

Although testosterone can permanently affect your fertility, there may still be a chance you could get pregnant even after starting hormone therapy. **Depending on how you have sex, you may need to use birth control.** It is also important to note that testosterone could cause some potential harm to a fetus and current guidelines advise against taking testosterone during pregnancy.

Testosterone does not decrease the risk of HIV and sexually transmitted infections. Depending on how you have sex, you may need to use condoms, gloves or other latex barriers. Testosterone tends to make the genital tissue dryer and the cervix more fragile, so if you have frontal or vaginal sex you should add extra lubricant to avoid breaking latex or tearing your tissue.

What are the risks?

The long-term safety of testosterone is not fully understood. Most of the studies on hormone therapy involve non-trans men taking testosterone at different doses. There may be long-term risks that are not yet known.

Heart disease, stroke and diabetes

Testosterone can increase the risk of heart disease, stroke and diabetes. Testosterone tends to:

- Decrease good cholesterol (HDL) and may increase bad cholesterol (LDL)
- Increase fat deposits around internal organs and in the upper abdomen
- Increase blood pressure
- Decrease your body's sensitivity to insulin
- Cause weight gain (mostly from muscle gain)
- Increase the amount of red blood cells and hemoglobin (a red protein responsible for transporting oxygen in the blood) you have in your body

The increase in the amount of red blood cells and hemoglobin is usually remains in the same range as someone who was assigned male at birth (which does not pose health risks). Occasionally, a higher increase can happen and can lead to life-threatening problems, like stroke and heart attack. You will have regular blood tests to check red blood cell and hemoglobin levels.

The risks are greater for people who smoke, are overweight or have a family history of heart disease. Your risk of heart disease, stroke and diabetes can be reduced by creating a care plan that is specific to you. A care plan includes regular blood tests and optimizing contributing factors. These include not smoking, exercising and eating well.

Headaches and migraines

Some people get headaches and migraines after starting testosterone. If you are getting more frequent headaches or migraines or the pain is unusually bad, talk to your primary healthcare provider.

Cancer

It is not known if testosterone increases the risks of breast cancer, ovarian cancer or uterine cancer. These types of cancer are all sensitive to estrogen, called estrogen-dependent cancer. Some testosterone is converted to estrogen so your body will have estrogen even if you don't have ovaries. You are at higher risk of estrogen-dependent cancer if you have a family history of these types of cancer, are age 50 or older or are overweight. Talk with us about screening tests available for these types of cancer.

Mental health

There are often positive emotional changes from reduced gender dysphoria. However, in some people testosterone can cause increased irritability, frustration and anger. There are reports of testosterone destabilizing people with bipolar disorder, schizoaffective disorder and schizophrenia. Taking testosterone via skin patch or cream/gel (transdermal application) can be helpful if the mood swings are linked to the highs and lows of an injection cycle.

Social repercussions

Living in a transphobic society can have social risks. Some people experience violence, harassment and discrimination, while others have lost support of loved ones. If you are worried about how others might react to the changes that come with hormone therapy, counseling can be useful. If you are looking for a therapist, see "How to Find a Therapist." seattlechildrens.org/pdf/PE2195.pdf.

How do I get the most benefit and minimize risks?

You can help make hormone therapy as effective and safe as possible. Here are steps you can take:

- **Be informed.** Understanding how hormones work, what to expect, and possible side effects and risks will give you the tools to be in charge of your health and make informed decisions. Do your own research and ask questions. To get started, see "Gender Clinic Booklist and Resources" seattlechildrens.org/pdf/PE2634.pdf.
- **If you smoke, stop or cut down.** Any smoking greatly increases the risks of taking hormones. If you are a smoker, your testosterone level may be kept low. If you need help to quit smoking, we can help you develop a plan or direct you to resources. You can contact QuitNow quitnow.net/Program/ as a first step. If you are not quite ready to quit, consider cutting down. Every little bit helps.
- **Find a healthcare provider you trust and can be honest with.** To get the most from hormone therapy, you need to be able to talk openly about what you want, concerns you have and problems you are experiencing. You should feel comfortable to talk openly with your healthcare provider about your health history, smoking, alcohol, street drugs, dietary supplements, herbs and any other medicines you are taking. The risks associated with taking testosterone can be affected by all of these things. Being honest about them will help your healthcare providers to create a hormone plan that is right for you.
- **Deal with problems early on.** If caught early enough, most of the problems that can result from testosterone can be dealt with in a creative way that

does not involve stopping testosterone treatment completely. Waiting to talk with your provider can make the problem worse.

- **Do not change medicine on your own.** Check with your healthcare provider if you want to start, stop or change the dose of any of your medicines. Taking testosterone more often or at a higher does than prescribed increases health risks and can slow down the changes you want. If you want to make changes, talk with your provider first.
- **Take a holistic approach to your health.** Health involves more than just hormone levels. Taking hormones is only one way for you to improve your quality of life. Building a circle of care that includes health professionals, friends, partners and other people who care about you will help you to deal with problems as they come up. This support will help you to heal from societal transphobia.
- **Know where to go for help.** The Seattle Children's Gender Clinic can help you find information on health and transition issues. We can also help you connect with support groups and community resources. We can help with referrals if you need assistance finding other medical providers, counselors or another type of health professional.

How often do I need to come in for appointments?

As long as you are taking testosterone (possibly for the rest of your life), you will need to have regular physical exams and lab tests to monitor your overall health. The first year after starting testosterone, the doctor who prescribes your hormones will want to see you at least every 3 months; after that, you will have appointments at least every 6 months.

What will happen at appointments?

At every appointment, we will:

- Ask questions about your overall health.
- Ask questions about your mood.
- Take your blood pressure and check your weight and your heart rate.
- Check for early warning signs of health problems that can be caused by testosterone or made worse by testosterone (e.g., heart disease, diabetes).
- Recommend blood tests to check your blood sugar, blood fats, blood cells and liver health.
- Recommend other tests (e.g., bone scan, heart stress function test) as needed, depending on your health history, age, and any signs of possible health problems.

To check for early signs of cancer, as part of the physical exam, your doctor or nurse will do breast and cervical screening tests starting at 21 years old.

While gender healthcare training for providers emphasizes the need to be creative and stopping hormones only as a last resort, there are some health problems that make it dangerous to take testosterone, such as uncontrolled heart disease. If your healthcare provider suspects you have one of these health problems, we will try to control it through medical treatment and changes to your diet or exercise routine. If the condition cannot be controlled, your provider may switch you to another type of hormone, or reduce or stop your dose until your other health problems can be controlled.

Resources

Masculinizing Hormone Therapy at Seattle Children's (video, 3:37)
youtu.be/dmjSEf2og1A

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transhealth.ucsf.edu

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PE2707

Menstrual Suppression and Breakthrough Bleeding For Gender Diverse Youth

What is menstrual suppression?

Menstrual suppression is using hormone medicines to stop monthly menstrual bleeding, also known as uterine bleeding or periods.

Why choose menstrual suppression?

There are many reasons why people choose to suppress menstrual bleeding.

- Many gender diverse people are uncomfortable during their menstrual cycles, or experience intense dysphoria from them. Stopping menstrual bleeding can be vital to improving mental health and comfort in their bodies.
- For some people, menstrual bleeding can be heavy and painful, and some have irregular bleeding that is hard to control.
- There are many other medical reasons to suppress menstrual bleeding, such as chronic pelvic pain, endometriosis, polycystic ovary syndrome, headaches, bleeding disorders, and developmental delay.

Is it safe?

Yes, it is safe to control or stop menstrual bleeding using hormone medicines. People have been safely doing this since the 1960s. It does not cause harm to your body.

The medicine and methods may have some side effects and risks. You can discuss them with your healthcare provider.

How long will it take?

All the options for menstrual suppression will take some time to shorten the length and heaviness of menstrual bleeding. For the first few months, you might have some unpredictable menstrual bleeding, but the bleeding will generally lighten or stop over time.

If you are not getting enough menstrual suppression after 2 to 3 months, you can talk to your provider about trying other options.

Can this be used at the same time as testosterone?

Yes, menstrual suppression medicines can be used with testosterone. Testosterone alone often causes menstrual bleeding to stop after about 6 months. You can start one of these medicines before starting testosterone to stop menstrual bleeding sooner, or after starting testosterone if you are still having menstrual bleeding while taking testosterone.

What are the options?

There are many hormone medicine options for controlling and suppressing menstrual bleeding. Discuss the options you would prefer with your healthcare provider, and they can give you a prescription. See the table below.

Unfortunately, no option is perfectly effective all of the time. You may need to try an option for a few months and then discuss a different one if that is not working.

To Learn More

- Adolescent Medicine 206-987-2028
- Ask your child's healthcare provider
- seattlechildrens.org

Free Interpreter Services

- In the hospital, ask your nurse.
- From outside the hospital, call the toll-free Family Interpreting Line, 1-866-583-1527. Tell the interpreter the name or extension you need.

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Menstrual Suppression Options

Medicine	How it is taken	Frequency	Full menstrual suppression	Advantages	Disadvantages
Progestin-only pill Norethindrone acetate (brand name Aygestin 5 mg)	Pill	Pill taken once a day at the same time each day	Up to 76% with high dose progestins at 2 years In our experience, this works well within 2 to 3 months (note: this data is from Progestin-only pills in general, not this specific one)	• Does not contain estrogen • The dose can be adjusted if you experience breakthrough bleeding	• Not approved as contraception • Breakthrough bleeding can happen if you miss doses or take them late or off schedule • Some experience hormonal side effects such as bloating and moodiness
Progestin-only pill Norethindrone (brand name Micronor 0.35 mg)	Pill	Pill taken once a day at the same time each day	Up to 76% with high dose progestins at 2 years (note: this data is from Progestin-only pills in general, not this specific one)	• Does not contain estrogen • The dose can be adjusted if you experience breakthrough bleeding	• Less effective contraception • Breakthrough bleeding can happen if you miss doses or take them late or off schedule • Some experience hormonal side effects such as bloating and moodiness
Oral combined contraceptive pills (contains estrogen and progesterone)	Pill	Pill taken once a day at the same time each day	70% at 1 year when taken continuously (skipping the last week of placebo pills that do not contain hormones)	• Provides contraception	• Breakthrough bleeding can happen if missed doses or take them late or off schedule • Small risk of blood clots • Some experience hormonal side effects such as chest tenderness, headaches, bloating and moodiness
Depo medroxyprogesterone acetate (brand name Depo Provera)	Intramuscular injection	Every 12 weeks (or as often as every 9 weeks if there is breakthrough bleeding)	50 to 60% at 1 year, 70% at 2 years	• Does not contain estrogen • Provides contraception • Less frequent dosing every 3 months	• Requires coming to clinic for injection • Some experience hormonal side effects such as bloating, weight gain, and moodiness • Prolonged use may affect bone density
Subdermal etonorgestral implant (brand name Nexplanon)	A tiny rod (smaller than a matchstick) inserted under the skin in your arm.	3 to 5 years	30%	• Does not contain estrogen • Provides very effective contraception	• Requires insertion and removal in clinic • Higher rates of breakthrough bleeding (in individuals not on testosterone)
Levonorgestrel intrauterine device (IUD) Dose varies by brand	A small device that is inserted once into the uterus	5 to 7 years	50% of people at 1 year, 60% at 5 years	• Does not contain estrogen • Provides very effective contraception	• Requires pelvic exam and intrauterine insertion in clinic • Some pain when placing the IUD • May fall out early • Initial breakthrough bleeding and cramping is common

What is breakthrough bleeding?

Breakthrough bleeding is a name for light menstrual bleeding or spotting. It can happen when you are taking medications for menstrual suppression.

Starting a medicine for menstrual suppression can cause breakthrough bleeding. Breakthrough bleeding is usually not a safety concern.

What causes breakthrough bleeding and what can I do?

Starting a new hormonal medication

Breakthrough bleeding is very common in the first 2 to 3 months of starting a new kind of menstrual suppression medicine or birth control.

If you are having breakthrough bleeding that is causing distress for more than 2 weeks after starting a new medicine or have any concerns for more serious breakthrough bleeding, please contact us via Mychart or phone to discuss whether a different dose or a different type of medicine would be better.

Other medicines

Some medicines can interfere with the effectiveness of your menstrual suppression medication. If you are starting or changing other medicines, please call us. We may need to change the menstrual suppression medicine you are taking.

Missing 1 or more pills

For information on what to do, read our handout “What If I Miss a Pill?”

seattlechildrens.org/pdf/PE1466.pdf

Taking your pill at different times

Try taking your pill at the exact same time every day. Some people set alarms on their cell phone or computers, use an iPhone app, or put the pills next to something they use every day like a toothbrush to help them remember.

Infection

Breakthrough bleeding can be associated with vaginal and cervical infections. If you do not know a likely cause of your bleeding (like missing a pill), you may want to make an appointment with us to see if there may be an infection.

What if I still have breakthrough bleeding?

Progestin-only pill

If you are on a progestin-only pill (such as norethindrone, Aygestin, or Micronor), it is usually started at a dose of 1 pill once a day. If you are still having bleeding after 2 weeks of taking the pill regularly, you can increase the dose to 2 pills once a day.

Please contact us via MyChart or phone so we can check in about how much bleeding you are having. Let us know if the bleeding is persistent and you need to increase the dose to 2 pills, so we make sure we update your prescription at your pharmacy if needed.

If you increase the dose to 2 pills, we may recommend trying a lower dose again at a later time.

Depo Provera injections

If you are using Depo Provera injections, they are usually given every 12 weeks. The injections can be given as early as every 9 weeks if needed for breakthrough bleeding.

If you begin to have bleeding more than 9 weeks after your last injection, call us to see if you can get your next injection sooner. A progestin-only pill (such as Aygestin) can sometimes be added if menstrual bleeding is happening in the first 9 weeks after the injection.

Nexplanon or IUD

If you are using Nexplanon or an IUD, a progestin-only pill (such as Aygestin) can sometimes be added.

When do I need to call the doctor?

If you have any of the following issues that can lead to large loss of blood:

- Heavy breakthrough bleeding (saturating a large product within 2 hours)
- Menstrual bleeding that previously required a trip to the emergency room
- A blood transfusion within the last 3 months
- A bleeding disorder like hemophilia or thalassemia
- Fainting, shortness of breath, and chest pain which can be signs of more serious bleeding

Call us Monday through Friday, 8 a.m. to 4:30 p.m. at 206-987-2028.

If it is after-hours, a weekend, or a holiday: call your primary care provider, go to Urgent Care, or the Emergency Room.

7/22
PE3715

Puberty Blockers

What are puberty blockers?

Puberty blockers are medicines that block puberty-related hormones that make your body go through puberty. Starting puberty blockers is a decision that is different for everyone. To make the most informed decision, this handout is meant to help you understand:

- What is puberty?
- What do puberty blockers do?
- What are the changes that will happen to my body?
- What are the benefits, risks and costs involved?

We will work with you to support the decision that is best for you. You can view a video about puberty blockers at seattlechildrens.org/gender.

How does puberty begin?

Puberty is the process the body goes through to become capable of making a baby (reproduction), as well as reach adult size and brain development. Puberty starts when your brain tells your pituitary gland to start releasing puberty-related hormones. This happens at different ages for different people.

During this time, your body starts to increase the amount of certain puberty-related hormones (Luteinizing Hormone (LH) and Follicle-Stimulating Hormone (FSH). This causes your testicles to start producing testosterone or your ovaries start producing estrogen. These hormones do not cause acne, pubic or armpit hair - those are caused by other hormones.

Body changes in people with testicles (without puberty blockers)

- Testicle growth (this improves the body's ability to make testosterone)
- Penis growth
- Pubic hair
- Increased acne, increased armpit and facial hair
- Rapid growth (growth spurt)
- Voice changes (deepens)

Body changes in people with ovaries (without puberty blockers)

- Breast changes
- Changes in body shape, including fuller hips
- Menstrual periods start (usually more than 2 years after breast changes begin)

To Learn More

- Adolescent Medicine 206-987-2028
- Ask your child's healthcare provider
- seattlechildrens.org/gender

Free Interpreter Services

- In the hospital, ask your nurse.
- From outside the hospital, call the toll-free Family Interpreting Line, 1-866-583-1527. Tell the interpreter the name or extension you need.

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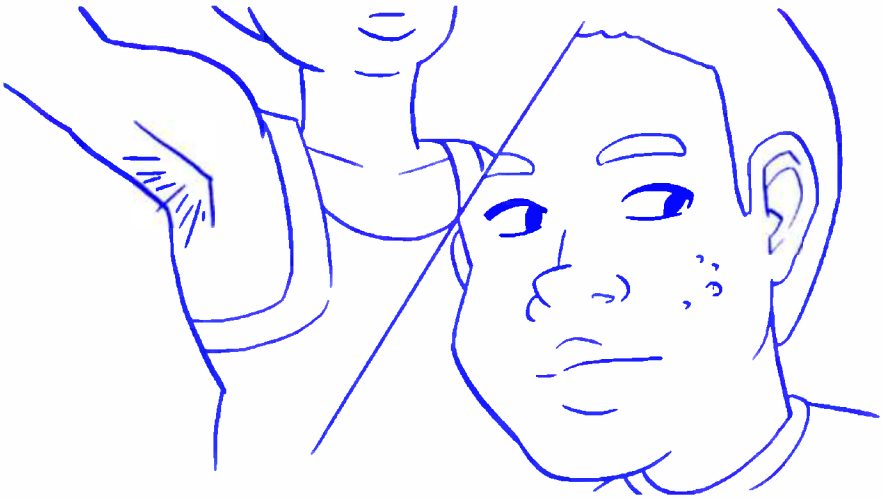
How do puberty blockers work?

Puberty blockers (called GnRH analogues) cause your body to stop releasing puberty hormones (LH and FSH). This is like hitting a 'pause button' on puberty.

Will puberty blockers stop all changes in my body?

No, puberty blockers will not stop pubic or armpit hair from growing or improve acne. Puberty blockers only make a difference for the puberty changes that make you look female or male. For example, in bodies with ovaries, breast size may get smaller if they have already started to develop. In bodies with testicles, testicle size may decrease, and penis growth will be halted.



What will happen if I start puberty blockers late in puberty?

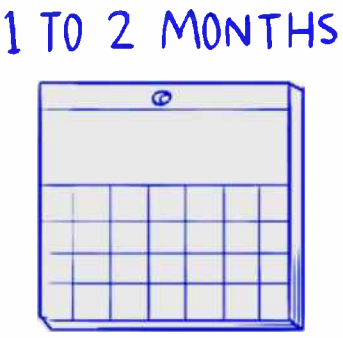
If puberty blockers are started late in puberty, they are not able to reverse most changes that have already happened. However, puberty blockers can stop any further puberty changes.

Are puberty blockers permanent?

No, puberty blockers are not permanent. If you decide to stop puberty blockers without starting cross sex hormones, your body will start going through the puberty of your sex at birth. You can stop the puberty blockers at any time, but we will work with you on how to do that.

How long will it take them to start working?

It can take 1 to 2 months for puberty blockers to start working. Everyone is a little different. It is hard to know exactly how quickly your body will respond. In the beginning, your body may actually show more signs of puberty, but this will lessen as you continue to take the blockers.



What are the different kinds of puberty blocking medicines?

Depo Lupron or Leuprolide

This medicine is given as an injection (shot) once every 3 months. If you use this kind of puberty blocker, you will need to come to clinic every 3 months for the injection.

Histrelin

This medicine is a little plastic rod that is placed under the skin (implant) in the upper arm. The implant works for a little more than 1 year, and sometimes up to 2 years or longer. After it stops working, it needs to be removed and replaced. This can be done in the clinic or in the operating room.

Are these medicines safety approved?

We can safely and legally recommend puberty blockers for you based on our medical experience and judgement and your specific health needs. The Endocrine Society and the World Professional Association for Transgender Health support puberty blockers. The Food and Drug Administration (FDA) approves puberty blockers for children who start puberty at a very young age, but has not approved puberty blockers for transgender children.

Will I have pain?

We partner with you to prevent and relieve any pain from taking these medicines as completely as possible. No matter what the level of your pain, we join you to assess and respond right away.

If you have pain from an injection or an implant, you can take Tylenol (acetaminophen) or Advil (ibuprofen) to help relieve the pain. Use these medicines only if recommended by your healthcare provider. Check with the healthcare provider first before taking any type of medicine. Contact your Gender Clinic doctor if the pain from the injection or implant gets worse the next day or you have a rash.

Will the Depo Lupron or Leuprolide injection hurt?

The injection is given in your arm, leg or bottom. The area where you get it may be sore for about 1 day after the injection.

Numbing cream (topical lidocaine) reduces pain from injections by numbing the skin before the needle stick. Ask us if you are interested in using numbing cream before your injection.

Will the Histrelin implant hurt?

If you get the implant inserted in clinic, we will give you an injection to numb your upper arm before the procedure. If you have it done in the operating room, we will give you medicine to make you sleep (anesthesia) during the procedure.

After the procedure, your arm may be sore for about 2 days where it was inserted.

What are the risks of puberty blockers?

The long-term safety of puberty-blocking medicines is not completely understood. There may be long-term risks that we do not know about yet.

Bone health

Blocking puberty can make your bones weaker (lower bone density). This may get better when you stop the puberty blockers or start cross-hormone therapy. While on puberty blockers, we recommend taking calcium, vitamin D and doing bone strength-building exercises like walking, jumping and weight lifting. We may check your bone health every 2 years while on blockers.

Fertility

Taking puberty blockers should not affect your ability to have a baby in the future (fertility).

However, permanent damage to fertility is a concern for people who stay on puberty blockers and then take cross-sex hormones. We recommend talking about this with us to understand the potential impact on your fertility before starting any medicines.

How much does it cost?

Puberty blocker medicines can be very expensive and the cost can change every year. Some insurance companies cover them. How much your insurance covers depends on your insurance plan and requires authorization from your plan. Sometimes insurance companies will only help pay for Depo Lupron (the injection) and not Histrelin (the implant).

If you have medicine to sleep (anesthesia) to get the Histrelin implant, the costs are higher. If you have questions about coverage, you can call your insurance company. Questions you may want to ask include:

- Are these medicines covered by my insurance plan?
- What is my deductible, copay and coinsurance?
- Have I met my deductible this year?

For help navigating the insurance process, contact:

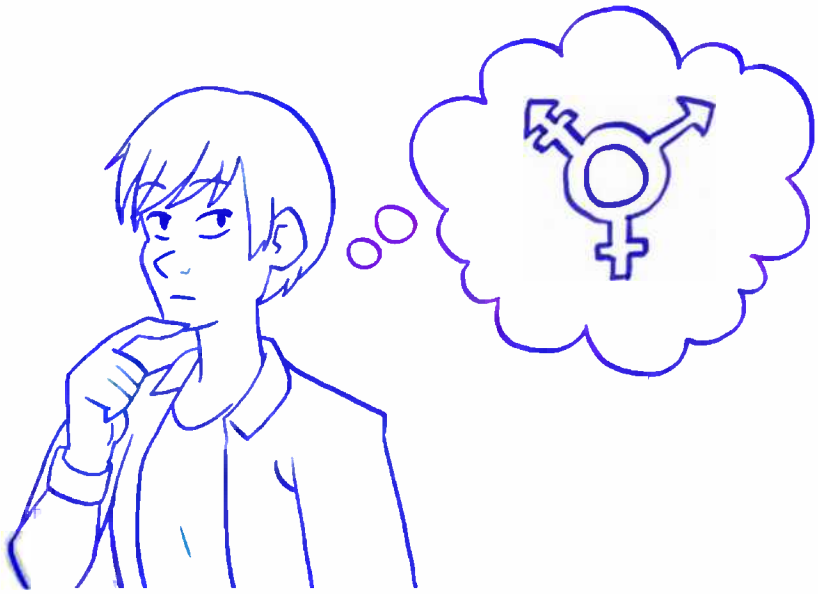
- Gender Clinic Care Navigator at 206-987-8319
- Seattle Children's Family Accounts Specialist at 206-987-5770

Are puberty blockers right for me ?

We will work hard to answer all of your questions about the benefits and risks of puberty blockers. We want you to have a good understanding of what to expect before you decide to start.

Starting puberty blockers can give you time before making more permanent gender decisions, like the starting cross-sex hormones. Puberty blockers prevent some of the male or female specific changes to the body that puberty causes. It can be distressing for transgender people to go through puberty. Puberty blockers can help with this distress by pushing the "pause button" on your puberty, which prevents puberty changes that do not match with your gender identity.

For some people, puberty blockers may reduce the need for future surgeries or other treatments. For example, breast removal (mastectomies) for transgender men, or hair removal and breast surgery for transgender women.



What about mental health therapy ?

In most cases, we ask that you and your family connect with a mental health therapist experienced in gender identity before and during treatment in the Gender Clinic. A mental health therapist can help you through decisions and changes that happen as you get older, and help your family learn how to support you through those changes.

Mental health therapists can also provide letters that are sometimes requested by doctors or insurance companies for gender-related care. Each person has a different situation. Please ask us about resources that may be right for you and your family.

When should I start taking puberty blockers?

You begin puberty blockers after your body shows signs of puberty. Usually this is after bodies with testicles have started to have increased testicle size and growth of the penis, and bodies with ovaries have started to have breast changes (breast buds). It is not safe to start puberty blockers before puberty.

How will my doctor know puberty has started?

Before starting puberty blockers, we might recommend some testing to confirm that puberty has started. These include a physical exam and a blood test called a Leuprolide Stimulation test. This type of blood test checks your hormone levels before and 1 hour after getting a Leuprolide injection. If the test shows that your hormone levels are higher after the injection, it confirms that puberty has begun.

How long can I stay on puberty blockers?

Puberty blockers are used until you decide you want to either resume the puberty process, or until you are ready to start cross-sex hormones. Because puberty blockers can make your bones weaker over time, it is best to stop taking them after about 4 years.

12/19
PE2572

GENDER-AFFIRMING HORMONE THERAPY: A TIMELINE

As part of the process of transition, some patients may seek gender-affirming hormone therapy. To help you understand the effects, we want to share this information with you. Everybody is different. The rate and extent of your changes take place depend on many factors, including your genetics, the age at which you start taking hormones, and your overall state of health.

Here is a timeline of changes promoted by the use of testosterone.

EFFECT	EXPECTED ONSET	EXPECTED MAXIMUM EFFECT	*REVERSIBLE* or PERMANENT
▶ Increased body hair and facial hair growth	1-6 months	1-2 years	Permanent
▶ Deepened Voice	3-12 months	1-2 years	Permanent
▶ Clitoral Enlargement (by 1-3 cm)	3-6 months	1-2 years	Permanent
▶ Male Pattern Baldness *(hair loss at temples and crown of head; highly dependent on age and inheritance)*	+12 months	Variable	Permanent
▶ Increased Muscle Mass and Strength *(dependent on amount of exercise)*	6-12 months	2-5 years	*Reversible*
▶ Cessation of Menstrual Periods	2-6 months	N/A	*Reversible*
▶ Body Fat Redistribution *(decreased on buttocks/hips/thighs; increased in abdomen)*	3-6 months	2-5 years	*Reversible*
▶ Skin Oiliness/Acne *(may be severe)*	1-6 months	1-2 years	*Reversible*
▶ Vaginal Atrophy *(drying)*	3-6 months	1-2 years	*Reversible*
▶ Increased Libido *(sex drive)*	Variable	Variable	*Reversible*

Here is a timeline of changes promoted by the use of estrogen.

EFFECT	EXPECTED ONSET	EXPECTED MAXIMUM EFFECT	*REVERSIBLE* or PERMANENT
▶ Breast Growth	3-6 months	2-3 years	Permanent
▶ Decreased Sperm Production/Maturation, Reduced Fertility	Variable	Variable	Possibly Permanent
▶ Decreased Testicular Volume/Size by 25-50 percent	3-6 months	2-3 years	Probably Permanent
▶ Thinning/Slowed Growth of Body and Facial Hair	6-12 months	+3 years	*Reversible*
▶ Softening of Skin/Decreased Oiliness	3-6 months	Unknown	*Reversible*
▶ Body Fat Redistribution to more Feminine Pattern	3-6 months	2-5 years	*Reversible*
▶ Decreased Muscle Mass and Strength	3-6 months	1-2 years	*Reversible*
▶ Decreased Libido *(sex drive)*	1-3 months	1-2 years	*Reversible*
▶ Decreased Spontaneous and/or Morning Erections	1-3 months	3-6 months	*Reversible*
▶ Male Sexual Dysfunction *(ex., erections not as firm)*	Variable	Variable	*Reversible*
▶ Cessation of Male Pattern Balding *(no regrowth, but loss stops)*	1-3 months	1-2 years	*Reversible*

Cox Exhibit 15 5/31/23

SO YOU WANT TO KNOW MORE ABOUT ESTROGEN...

Basic Overview

Hormone therapy for trans women is meant to feminize patients by changing fat distribution, inducing breast formation, and reducing male pattern hair growth. Estrogen is the mainstay therapy for trans female patients but there are other options that may or may not be the right choice for you. Hormone therapy is a long-term treatment that can help the patient to be happier with their body as it will be more congruent with their gender identity. Hormone therapy is not a wonder drug that will solve all problems in a patient's life but can be a step in the right direction. Guidelines do exist to help medical providers to determine when hormone therapy is appropriate for treatment and how the treatment should take place.

Things to think about

- Psychotherapy – As with any transition in life and knowing that psychotherapy is not for everyone, most people would benefit from supportive psychotherapy with a qualified psychotherapist. The therapist can help you explore new thoughts and feelings and get to know your new body and self.
- Do your research on any and all treatments that are suggested by your doctors but also understand that everyone is different. Your response or development may be very different from friends or those you see in the community and online.
- Be patient – Transitions and medications take time to see the full results. This can take 2-3 years to see the results of the medications and therapies before getting discouraged. You should also wait at least this long before seeking further invasive procedures for facial feminization. Higher doses will not bring changes faster and could endanger your general health.
- Continual care- monitoring by a doctor must be done on a routine basis to ensure that hormone levels remain at correct levels to achieve desired results.

Types of hormones

Hormone therapy for trans women can include three kinds of medications; estrogen, testosterone blockers and progesterone. Estrogen is the most common therapy but alone is often not enough to achieve desirable androgen suppression, and additional anti-androgenic therapy is also usually necessary.

Estrogen is the most common hormone and is responsible for most female characteristics. Estrogen can be given in pill, injection, creams, gel, spray or a patch. Contrary to what many have heard or believe a small dose of estrogen can achieve maximum effect for you. Higher doses do not necessarily make changes happen quicker but can endanger your general health.

- Pills are convenient, cheap and effective but less safe for those that are over 35 or smoke.
- Patches are effective and safe but can cause skin irritation as they must be worn at all times.
- Injections can cause more fluctuation in estrogen levels. These fluctuations can cause mood swings, weight gain, migraines, anxiety and possible hot flashes.

Testosterone Blockers come in two different categories. The first blocks the actions that testosterone in your body and the second prevents the production of testosterone in your body. Both are safe but do have side effects:

- Spironolactone is the most commonly used blockers and can cause excessive urination, lightheadedness and dizziness especially when first taking it. Drink plenty of fluids on this medication. This medication can have serious side effects for those with kidney problems and on some blood pressure medications. It can also cause an increase in potassium production and levels should be checked periodically.
- Finasteride and Dutasteride block the production of dihydro-testosterone which affects skin, hair and prostate. These medications are a weaker blocker than Spironolactone but also have fewer side effects. Common side effects for these drugs include impotence, loss of sex drive, dizziness, tenderness in breast.

Progesterone is a major sex hormone in women. Progesterone is typically involved in menstrual cycles and pregnancy. In trans women there is a little scientific evidence to support claims of better breast development, improved energy and better mood and sex drive. There are some studies that suggest that there is an increased risk of developing blood clots, strokes and cancer. There may be a decrease in the chance of prostate cancer but an increase in the risk of breast cancer associated with taking progresterone. You should follow all medical guidelines for someone your age in screenings for both diseases.

Medication Types

Oral	Estradiol
Parental	Estradiol valerate
(subcutaneous/intramuscular)	
Transdermal	Estradiol
Anti-androgens	Progesterone
	Medroxyprogesterone acetate
	GnRH agonist (leuprolide)
	Histrelin implant
	Spironolactone
	Finasteride

The most serious risks when taking estrogens are:

- Thrombosis
  - Deep vein thrombosis (DVT)
  - Stroke
  - Pulmonary embolism (block in a blood vessel in the lungs)
- Altered liver function.

Tips for administration of the medications

- Injections.
  - Always clean the area with alcohol before injecting and allow the alcohol to dry completely.
  - The directions will tell you to inject at a 90-degree angle to the muscle in your thigh. Before injecting pull the skin tightly in one direction and then releasing immediately after pulling the needle out will help to ensure no medication leaks out of the injection side.
  - Do not ever reuse your needles due to the risk of infection.
  - Always dispose of your needles in a safely.
  - Pull a little air into the syringe before getting the medication and push the air into the open space in the medication bottle. Then flip the medication over and line up the syringe to dose the prescribed amount.
  - Look for air bubbles in the syringe. Flick the side of the syringe to get these bubbles to rise to the top. Make sure you get all the air bubbles out of the syringe to ensure no complication.

- Patch
  - you will apply onto your back, stomach, upper arms, or thighs nightly for 24 hours.
  - At the end of that 24 hours, you will need remove the used patch and put on a new one.
  - The patch site should be rotated, with an interval of 7 days between applications to the same site.

- Storage
  - Keep out of the reach of children.
  - Do not keep outdated medicine or medicine you no longer need.
    - Ask your healthcare professional how you should dispose of any medicine you do not use.
  - Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.
  - Keep the medicine in a safe place. Do not give it to anyone else, even if you have the same symptoms.

What to expect

Consider the effects of hormone therapy as a second puberty, and puberty normally takes years for the full effects to be seen. Taking higher doses of hormones will not necessarily bring about faster changes, but it could endanger your health. And because everyone is different, your medicines or dosages may vary widely from those of your friends, or what you may have read in books or online.

3 areas to expect changes

- ***Physical***
  - Skin will be one of the first changes you notice in that it will become drier, thinner, pores will shrink and there will be less oil production.
  - You may notice things "feel different" when you touch them and the way you perceive pain and temperature may change.

- Within a few weeks you may develop small buds under your nipples which may be slightly painful to the touch. They may be uneven from right and left. This is normal and the pain will decrease of the next few months.
  - It is important to note that breast development will vary from woman to woman. Many trans women only develop to an A cup or a small B cup.
  - High doses of estrogen can cause abnormal breast development so sticking to your doctor's prescription is necessary.
- Body fat redistribution will start with your hips and thighs. The muscles in your arms and legs will become less defined and as the fat below the surface thickens it will become much smoother. Your eyes and face will also develop a thicker fat layer which will feminize your features but this process can take 2-3 years to fully develop. Your muscle mass and strengths will decrease significantly. Exercise should be a part of your routine for both general health but also to decrease the likelihood of weight gain during this process.
- The body hair that you have will decrease in thickness and growth rate. It may not go away altogether, which is normal for all women. Facial hair will act the same way and may not go away all together. If you have a scalp that is balding, hormone therapy may stop it or slow it but likely will not regrow hair.

- ***Emotional***
  - Emotional changes vary from person to person. Hormone therapy is similar to going through puberty and for many puberty can be a roller-coaster of emotions. You may find that some of your interests, tastes or pastimes may change. You may also notice that you have a wider range of emotions or feelings or that your relationships with people change.

- ***Reproductive System***
  - You should assume that within a few months of starting hormone therapy you will become permanently sterile. Some people do retain a sperm count during hormone therapy but that is not the norm.
    - If you wish to have biological children in the future or are unsure you will need to preserve your sperm in a sperm bank prior to starting hormone therapy.
    - If you are sexually active with a woman who is able to become pregnant, you should always use birth control.
  - Your testicles will shrink in size likely to less than half their original size.

What Not to expect

- Hormones will not be able to change the tone and pitch of your voice. During puberty, the larynx or voice box grows thicker and larger which deepens the voice. Hormone therapy will not reverse thickening of vocal cords that happened during puberty. Changes in voice can be attainted through voice therapy which is a non-surgical intervention with a speech therapist or pathologist.
- Change shape, size, structure of bones will not change based on estrogen. There will be a change over time in the look of the face due to a redistribution of fat so you should wait at least 2-3 before undertaking any facial feminization surgeries to give the hormones time to work fully

- Reduce or eliminate Adam's apple which can only be done through a Chondrolaryngoplasty (commonly called tracheal shave). A tracheal shave will not change or alter the voice in any way.
- As stated about estrogen will help hair to decrease in thickness and growth rate over the body but it will not eliminate all terminal hair follicles that are associated with masculine hair growth patterns. Chest, back, facial hair may need additional interventions such as laser hair removal to achieve your desired effect.

Do I need to be monitored?

Being under proper medical supervision will ensure that your body is absorbing the medication properly. This will also help your doctor to ensure to identify any health issues early and allow for your hormone therapy to be adjusted to compensate or to change any other medications. It is also important to give your doctor your entire family medical history and any additional medications you may be taking to ensure there is no negative interactions.

What if I take hormones bought without a prescription?

It can be very tempting to purchase without a prescription from a doctor. While making this choice may be understandable it is unwise due to the risks to your general health. The hormones and doses that you read about on the internet or that are prescribed for a friend will likely not be the correct dosing for you as each individual is different.

The main risks and dangers of self-medicating:

- The products may not be authentic and may therefore have no effect at all, so you may be wasting your money.
- The products may be of poor quality and may even be harmful to your general health. There is not way for you to be sure that the oil
- You may not have a full understanding the possible risks and side effects for the doses and hormones you are taking.
- You may not have a full understanding of the consequences of combining hormones with any other medication or herbal or supplement products that you might be taking
- You will not have had a full medical work up to ensure you have no other conditions that will be affected by the hormones you are taking
- The dose and the manner you are taking the medication (pills vs patches) may not be appropriate for you

SO YOU WANT TO KNOW MORE ABOUT "T"...

Testosterone Basic Overview

Hormone therapy for trans men is meant to suppress female secondary sex characteristics such as menstruation, fat redistribution and to masculinize. Testosterone can show effects within the first few months of treatment and patients will continue to see changes for the next few years. Hormone therapy is a long-term treatment that will help the patient to be happier with their body as it will be more congruent with their gender identity. Hormone therapy is not a wonder drug that will solve all problems in a patient's life but can be a step in the right direction. Guidelines do exist to help medical providers to determine when hormone therapy is appropriate for treatment and how the treatment should take place.

Things to think about

- Psychotherapy – As with any transition in life and knowing that psychotherapy is not for everyone, most people would benefit from supportive psychotherapy with a qualified psychotherapist. The therapist can help you explore new thoughts and feelings and get to know your new body and self.
- Do your research on any and all treatments that are suggested by your doctors but also understand that everyone is different. Your response or development may be very different from friends or those you see in the community and online.
- Be patient – Transitions and medications take time to see the full results. This can take 2-3 years to see the results of the medications and therapies before getting discouraged. You should also wait at least this long before seeking further invasive procedures. Higher doses will not bring changes faster and could endanger your general health.
- Continual care- monitoring by a doctor must be done on a routine basis to ensure that hormone levels remain at correct levels to achieve desired results.

Types of hormones

Testosterone comes in several forms with most transgender men use an injectable form at the beginning. Some patients start slowly and increase the dose over time while others begin at the typical dose levels. Both approaches have their pros and cons and remember that treatment will be different from patient to patient and you should discuss any and all concerns you have with your doctor. Regardless of your approach it is important to remember that more testosterone will not increase the changes or speed them up. Too much testosterone can be converted to estrogen which can lead to increased risk of uterine imbalance and cancer. It can also make you feel more anxious and agitated.

Medication Types

Oral	Testosterone undecanoate
(not available in United States)	
Parental	Testosterone enanthate, cypionate
(subcutaneous, intramuscular)	
Implant	Testopel®
(subcutaneous)	
Transdermal	Testosterone gel (1%)
	Testosterone patch

The most serious risk when taking testosterone is polycythaemia (over-production of red blood cells).

Tips for administration of the medications

- ***Gel***
  - Make sure that you wash your hands with soap and water before and after applying the gel.
    - The gel can be transferred to another person if they touch or rub the skin where it has been applied. Make sure to wash your hands after applying gel.
  - Apply gel to a clean, dry, intact skin where your doctor has prescribed it to go. Applying it to other places (i.e. face) will not assist in quicker results.
  - Allow the gel to dry on your skin before you cover it with clothing.
  - Wait for at least 2 – 5 hours after applying this medicine before showering or swimming.

- ***Injections***
  - Note: testosterone is a thick medication and can be difficult to work with at first.
  - Always clean the area with alcohol before injecting and allow the alcohol to dry completely.
  - The directions will tell you to inject at a 90-degree angle to the muscle in your thigh. Before injecting pull the skin tightly in one direction and then releasing immediately after pulling the needle out will help to ensure no Testosterone leaks out of the injection side.
  - Do not ever reuse your needles due to the risk of infection.
  - Always dispose of your needles in a safely.
  - Pull a little air into the syringe before getting the medication and push the air into the open space in the medication bottle. Then flip the medication over and line up the syringe to dose the prescribed amount.
  - Look for air bubbles in the syringe. Flick the side of the syringe to get these bubbles to rise to the top. Make sure you get all the air bubbles out of the syringe to ensure no complication.

- ***Patch***
  - You will apply onto your back, stomach, upper arms, or thighs nightly for 24 hours.
  - At the end of that 24 hours, you will need remove the used patch and put on a new one.
  - The patch site should be rotated, with an interval of 7 days between applications to the same site.

- ***Storage***
  - Keep out of the reach of children.
  - Do not keep outdated medicine or medicine you no longer need.
    - Ask your healthcare professional how you should dispose of any medicine you do not use.
  - Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light. Keep from freezing.
  - Keep the medicine in a safe place. Do not give it to anyone else, even if you have the same symptoms.

What to expect

Consider the effects of hormone therapy as a second puberty, and puberty normally takes years for the full effects to be seen. Taking higher doses of hormones will not necessarily bring about faster changes, but it could endanger your health. And because everyone is different, your medicines or dosages may vary widely from those of your friends, or what you may have read in books or online.

3 areas to expect changes

- ***Physical***
  - Skin will be one of the first changes you notice in that will become thicker and oily. Pores will get larger. You may develop acne, which can be severe. Skin care practices and cleansing will be important during this time. You may also notice your body odor and urine will change and you may sweat more.
  - You may notice things "feel different" when you touch them and the way you perceive pain and temperature may change.
  - Your eyes and face will also develop a thinner fat layer and become more angular which will masculinize your features but this process can take 2-3 years to fully develop.
  - You will not see a major change in your breasts other than a possible slight decrease. There may be some breast pain.
  - Body fat redistribution will start with your hips and thighs becoming smaller. Arms will start to have more muscle definition. You may also notice an increase in fat around your abdomen.
  - Your muscle mass and strengths will increase. Exercise should be a part of your routine for both general health but also to decrease the likelihood of weight gain during this process, especially around the abdomen.
  - Many trans men notice some degree of balding, especially in the front temples. Depending on genetics and age you may experience male pattern baldness to some degree.
  - The body hair that you have will increase in thickness and growth rate. This can be a slow process and take up to 5 years to see final results. You will likely see a hair pattern similar to those of men in your family.

- Facial hair varies from person to person as it does with non-trans men. Some men will grow full beards quickly while others can take years to full grow one and others will be unable to do so. This change depends on genetics and what age you start your testosterone therapy.

- ***Emotional***
  - Emotional changes vary from person to person. Hormone therapy is similar to going through puberty and for many, puberty can be a roller-coaster of emotions. You may find that some of your interests, tastes or pastimes may change. You may also notice that you have a change in the range of emotions or feelings or that your relationships with people change.

- ***Reproductive System***
  - You may notice a change in your periods at first which can vary from person to person on being lighter and for a shorter time to being thicker and longer lasting before they stop.
  - Testosterone will lower your ability, but will not eliminate, your changes of getting pregnant. You should always use a method of birth control to prevent pregnancy. If you do think you are pregnant you will not to stop testosterone as it can endanger the fetus.
  - You may notice soon after starting treatment you will likely notice a change in your libido. You will also notice that your clitoris will begin to grow and will be larger when aroused. You will also find different sex acts and parts of your body will bring you pleasure. Your orgasms will also feel different, less than a full body experience. Some people do find that their sexual orientation changes on testosterone and those feeling should be explored. Psychotherapy will assist with dealing with these changing feelings and let you explore them in a safe environment.

What Not to expect

- Testosterone will not get rid of breast tissue. While there will be a redistrubiton of fat, there will not be a way to get rid of the breast tissue or make you have a flat or masculine chest.
- Testosterone will not make you taller. Do not expect a growth spurt from starting hormones as your growth plates have likely fused.
- Muscles will not appear with no work for it. Testosterone may make it easier for you to gain muscle mass but you will likely need to add or increase strength training to your routine to gain significant muscle mass.

Do I need to be monitored?

Being under proper medical supervision will ensure that your body is absorbing the medication properly. This will also help your doctor to ensure to identify any health issues early and allow for your hormone therapy to be adjusted to compensate or to change any other medications. It is also important to give your doctor your entire family medical history and any additional medications you may be taking to ensure there is no negative interactions.

What if I take hormones bought without a prescription?

It can be very tempting to purchase hormones without a prescription from a doctor. While making this choice may be understandable it is unwise due to the risks to your general health. The hormones and doses that you read about on the internet or that are prescribed for a friend will likely not be the correct dosing for you as each individual is different.

The main risks and dangers of self-medicating:

- The products may not be authentic and may therefore have no effect at all, so you may be wasting your money.
- The products may be of poor quality and may even be harmful to your general health.
- You may not have a full understanding the possible risks and side effects for the doses and hormones you are taking.
- You may not have a full understanding of the consequences of combining hormones with any other medication or herbal or supplement products that you might be taking
- You will not have had a full medical work up to ensure you have no other conditions that will be affected by the hormones you are taking
- The dose and the manner you are taking the medication (pills vs patches) may not be appropriate for you

Is Gender Affirming Care Safe & Effective

- Gender Affirming care is safe, effective, and important to the health and well-being of transgender people. This life-saving care encompasses both social affirmation (e.g., supporting a transgender person's chosen name, dress etc.) and medical affirmation, which allows transgender people to live in a body that matches the gender with which they identify.
- Expert medical standards of care on the provision of gender-affirming care have been continuously maintained and updated for more than 40 years. These standards require providers to carefully evaluate each patient and make decisions in the patient's best interest.
- Every major U.S medical and mental health organization, including the American Medical Association, American Academy of Pediatrics, Federation of Pediatric Organizations, and American Psychological Association, supports access to gender affirming support and care for transgender young people and adults.
- Researchers and health experts have studied the effects of gender-affirming care for decades. The scientific evidence shows that transgender people who have access to the care they need see a positive impact on their mental and physical health. (See further detail below.)

Standards of Care for Gender Affirming Care

- Every person has unique health needs, including transgender people. Health care providers follow well-established expert best practices to prescribe age-appropriate gender-affirming support and care.
    - For prepubertal children, the only intervention is social support, such as wearing different clothes or using a chosen name. Social support (sometimes called social transition) can help kids understand and explore their gender as they grow up and is endorsed by the American Academy of Pediatrics, which is the national expert medical society for pediatricians. Social transition is entirely reversible.
    - For adolescents with clinically recognized gender dysphoria who have just started or are well into puberty, the first step in medical gender affirmation is typically the use of medications that temporarily pause puberty, otherwise known as puberty blockers. These medications have been used to treat both transgender and non-transgender young people experiencing puberty at the wrong time for more than 30 years and have been shown to be safe and effective.[i]
    - Puberty delay medications can be stopped at any time, and puberty starts back up after being temporarily paused.
    - If an adolescent continues to experience gender dysphoria, gender-affirming hormones are often used to help bring the person's body into alignment with their gender. Gender-affirming hormone therapy has been safely and effectively used for both transgender and non-transgender people.

- It is recommended that genital surgeries (commonly referred to as "top" or "bottom" surgeries) should not be carried out until (i) patients reaches the legal age of majority, and (ii) patients have lived continuously for at least 12 months in the gender role that is congruent with their gender identity.[ii]
- Mental health professionals are an integral part of gender affirmation for transgender youth to make sure that young people and their families feel safe and supported.

Substantial Scientific Evidence Supports Access to Gender-Affirming Care

- Recent research found that 98% of transgender youth who begin gender affirming medical treatment in adolescence continue gender-affirming medical care into young adulthood.[iii] This adds to the vast body of scientific evidence demonstrating that gender-affirming care is essential for improving the mental health and overall well-being of transgender people.

- Other studies have found similar positive impacts[iv] on the mental health of transgender and nonbinary youth.
  - Example: A 2018 review of over 50 research studies indicated that gender-affirming health care services are associated with better mental health for transgender people, including reduced suicide attempts, less depression, and higher life satisfaction.
  - Example: A 2022 review of over 50 studies found reduced rates of suicide attempts, anxiety, depression, and symptoms of gender dysphoria along with higher levels of life satisfaction, happiness, and quality of life after gender affirming surgery among transgender adults.
  - Example: A 2022 peer-reviewed study found that receipt of gender affirming care among young people aged 13 to 20 was associated with 60% lower odds of depression and 73% lower odds of suicidality over a 12-month follow-up.
  - Example: A 2021 peer-reviewed study found that transgender and nonbinary adolescents (those that don't identify with one particular sex) with access to gender affirming hormone therapy treatments had nearly 40% lower odds of having had a suicide attempt in the past year, compared to peers who did not have access to affirming care.
  - Example: A 2022 review of 16 studies on gender affirming care for transgender youth found that this care results in favorable mental health outcomes.
  - Example: A 2016 peer-reviewed study showed that transgender youth who were socially supported in their gender identity had much better mental health than those who were not supported in their identity.

Gender Affirming Care Services at Riley Hospital for Children

- At Riley, all gender affirming Care interventions are done in consultation and with consent of parent(s) or legal guardian(s) when the patient is a minor.
    - All are done in consultation and review by a mental health professional, confirming the patient's diagnosis of gender dysphoria. (NOTE: Gender Dysphoria is defined as the distress and unease experienced if the gender identity and sex at birth are not completely congruent.)
    - All are done in alignment with national and international guidelines of care for children, adolescents, and adults who are transgender.
    - All include consistent appointments over time to follow a patient's mental and physical health throughout treatment.
- As discussed above, puberty (hormone) blockers, which have been around since the early 1990s, are very safe when appropriately used. At Riley, we typically stop hormone blockers between the ages of 14-16 years old to avoid any long term impacts to bone growth and development.
- Gender affirming hormones are largely reversible therapies. They can be initiated at the age of 14 or older, with a step-wise increase in doses over 12-24 months. When on gender affirming hormones, a patient typically has appointments every 3 months for the first 2-3 years, and then at least annually.
- Consistent with current standards of care in the U.S. , Riley does not conduct top or bottom surgeries on any patient before the age of 18. These guidelines exist to ensure that patients receive the individualized and age-appropriate care they need in consultation with their families and their doctors.

Gender Affirming Interventions for *Pediatric Patients* (less than 18yo) at Riley Hospital for Children

Services Provided	Services NOT Provided
Ambiguous genitalia surgery	Top Surgery
Treatment for menstrual suppression	Bottom Surgery
Gender-affirming hormone therapy	
Surgery consultation and coordination	

[i] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7430465/#CIT0061

[ii] SOC V7_English.pdf (wpath.org), see page 21

[iii] Van der Loos, M. A. T. C., Hannema, S. E., Klink, D. T., den Heijer, M., & Wiepjes, C. M. (2022). Continuation of gender-affirming hormones in transgender people starting puberty suppression in adolescence: A cohort study in the Netherlands. The Lancet Child & Adolescent Health, 6(12), 869–875. https://doi.org/10.1016/s2352-4642(22)00254-1

[iv] Ramos, G. G. F., Mengai, A. C. S., Daltro, C. A. T., Cutrim, P. T., Zlotnik, E., & Beck, A. P. A. (2021). Systematic Review: Puberty suppression with GnRH analogues in adolescents with gender incongruity. Journal of Endocrinological Investigation, 44(6):1151-1158. doi: 10.1007/s40618-020-01449-5

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

K.C., *et al.*,

Plaintiffs,

v.

THE INDIVIDUAL MEMBERS OF THE MEDICAL LICENSING BOARD OF INDIANA, in their official capacities, *et al.*,

Defendants.

No. 1:23-CV-595

EXPERT REBUTTAL DECLARATION OF DAN H. KARASIC, M.D.

I, DAN H. KARASIC, M.D., hereby declare and state as follows:

1. I am over 18 years of age, of sound mind, and in all respects competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

4. I incorporate as part of this rebuttal declaration my opinions and qualifications set forth in the expert declaration I filed in this matter dated April 17, 2023 and filed on April 21, 2023. Since then, I have testified as an expert at trial in: *Dekker et al., v. Weida et al.*, No. 4:22-cv-325 (N.D. Fla.).

5. As with my April 21, 2023 expert declaration, my opinions contained in this rebuttal declaration are based on: my thirty years of clinical experience as a psychiatrist treating thousands of patients with gender dysphoria, including adolescents and young adults; my knowledge of the peer-reviewed research, regarding the treatment of gender dysphoria, which

reflects advancements in the field of transgender health; my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of the eighth edition of the World Professional Association for Transgender Health ("WPATH") *Standards of Care for the Health of Transgender and Gender Diverse People* (SOC 8); and my review of any of the materials cited herein.

6. I submit this rebuttal declaration to respond to the expert declarations of Drs. James Cantor, Paul Hruz, Kristopher Kaliebe, Dianna Kenny, and Daniel Weiss.[1]

7. In this rebuttal, I respond to some of the central points made in those declarations. I do not address each and every assertion made in those reports that I believe are baseless, misleading, or mischaracterizations of the evidence, as there are many. Instead, my aim is to provide an explanation of the erroneous premises upon which their conclusions are based.

SUMMARY OF OPINIONS

8. The State's expert witnesses' description of gender-affirming care for adolescents with gender dysphoria bears no resemblance to the prevailing treatment protocols.

9. The State's expert witnesses offer no alternative effective treatment for adolescents with gender dysphoria.

10. The State's expert witnesses draw inappropriate conclusions from the numbers and sex-ratios of gender clinic referrals.

11. Some of the State's expert witnesses quarrel with the field of psychiatry and their opinions reflect their lack of experience in the field generally or with minors with gender dysphoria specifically.

[1] I have cited to the State's expert witnesses' respective declarations by last name and paragraph number, and to their respective deposition transcripts, where appropriate, by page and line.

12. The State's expert witnesses' attempts to discredit WPATH, the WPATH Standards of Care and all of the professional groups that accept them are baseless.

13. Gender-affirming medical care can have long-term benefits to patients.

THE STATE'S EXPERT WITNESSES' DESCRIPTION OF GENDER-AFFIRMING CARE FOR ADOLESCENTS WITH GENDER DYSPHORIA BEARS NO RESEMBLANCE TO THE PREVAILING TREATMENT PROTOCOLS

14. The State's expert witnesses offer descriptions of medical care for adolescents with gender dysphoria that bear no resemblance to the widely accepted protocols for treatment articulated in WPATH Standards of Care 8 ("WPATH SOC 8"), or its predecessor WPATH Standards of Care 7 ("WPATH SOC 7"), and the Endocrine Society Guideline. Throughout their declarations, the State's experts claim that doctors who provide medical interventions to treat gender dysphoria or who evaluate adolescents in advance thereof "actively encourage" or "push" patients to be transgender, rush to provide or recommend medical interventions without sufficient psychiatric assessments, disregard other mental health and family issues that could be causing the patient distress, oppose psychotherapy, and fail to inform patients and their families of the risks associated with treatments. (*See, e.g.*, Kaliebe, ¶ 154 (claiming that therapists "advise a patient to change a gender identity"); Weiss, ¶¶ 27, 33, 148 (claiming that clinicians "without question 'affirm' the child's self-diagnosis," "fail to address psychiatric comorbidities," provide an "assembly line" or "one size fits all" protocol, and use a "perfunctory" informed consent process)). None of that is accurate.

15. The State's experts call this "affirmative care" (Kaliebe, ¶ 22; Kenny, ¶ 158), implying that it is an accepted mode of treatment, but the model they describe is completely at odds with the WPATH SOC 7, WPATH SOC 8, and the Endocrine Society Guideline:

a. Under the WPATH SOC 7, WPATH SOC 8, and Endocrine Society Guideline, care for transgender youth that is described as "affirming" or "gender affirming" does not mean steering them in any particular direction, but rather supporting them through their period of exploration of gender expression and increasing self-awareness of their identity. (Coleman, et al., 2012, at 18; Ehrensaft, 2017).

b. The protocols provide that before any medical or surgical interventions are provided to adolescents, a careful mental health assessment should be conducted to ascertain whether the diagnostic criteria for Gender Dysphoria in Adolescents and Adults are met and the appropriateness of such care for the patient. (Coleman, et al., 2022, at S50; Hembree, et al., 2017, at 3877).

c. The protocols provide that clinicians should ensure that any psychiatric conditions are appropriately addressed and that it is important that mental health care is available to patients before, during, and sometimes after transitioning. (Coleman, et al., 2022 at S256-7; Hembree, et al., 2017, at 3876, 3879).

d. The protocols provide for a rigorous informed consent process that includes informing the patient and their parents of side effects of treatment, including the potential loss of fertility. For hormone therapy, in addition to requiring the parents' informed consent, the adolescent must have "sufficient mental capacity . . . to estimate the consequences of this (partly) irreversible treatment, weigh the benefits and risks, and give informed consent." (Hembree, et al., 2017, at 3878).

16. In sum, the State's experts create a straw man by providing a false description of care under the prevailing protocols and then attacking it. None of the State's expert witnesses point to any examples of this happening, or even citations to literature, but rather rely on their own deliberate misreading of existing protocols and Internet sources. Indeed, Dr. Kaliebe admitted in his deposition that his example of a rush to affirmation in the face of acute traumatic events was just a hypothetical, not based on any real case or patient. (*Compare* Kaliebe, ¶ 153 ("Is it, for example, sensible, compassionate, or good medical practice to, for instance, soon after a sexual assault, automatically agree with a teen's new self-assigned gender label?") *with* Kaliebe Dep. 179:11 – 180:3 ("Well, that is, that particular vignette would be a hypothetical.")). The State's expert witnesses' either misunderstand the prevailing protocols or assume, without basis, that all or most gender clinics or clinicians providing care to minors with gender dysphoria disregard them.

17. As a clinician who, unlike the State's experts, actively works and consults with clinicians providing care to transgender youth and adults on a regular basis, I know firsthand that their characterization of treatment is wholly inconsistent with the prevailing practice in the United States. If there are individual doctors who deviate from the accepted protocols and inappropriately provide care that is harmful to patients, medical licensing boards can address that without denying care to those who have been appropriately assessed and determined to need it. The reality, in my experience, is that the majority of adolescents and young adults with gender dysphoria experience significant barriers to diagnosis and treatment—the opposite of the problem the State's expert witnesses suggest.

18. The WPATH SOC 8 explicitly recommends psychotherapy for the treatment of adolescents with gender dysphoria stating: "We recommend health care professionals working

with gender diverse adolescents facilitate the exploration and expression of gender openly and respectfully so that no one particular identity is favored." (Coleman, et al 2022).

19. Unlike the State's experts, I have regularly seen transgender adolescents in psychotherapy over the course of decades. The false accusations regarding my views on psychotherapy and my practice of psychotherapy bear no resemblance to reality.

20. It would be unethical for any clinician to "push" a patient to assume an identity – either a cisgender or a transgender identity. Clinicians have ethical obligations to provide appropriate medical care, and every incentive not to mis-diagnose patients with gender dysphoria if, in fact, they have a different condition. It is clear from some of the State's experts' declarations that their concern is not about the alleged lack of thorough mental health assessments or access to psychotherapy for patients; it is about categorical opposition to treatment in all cases. (*See, e.g.*, Kenny ¶¶ 141, 186 (objecting to "transgendering children and young people" and a parental failure to enforce "boundaries" around "fantasies" and describing those young people as "totally ruined as social human beings")).

THE STATE'S EXPERT WITNESSES OFFER NO ALTERNATIVE EFFECTIVE TREATMENT FOR ADOLESCENTS WITH GENDER DYSPHORIA

21. The State's expert witnesses disapprove of existing protocols for treating gender dysphoria in adolescents. But the alternative treatments they propose are not supported by the rigorous evidentiary standards they hold existing protocols to and in fact lack any evidence of effectiveness at all.

22. Dr. Kaliebe claims psychotherapy can sometimes enable a return to a gender identity that matches sex assigned at birth, but offers nothing but an untested hypothesis based on the effectiveness of cognitive behavioral therapy for other, unrelated conditions. (*See* Kaliebe, ¶¶

167, 184). Dr. Kaliebe also asserts, without any evidence, that an alternative to gender-affirming medical care is to encourage mindfulness meditation or trauma-focused yoga. (*See* Kaliebe, ¶¶ 150, 167).

23. Dr. Kaliebe appears to support conversion therapy while admitting that there is no evidence to support its use. (*See* Kaliebe, ¶¶ 160-161). He tries to rename it or redefine it, but mostly creates a strawman fantasy of the practice of others, and compares it to the "quality" therapy he provides. And yet, when he recommends cognitive behavioral therapy as a substitute for medical interventions for those who need them, he is without any evidence that such intervention effectively treats gender dysphoria. Cognitive behavioral therapy, as well as psychoanalytic psychotherapy, were used for decades in attempts to treat the dysphoria of gender diverse youth as part of efforts to try to make them more gender conforming. Ultimately, these practices over decades resulted in no evidence of such interventions being effective. And those of us who have treated transgender youth and adults have heard many reports from patients about both its lack of efficacy and its harms. That's why treatment with the goal of changing a person's gender identity is no longer considered ethical. (Coleman, et al., 2012, at 16; American Psychological Association, 2021). The comparison of such efforts to a purported "longstanding tradition" of mental health practitioners "get[ting] patients to accept and live comfortably with their bodies" (Kaliebe, ¶ 161) reflects a profound misunderstanding of gender dysphoria as a condition and its treatment. As a clinician who has treated transgender patients for decades, I have worked with many people who attempted conversion therapy, or who were sent to treatment designed to "cure" them of their transgender identity. These efforts were universally unsuccessful and harmful to my patients.

24. Dr. Kenny also suggests that, as an alternative to medical interventions, health care providers can address gender dysphoria by helping patients understand that they are "pregay

children" and have "incipient fantasies, desires, and gender role performances that are not consonant with gender social roles for their natal sex." (Kenny, ¶ 241). This represents a misunderstanding of gender dysphoria and its diagnoses and treatment, as well as a conflation of gender identity and sexual orientation. If a patient's distress relates only to a sense of limitation on behaviors related to gender and they do not have a strong understanding of themselves as a different gender than that assigned to them at birth, they would not meet the criteria for diagnosis and medical treatment of gender dysphoria.

25. Dr. Weiss—an adult endocrinologist who has never treated a minor with gender dysphoria—claims that psychotherapy can "lead to…desistance" in patients with gender dysphoria. (Weiss, ¶ 26). Psychotherapy generally is certainly appropriate and is an aspect of care for children and adolescents with gender dysphoria. But those types of interventions do not resolve the dysphoria and are not alternatives to medical interventions for adolescents who need them. My initial declaration discusses the harms that can result from the denial of medically indicated gender-affirming medical care. (*See* Expert Declaration of Dan. K. Karasic, MD, filed at ECF 26-1, ¶¶ 57-60).

26. The State's experts point to "watchful waiting" as an alternative treatment approach to the existing treatment paradigms outlined in the WPATH SOC 7, WPATH SOC 8, and the Endocrine Society Guideline. (*See* Kaliebe, ¶ 89; Kenny, ¶ 197). While "watchful waiting" is an approach for prepubertal children followed by some clinicians, it is not an accepted approach used with adolescents. That is because, while there are studies finding that many prepubertal children diagnosed with Gender Identity Disorder (a precursor diagnosis to Gender Dysphoria in Children) identified with their sex assigned at birth at a later follow up, there is no evidence that gender

dysphoria that continues into adolescence is likely to desist. (DeVries, et al., 2011, Wiepjies, et al. 2018, Brik, et al., 2020).[2]

27. There is likewise no basis for suggesting that providing gender-affirming medical care will *cause* youth with gender dysphoria who would otherwise desist to, instead, persist. This claim erroneously relies on the assertion that social transition in prepubertal children can cause their gender dysphoria to persist into adolescence. First, the fact that there is a correlation between social transition prior to puberty and persistence does not establish that social transition causes persistence of gender dysphoria. The intensity of gender dysphoria prior to puberty predicted persistence, and children with more intense dysphoria were more likely to socially transition. (Steensma, 2013). Rae, et al. (2019) found that "stronger cross-sex identification and preferences expressed by gender-nonconforming children at initial testing predicted whether they later socially transitioned." Further, whatever conclusions can be drawn from these desistance studies about the impact of gender affirmation on the persistence rates in prepubertal children, this research does not apply to adolescents with gender dysphoria, for whom desistance is rare, and the treatments banned by SEA 480 are not indicated until adolescence.

28. The suggestion that adolescents can just wait until they are 18 years old to get care ignores the harm of not providing the care. Allowing endogenous puberty to advance is not a neutral decision. For many adolescents, the development of secondary sex characteristics that do

[2] Although the work of Kenneth Zucker is often cited in support of "watchful waiting," Dr. Zucker recognized the need for medical interventions for gender dysphoria in adolescence and treated adolescent patients with persistent gender dysphoria with the medical interventions now banned by Indiana. (Zucker, et al., 2010). Similarly, the Dutch researchers who coined the term "watchful waiting" for prepubertal children did the seminal research on medical interventions for those patients whose gender dysphoria persists until adolescence. (de Vries, 2011; Steensma, 2011; de Vries, 2014).

not match their gender identity can have a severe negative impact on their mental health and can exacerbate lifelong dysphoria because some of those characteristics are impossible to change later through surgeries. In addition, youth may suffer needlessly from untreated gender dysphoria while waiting to turn 18.

THE STATE'S EXPERTS DRAW INAPPROPRIATE CONCLUSIONS FROM THE NUMBERS AND SEX RATIOS OF GENDER CLINIC REFERRALS

29. The State's experts devote many pages to the increase in the numbers of referrals to gender clinics, and changes in sex ratios of patients. (*See, e.g.*, Kaliebe, ¶¶ 25-55; Kenny, ¶¶ 86-109). As an initial matter, in their caricature of doctors pushing medical transition, the State's experts say the field is ignoring and avoiding exploration of these developments. That is not the case. Indeed, the chapter on adolescents in WPATH SOC 8 specifically discusses the increase in referrals to gender clinics and the sex ratios of these young patients. (*See* WPATH SOC 8 at Chapter 6). But the State's experts draw unsupported conclusions about the rise in number of referrals and changes in sex ratios observed in some clinics. They claim this means adolescents are adopting a transgender identity due to "social contagion," leading them to undergo irreversible medical treatments they later regret. (*See, e.g.*, Kenny, ¶¶ 71-85). This conclusion is baseless.

30. The rise in numbers of referrals is hardly surprising given the greater awareness on the part of youth and their parents of what gender dysphoria is and that care is available, as well as the significant increase in the number of clinics available to provide care. In addition, the stigma associated with being transgender, while still significant, has lessened in recent years. Coming out to parents and seeking care are options that did not exist for many youth until recently, so an increase in numbers of referrals to gender clinics is not surprising. While there is a documented

increase in clinic referrals, the State's experts exaggerate the increase by making inappropriate comparisons.

31. Until the past decade, little data on the number of people identifying as transgender was available. From 2007 to 2009, a question asking whether the respondent identified as transgender was added to a large population-based health survey conducted in Massachusetts, and 0.5% of study participants identified as transgender. (Conron, et al., 2012). Since then, this question was added to large health surveys in other states, and analyses of surveys done in 2014 found that, nationally, 0.5-0.6% of adults identified as transgender, and 0.7% of youth ages 13 to 17 identified as transgender. (Crissman, et al., 2017; Flores, et al., 2016; Herman, et al., 2017).

32. While increases in numbers and changes in sex ratios of patients referred to some gender clinics have been reported, since the number of patients referred to gender clinics reflect only a small fraction of the people identifying as transgender, these changes may reflect changes in referral patterns to clinics rather than changes in the number of people identifying as transgender.

33. Sex ratios of patients vary from clinic to clinic and over time. When I was the psychiatrist for the Dimensions Clinic for transgender youth in San Francisco from 2003 to 2020, a consistent majority of my patients were assigned female at birth. Other clinics have had more assigned male at birth patients. The rise in numbers and percentage of patients assigned female at birth observed at some clinics in recent years is not surprising given the historical development of the study of gender dysphoria in youth. The first large American study of gender non-conforming youth was the Feminine Boy Study at UCLA. There was significant societal discomfort with and rejection of boys who departed from sex stereotypes—the director of the study referred to them as "sissy boys" in the book resulting from the study—and these boys often experienced bullying from

peers. In this context, boys who were perceived to be effeminate were the population brought in to psychiatrists by their parents and were the population that was initially studied by researchers. (Green, 1987). Parents were not as concerned about gender non-conforming girls as they were more socially accepted. There was also less awareness among the general public of the existence of transgender males and that transitioning was an option for individuals assigned female at birth who were experiencing gender dysphoria. The increase in awareness in recent decades made it possible for individuals who ultimately came to identify as transgender men to come out and seek care.

34. Ultimately, the diagnostic criteria for gender dysphoria are rigorous: if there were individuals claiming a transgender identity to fit into a peer group, they would not meet the criteria for a gender dysphoria diagnosis, let alone be deemed to need medical interventions.

SOME OF THE STATE'S EXPERT WITNESSES QUARREL WITH THE FIELD OF PSYCHIATRY AND THEIR OPINIONS REFLECT THEIR LACK OF EXPERIENCE IN THE FIELD GENERALLY OR WITH MINORS WITH GENDER DYSPHORIA SPECIFICALLY

35. Gender dysphoria is a psychiatric diagnosis. Some of the State's expert witnesses critique the diagnosis of gender dysphoria for being based on self-reports from patients. (*See, e.g.*, Cantor, ¶ 107 (critiquing gender identity as lacking scientific meaning because it is not "objectively measurable"); Kenny, ¶ 187 & fn. 30 (criticizing the DSM-5 based on "the absence of diagnostic tests for many of the conditions, which is unlike almost any other field of medicine, and nowhere more problematic than in the area of gender dysphoria, that overly relies on patients' subjective reports and reconstructed memories…")). But clinical interviews with patients are typically used to diagnose other DSM diagnoses and determine treatment. This widely used assessment tool is not unique to gender dysphoria.

36. Based on their declarations and curriculum vitae, Drs. Kaliebe, Kenny, and Weiss do not appear to have a sufficient clinical basis for offering expert opinions regarding the diagnosis and treatment of gender dysphoria in children and adolescents, or the assessment and informed consent process when treating adolescents with gender dysphoria and gender affirming care. Notwithstanding their lack of qualifications, these witnesses did not hesitate to offer opinions about psychiatric care for minors diagnoses with gender dysphoria. Overall, their declarations in this regard appear to be based on a series of hypothetical assumptions about how other mental health practitioners are diagnosing minors with gender dysphoria and recommending treatment—with minimal (if any) experience doing so themselves, and without any apparent knowledge of how care is provided by others.

37. Dr. Kaliebe has only treated approximately 13 minors with gender dysphoria. (*See* Kaliebe Dep. 35:7 – 36:11). He speculates about how other mental health practitioners are diagnosing minors with gender dysphoria and recommending treatment, again without any apparent knowledge about how care is actually provided by others. (*See, e.g.*, Kaliebe, ¶¶ 150-155 (speculating about the lack of interest in supportive psychotherapy among clinicians treating adolescents with gender dysphoria), ¶¶ 171-185 (hypothesizing about clinicians' alleged failure to consider autism, trauma, and borderline personality disorder as comorbid conditions), ¶¶ 186-189 (guessing that clinicians reduce adolescents with gender dysphoria to their gender identity to the exclusion of other aspects of self)).

38. Rather than the picture of care the Defendants' experts paint, in my over thirty years of clinical experience working with thousands of adolescents and young adults with gender dysphoria, psychotherapy has been a central part of treating minors with gender dysphoria, as it is with many conditions; and diagnosing and treating gender dysphoria involves careful assessment,

differential diagnosis and management of comorbid conditions. Though psychotherapy can be a critical part of managing a patient's well-being, it does not treat a patient's underlying dysphoria, which stems from the incongruence between a patient's physiological sex-based characteristic and gender identity.

39. Dr. Kenny admits that she practices "exploratory psychotherapy"—which has no evidence base—with a small population of families who reject their children's gender dysphoria diagnoses or transgender identities. (*See* Kenny, ¶ 9; Kenny Dep. 30:24 – 33:17, 34:23 – 35:10). Professor Kenny also appears to dispute gender dysphoria as a legitimate diagnosis, apparently disagreeing with the DSM-5-TR's de-pathologizing of transgender identity. (*See* Kenny, ¶ 187 ("Because the DSM-5 contends that "being transgender" is not a pathological condition, it has accordingly revised the diagnostic criteria (and name) of gender identity disorder to GD to "recognize" the clinical distress as the focus of the treatment, not the patient's transgender status per se.")).

40. To the contrary, gender dysphoria is a legitimate diagnosis. Though being transgender is not a pathology, this change ultimately has no bearing on the diagnostic criteria for gender dysphoria outlined in the DSM. Dr. Kenny seems to offer the view that pushing people to be cisgender should be the prevailing paradigm of treatment, but as discussed above, this is neither effective nor ethical.

41. Dr. Weiss is an adult endocrinologist and has not treated any minors with gender dysphoria. (*See* Weiss, ¶¶ 1-4, 8; Weiss Dep. 10:4-6, 112:22-113:6, 201:24-202:4). Nonetheless, Dr. Weiss did not hesitate to offer opinions about psychiatric care. (*See, e.g.*, Weiss, ¶¶ 24-26 (hypothesizing that a gender dysphoria diagnosis may be influenced by gender stereotypes or peer or social media influence and claiming that psychotherapy can "lead to…desistance" in patients

with gender dysphoria), ¶ 35 (claiming "With gender identity issues, open, exploratory psychotherapy or talk therapy is too often dispensed with entirely.")).

42. Dr. Weiss reports that most of his patients with gender dysphoria stopped treatment with gender affirming hormones. He measured this claim by the fact that his patients did not continue appointments with him. But there are many reasons a patient might discontinue treatment with a provider or stop accessing hormone therapy that are unrelated to either regret or detransition. For example, there have been many barriers, including lack of insurance reimbursement, to patients following up in care. Dr. Weiss states in his deposition that many of his patients were Medicaid recipients. (*See* Weiss Dep. 72:23 – 73:2). Ohio historically excluded gender affirming care from Medicaid coverage. Even after there were some federal and state moves to expand Medicaid coverage, in 2015 the state of Ohio enacted an exclusion of gender affirming care from Ohio Medicaid.[3] Exclusions for gender affirming care also were present in many private insurance policies as well during the period Dr. Weiss provided gender-affirming care. The patients that Dr. Weiss no longer saw also had other treatment options in Ohio: Dr. Weiss reports referring patients to MetroHealth (*see* Weiss Dep. 49:15-23, 117:1-21, 118:5 – 119:8), which for over 15 years has provided a welcoming environment for gender affirming care in northern Ohio, despite Medicaid and private healthcare exclusions.[4]

[3] *See, e.g.*, Christy Mallory & William Tentindo, *Medicaid Coverage for Gender-Affirming Care* (Oct. 2019), available at https://williamsinstitute.law.ucla.edu/wp-content/uploads/Medicaid-Gender-Care-Oct-2019.pdf.

[4] *See* MetroHealth, Adult Transgender & Non-Binary Care, https://www.metrohealth.org/lgbtqi-pride-network/adult-transgender-non-binary-care (last visited June 5, 2023).

43. Dr. Weiss states that, in addition to patients not returning to him to receive gender-affirming care, he saw two adult patients who regretted having orchiectomies, one because of sexual dysfunction.[5] The fact that some patients may regret surgical interventions in adulthood is certainly no reason to ban all treatment for adolescents. Regret for orchiectomy is rare: 0.6% over a 43 year period in the Netherlands. (Wiepjes et al, 2018). But in any event, Dr. Weiss knows that any treatment comes with the potential for negative effects. For example, Dr. Weiss works for Eli Lilly promoting the use of Mounjaro. In Lilly's report of the data supporting the approval of Mounjaro for weight loss, over 80% of trial participants had adverse effects, 111 participants stopped Mounjaro due to adverse effects, and 7 study participants died after taking Mounjaro.[6]

THE STATE'S EXPERT WITNESSES' ATTEMPTS TO DISCREDIT THE WPATH STANDARDS OF CARE AND ALL OF THE PROFESSIONAL GROUPS THAT ACCEPT THEM ARE BASELESS

44. The State's expert witnesses characterize WPATH as an ideological, non-scientific, advocacy organization, open to transgender activists outside of the health field. (*See* Kaliebe, ¶¶ 122-126; Kenny, ¶¶ 98, 147; Weiss, ¶ 40). Many WPATH members are academics who publish in peer-reviewed journals. Many are academic leaders in endocrinology, internal medicine, plastic surgery, urology, psychiatry, psychology, and other disciplines of the health sciences. WPATH restricts its full membership to those with professional credentials and most members are licensed

[5] These anecdotes are not representative of the broader literature around this surgical intervention. A review of 6793 patients seen in the Dutch gender clinic over 43 years found that only 0.6% regretted having an orchiectomy (Wiepjes et al, 2018). Wiepjes CM, Nota NM, de Blok CJM, Klaver M, de Vries ALC, Wensing-Kruger SA, de Jongh RT, Bouman MB, Steensma TD, Cohen-Kettenis P, Gooren LJG, Kreukels BPC, den Heijer M. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in Prevalence, Treatment, and Regrets. J Sex Med. 2018 Apr;15(4):582-590. doi: 10.1016/j.jsxm.2018.01.016. Epub 2018 Feb 17. PMID: 29463477.

[6] *See* Jastreboff, A.M., et al. (2022). Tirzepatide Once Weekly for the Treatment of Obesity. N Engl J Med 2022; 387:205-216. https://www.nejm.org/doi/full/10.1056/NEJMoa2206038.

clinicians. The fact that WPATH engages in advocacy on behalf of its patient population for access to beneficial care is typical of medical associations. For example, the American Psychiatric Association advocates for a wide range of public policy changes to improve access to mental health care, e.g., for migrants and for incarcerated people.[7]

45. I have been involved with WPATH for many years and have 35 years of experience treating people with mental illnesses. And there are many others like me in WPATH. Mental health providers make up the largest percentage of WPATH's membership. These mental health professionals are licensed and regulated by state licensing boards, and most provide care to both cisgender and transgender clients—including those with serious mental illness.

46. Having been actively involved for over three decades as a UCSF professor in the training of psychiatry residents, internal medicine residents and fellows, and medical students, as well as of mental health and medical professionals at conferences around the nation, by my observation, the mainstream views of health professionals on transgender care include widespread acceptance of the WPATH Standards of Care

47. The State's expert witnesses also argue that dissenting views are not tolerated in WPATH. (*See, e.g.*, Kaliebe, ¶¶ 123-126). I have attended several WPATH conferences since 2001, and have been a member of the Scientific Committees that have reviewed abstract

[7] *See* American Psychiatric Association. (2019). Position Statement on the Care of Medically Vulnerable Migrants in the United States. Available at https://www.psychiatry.org/File%20Library/About-APA/OrganizationDocuments-Policies/Policies/Position-Care-of-Medically-Vulnerable-Migrants-in-the-US.pdf; American Psychiatric Association. (2016). Position Statement on Treatment of Substance Use Disorders in the Criminal Justice System. Available at https://www.psychiatry.org/File%20Library/About-APA/Organization-DocumentsPolicies/Policies/Position-2016-Substance-Use-Disorders-in-the-Criminal-Justice-System.pdf; *see generally* American Psychiatric Association Policy Finder, available at https://www.psychiatry.org/home/policy-finder.

submissions for the conferences, and the diversity of views presented and discussed has always been notable. For example, as chair of the Scientific Committee for the 2017 USPATH conference, I helped organize a panel of therapists and trainees who had themselves detransitioned, and the presentations and discussion were well-received by attendees.

48. According to the State's experts, it is not just WPATH and USPATH, but also the American Medical Association, the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, the American Psychological Association, the American Psychiatric Association, the American College of Physicians, the American Academy of Family Physicians, the Endocrine Society, and the Pediatric Endocrine Society, that act based on political ideology rather than evidence-based scientific methodologies. (*See* Kaliebe, ¶¶ 89-130; Kenny, ¶¶ 144-145; Weiss, ¶ 70).

49. These unsupported claims that all of these major medical groups are sacrificing adolescents' health to promote a particular ideology is staggering. Nonetheless, the State's expert witnesses claim the existence of a "transactivist lobby," "transgender marketing machine," "transgender medical industry," and "transgender agenda." (*See, e.g.*, Kenny, ¶¶ 30, 115, 146, 149). Health professionals across disciplines providing medically necessary care for their gender dysphoric patients, as they do for their other patients, do not constitute a conspiracy. The suggestion that health care providers across specialties and around the world are somehow influenced by a shadow lobby of transgender activists is without basis.

GENDER-AFFIRMING MEDICAL CARE HAS LONG-TERM BENEFITS

50. I have treated people ranging from adolescents to the elderly. And many of my patients have remained with me for decades, e.g., where a patient is on medications that need to

be monitored, and their medical transition was a positive health care decision not just in the short term but for the course of their lives.

51. The State's expert witnesses' anecdotes and assertions regarding the incidence of regret and "detransition" are inconsistent with the data and my clinical experience. (*See* Kaliebe, ¶¶ 173, 175; Kenny, ¶¶ 125-137; Weiss, ¶¶ 136-140). A study of everyone receiving gender-affirming surgery in Sweden over 50 years (1960 to 2010) found a regret rate of 2.2.%, declining over the years. There were ten cases of regret from 1960 to 1980, and only five cases of regret total in the last 30 years that were reviewed, from 1981-2010. (Dhejne, et al., 2014). A meta-analysis of 27 studies which reported regret after gender-affirming surgery found that of 7928 people having gender-affirming surgery, the regret rate was 1%. (Bustos, et al., 2021). These experts' assertions are also at odds with my clinical experience over decades. I have had some patients who halted their transition due to challenging personal circumstances—e.g., fear of losing family support— but they still had gender dysphoria. And some came back years later to resume their transition. I have also had patients discontinue medical treatment for other reasons, including being happy with the existing changes and continuing to live and identify as transgender. But in 30 years, I have never seen a patient who had undergone hormone therapy and surgery and later came to identify with their sex assigned at birth and regret the treatment they had received.

52. The State's expert witnesses point to elevated rates of mental health problems and substance use in the transgender community, suggesting that being transgender is the cause of these negative outcomes and, thus, something doctors should try to prevent. (*See* Cantor, ¶ 55; Kaliebe, ¶¶ 186-189; Kenny, ¶ 137; Weiss, ¶ 58). As discussed above, being transgender is not something doctors can prevent. And these comments disregard the significant stigma transgender

people continue to face, and stigma is a well-documented risk factor for mental health and substance use issues.

53. Apparently in support of the unattainable goal of trying to deter people from being transgender or receiving any gender affirming medical care, the State's expert witnesses' claim that: gender affirming care comes at the expense of "not developing functional aspects [of identity], such as educational excellence, productive work skills, well-rounded leisure pursuits, and purpose and meaning through supportive communities," (Kaliebe, ¶ 189); that the "longer-term outlook for transgender adults appears bleak," (Kenny, ¶ 137); and that transgender young people who receive gender affirming care are "totally ruined as social human beings." (Kenny, ¶ 141). That may be their own views of transgender people, but it is not at all consistent with clinical experience, including my own. Many transgender people, when appropriately treated, lead fulfilling lives, forming romantic relationships and having families, and having close relationships with friends and extended family.

RESPONSE TO CRITICISMS IN THE EXPERT DECLARATION OF JAMES CANTOR

54. I have reviewed the declaration from James Cantor, specifically his critique of my declaration. (*See* Cantor, ¶¶ 272-283). I note briefly that, contrary to Dr. Cantor's assertions, my declaration includes extensive citation to relevant research literature. (*Compare* Cantor, ¶ 273 *with* ECF 26-1 (Exhibit B – Dan Karasic Bibliography)). Contrary to Dr. Cantor's general critiques of the WPATH SOC 7 and SOC 8, those standards of care are based upon a rigorous and methodological approach to outline treatment recommendations, informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options, as well as expert consensus. The rigor of that approach is confirmed, not contradicted, by the changes across

SOC 6, 7, and 8, as clinicians and researchers steeped in this area of medicine continually endeavor to refine the treatment recommendations based on the best currently available evidence.

55. After lengthy criticism of literature supporting gender affirming care, which Dr. Cantor distorts through cherry-picking, Dr. Cantor uses Diaz and Bailey (2023) to draw the conclusion that the body of research supporting gender-affirming care cannot be applied to current transgender youth. Diaz and Bailey's paper has received extensive criticism, including that its first author is anonymous and did not seek the human subjects review that is a standard requirement, and that the data was obtained from parents of trans people visiting a site that is named after the phenomenon the paper purports to examine—a site that opposes gender affirming care. The second author, Dr. Bailey, is listed as an editorial board member of the journal that published the paper, despite the fact that Bailey's institutional review board at Northwestern University refused to approve the research protocol. Ultimately, Springer Nature, publisher of the journal, retracted the article, reportedly due to ethical concerns, including lack of informed consent.[8]

56. Dr. Cantor refers to systematic reviews of the literature of gender affirming care for minors. It is important to put GRADE scores of systematic reviews in context. Only a small percentage of systematic reviews of medical interventions have a high GRADE score; for a majority of systematic reviews of medical interventions, GRADE scores are low or very low. (Fleming et al., 2016, Howick, et al., 2020). For complex interventions, for which gender affirming care certainly qualifies, no high GRADE scores were found for systematic reviews of any complex

[8] *See, e.g.*, Ellie Kincaid, *After backlash, publisher to retract article that surveyed parents of children with gender dysphoria, says co-author*, (May 24, 2023), https://retractionwatch.com/2023/05/24/after-backlash-publisher-to-retract-article-that-surveyed-parents-of-children-with-gender-dysphoria-says-co-author.

intervention. (Movsisyan, et al., 2016). If only medical interventions with high GRADE scores were permitted by law, most medical interventions and all complex interventions would be banned.

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

Executed this 6th day of June, 2023.

Dan H. Karasic, M.D.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

K.C., *et al.*,

Plaintiffs,

v.

THE INDIVIDUAL MEMBERS OF THE MEDICAL LICENSING BOARD OF INDIANA, in their official capacities, *et al.*,

Defendants.

No. 1:23-CV-595

EXPERT REBUTTAL DECLARATION OF DANIEL SHUMER, M.D.

I, Daniel Shumer, M.D., hereby declare and state as follows:

1. I am over 18 years of age, of sound mind, and in all respects competent to testify.

2. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

3. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

4. I incorporate as part of this rebuttal declaration my opinions and qualifications set forth in the expert declaration I filed in this matter dated April 18, 2023 and filed on April 21, 2023. Since that date, I have testified as an expert at trial in: *Dekker et al., v. Weida et al.*, No. 4:22-cv-325 (N.D. Fla.).

5. As with my expert declaration, my opinions contained in this rebuttal declaration are based on, in part, my extensive experience working with and treating children and adolescents with endocrine conditions, my extensive experience working with and treating children and adolescents with gender dysphoria, which I have been treating since 2015, as well as my ongoing

review of the research in these areas of medicine and my conversations with colleagues across the United States. I have personally evaluated and treated over 400 patients with gender dysphoria. C.S. Mott Children's Hospital's Children and Adolescent Gender Services Clinic, which I founded and where I serve as clinical director, has treated over 600 patients since its founding. I actively conduct research related to transgender medicine, gender dysphoria treatment, and mental health concerns specific to transgender youth.

6. I submit this rebuttal declaration to respond to the expert declarations of Drs. James Cantor, Paul Hruz, Kristopher Kaliebe, Dianna Kenny, and Daniel Weiss.

7. In this rebuttal, I respond to some of the central points made in those declarations. I do not address each and every assertion made in those reports that I believe are baseless, misleading, or mischaracterizations of the evidence, as there are many. Instead, my aim is to provide an explanation of the erroneous premises upon which their conclusions are based.

SUMMARY OF OPINIONS

8. The treatment protocols for adolescents with gender dysphoria require rigorous informed consent processes and mental health assessments prior to the prescription of puberty blockers or hormone therapy.

9. "Puberty blockers," i.e. gonadotropin-releasing hormone agonists ("GnRHa") are safe and effective for treating adolescents with gender dysphoria. This treatment is based on robust research and clinical experience, which consistently demonstrate safety and efficacy.

10. Hormonal interventions, e.g. testosterone for transgender boys and young men or estrogen and testosterone suppression for transgender girls and young women, are safe and effective for treating adolescents with gender dysphoria. This treatment is also based on robust research and clinical experience, which also consistently demonstrate safety and efficacy.

11. The State's expert witnesses' evaluation of the Minor Plaintiffs' medical records suggests a lack of familiarity with the patient population of adolescents with gender dysphoria.

TREATMENT PROTOCOLS FOR ADOLESCENTS WITH GENDER DYSPHORIA

12. The State's experts suggest that clinicians routinely provide medical interventions to adolescents without proper mental health assessments and without informing patients and their parents of the potential risks of treatment. I cannot speak to the practice of every clinician in the country, but both the Endocrine Society Clinical Practice Guideline (the "Endocrine Society Guideline") and the World Professional Association of Transgender Health Standards of Care (the "WPATH SOC") require rigorous mental health assessments and informed consent processes before any medical treatment is initiated. (Coleman, et al., 2022; Hembree, et al., 2017).

13. In my experience personally treating over 400 youth with gender dysphoria, and as the clinical director for the Child and Adolescent Gender Services Clinic, each patient undergoes an extensive psychological assessment and, if medical interventions are deemed medically appropriate, an extensive informed consent process before such interventions is provided.

14. In my practice, I regularly communicate with practitioners who treat adolescents with gender dysphoria. The assessment and informed consent process that we utilize at the Child and Adolescent Gender Services is comparable to the processes used at similar clinics across the country as I understand them. If providers are foregoing assessments and informed consent, such practice would be outside the recommended guidelines for care.

15. It is not the case that clinicians "encourage" any patient to initiate gender-affirming care as some of the State's experts suggest. (*See* Hruz, ¶ 56). Consistent with the WPATH SOC and the Endocrine Society Guideline, each patient is met first by providers who explore the patient's medical and mental health history and identity. Under the standards of care, no patient

is rushed into medical treatment, and no treatment is initiated without appropriate evaluation and an informed consent process. Consistent with SOC 8, gender clinics use a multidisciplinary approach and the decision to initiate gender affirming care is made by involving relevant disciplines, including mental health and medical professionals, to reach a decision with families about whether medical intervention is appropriate and remain indicated through the course of treatment. (Coleman, et al., 2022; Hembree, et al., 2017). As clinicians our jobs are not to "encourage" any particular identity or outcome but rather to assess and treat our patients.

16. It appears to be the position of the State's experts that "watchful waiting" or delay until a patient turns 18 years of age before initiating medical treatment for gender dysphoria would not cause harm to minor patients. (*See, e.g.*, Kaliebe, ¶ 89). This is inconsistent with a robust body of research and my clinical experience. Many physiological changes that happen during endogenous puberty cause severe distress for patients with gender dysphoria and can be difficult, if not impossible, to reverse with subsequent treatment. Based on my clinical experience, patients with severe dysphoria who are able to receive treatment prior to age 18 experience substantial mental health improvements from gender-affirming medical interventions.

17. The State's experts attempt to discredit WPATH as an advocacy organization. This critique is also misplaced. (*See* Kaliebe, ¶ 126). Like many medical associations, WPATH both advocates for patients and pursues rigorous scientific research. This is not a new phenomenon in medicine. The American Diabetes Association, for example, is a professional association that both advocates for patients with diabetes and is a scientific organization. Similarly, the American Heart Association has scientific meetings, community engagement and advocacy arms.

SAFETY AND EFFICACY OF GnRHa TO TEMPORARILY SUPPRESS PUBERTY

18. GnRHa have been used extensively in pediatrics for several decades. Prior to their use for gender dysphoria, they were used (and still are used) to treat precocious puberty. Extensive data supports their safety and efficacy. It is therefore not accurate to suggest that little is known about the effects of puberty blockers.

19. Though the State's experts warn about delaying puberty, (*see* Cantor, ¶¶ 213, 230; Hruz, ¶¶ 45, 61), use of GnRHa in transgender youth does not delay puberty beyond the typical age range. There is diversity in the age of pubertal onset and duration. Most adolescents begin puberty between ages 10 and 12 years, but puberty may begin as early as 8 or 9 years, or as late as 13 or 14 years (or later in the case of delayed puberty). Protocols used to treat adolescents with gender dysphoria would tend to put them toward the latter end, but still within this typical range. Partly in recognition of the natural diversity in pubertal onset, WPATH SOC 8 removed strict age guidelines for hormone therapy was so that patients moving from GnRHa to testosterone or estrogen could have an individualized assessment about when initiating puberty is appropriate. There is no data to support the State's experts' assumption of that delaying puberty within these normal age ranges will have negative short- or long-term social and developmental consequences.

20. In my clinical experience, GnRHa greatly reduce distress both at the time of treatment and later in life. At the time of treatment, GnRHa reduces the worsening gender dysphoria and mental health deterioration that accompanies the development of secondary sex characteristics incongruent with an adolescent's gender identity. Later in life, patients treated with GnRHa benefit from a reduced need for surgical or other invasive interventions to overcome the effects of endogenous puberty. In my clinical experience, providing individualized care based on individual patient characteristics, using the WPATH Standards of Care as the foundation, provides significant benefit to patients, minimizes gender dysphoria, and can eliminate the need

for surgical treatments in adulthood. The side effects of GnRHa are easily managed, and, for the majority of patients, the risks outweigh the benefits. In my practice, adolescent patients struggling with significant distress at the onset of puberty routinely have dramatic improvements in mood, school performance, and quality of life with the appropriate use of GnRHa. Allowing puberty to progress in such situations often results in worsening distress. This has been what I have observed personally in situations when a patient eligible to receive GnRHa is unable to obtain it for various reasons (lack of insurance, parental disagreement, etc.). Sometimes mood remains relatively stable on GnRHa without marked improvement or deterioration. This is not a sign of treatment failure, but rather a much preferrable outcome to the counterfactual of withholding treatment resulting in mental health deterioration.

21. The State's experts claim that patients treated with GnRHa will experience a range of health consequences. (*See* Cantor, ¶¶ 200-236). For example, they say that patients treated with GnRHa will be at an elevated risk of lower bone mineral density. (*See* Hruz, ¶ 66; Weiss, ¶¶ 92-101). The risk of lower bone mineral density in prolonged use of GnRHa can be mitigated by screening for and (when present) treating vitamin D deficiency, and by limiting the number of years of treatment based on a patient's clinical course. (Rosenthal, 2014). As I explain to my patients, every year, a child's bone density gets a little stronger. When a patient is on GnRHa, their bone density increases every year, at a pre-pubertal speed. During puberty, whether from testosterone or estrogen, bone density increases at a faster rate—a bone density spurt, almost like a growth spurt. Once a patient stops using GnRHa and begins puberty, either endogenously or through exogenous testosterone or estrogen, they will undergo their bone density spurt.

22. The State's experts raise the issue of risk of fracture later in life, (*see* Cantor, ¶ 217; Weiss, ¶ 92), but no such long-term effects have been observed in patients treated with GnRHa

for either precocious puberty or gender dysphoria. As with all of the risks of GnRHa, the risks related to bone mineralization and the state of the evidence are discussed with patients and their parents during the informed consent process and are weighed against the risks of not providing treatment.

23. With respect to claims about weight gain, (*see* Cantor, ¶ 219; Weiss, ¶ 90), it is appropriate to counsel patients on the potential risk of weight gain while using GnRHa, along with the benefits of maintaining a healthy diet and promoting physical activity, and to provide nutritional support for those at risk of obesity. In my clinical experience, families and adolescents consider this potential side effect—common to other medications used to treat endocrine disorders and other conditions in adolescents—when weighing the risks and benefits of treatment. It is also true that patients with untreated anxiety or depression are at higher risk for weight gain, and withholding GnRHa could serve as a risk factor for unhealthy weight.

24. Additionally, the State's experts suggest that patients on puberty blockers will have slower rates of growth in height. (*See* Hruz, ¶ 213). Just as the bone density spurt associated with puberty will not occur while using GnRHa, so too will the growth spurt associated with puberty not occur while using GnRHa. Again, once puberty resumes, either endogenously or through exogenous hormone therapy, adolescents will begin to grow into their adult height. For transgender girls, use of GnRHa may reduce final adult height somewhat, but that is usually considered a benefit of treatment and consistent with gender-affirming goals. For transgender boys, treatment increases final adult height which is very often consistent with gender-affirming goals as well.

25. The State's experts' claim that brain development occurring during puberty may be negatively affected by GnRHa is not accurate. (*See* Cantor, ¶ 89; Hruz ¶¶ 64-65; Weiss, ¶ 102).

Patients with gender dysphoria who are treated with GnRHa will later undergo hormonal puberty with all the same brain and other developments. I am unaware of any research suggesting that treatment has negative impact on brain development or executive functioning, and I have not seen this in my clinical practice. Such a claim would also be inconsistent with my clinical experience treating patients with delayed puberty. Those individuals still have normal brain development with respect to cognition and executive function despite starting puberty at a similar age as patients with gender dysphoria treated with GnRHa.

SAFETY AND EFFICACY OF HORMONE THERAPY

26. Hormone therapy is safe and effective to treat adolescents with gender dysphoria. As with the use of GnRHa, where medically indicated, testosterone or estrogen (along with a testosterone suppressant) are provided after a discussion among the patient, their parents, and the patient's care team, as well as an extensive informed consent process. Hormone therapy treats gender dysphoria in adolescents by facilitating the development of physical changes congruent with a patient's gender identity.

27. Defendants' claim that hormone therapy is harmful because adolescents receive inappropriately high levels of hormones. (*See* Hruz, ¶ 48; Weiss, ¶¶ 107-108). The goal of hormone therapy is to maintain the patient's hormone levels within the normal range for their gender identity. This is true for all of my patients for whom I prescribe testosterone or estrogen, including non-transgender adolescents with conditions such as delayed puberty, hypogonadism, Turner Syndrome, Klinefelter Syndrome, agonism, premature ovarian failure, and disorders of sex development. Laboratory testing is recommended to ensure proper dosing and hormonal levels within the normal male or female range for the patient's age. We closely track dosing and

circulating hormone levels to minimize any risk of adverse effects, in patients with gender dysphoria and any other conditions requiring hormonal treatment.

28. Treatment of gender dysphoria with testosterone or estrogen is highly beneficial for both short-term and long-term psychological functioning of adolescents with gender dysphoria. (*See* Achille, et al., 2020; Allen, et al., 2019; Chen, et al., 2023; de Lara, et al., 2020; de Vries, et al., 2014; Grannis, et al., 2021; Green, et al., 2022; Kaltiala, et al., 2020; Kuper, et al., 2020). I observe this in my clinical practice: my patients who receive medically appropriate hormone therapy and who are treated consistent with their gender identity in all aspects of life experience significant improvement in their health.

29. The State's experts claim that the risks of hormone therapy include disfiguring acne, high blood pressure, weight gain, abnormal glucose tolerance, breast cancer, liver disease, thrombosis, and cardiovascular disease. (*See* Hruz, ¶¶ 52, 54; Weiss, ¶¶ 105-125). In my clinical experience, transgender boys on testosterone experience acne similar to any other boy going through a testosterone-driven puberty. Breast cancer is more common in people with breasts, but not more common in transgender women when compared to other women. Other medical problems occur no more frequently than what is expected in the general population when hormone levels are monitored and adjusted effectively.

30. The State's experts seem to suggest that hormone treatment is harmful because it leads to a "lifetime" of continuing to receive such therapy. (*See* Cantor, ¶ 223 ("lifetime dependence on cross-sex hormones")). In every encounter with my care team, there is a re-evaluation of treatment, including the benefits, side effects, and trajectory of the treatment for the individual patient. For some patients, they may undergo hormone treatment for a period of time and then discontinue the treatment if dysphoria is well-managed and the changes from the

hormone therapy have adequately addressed the underlying dysphoria. For my patients who do remain on maintenance doses of hormone therapy, the risks of ongoing hormone therapy can be well-managed and are not unlike risks associated with those present for other patients who undergo long-term sex hormone therapy for different conditions like Kleinfelter's Syndrome, Turner Syndrome, patients who have to have their ovaries or testicles removed due to cancer, torsion or other causes as well as those with hypopituitarism. Many endocrine conditions are lifelong and require lifelong use of hormone replacement including Type 1 diabetes and hypothyroidism, which require insulin or thyroid hormone treatment for life, respectively. Ultimately, many endocrine conditions are treated with lifelong medical management – including hormone therapy – and that does not pose an inherent risk to patient health but rather is critical to patient health.

31. Defendants' experts also discuss the fertility implications of gender-affirming care. (*See* Cantor, ¶¶ 89, 204-205; Hruz, ¶¶ 51-52, 89; Weiss, ¶¶ 96-98, 110). The sweeping suggestion that hormone therapy affects fertility for all patients is simply incorrect. As set forth below, there are options for preserving the fertility of adolescents with gender dysphoria who first begin treatment with GnRHa and then proceed to hormone therapy, and adolescents who undergo their endogenous puberty prior to commencing hormone therapy often achieve fertility upon cessation of exogenous hormone therapy.

32. For minors who are first treated with GnRHa, there is decades of research showing that GnRHa alone has no long-terms implications for fertility. (Guaraldi, et al., 2016; Martinerie, et al., 2021). Progression through natal puberty is required for maturation of egg or sperm. If a patient who first received GnRHa and then hormone therapy wishes to be fertile, they can withdraw from exogenous hormones and allow pubertal progression. Caanen et al. demonstrated

that transgender men have similar ovarian morphology to cisgender women, even when treated with GnRHa followed by testosterone. These treatments did not cause the ovarian changes which are seen in hyperandrogenic women with polycystic ovarian syndrome and infertility. (Caanen, 2017). This lends support to the expectation that the sequence of GnRHa to testosterone does not necessarily cause permanent infertility.

33. Patients who initiate hormones after completing puberty are offered gamete preservation prior to hormonal initiation. (Coleman, et al., 2022). But even when patients do not undertake gamete preservation, withdrawal of hormones in adulthood often is successful in achieving fertility when it is desired. (Light, et al., 2014; Knudson, et al., 2017). For transgender men and women, pregnancies have occurred even when on testosterone or estrogen treatment, and transgender patients are regularly advised that testosterone and estrogen are not effective forms of birth control.

34. For all medications with potential impacts on fertility, the potential risks and benefits of both treatment and non-treatment should be reviewed and data regarding risk for infertility clearly articulated prior to the consent or assent of the patient. Risk for fertility changes must be balanced with the risk of withholding treatment. All of these risks—which the State's experts, in my opinion, overstate—are disclosed to parents and youth during the informed consent process, during which families can weigh the risks and benefits before making a decision. This decision-making process is not unique to the treatment of gender dysphoria in the pediatric patient populations. Medications used for other conditions, such as chemotherapy, can affect fertility, and the risks for fertility changes must be balanced against the risk of withholding treatment.

35. The State's expert witnesses also critique an update to the WPATH SOC, which no longer sets more rigid age limitations around the initiation of hormone therapy. (*See* Hruz, ¶ 59).

This allows for flexibility in caring for patients who have a need to access hormones earlier due to early puberty or earlier onset and severity of dysphoria. This is consistent with the practice of individualized medicine, using WPATH SOC as a foundation.

36. Ultimately, in my clinical experience, gender-affirming medical care dramatically improves the health and well-being of adolescents with gender dysphoria for whom the care is medically indicated.

37. For patients for whom these medical interventions are indicated, withdrawing GnRHa or hormone therapy is harmful. Discontinuation of GnRHa would cause the onset of a puberty discordant from gender identity, a significant source of distress for patients with gender dysphoria. Similarly, discontinuation of gender-affirming hormone therapy for adolescents with gender dysphoria will cause adolescents receiving treatment to experience physiological changes inconsistent with their gender identity. An increase in gender dysphoria can increase depression, anxiety, self-harm, hospitalizations, and suicidality in transgender adolescents. These permanent changes can lead to the need for future surgical interventions that could have been prevented by maintaining earlier treatment.

38. As the clinical director of the Children and Adolescent Gender Services Clinic, I see patients who typically live in Michigan or Ohio. Even with our clinic and clinics like ours, families often have difficulty in accessing gender-affirming care, including long wait times and barriers associated with insurance and travel. Prior to this current legislation's passage, providers from Indiana contacted me for information about gender affirming care in Michigan anticipating that many families would come north for this care. I anticipate this will occur if this legislation succeeds, access to care will become even more challenging, and it will become restricted to Hoosier families financially able to travel out of state. The longer the patient is unable to access

their medically necessary care, the worse their suffering will be. In addition, transgender youth are often wary of medical providers and can take longer to develop a therapeutic and trusting relationship with their provider. This change in providers can set them back in their care and can have lasting physical and mental health effects.

THE STATE'S EXPERTS' REVIEW OF THE MINOR PLAINTIFFS' MEDICAL RECORDS

39. I have reviewed the comments made by Drs. Kenny and Weiss regarding the Minor Plaintiffs' medical records. (*See* Kenny, ¶¶ 187-246; Weiss, ¶¶ 28-35). Without addressing each and every issue, there are at least three significant thematic errors in their assessments.

40. First, Drs. Kenny and Weiss assume that the existence of other medical conditions precludes treating gender dysphoria, or that treatment of gender dysphoria occurred to the exclusion of treating other comorbidities. (*See* Kenny, ¶¶ 240-246; Weiss, ¶ 28). That is inconsistent with the WPATH Standards of Care and the Endocrine Society Guideline, both of which recommend comprehensive mental health assessments for adolescents with gender dysphoria prior to initiating treatment. In my clinical practice, as part of our individualized treatment of every patient, we consider whether or to what extent a patient's other medical conditions, and their management, may affect the suitability of gender-affirming treatments like GnRHa or hormone therapy. A categorical skepticism of using GnRHa or hormone therapy to treat gender dysphoria based on the existence or other comorbid conditions suggests a lack of familiarity with this patient population.

41. Second, Drs. Kenny and Weiss assume that the age of the onset of gender dysphoria calls into question the accuracy or legitimacy of the underlying diagnosis. (*See* Kenny, ¶ 235; Weiss, ¶ 30). I have treated patients whose gender dysphoria became apparent and clinically

significant pre-pubertally, and I have also treated patients for whom the onset of puberty created clinically significant distress and the appearance of expressed symptoms of gender dysphoria for the first time. Given the comprehensive assessments required by WPATH Standards of Care and the specificity of the diagnostic criteria in the DSM-5 TR, I do not consider the age of onset alone to be a reason to question the accuracy of the diagnosis, although in my clinical practice we do take into account the persistence of the feeling of incongruence when evaluating the appropriate course of treatment. It is also my experience, in speaking with my patients, that many of them experience gender dysphoria for quite some time before informing their parents, or anyone, and so the age at which they confide in an adult about their feelings or present for treatment does not always reflect the age at which they began experiencing distress.

42. Third, Drs. Kenny and Weiss assume that transgender identity or experience of gender dysphoria arises from trauma. (*See* Kenny, ¶¶ 196, 204-206; Weiss, ¶¶ 29, 32, 33). In my clinical practice, I have treated patients who have experienced various kinds of trauma, and those who have not. The multidisciplinary team that I practice within considers the full patient history when evaluating an adolescent for gender dysphoria, and we consider the whole patient when discussing with parents and the patient themselves the appropriate course of treatment for their condition.

43. In my clinical experience, providing individualized care based on individual patient characteristics, using the WPATH Standards of Care as the foundation, provides significant benefit to patients, minimizes gender dysphoria, and improves patient outcomes. In the Children and Adolescent Gender Services Clinic, we encounter patients with other medical conditions. As part of our holistic treatment of the entire patient, we carefully consider what other support our patients with gender dysphoria need in addition to treatments directly addressing their gender dysphoria.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 7th day of June, 2023.

Daniel Shumer, M.D.

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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

K.C., *et al.*,

Plaintiffs,

v.

THE INDIVIDUAL MEMBERS OF THE MEDICAL LICENSING BOARD OF INDIANA, in their official capacities, *et al.*,

Defendants.

No. 1:23-CV-595

EXPERT REBUTTAL DECLARATION OF JACK TURBAN, MD, MHS

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation.

2. I have actual knowledge of the matters stated herein.

3. My background and credentials are outlined in my initial declaration.

4. I reviewed the declarations of Drs. James Cantor, Paul Hruz, Dianna Kenny, Kristopher Kaliebe, and Daniel Weiss. Here, I respond to some of the central points in those declarations. I do not specifically address each study or article cited, but instead explain the overall problems with some of the conclusions Defendants' experts draw and provide data showing why such conclusions are in error. I reserve the right to supplement my opinions if necessary as the case proceeds.

DEFENDANTS' EXPERTS' CLAIM THAT INDIANA'S BAN ON GENDER-AFFIRMING MEDICAL CARE FOR ADOLESCENT GENDER DYSPHORIA IS CONSISTENT WITH INTERNATIONAL CONSENSUS IS NOT ACCURATE

5. Defendants' experts rely on reports from a handful of European countries and imply that Indiana's ban on gender-affirming medical care is in line with "international consensus." (*See*

Cantor, ¶¶ 17-33; Kaliebe, ¶¶ 104, 136; Kenny, ¶¶ 183-184; Weiss ¶¶ 130-135). This is not accurate. Of note, the vast majority of these reports were not peer-reviewed. Some of these reports are older and do not include the most recent research demonstrating the efficacy of the banned treatments. And others do not include all of the relevant literature. Most importantly, though, Defendants' experts fail to emphasize that *none* of these countries have banned gender-affirming medical care for adolescents with gender dysphoria as Indiana does. Rather, the select countries referenced have changed the way in which gender-affirming care is being delivered (*e.g.,* moving care to settings where more data can be collected, as in Sweden, or creating several regional clinics instead of one centralized clinic, as in the United Kingdom). Rather than put it in line with "international consensus," Indiana's broad ban on gender-affirming medical care for adolescent gender dysphoria puts the law squarely outside of mainstream medical views and policies around the world. In the United States, the major relevant expert medical organizations (*e.g.*, the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, and the American Academy of Child & Adolescent Psychiatry) explicitly oppose such bans.[1]

DEFENDANTS' EXPERTS MISREPRESENT THE GENDER-AFFIRMING MODEL OF CARE FOR ADOLESCENT GENDER DYSPHORIA AND MENTAL HEALTH INVOLVEMENT

6. Defendants' experts note that adolescents presenting to gender clinics may have complex psychiatric presentations including autism spectrum disorder, borderline personality disorder, or body dysmorphic disorder, among others. It is important to note that the current standards of care require a biopsychosocial mental health assessment prior to initiating gender-

[1] For a list of statements from major medical organizations opposing legislative bans on gender-affirming medical care for adolescent gender dysphoria, please see Turban, J. L., Kraschel, K. L., & Cohen, I. G. (2021). Legislation to criminalize gender-affirming medical care for transgender youth. *JAMA*, *325*(22), 2251-52.

affirming medical intervetions for minors.[2] Such mental health assessments exist to distinguish other mental health conditions from gender dysphoria and to determine if gender-affirming medical interventions may be appropriate or not. While there has been rhetoric such as "affirmation on demand" used by defendants' experts (Cantor, ¶ 289), this is not the reality of how gender-affirming medical care for adolescents is delivered under existing guidelines. As the WPATH Standards of Care note, this biopsychosocial assessment is often extended "for youth with more complex mental health presentations (e.g., complicating mental health histories), co-occuring autism spectrum characteristics, or an absence of experienced childhood gender incongruence."[3] It is important to highlight that the Indiana ban did not merely ban gender-affirming medical care for adolescent gender dysphoria without following existing guidelines (i.e., without a comprehensive biopsychosocial mental health assessment); it banned it across the board.

THOUGH RANDOMIZED CONTROLLED TRIALS OFTEN REPRESENT HIGHER QUALITY EVIDENCE THAN OTHER STUDY DESIGNS, THEY ARE NOT ETHICAL IN THE REALM OF GENDER-AFFIRMING CARE FOR ADOLESCENT GENDER DYSPHORIA AND EXISTING RESEARCH PROVIDES VALUABLE INFORMATION ON QUESTIONS OF CORRELATION VERSUS CAUSATION

7. Defendants' experts spend a great deal of time focusing on randomized controlled trial study designs and questions of correlation versus causation. It is true that randomized controlled trials provide valuable information that other studies do not; however, as noted in my initial declaration, they are not considered ethical in this area and would not be approved by an Institutional Review Board. For this reason, experts in this field look at the body of a literature as

[2] Coleman, E., Radix, A. E., Bouman, W. P., Brown, G. R., De Vries, A. L. C., Deutsch, M. B., ... & Arcelus, J. (2022). Standards of care for the health of transgender and gender diverse people, version 8. *International Journal of Transgender Health*, *23*(sup1), S1-S259.

[3] *Id.*

a whole to address certain questions. Though each study in medicine has relative strengths and weaknesses, examining the body of literature as a whole provides a rich scientific perspective.

8. As Dr. Cantor notes in his declaration, there are three possibilities when a study finds a correlation between two variables X and Y: "that X causes Y [causation], that Y causes X [reverse causation], or that there is some other variable Z, that causes both X and Y [confounding effect]." (Cantor, ¶ 58). In this case, the question is whether gender-affirming medical care (X) causes improved mental health outcomes for adolescents with gender dysphoria (Y).

9. The question of "reverse causation" (*i.e.,* the notion that improved mental health causes one to access gender-affirming medical care rather than the reverse, that gender-affirming medical care leads to better mental health) has been examined in the literature. For example, in a recent major publication in *The New England Journal of Medicine*, Chen et al. used a technique called parallel process modeling and found that improvements in mental health tracked along with improvements in appearance congruence over time (a measure of the degree to which study participants' bodies aligned with their gender identities), suggesting that gender-affirming medical care, and its subsequent physical effects, was the cause of the improvements in mental health, and arguing against the notion of reverse causation.[4]

10. The question of "confounding effect" has also been examined in several ways. For instance, a 2022 paper from my research group assessing the relationship between treatment with gender-affirming medical interventions and improved mental health statistically adjusted for a range of potentially confounding variables including age, gender identity, sex assigned at bith, sexual orientation, race/ethnicity, level of family support for gender identity, relationship status,

[4] Chen, D., Berona, J., Chan, Y. M., Ehrensaft, D., Garofalo, R., Hidalgo, M. A., ... & Olson-Kennedy, J. (2023). Psychosocial Functioning in Transgender Youth after 2 Years of Hormones. *New England Journal of Medicine*, *388*(3), 240-50.

level of education, employment status, household income, having ever received pubertal suppression, having ever been exposed to gender identity conversion efforts, and having experienced any harassment based on gender identity in school.[5] Even after statistically adjusting for these potential confounding factors, the study found that treatment with gender-affirming medical care during adolescence was associated with lower odds of adverse mental health outcomes.

11. Another potential confounder that Defendants' experts raise is whether or not participants received supportive psychotherapy in addition to gender-affirming medical care. Of note, there is no evidence-based psychotherapy that treats gender dysphoria itself, so such therapy is generally aimed at supporting the patient in general with their mental health. At least two studies provide evidence against the notion that mental health improvements were due to supportive psychotherapy rather than gender-affirming hormone treatment. Achille et al. ran regression analyses in order to separate out the impacts of gender-affirming medical interventions from the impact of counseling and psychiatric medications.[6] Though the sample size made it difficult to detect differences, they nonetheless found that pubertal suppression was associated with better scores on the Center for Epidemiology Studies Depression Scale, which was a statistically significant finding.[7]

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[5] Turban, J. L., King, D., Kobe, J., Reisner, S. L., & Keuroghlian, A. S. (2022). Access to gender-affirming hormones during adolescence and mental health outcomes among transgender adults. *PLoS One*, *17*(1), e0261039.

[6] Achille, C., Taggart, T., Eaton, N. R., Osipoff, J., Tafuri, K., Lane, A., & Wilson, T. A. (2020). Longitudinal impact of gender-affirming endocrine intervention on the mental health and well-being of transgender youths: preliminary results. *International Journal of Pediatric Endocrinology*, *2020*(1), 1-5.

[7] It is important to note that in statistics, a statistically significant finding tells you that a finding is likely to represent a true effect and the finding wasn't due to random chance. In contrast, the

12. Dr. Cantor spends considerable time in his lengthy declaration attempting to discredit existing studies. He does so based largely on critiques that are inapplicable to the various studies he applies them to. But perhaps more importantly, he fails to look at the body of research as a whole. For example, Dr. Cantor claims that Achille et al. "failed to account for the multiple comparisons it conducted" and asserts that "had the study applied the standard adjustment for correcting for multiple comparisons, the remaining predictor would also have ceased to be statistically significant (Cantor, ¶ 195). Though he doesn't specify which "standard adjustment" technique he is referring to, Dr. Cantor is presumably referring to techniques such as Bonferroni correction, which are designed to correct for comparisons in studies where large numbers of statistical tests are run. But such a correction would be inppropriate in studies such as Achille et al., which run a small number of statistical tests.[8]

13. Dr. Cantor also critiques Costa et al., which examined two cohorts of adolescents with gender dysphoria. Both cohorts received six months of supportive psychotherapy for the initial six months of the study. For the next six months, one group continued to receive supportive psychotherapy alone, while the other received supportive psychotherapy *and* pubertal suppression. The group that received pubertal suppression in addition to psychotherapy experienced statistically significant improvement in global functioning (measured by the Children's Global Assessment Scale, CGAS) over that second course of six months, while the group that received supportive

lack of a statistically significant finding doesn't tell you one way or another if there is an effect. I would caution against over-interpreting non-statistically significant findings. Lack of a statistically significant finding doesn't mean that no effect exists; it simply means the analysis in question does not tell the researchers one way or another if an effect exits.

[8] Nakagawa S. A farewell to Bonferroni: the problems of low statistical power and publication bias. Behavioral Ecology. 2004; 15(6):1044–5.

psychotherapy alone did not.[9] Dr. Cantor claims that these results are "moot" because another publication from this clinic (Carmichael et al. 2021)[10] did not find "any significant improvement at all." (Cantor, ¶ 195). What Dr. Cantor fails to explain is that this second paper did not run any statistical analyses on the CGAS global functioning score, which had shown statistically significant improvement in the first study. In the methods section, the authors explain that they only conducted statistical comparisons on other variables (CBCL, YSR, CBCL self-harm index, and YSR self-harm index).[11] In the discussion of Carmichael et al. 2021, the authors highlight, "CGAS scores in this previous study [Costa et al. 2015] increased from 61 to 67 with GnRHa treatment, similar to those (63 at baseline, 66 at 24 months) in our [Carmichael et al. 2021] study."[12]

DEFENDANTS' EXPERTS' DISCUSSION OF CHILDHOOD VERSUS ADOLESENT ONSET OF GENDER DYSPHORIA DOES NOT SUPPORT BANNING GENDER-AFFIRMING MEDICAL CARE

14. Defendants' experts draw a distinction between those who first come to experience gender dysphoria in early childhood and those who first come to experience gender dysphoria in adolescence (i.e., after the onset of puberty). They imply that those who first recognize gender dysphoria in adolescence will not continue to hold a gender identity different from their sex

[9] Costa, R., Dunsford, M., Skagerberg, E., Holt, V., Carmichael, P., & Colizzi, M. (2015). Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria. *The Journal of Sexual Medicine*, *12*(11), 2206-14.

[10] Carmichael, P., Butler, G., Masic, U., Cole, T. J., De Stavola, B. L., Davidson, S., ... & Viner, R. M. (2021). Short-term outcomes of pubertal suppression in a selected cohort of 12 to 15 year old young people with persistent gender dysphoria in the UK. *PloS one*, *16*(2), e0243894.

[11] The authors of this study note there are several possibilities, not mentioned by Dr. Cantor, for why the outcomes they examined were not statistically different. These included that the sample size was too small and that, "lack of change in an outcome that normally worsens in early adolescence may reflect a beneficial change in trajectory for that outcome, i.e. that GnRHa treatment reduced this normative worsening of problems."

[12] *Id.*

assigned at birth later in life. There is no evidence to support this claim. Additionally, it is important to note that Indiana's ban on gender-affirming medical care is a broad ban on all gender-affirming medical care, regardless of whether the patient experienced childhood-onset gender dysphoria or adolescent-onset gender dysphoria.

15. It is true that some past studies on the benefits of gender-affirming medical care were limited to patient populations who first knowingly experienced gender dysphoria in early childhood (e.g., deVries et al. 2014). However, these are not the only studies documenting improved mental health from treatment. Other studies have similarly shown improved mental health for adolescents with gender dysphoria treated with pubertal suppression and gender-affirming hormones in contexts where the studied population was not limited to those experiencing early childhood onset gender dypshoria. Correspondingly, the clinical guidelines do not recommend that those who first experience gender dysphoria in adolescence be ineligible for gender-affirming medical care. The WPATH Standards of Care 8, for instance, highlight that those with an absence of gender incongruence during the prepubertal childhood period may warrant "a more extended assessment process," but are still candidates for care. Likewise, a recent publication from our group found that it is not uncommon for transgender people to first come to understand their transgender identity in adolescence or later.[13] In this sample of over 27,000 transgender adults, 40.8% reported first coming to realize their transgender identity during adolescence or adulthood. Though one's transgender identity has a strong biological basis, as described later in this declaration, it can take some time for individuals to ascribe language to their transgender identity or gender dysphoria, and it can also take a substantial period of time to overcome the

[13] Turban, J. L., Dolotina, B., Freitag, T. M., King, D., & Keuroghlian, A. S. (2023). Age of Realization and Disclosure of Gender Identity Among Transgender Adults. *Journal of Adolescent Health*, *72*(6), 852-59.

stigma associated with a transgender identity to be able to openly accept one's transgender identity. Thus, a lack of expressed early childhood gender incongruence does not necessarily indicate less severe gender dysphoria, or that gender-affirming medical care will not be effective. Though as the WPATH Standards of Care note, it may necessitate an extended biopsychosocial assessment period.[14]

16. Dr. Cantor raises "particular concern" that adolescent-onset gender dysphoria may actually represent borderline personality disorder (BPD). (Cantor, ¶ 159). There is no evidence to support this theory. Existing guidelines emphasize the importance of a comprehensive biopsychosocial mental health evaluation, designed to differentiate other mental health conditions (e.g., BPD or body dysmorphic disorder from gender dysphoria), prior to initiating gender-affirming medical care. Of further note, despite Dr. Kaliebe's assertion that "little scholarly guidance exists regarding specific approaches related to the various personality disorders with comorbid gender dysphoria," (Kaliebe, ¶ 179), a recent peer-reviewed paper in *The Harvard Review of Psychiatry* emphasized the ways in which certain potential indicators of other conditions, like BPD, can be differentiated from gender dysphoria.[15] It also noted that it is rare for BPD to lead to a transgender identity through "identity diffusion."[16]

[14] Coleman, E., Radix, A. E., Bouman, W. P., Brown, G. R., De Vries, A. L. C., Deutsch, M. B., ... & Arcelus, J. (2022). Standards of care for the health of transgender and gender diverse people, version 8. *International Journal of Transgender Health*, *23*(sup1), S1-S259.

[15] Goldhammer, H., Crall, C., & Keuroghlian, A. S. (2019). Distinguishing and addressing gender minority stress and borderline personality symptoms. *Harvard Review of Psychiatry*, *27*(5), 317-25.

[16] *Id.*

DR. CANTOR FALSELY CLAIMED THAT I MADE AN ERROR IN MY CHARACTERIZATION OF HOW DIAGNOSTIC CRITERIA CHANGED FROM DSM-IV TO DSM-5

17. In my initial declaration, I explained that the DSM-IV diagnosis of "gender identitiy disorder in children" did not require a child to identify as a gender different from their sex assigned at birth, an issue that was remedied with the DSM-5's "gender dysphoria" diagnosis. This change was relevant to the so-called desistance studies because many of the pre-pubertal children studied likely did not have a transgender identity in childhood such that it was unsurprising that they did not have a transgender identity later in life. Dr. Cantor claims that the DSM-5 diagnosis of gender dysphoria in children does not require one to identify with a gender different from their sex assigned at birth and the the DSM-IV diagnosis of "gender identity disorder in children" did. (Cantor, ¶ 266). However, Dr. Cantor fails to note, despite pasting the DSM-5 criteria into his declaration, that the DSM-5 gender dysphoria diagnosis states that the criterion A1 is required for the diagnosis: "a strong desire to be of the other gender or an insistence that one is the other gender (or some alternative gender different from one's assigned gender." The prior DSM-IV diagnosis of "gender identity disorder in children" did not require this, and one could qualify for the diagnosis by meeting criertion A2-A5, none of which require a gender identity different from one's sex assigned at birth, creating the potential for cisgender "tomboys" or cisgender males with "feminine interests" to meet those old diagnostic criteria.

DEFENDANTS' EXPERTS' ASSERTION THAT SOCIAL TRANSITION AND/OR GENDER-AFFIRMING MEDICAL CARE INTENSIFY GENDER INCONGRUENCE IS NOT SUPPORTED BY EVIDENCE

18. The Defendants' experts spend a considerable portion of their declarations discussing social transition. This refers to when a transgender person adopts a gender expression (i.e., a name, pronouns, clothes, etc.) that aligns with their gender identity. This does not involve any of the medical interventions banned by the Indiana law at issue in this case. Nevertheless, it is

worth noting that the assertions made by the Defendants' experts about this issue are not supported by evidence. For example, Dr. Cantor states: "[S]ocial transition seems to prevent desistance." (Cantor,¶ 120). Despite Dr. Cantor spending a considerable portion of his declaration on the importance of differentiating correlation from causation, he appears unable to apply that to the findings that social transition is correlated with "persistence." He outlines data showing that youth who socially transition are more likely to continue to identify as transgender later in life (i.e., correlation). But this correlation could be due to two possibilities: (1) social transition could influence a child's gender identity, making them identify more strongly as transgender and thus more likely to persist, or (2) children who go on to socially transition identified more strongly as transgender than those who did not *prior* to social transition, and thus their pre-transition gender incongruence lead to the social transition in the first place.

19. Research by Rae et al. has shown that the second possibility is far more likely to be what is occurring.[17] Their 2019 study showed that gender identification is not significantly different before and after a social transition. The study made clear that this correlation—between pre-pubertal social transition and transgender identity—is because those who undergo a pre-pubertal social transition had stronger discordance between their sex assigned at birth and their gender identity to begin with, and that social transition itself does not increase gender discordance.

20. Defendants' experts proceed to point to studies showing that over 98% of transgender adolescents who start pubertal suppression go on to start gender-affirming hormones, in order to suggest that pubertal suppression increased these adolescents' gender incongruence and thus likelihood of "persistence.". It is another logical fallacy to infer that a study showing that 98%

[17] Rae, J. R., Gülgöz, S., Durwood, L., DeMeules, M., Lowe, R., Lindquist, G., & Olson, K. R. (2019). Predicting early-childhood gender transitions. *Psychological Science*, *30*(5), 669-81.

of adolescents on puberty blockers proceeding on to gender-affirming hormones is evidence that puberty blockers increase the likelihood of persistence; rather, it is just as possible, and in my opinion more likely, that, given the biopsychosocial mental health assessment that is done prior to starting gender-affirming medical interventions under current guidelines, the adolescents who started pubertal suppression were those who were, through medical and mental health screening, determined, prior to starting pubertal suppression, to have a low likelihood of future desistence.

DEFENDANTS' EXPERTS' SUGGESTION THAT GENDER-AFFIRMING TREATMENT SHOULD NOT BE AVAILABLE BECAUSE GENDER DYSPHORIA IS THE RESULT OF "SOCIAL CONTAGION" AND "RAPID ONSET GENDER DYSPHORIA" IS WITHOUT BASIS

21. Defendants' experts suggest that gender-affirming medical care should be banned because, they claim, peer influence is responsible for adolescents seeking gender-affirming medical care that they will later come to regret. (*See, e.g.*, Cantor, ¶ 109; Kaliebe, ¶¶ 42-43; Kenny, ¶¶ 33, 81). They assert that "social contagion" is the driver of gender dysphoria and that there is a phenomenon of "rapid-onset gender dysphoria" or ROGD. Such a view is not supported by evidence.

22. Several of Defendants's experts use or allude to the term "rapid onset gender dysphoria" – failing to note that this is not a recognized mental health condition.[18] The term "rapid onset gender dysphoria" entered the literature in 2018 through a publication by Dr. Lisa Littman.[19] Soon after the initial publication of Dr. Littman's article, a correction was published.[20] The

[18] Littman, L. (2019). Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. *PLoS One*, *14*(3), e0214157.

[19] Littman, L. (2018). Rapid-onset gender dysphoria in adolescents and young adults: A study of parental reports. *PLoS One*, *13*(8).

[20] Littman, L. (2019). Correction: Parent reports of adolescents and young adults perceived to show signs of a rapid onset of gender dysphoria. *PLoS One*, *14*(3), e0214157.

correction noted, "Rapid onset gender dysphoria (ROGD) is not a formal mental health diagnosis at this time . . . This report did not collect any data from the adolescents and young adults (AYAs) or clinicians and therefore does not validate the phenomenon." [21] The correction goes on to say "the term should not be used in any way to imply that it explains the experiences of all gender dysphoric youth . . . ." Despite this, Defendants' experts repeatedly cite this article to make unsubstantiated claims. For example, citing to Littman, Dr. Kaliebe states, "significant evidence suggests that the dramatic rise in minors presenting with gender dysphoria may be attributable to technologically induced contagion effects." (Kaliebe, ¶ 42). Dr. Kaliebe claims that a paper published in 2015, prior to publication of the Littman paper, validated the same phenomenon that Littman described in her paper.[22] (Kaliebe, ¶ 45). But it did no such thing. This paper reports on 47 adolecents who were referred to a gender clinic in Finland between 2011 and 2013. It describes the existence of cohort of patients in which there were more adolescents assigned female at birth, several of whom came to understand their gender identity after adolescence, and many of whom experienced other mental health challenges (anxiety, depression, etc.). But there is no mention in this 2015 paper of "social contagion" or "rapid-onset gender dysphoria."

23. The Littman study was an anonymous online survey of the parents of transgender youth, recruited from websites where this notion of "social contagion" leading to transgender

[21] A recent study by Bauer et al. in *The Journal of Pediatrics* examined some of the associations that would be consistent with the existence of "rapid-onset gender dysphoria" and concluded that their results "did not support the rapid onset gender dysphoria hypothesis." Bauer, G. R., Lawson, M. L., Metzger, D. L., & Trans Youth CAN! Research Team. Do Clinical Data from Transgender Adolescents Support the Phenomenon of "Rapid Onset Gender Dysphoria"?. *The Journal of Pediatrics*, S0022-3476.

[22] Kaltiala-Heino, R., Sumia, M., Työläjärvi, M., & Lindberg, N. (2015). Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child and Adolescent Psychiatry and Mental Health*, *9*(1), 1-9.

identity is popular. The anonymous survey participants were asked what they thought was the etiology of their children's transgender identity. Some of these parents believed that their children became transgender as a result of watching transgender-related content on websites like YouTube and having LGBTQ friends. The alternative interpretation, and in my opinion more likely interpretation, is that these youth sought out transgender-related media and LGBTQ friends because they wanted to find other people who understood their experiences and could offer support. The parent respondents also noted that, from their perspective, their children became transgender "all of a sudden," hence the term "rapid onset." Once again, the problem here is that the study did not interview the adolescents themselves, nor their healthcare providers. It is common for transgender (as with gay, lesbian, and bisexual) children and adolescents to conceal their identity from their parents for long periods of time. In a recent study from our research group, transgender people who first understood their gender identity in childhood waited a median 14 years before sharing this with another person.[23] In my experience working with transgender youth and adults, the reasons for this tend to be out of fear of negative repercussions (rejection, being kicked out of the house, or even physical assault) if their parents were to find out that they are transgender. Children often learn to conceal their gender non-conforming behaviors and transgender identity early, particularly if their parents have strong negative reactions to them exhibiting gender non-confirming behavior.

24. Dr. Cantor attempts to add credence to this 2018 Littman study by stating that it was "independently replicated by another study." (Cantor, ¶ 135). The "replicated" study (the

[23] Turban, J. L., Dolotina, B., Freitag, T. M., King, D., & Keuroghlian, A. S. (2023). Age of Realization and Disclosure of Gender Identity Among Transgender Adults. *Journal of Adolescent Health*, *72*(6), 852-59.

"Diaz Study")[24] referenced by Dr. Cantor used the same methodology as the original Littman study of recruiting participants from websites where the idea of "social contagion" is popular, and thus carries the same limitations. Specifically, the Diaz Study used an identical methodology to the one used by Dr. Littman in her paper, and recruited participants from a website called "ParentsofROGDKids.com." Once again, the only thing that this study shows is that a number of people online have the belief that the politicized notion of ROGD is true. Due to this biased methodology, the Diaz Study referenced by Dr. Cantor likewise does not establish that ROGD is a valid mental health diagnosis. Furthermore, after publication, the Diaz Study was updated with a notification from the journal stating, "readers are alerted that concerns have been raised regarding methodology as described in this article. The publisher is currently investigating this matter an a further response will follow the conclusion of this investigation."[25] The author of the paper subsequently announced that the paper was retracted, stating: "I have just been notified that my paper with Susanna Diaz will be retracted by the publisher due to concerns about the lack of informed consent."[26] Also of note, the original paper contains a notation that the first author "Susanna Diaz" is a pseudonym – an unusual practice in peer-reviewed journals.

25. Defendants' experts assert that the increase in referrals to gender clinics over the past few decades supports a "social contagion" theory. It does not. The increase in referrals has coincided with increased visibility of transgender people in society and greater awareness of

[24] Diaz, S., & Bailey, J. M. (2023). Rapid Onset Gender Dysphoria: Parent Reports on 1655 Possible Cases. *Archives of Sexual Behavior*, *52*(3), 1031-43.

[25] *Id.*

[26] Blanchard, R. Statement on Twitter May 23, 2023. Available at: https://twitter.com/profjmb/status/1661022522446610434?s=20. Accessed: May 28, 2023.

gender dysphoria and access to medical care to treat it. Whereas parents in the past may have had limited literacy regarding gender diversity in adolescents, today more Americans, as well as people abroad, have greater understanding of the experiences of transgender youth. This fact has undoubtedly increased the number of parents bringing their adolescents to gender clinics for evaluation. Additionally, insurance coverage of gender-affirming medical interventions has improved drastically, meaning that more families are able to afford care, which results in an increase in referrals for evaluation. Of note, not all adolescents who present for treatment ultimately go on to receive gender-affirming medical interventions.[27] In fact, in a large study from a Netherlands gender clinic, the percentage of patients who presented for evaluation who actually started any kind of gender-affirming treatment has decreased over time.[28] As the authors of that study note, "this finding may be explained by the fact that in the past it was harder to find information about [gender dysphoria] and its treatment, and only people with extreme types of [gender dysphoria] managed to visit our gender identity clinic for treatment. Currently, owing to media attention and the internet, it is easier to access information about our gender identity clinic, making the threshold lower to search for help." This shows that while more people may be coming in for evaluation, the criteria for diagnosis and treatment remain stringent and a smaller percentage of patients are actually being diagnosed with gender dysphoria and referred on for medical treatment.

26. Defendants' experts point to changes in sex ratios of patients at some clinics (where "birth-assigned females" are appearing in greater numbers relative to "birth-assigned males" than

[27] Wiepjes, C. M., Nota, N. M., de Blok, C. J., Klaver, M., de Vries, A. L., Wensing-Kruger, S. A., ... & den Heijer, M. (2018). The Amsterdam cohort of gender dysphoria study (1972–2015): trends in prevalence, treatment, and regrets. *The Journal of Sexual Medicine*, *15*(4), 582-590.

[28] *Id.*

in the past), and claim that this assertion supports their "social contagion" theory. However, there are many potential explanations for a change in sex ratio that do not involve social contagion. One likely possibility is that more birth-assigned females are being referred to gender clinics by their pediatricians due to greater understanding among pediatricians that birth-assigned females can have gender dysphoria. In the past, physicians thought of gender dysphoria as something that primarily impacted birth-assigned males. This likely led to many cases of gender dysphoria among birth-assigned females being undiagnosed or "missed." In recent years, literacy regarding gender dysphoria among birth-assigned females has increased among physicians. As fewer birth-assigned females go undiagnosed, the sex ratio in gender clinics has shifted away from predominantly birth-assigned males. This is similar to a pattern that has been seen in autism spectrum disorder. For example, a large study found that with increasing awareness that autism spectrum disorder can impact birth-assigned females as well as birth-assigned males, the sex ratio shifted more toward birth-assigned females, from 5.1:1 (birth-assigned males to females) to 3.1:1.[29] The same study saw the sex ratio for the related diagnosis of Asperger's syndrome similarly shift from 8.4:1 to 3.0:1.

27. Furthermore, if the Defendants' experts' theory that sex ratios have shifted due to social contagion and that there exists a unique susceptibility among people assigned female at birth were true, one would expect not just a shift in the sex ratios among those referred to gender clinics, but a shift in the sex ratio of adolescents identifying as transgender among the general population.

[29] Jensen, C. M., Steinhausen, H. C., & Lauritsen, M. B. (2014). Time trends over 16 years in incidence-rates of autism spectrum disorders across the lifespan based on nationwide Danish register data. *Journal of Autism and Developmental Disorders*, *44*(8), 1808-18.

A recent study from our research group,[30] utilizing data from the Center for Disease Control and Preventions Youth Risk Behavior Survey, and including 91,937 adolesents in 2017 and 105,433 adolescents in 2019, found that in both years the sex ratio was close to 1:1, slighty favoring those assigned male at birth.[31] This study also examined the hypothesis that adolescents may be coming to identify as transgender in an attempt to flee the stigma of being cisgender and gay. The results did not support that hypothesis.

28. Some have raised the question that if decreased stigma were driving the higher rates of adolescents openly identifying as transgender, we should be witnessing a parallel in documentable rise in gender dysphoria among, say, middle-aged adults. However, transgender middle-aged adults have endured decades of stigma for their transgender identities that, despite improvements in contemporary social attitudes, make them far less likely to come out as transgender. The "gender minority stress" model explains that these decades of exposure to unaccepting environments leads to expectations of future rejection and internalized transphobia (i.e., internalization of society's negative messages about transgender people leading to hate of oneself for being transgender), as well as identity concealment.[32] These factors make it less likely

[30] Turban, J. L., Dolotina, B., King, D., & Keuroghlian, A. S. (2022). Sex assigned at birth ratio among transgender and gender diverse adolescents in the United States. *Pediatrics*, *150*(3).

[31] As with many papers in this field, this study garnered a great deal of attention, including a letter to the editor questioning the methodology. We responded to these concerns with additional analyses that reaffirmed the study's conclusions, and this paper was not retracted: Turban, J. L., Dolotina, B., King, D., & Keuroghlian, A. S. (2022). Author Response to: Science and Public Health as a Tool for Social Justice Requires Methodological Rigor. *Pediatrics*, *150*(6), e2022059680.

[32] Hendricks, M. L., & Testa, R. J. (2012). A conceptual framework for clinical work with transgender and gender nonconforming clients: An adaptation of the Minority Stress Model. *Professional Psychology: Research and Practice*, *43*(5), 460.

for middle-aged transgender adults to come out, despite the recently observed increase in societal acceptance for transgender people in the United States. Transgender youth are, for the first time, growing up in environments where transgender identity is not as stigmatized, making it easier for them to come out when compared to transgender adults plagued by anxiety due to decades of living in societies where being transgender was not recognized or accepted.

DEFENDANTS' EXPERTS' STATEMENTS THAT TRANSGENDER IDENTITY IS NOT BIOLOGICALLY BASED IS NOT ACCURATE

29. Defendants' experts' assertion that transgender identities are not biologically based is not accurate. There is a substantial body of peer-reviewed scientific evidence showing that transgender identity has a strong biological basis. One of the strongest lines of evidence comes from so-called "twin studies"[33] that allow researchers to look at the differential impact of environment (presumed to be similar for twins) and innate genetic factors (similar for identical twins but different for fraternal twins). Researchers have examined identical twins (with the same DNA) and fraternal twins (with different DNA) and found that identical twins of transgender people are far more likely to be transgender than fraternal twins of transgender people, pointing to a strong genetic link.[34] Functional neuroimaging studies have shown that transgender adolescents have patterns of brain activation most similar to non-transgender adolescents with their same

[33] Other conditions in psychiatry including autism spectrum disorder, were previously thought to be due to environmental influences, until twin studies in these fields similarly made it clear that they had a strong innate genetic biological basis: Folstein, S., & Rutter, M. (1977). Infantile autism: a genetic study of 21 twin pairs. *Journal of Child psychology and Psychiatry*, *18*(4), 297-321.

[34] Diamond, M. (2013). Transsexuality among twins: identity concordance, transition, rearing, and orientation. *International Journal of Transgenderism*, *14*(1), 24-38.

gender identity rather than those of their sex assigned at birth.[35] Sophisticated gene sequencing studies have suggested that genes involved in estrogen processing play a role in the development of gender identity among transgender people.[36] Though the precise etiology of gender identity has yet to be identified, these studies together all establish that there is a strong innate biological basis for transgender identities.

DEFENDANTS' EXPERTS' CLAIMS THAT "SELF-REPORT" AND "SURVEY" DATA ARE NOT VALID REPRESENT A MISUNDERSTANDING OF PSYCHIATRIC RESEARCH

30. Clinical psychiatry relies heavily on self-report and data collected via questionnaires. Defendants' experts' claims that self-report and "survey" data are not valid represent a broad misunderstanding of psychiatry. Clinical psychiatry and clinical psychiatric research almost always involve patient reports of their symptoms. Because psychiatric conditions (e.g., generalized anxiety disorder, major depressive disorder, schizophrenia, obsessive compulsive disorder, and gender dysphoria, among many others) do not have laboratory tests, diagnosis is made largely based on patient reports of their symptoms. At times these may be supplemented by reports from parent and clinician observations, particularly for establishing a diagnosis; however, they are not considered standard or necessary in clinical trials that track symptoms over time or compare the mental health of those receiving treatment to those not receiving treatment. The studies cited throughout my initial declaration utilize commonly used and validated self-report psychometric measures including the Kessler-6 measure of past-month severe

[35] Burke, S. M., Cohen-Kettenis, P. T., Veltman, D. J., Klink, D. T., & Bakker, J. (2014). Hypothalamic response to the chemo-signal androstadienone in gender dysphoric children and adolescents. *Frontiers in Endocrinology*, *5*, 60.

[36] Theisen, J. G., Sundaram, V., Filchak, M. S., Chorich, L. P., Sullivan, M. E., Knight, J., ... & Layman, L. C. (2019). The use of whole exome sequencing in a cohort of transgender individuals to identify rare genetic variants. *Scientific Reports*, *9*(1), 1-11.

psychological distress,[37] Beck Depression Inventory II,[38] and self-report measures from the National Institutes of Health Toolbox Emotion Battery.[39] These self-report instruments are standard in psychiatric research. Of note, defendants' experts repeatedly cite survey research in their own reports (*e.g.,* Littman 2018,[40] Diaz 2023,[41] Litman 2021[42]).

31. It is worth highlighting that there exist both high quality and low quality survey methodologies. For example, Littman 2018 has been criticized for asking leading questions to a group that is ideologically focused, making it easy for participants to bias results and analyses.[43] Another example of a low quality survey design is a single vague audience poll, as is cited by Dr. Kaliebe. (Kaliebe, ¶ 135). He describes that, during a presentation at The American Academy of Child & Adolescent Psychiatry, Dr. Paul Weigle informally surveyed the audience asking, "How

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[37] Kessler, R. C., Green, J. G., Gruber, M. J., Sampson, N. A., Bromet, E., Cuitan, M., ... & Zaslavsky, A. M. (2010). Screening for serious mental illness in the general population with the K6 screening scale: results from the WHO World Mental Health (WMH) survey initiative. *International Journal of Methods in Psychiatric Research*, *19*(S1), 4-22.

[38] Beck, A. T., Steer, R. A., & Brown, G. (1996). Beck depression inventory–II. *Psychological Assessment*.

[39] Slotkin, J., Nowinski, C., Hays, R., Beaumont, J., Griffith, J., Magasi, S., & Gershon, R. (2012). NIH Toolbox scoring and interpretation guide. *Washington (DC): National Institutes of Health*, 6-7.

[40] Littman, L. (2018). Rapid-onset gender dysphoria in adolescents and young adults: A study of parental reports. *PloS One*, *13*(8).

[41] Diaz, S., & Bailey, J. M. (2023). Rapid Onset Gender Dysphoria: Parent Reports on 1655 Possible Cases. *Archives of Sexual Behavior*, *52*(3), 1031-1043.

[42] Littman, L. (2021). Individuals treated for gender dysphoria with medical and/or surgical transition who subsequently detransitioned: A survey of 100 detransitioners. *Archives of Sexual Behavior*, *50*(8), 3353-3369

[43] Littman, L. (2018). Rapid-onset gender dysphoria in adolescents and young adults: A study of parental reports. *PloS One*, *13*(8).

often do you see teens who seem to be influenced by social media in regards to their sexual and/or gender identity?" In this case, the question asked was overly vague—it was not clear what Dr. Weigle meant by "influenced" (e.g., how and in what ways) nor was it clear whether respondents were referring to sexual orientation or gender identity in their responses. Dr. Kaliebe notes that these informal poll "data" were published in *Psychiatric Times*. What he fails to note is that *Psychiatric Times*, of which I am a member of the advisory board, is not a peer-reviewed journal. It primarily publishes non-peer reviewed opinion pieces. Furthermore, the article in question that published this underlying data was discussing patients hearing about diagnoses online that are ultimately not accurate. If an adolescent were to inaccurately think they have gender dysphoria, this would be explored during the comprehensive biopsychosocial evaluation that is conducted prior to considering gender-affirming medical interventions.[44]

32. In contrast to the Littman and Weigle surveys, the 2015 US Transgender Survey had over 180 questions across 32 sections.[45] If participants were to attempt to bias the results in a certain direction, they would have needed to answer questions at distant parts of the survey in a particular fashion, based on what study design they believed researchers would use. Our analyses also utilized regression analyses that adjusted for a range of potentially confounding variables, further adding to the complexity of the analyses. Of note, the analysis plans for our group's studies were designed only after the 2015 USTS was already administetred.

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[44] Coleman, E., Radix, A. E., Bouman, W. P., Brown, G. R., De Vries, A. L. C., Deutsch, M. B., ... & Arcelus, J. (2022). Standards of care for the health of transgender and gender diverse people, version 8. *International Journal of Transgender Health*, *23*(sup1), S1-S259.

[45] James, S. E., Herman, J. L., Rankin, S., Keisling, M., Mottet, L., & Anafi, M. (2016). The Report of the 2015 U.S. Transgender Survey. Washington, DC: National Center for Transgender Equality.

DEFENDANTS' EXPERTS' VIEWS DO NOT ALIGN WITH MAINSTREAM PSYCHIATRY OR PSYCHOLOGY

33. As noted in my initial declaration, bans on gender-affirming medical care for adolescent gender dysphoria are opposed by all relevant major medical organizations including the American Medical Association, the American Academy of Pediatrics, the American Psychiatric Association, the American Academy of Child & Adolescent Psychiatry, the Endocrine Society, and the Pediatric Endocrine Society, among others.[46] Defendants' experts, which include experts in unrelated fields (e.g., Dr. Cantor is a pedophilia researcher, having never published original data in the field of child or adolescent gender dysphoria research, and has stated under oath that he has not treated any child or adolescent for gender dysphoria),[47] present views that do not align with mainstream psychiatry or medicine, as it pertains to the treatment of adolescents with gender dysphoria. Their reliance on non-peer-reviewed reports from various countries in Europe (e.g., Sweden, Finland, the United Kingdom, etc.), none of which have banned gender-affirming medical care for adolescents with gender dysphoria, represent an attempt to circumvent the actual peer-reviewed literature and expert consensus in the field.

DR. CANTOR'S PUBLISHED CRITIQUE OF THE AMERICAN ACADEMY OF PEDIATRICS GUIDELINES IS IRRELEVANT TO BANS ON GENDER-AFFIRMING MEDICAL CARE

34. Dr. Cantor asserts that his "most cited peer-reviewed paper relating to gender dysphoria in minors illustrates the expertise in the evaluation of scientific evidence that [he has] and [is] known for" (Cantor, ¶ 13), citing his 2019 pubication in the *Journal of Sex & Marital*

[46] For a list of statements, please see Turban, J. L., Kraschel, K. L., & Cohen, I. G. (2021). Legislation to criminalize gender-affirming medical care for transgender youth. *JAMA*, *325*(22), 2251-52.

[47] *Eknes-Tucker v. Marshall*, 603 F. Supp. 3d 1131, 1141-42 (M.D. Ala. 2022).

Therapy.[48] According to the National Institute of Health's PubMed library of peer-reviewed research, it has been cited only three times as of June 6, 2023.[49] The paper itself does not discuss pubertal suppression, gender-affirming hormones, or gender-affirming surgery. Rather, it solely discusses approaches to supporting pre-pubertal children. It thus is not relevant to Indiana's ban on gender-affirming medical care, which is not considered or prescribed until after the onset of puberty.

DR. KALIEBE PRESENTS AN IMPLAUSBLE THEORY THAT ALL MAJOR MEDICAL ORGANIZATIONS ARE INVOLVED IN A CONSPIRACY TO ADVANCE GENDER-AFFIRMING MEDICAL CARE FOR ADOLESCENTS WITH GENDER DYSPHORIA

35. Much of Dr. Kaliebe's declaration focuses on the notion that major medical organizations have been inappropriately influenced in some way to advance gender-affirming medical care for adolescents with gender dysphoria. For this implausible assertion to be true, the following medical organizations would all need to have been independently influenced: The American Medical Association, The American College of Physicians, The American Academy of Family Physicians, The American Academy of Obstetricians and Gynecologists, The American Osteopathic Association, The American Academy of Pediatrics, The American Psychiatric Association, The American Academy of Child & Adolescent Psychiatry, The Endocrine Society, and The Pediatric Endocrine Society.[50]

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[48] Cantor, J. M. (2020). Transgender and gender diverse children and adolescents: fact-checking of AAP policy. *Journal of Sex & Marital Therapy*, *46*(4), 307-313.
[49] PubMed entry for *Id*. Available at: https://pubmed.ncbi.nlm.nih.gov/31838960/. Accessed: June 6, 2023.

[50] For a list of statements from major medical organizations opposing legislative bans on gender-affirming medical care for adolescent gender dysphoria, please see Turban, J. L., Kraschel, K. L., & Cohen, I. G. (2021). Legislation to criminalize gender-affirming medical care for transgender youth. *JAMA*, *325*(22), 2251-52.

36. Dr. Kaliebe similarly labels me as "a psychiatrist and transgender activist" in an attempt to imply that my work is biased. (Kaliebe,¶ 47). I, like many physicians, advocate for evidence-based public policies that will result in better health outcomes for my patients. If wanting patients to receive the best possible evidence-based medical care is the definition of an "activist," then this hopefully will apply to all physicians. In a further attempt to discredit my work, Dr. Kaliebe notes that there was a letter to the editor published in response to my group's recent publication in the journal *Pediatrics*[51] (the official journal of The American Academy of Pediatrics). This letter to the editor brought up several methodological questions, highlighting that the authors of the letter would have designed analyses different than our team had. In response, our research group published several supplemental analyses, which reaffirmed our initial findings.[52] Our published response concluded, "In summary, we appreciate the interest in our article that led us to share these additional analyses, showing that the original findings are robust across analytical approaches."[53] In contrast to Dr. Kaliebe's assertion that the journal has become ideologically biased into not applying methodological rigor, this letter to the editor and response highlight the journal's commitment to rigorious academic discource that pushes the field toward through adademics' critical analysis of each others' published research.

[51] Turban, J. L., Dolotina, B., King, D., & Keuroghlian, A. S. (2022). Sex assigned at birth ratio among transgender and gender diverse adolescents in the United States. *Pediatrics*, *150*(3).

[52] Turban, J. L., Dolotina, B., King, D., & Keuroghlian, A. S. (2022). Author Response to: Science and Public Health as a Tool for Social Justice Requires Methodological Rigor. *Pediatrics*, *150*(6), e2022059680.

[53] *Id.*

THE ASSERTION THAT EXPERTS IN THE REALM OF ADOLESCENT GENDER DYSPHORIA ALL HAVE FIANCIAL BIAS IS UNFOUNDED

37. Dr. Cantor asserts that all experts in the realm of adolescent gender dysphoria clinical care and research have financial bias and thus are not reliable experts. For instance, he asserts: "Dr. Turban's employment as director of a gender program in child and adolescent psychiatry represents a significant conflict of interest: The income he derives from medical treatment of these children would be directly affected by the outcome of this case." (Cantor, ¶ 47). What he neglects to mention is that psychiatrists do not prescribe puberty blockers or gender-affirming hormones. As an academic psychiatrist, my salary derives from the Department of Psychiatry & Behavioral Sciences, not the Department of Pediatrics, which employs physicians who prescribe gender-affirming medical interventions. But in any event, regardless of what the standard of care is, I would continue to provide mental health support to adolescents with gender dysphoria. Furthermore, academic psychiatrists consistently have lower salaries than community psychiatrists.

38. Dr. Kaliebe similarly asserts that, "those who venture into medicalized gender care are already a select few who bring to this work certain viewpoints and aspirations. Just as with the psychopharmacology or psychotherapy committee members [of AACAP], gender committee members have strong personal and professional investments in the success of their favored type of treatment. This created a well-intentioned but homogeneous group of supporters of "gender affirming care." (Kaliebe, ¶ 87). However, this is not an accurate representation of mental health providers who care for adolescents with gender dysphoria. For instance, the AACAP committee Dr. Kaliebe is referencing is the "Sexual Orientation and Gender Identity Committee." This committee is defined by caring for a certain population (i.e., youth with concerns related to sexual orientation or gender identity), not a particular modality of care. These physicians are going to

care for patients however the evidence points; they care about a patient population they specialize in caring for, not about specific treatments. Dr. Kaliebe uses his presentations not being accepted at annual meetings as evidence of bias on the selection committee, failing to note that it is common for presentations to be rejected. I myself have had talks not accepted for annual meetings – and these rejections can be due to any number of reasons including logistical ones like space constraints. Dr. Kaliebe also notes that one submission was rejected due to, among other issues, concern regarding the "methods employed in several of he presenations" (Kaliebe, ¶ 100). It is, of course, quite reasonable for an academic conference to reject a submission based on the research having methodological failing alone.

DR. KALIEBE IMPLIES THAT PSYCHOTHERAPIES SUCH AS COGNITIVE BEHAVIORAL THERAPY (CBT), DIALECTICAL BEHAVIOR THERAPY (DBT), AND MENTALIZATION-BASED THEARPY (MBT) MAY BE EFFECTIVE IN TREATING ADOLESCENT GENDER DYSPHORIA, THEN GOES ON TO CONCEDE THERE IS NO EVIDENCE THIS IS TRUE

39. Dr. Kaliebe asserts that psychotherapies such as cognitive behavioral thearpy (CBT), dialectic behavioral therapy (DBT), and mentalization based therapy (MBT) should be used to treat adolescent gender dysphoria. (Kaliebe, ¶ 167, 181). It is true that treatment manuals exist for CBT for the treatment of anxiety, depression, and PTSD. Similar, there are DBT and MBT manuals for the treatment of borderline personality disorder. Many of these treatments have been shown effective for specific conditions. However, as Dr. Kaliebe notes, "psychotherapy has not been systematically studied as a a solo treatment for gender dysphoria." (Kaliebe, ¶ 183). To my knowledge, there are no CBT, DBT, or MBT manuals for the treatment of gender dysphoria, and there are no published clinical trials. As I noted in my initial declaration, there are no evidence-based psychotherapy treatments for adolescent gender dysphoria.

CONCLUSION

40. In summary, the reports from the Defendants' experts do not provide justification for banning gender-affirming medical care for adolescents with gender dysphoria. Their view, that gender-affirming medical care for adolescents with gender dysphoria should be legislatively banned, is a fringe view, not consistent with mainstream medicine or science.[54] None of the European countries they cite have banned care. All major medical organizations in the United States disagree with the views expressed by Defendants' experts about the banned treatment.[55]

41. Under current guidelines, medical interventions for adolescents with gender dysphoria are only considered after a comprehensive biopsychosocial evaluation, consent is provided by legal guardians, assent is provided by the patient, and all stakeholders (patient, guardians, mental health professional, prescriber) are in agreement that the benefits outweigh the risks for a given adolescent.

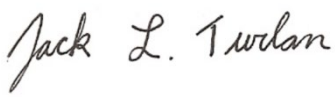
42. As I have outlined above and in my initial declaration, there is a substantial body of literature showing that gender-affirming medical care results in better mental health outcomes for adolescents with gender dysphoria. This research is consistent with the decades of clinical experience from around the world of improved mental health outcomes from these interventions. Furthermore, there are no evidence-based alternatives for treating gender dysphoria. While Defendants' experts critique the literature regarding the benefits of gender-affirming medical care, the studies they present on rapid-onset gender dysphoria and social contagion meet none of their

[54] For a list of statements from major medical organizations opposing legislative bans on gender-affirming medical care for adolescent gender dysphoria, please see Turban, J. L., Kraschel, K. L., & Cohen, I. G. (2021). Legislation to criminalize gender-affirming medical care for transgender youth. *JAMA*, *325*(22), 51-2252.

[55] *Id.*

proposed criteria for what research they would consider valid. Though they repeatedly advocate for "psychotherapy" alternatives to gender-affirming medical care, they fail to cite a single study showing that such strategies are effective. The Indiana ban would leave physicians, adolescents, and their parents without any evidence-based treatments for adolescent gender dysphoria, a condition that can cause immense suffering.

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



Executed on: June 9, 2023

JACK L. TURBAN, MD, MHS

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