

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

BONGO PRODUCTIONS, LLC, ROBERT)
BERNSTEIN, SANCTUARY PERFORMING)
ARTS LLC, and KYE SAYERS,)

Plaintiffs,)

v.)

CARTER LAWRENCE, Tennessee State Fire)
Marshal, in his official capacity,)
CHRISTOPHER BAINBRIDGE, Director of)
Codes Enforcement, in his official capacity,)
GLENN R. FUNK, District Attorney General)
for the 20th Judicial District, in his official)
capacity, and NEAL PINKSTON, District)
Attorney General for 11th Judicial District, in)
his official capacity,)

Defendants.)

Civ. Action
No. 3:32-cv-00490
Judge Trauger

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS’
MOTION FOR PRELIMINARY INJUNCTION**

TABLE OF CONTENTS

TABLE OF AUTHORITIES ii

I. PRELIMINARY STATEMENT 1

II. STATEMENT OF FACTS 3

 A. The Act’s Requirements and Legislative History 3

 B. “Biological Sex” Is a Contested Term 5

 C. Plaintiffs’ Restroom Policies 9

 D. The Impact of the Act on Plaintiffs..... 11

III. ARGUMENT 13

 A. Applicable Legal Standards 13

 B. Plaintiffs Are Likely to Succeed on the Merits..... 13

 1. *The Act unconstitutionally compels controversial speech* 14

 2. *The Act cannot survive strict scrutiny* 17

 C. Absent an Injunction, Plaintiffs Will Suffer Irreparable Injury 20

 D. An Injunction Would Not Harm Defendants and Would Serve the Public Interest ... 20

IV. CONCLUSION..... 21

TABLE OF AUTHORITIES

Cases

Am. C.L. Union Fund of Mich. v. Livingston Cnty.,
796 F.3d 636 (6th Cir. 2015) 12, 20

Am. C.L. Union of Ky. v. McCreary Cnty., 354 F.3d 438 (6th Cir. 2003)..... 19

Appalachian Reg’l Healthcare, Inc. v. Coventry Health and Life Ins. Co.,
714 F.3d 424 (6th Cir. 2013) 20

Chamber of Com. v. Edmondson,
594 F.3d 742 (10th Cir. 2010) 20

Discount Tobacco City & Lottery, Inc. v. United States,
674 F.3d 509 (6th Cir. 2012) 15

Elrod v. Burns,
427 U.S. 347 (1976)..... 19

Hamilton’s Bogarts, Inc. v. Michigan,
501 F.3d 644 (6th Cir. 2007) 13

Ibanez v. Fla. Dep’t of Bus. and Pro. Regul., Bd. of Acct.,
512 U.S. 136 (1994)..... 19

In re R.M.J.,
455 U.S. 191 (1982)..... 16

Janus v. Am. Fed’n of State, Cnty., & Mun. Emps. Council 31,
138 S. Ct. 2448 (2018)..... 14, 17

Moltan Co. v. Eagle-Picher Indus., Inc.,
55 F.3d 1171 (6th Cir. 1995) 20

Nat’l Inst. of Fam. Life Advocs. v. Becerra,
138 S. Ct. 2361 (2018)..... 14, 16, 19

Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n of Cal.,
475 U.S. 1 (1986)..... 17

Planned Parenthood Ass’n of Cincinnati, Inc. v. City of Cincinnati,
822 F.2d 1390 (6th Cir. 1987) 20

Planned Parenthood of Se. Pa. v. Casey,
505 U.S. 833 (1992)..... 15

<i>Reed v. Town of Gilbert</i> , 576 U.S. 155, 163 (2015).....	14, 17
<i>Riley v. Nat’l Fed’n of the Blind of N.C., Inc.</i> , 487 U.S. 781 (1988).....	13
<i>Snyder v. Phelps</i> , 462 U.S. 443 (2011).....	17
<i>W. Va. State Bd. of Educ. v. Barnette</i> , 319 U.S. 624 (1943).....	14
<i>Ward v. Polite</i> , 667 F.3d 727 (6th Cir. 2012)	14
<i>Wooley v. Maynard</i> , 430 U.S. 705 (1977).....	13
<i>Zauderer v. Office of Disciplinary Counsel of the S. Ct. of Ohio</i> , 471 U.S. 626 (1985).....	15, 16, 17, 19

Statutes

2020 Or. Laws 1st Spec. Sess. Ch. 19, § 7a.....	5
H.B. 1274/S.B. 1499, 111th Gen. Assemb., 1st Reg. Sess. (Tenn. 2019)	6
H.B. 1288/S.B. 1224, 112th Gen. Assemb., 1 st Reg. Sess. (Tenn. 2021)	<i>passim</i>
H.B. 2, § 1.2, 2015 Gen. Assemb., 2nd Extra Sess. (N.C. 2016)	5
H.B. 2414/S.B. 2387, 109th Gen. Assemb., 2nd Reg. Sess. (Tenn. 2015).....	6
H.B. 2620/S.B. 2480, 110th Gen. Assemb., Reg. Sess. (Tenn. 2018).....	6
H.B. 888/S.B. 771, 110th Gen. Assemb., 1st Reg. Sess. (Tenn. 2017)	6
Idaho Code Ann. § 33-6203 (West 2020).....	5
Miss. Code Ann. § 11-62-3 (2016).....	6
S.B. 1297/H.B. 1151, 111th Gen. Assemb., Reg. Sess. (Tenn. 2019).....	6
S.B. 1367/H.B. 1233, 112th Gen. Assemb., 1st Reg. Sess. (Tenn. 2021)	6
Tenn. Code Ann. § 40-35-111(e)(2)	4
Tenn. Code Ann. § 4-24-303	5

Tenn. Code Ann. § 68-120-101 *et seq.* 1, 4, 5, 20

W. Va. Code Ann. § 18-2-25d (West 2021) 5

Other Authorities

Debate of H.B. 1182 Before the H. Pub. Serv. Comm.,
112th Gen. Assemb. (Mar. 10, 2021)..... 4, 18

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112th Gen. Assemb. (Mar. 23, 2021)..... 4, 15, 18

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N.Y. Times (Oct. 28, 2018) 9

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112th Gen. Assemb. (Mar. 29, 2021)..... 4

Editorial, *Anatomy Does Not Define Gender*,
365 Nature 5 (Oct. 30, 2018). 7

Erica Green, Katie Benner, & Robert Pear, *‘Transgender’ Could Be Defined Out of
Existence Under Trump*, N.Y. Times (Oct. 21, 2018) 7

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the Forefront with Anti-Transgender Laws*, Associated Press (May 23, 2021). 7

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171 Annals of Internal Med. 171:ITC1 (July 2, 2019) 8

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394 The Lancet 1898 (Nov. 23, 2019)..... 5

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Washington Blade (Mar. 31, 2016)..... 18

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Legal Definition of Gender (Oct. 26, 2018), <https://not-binary.org/statement/> 7

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Say They #Won’t Be Erased*, N.Y. Times (Oct. 22, 2018) 7

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People’s Health and Participation in Public Life*, The Fenway Inst. (2016),
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Incongruent Persons: An Endocrine Society Clinical Practice Guideline*
102 J. of Clinical Endocrinology & Metabolism 3869 8

I. PRELIMINARY STATEMENT

H.B. 1182 (“the Act”), enacted by the Tennessee General Assembly this spring in the middle of a global pandemic, is a solution in search of a problem. There is no evidence of safety or security issues posed by transgender people using public restrooms that accord with the sex they live as every day in Tennessee and other states throughout the country. Yet, the Tennessee legislature last month chose to enact a law requiring businesses and other entities with public restrooms to parrot the legislature’s viewpoint on controversial issues regarding the nature of sex. Plaintiffs are Tennessee businesses and service providers with formal or informal policies allowing their transgender employees, customers, or clients to use the restrooms that accord with their identity. H.B. 1182 forces them to post a government-mandated warning sign with large red and yellow “NOTICE” text at the top, and boldface black block letters on a white background stating that “THIS FACILITY MAINTAINS A POLICY OF ALLOWING THE USE OF RESTROOMS BY EITHER BIOLOGICAL SEX, REGARDLESS OF THE DESIGNATION ON THE RESTROOM.” *See* Compl. Exh. B. The proffered justification for this mandate? That the federal government issued an executive order indicating that it will follow binding Supreme Court precedent recognizing that discrimination based on transgender status is sex discrimination. The Act compels Plaintiffs to engage in unwanted controversial speech or risk six months’ imprisonment and/or a fine of up to \$500, as well as other enforcement actions or civil penalties under Title 68, Chapter 120.

In addition to requiring Plaintiffs to communicate the legislature’s controversial viewpoint about sex, H.B. 1182 will create confusion and presents fundamental problems of enforceability. The only way to avoid H.B. 1182’s notice requirement would be for Plaintiffs to prohibit transgender people from using the appropriate facilities—but Plaintiffs have no way to verify anyone’s “biological sex,” nor do they wish to invade their customers’, employees’ or

clients' privacy by attempting to do so. It is impossible to determine whether any person is or is not transgender just by looking at them. Therefore, *any* business or entity in Tennessee with public restrooms or other facilities that does not verify people's sex before they enter the restroom has an "informal policy" allowing transgender people to use the appropriate restroom, and will consequently be required to display this warning notice, or face enforcement of the Act and a criminal penalty. Many entities, including, currently, one of the Plaintiffs in the instant case, do not have all-gender restrooms—they simply allow transgender people to use the appropriate sex-designated restroom. By forcing those entities to communicate that anyone can use the restrooms designated for men or women, the Act's required notice is also factually inaccurate and will create the very confusion that H.B. 1182 purports to address.

Plaintiffs recognize that as businesses open to the public, they are subject to regulation, and that such regulation may sometimes require them to post specific notices. Indeed, existing Tennessee law requires them to post signs in their restrooms regarding sanitation, *see* Tenn. Code Ann. § 68-15-301 (requiring entities with restrooms open to the public to post a sign saying "FOR GOOD HEALTH, PLEASE WASH YOUR HANDS!" to advance state interest in public health). Federal law requires certain businesses to post notices regarding workplace safety (Occupational Safety and Health Act), labor rights (National Labor Relations Act), and equal opportunities (Title VII of the Civil Rights Act of 1964 and the Americans with Disabilities Act). Unlike the warning notice required by the Act, those notices communicate purely factual and non-controversial speech that does not offend the First Amendment. Here, by contrast, the Act requires Plaintiffs and all other similarly situated businesses to communicate a hotly contested, controversial, and misleading message on issues of sex and transgender rights—and to characterize it as their own policy.

Plaintiffs seek a preliminary injunction to preserve the status quo and prevent irreparable harm to themselves and their employees, customers, and clients. Unless enjoined by this Court, the Act will go into effect on **July 1, 2021**.

II. STATEMENT OF FACTS

A. The Act's Requirements and Legislative History

H.B. 1182 requires “[a] public or private entity or business that operates a building or facility open to the general public and that, as a matter of formal or informal policy, allows a member of either biological sex to use any public restroom within the building or facility” to post a government-prescribed sign at the entrance of public restrooms in the building or facility with a red and yellow “NOTICE” text at the top, and boldface black block letters on white background stating that “THIS FACILITY MAINTAINS A POLICY OF ALLOWING THE USE OF RESTROOMS BY EITHER BIOLOGICAL SEX, REGARDLESS OF THE DESIGNATION ON THE RESTROOM.” *See* Compl., Exh. B.

The Act defines covered entities to “include” those with facilities that are designated for “a specific biological sex,” and to “exclude” “a unisex, single-occupant restroom or family restroom intended for use by either biological sex.” While the Act does not define “biological sex,” the legislative history shows that the Act uses that term to reference a person’s sex assigned a birth, and is intended to apply to entities that allow transgender people¹ to use a restroom facility that accords with their gender identity, rather than with the sex they were assigned at birth.

¹ Transgender people are people whose gender identity—their deeply held internal understanding of who they are – differs from the sex they were assigned at birth. *See* Exh. C, Decl. of Shayne Sebold Taylor, MD (“Taylor Decl.”) ¶¶ 15, 18.

During the legislative debates on H.B. 1182, bill sponsor Representative Tim Rudd stated that the bill was a response to “new laws giving transgenders [sic] more rights.”² Representative Rudd also stated that it is “shocking and a danger to people that enter a bathroom marked ‘men’ or ‘women’ and someone of the opposite sex is standing there, which could scare people and provoke violence,”³ in a context that again makes clear he is referring to transgender people using the appropriate sex-designated restroom.

There was no testimony offered in support of the bill, nor any safety or security issues cited in Tennessee or elsewhere that might possibly have warranted the Act’s mandated warning notice. Nonetheless, it was passed by the House on March 29, 2021 and the Senate on April 29, 2021. Governor Bill Lee signed H.B. 1182 into law on May 17, 2021. It has an effective date of July 1, 2021.

A violation of the Act is a Class B misdemeanor, *see* Tenn. Code Ann. § 68-120-108, which carries a penalty of up to six months’ imprisonment and/or a fine of \$500, *see* Tenn. Code Ann. § 40-35-111(e)(2). Under the Act, “[i]f an entity or business is notified that it is not in compliance with this section, the entity or business has thirty (30) days in which to comply before any action is taken against the entity or business.” A violation of the Act might also result

² *Debate of H.B. 1182 Before the H. Pub. Serv. Comm.* at 31:49, 112th Gen. Assemb. (Mar. 10, 2021), available at https://tnga.granicus.com/MediaPlayer.php?view_id=610&clip_id=24150; *see also Debate of H.B. 1182 Before the H. State Gov’t Comm.* at 1:14:50, 112th Gen. Assemb. (Mar. 23, 2021), available at http://tnga.granicus.com/MediaPlayer.php?view_id=610&clip_id=24337&meta_id=575940 (claiming that the bill was necessary because of the executive orders regarding rights for transgender people “coming out of Washington”); *id.* at 1:04:40 (“a woman has the right to know whether a man is going to be in her bathroom and vice versa for a man,” with reference to transgender people using the restrooms that accord with their gender identity).

³ *Discussion of H.B. 1182 Before H. Floor Sess., 18th Legis. Day* at 1:49:40, 112th Gen. Assemb. (Mar. 29, 2021), available at http://tnga.granicus.com/MediaPlayer.php?view_id=610&clip_id=24423&meta_id=579987

in other enforcement actions or civil penalties under Title 68, Chapter 120. Defendants have concurrent responsibility for enforcement of the Act. *See* Tenn. Code Ann. § 68-120-106.

B. “Biological Sex” Is a Contested Term

Before H.B. 1182 was enacted, no Tennessee laws referenced “biological sex.” When Tennessee law referenced sex-designated restrooms, it used the terms “men” and “women,” “male” or “female,” or simply “sex.” *See, e.g.*, Tenn. Code Ann. § 68-120-503 (requiring equitable restrooms in public spaces); Tenn. Code Ann. § 4-24-303 (addressing restrooms and other sex segregated spaces in fire houses). In fact, the phrase “biological sex” is a relatively recent one without a fixed or uniform definition, and is not typically used in science or medicine. *See* Exh. C, Decl. of Shayne Sebold Taylor, MD (“Taylor Decl.”) ¶ 28; *see also* Att’y Decl. Exh. A, Katrina Kazarkis, *The Misuses of ‘Biological Sex,’* 394 *The Lancet* 1898 (Nov. 23, 2019), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)32764-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)32764-3/fulltext).

Nonetheless, those seeking to limit rights for transgender people frequently use the phrase “biological sex” to contrast with a transgender person’s gender identity. Since 2013, state legislatures across the country have introduced bills to restrict transgender people’s ability to access single-sex spaces such as restrooms or youth sports, many of which use the phrase “biological sex.” For example, North Carolina’s House Bill 2 (the “Public Facilities Privacy & Security Act”) restricted access to multiple-occupancy restrooms based on “biological sex,” which the bill defined as “[t]he physical condition of being male or female, which is stated on a person's birth certificate.” H.B. 2, § 1.2, 2015 Gen. Assemb., 2nd Extra Sess. (N.C. 2016). Some statutes that use the term “biological sex,” like the Act, do not define it. *See, e.g.*, 2020 Or. Laws 1st Spec. Sess. Ch. 19, § 7a(3)(b)(L). Others use different and sometimes conflicting definitions. *See, e.g.*, W. Va. Code Ann. § 18-2-25d (West 2021) (defining “biological sex” as “an individual’s physical form as male or female based solely on the individual’s reproductive

biology and genetics at birth”); Idaho Code Ann. § 33-6203 (West 2020) (providing that “biological sex” may be “verified” relying on “reproductive anatomy, genetic makeup, or normal endogenously produce testosterone levels,” or a combination of those factors); Miss. Code Ann. § 11-62-3 (2016) (stating “biological sex” is “immutable” and “objectively determined by anatomy and genetics at time of birth”); *see also* S.B. 1367/H.B. 1233, 112th Gen. Assemb., 1st Reg. Sess. (Tenn. 2021) (providing that “‘sex’ means a person’s immutable biological sex as determined by anatomy and genetics at the time of birth,” and that “[e]vidence of a person’s biological sex includes, but is not limited to, a government issued document that accurately reflects a person’s sex listed on the person’s original birth certificate”).

Since 2016, the Tennessee General Assembly has introduced, and in some instances passed, multiple bills that would restrict or impair transgender people’s access to the restroom that accords with their gender identity in schools or other public spaces. *See, e.g.*, H.B. 2414/S.B. 2387, 109th Gen. Assemb., 2nd Reg. Sess. (Tenn. 2015) (requiring public schools to restrict access to restrooms based on sex assigned on original birth certificates) (did not pass); H.B. 888/S.B. 771, 110th Gen. Assemb., 1st Reg. Sess. (Tenn. 2017) (requiring public schools and higher education institutions to have each student use the restroom and locker room facilities consistent with the student’s sex indicated on their original birth certificate) (did not pass); H.B. 2620/S.B. 2480, 110th Gen. Assemb., Reg. Sess. (Tenn. 2018) (requiring the attorney general to defend or pay legal expenses for any school district that restricts access to multiuser restrooms on the basis of “biological sex”) (did not pass); S.B. 1297/H.B. 1151, 111th Gen. Assemb., Reg. Sess. (Tenn. 2019) (expanding offense of indecent exposure to apply to restrooms or locker rooms) (passed with amendments); H.B. 1274/S.B. 1499, 111th Gen. Assemb., 1st Reg. Sess. (Tenn. 2019) (similar to H.B. 2620); S.B. 1367/H.B. 1233, 112th Gen. Assemb., 1st Reg. Sess.

(Tenn. 2021) (creating a private right of action against a public school or Local Education Agency for a student, teacher, or school employee who encounters “a member of the opposite sex in a multi-occupancy restroom or changing facility”). These bills, and similar bills nationwide, have been hotly contested and the subject of intense legislative and social debate.⁴

In 2018, federal efforts to rescind regulatory protections for transgender people were also framed in terms of exclusions based on “biological sex.” *See, e.g.*, Erica Green, Katie Benner, & Robert Pear, *‘Transgender’ Could Be Defined Out of Existence Under Trump*, N.Y. Times (Oct. 21, 2018), <https://www.nytimes.com/2018/10/21/us/politics/transgender-trump-administration-sex-definition.html> (citing leaked memo from Trump administration Department of Health and Human Services proposing to define “gender as a biological, immutable condition determined by genitalia at birth”). This draft policy prompted protests, rallies and extensive public debate. *See, e.g.*, Sarah Mervosh & Christine Hauser, *At Rallies and Online, Transgender People Say They #Won’t Be Erased*, N.Y. Times (Oct. 22, 2018), <https://www.nytimes.com/2018/10/22/us/transgender-reaction-rally.html>; Open Letter from Over 2600 Scientists Opposing Proposed Legal Definition of Gender (Oct. 26, 2018), <https://not-binary.org/statement/> (“The proposal is in no way ‘grounded in science’ as the administration claims. The relationship between sex chromosomes, genitalia, and gender identity is complex, and not fully understood. There are no genetic tests that can unambiguously determine gender, or even sex. Furthermore, even if such tests existed, it would be unconscionable to use the pretext of science to enact policies that overrule the lived experience of people’s own gender identities.”).

⁴ *See, e.g.*, Jonathan Mattise, Kimberlee Kruesi, & Lindsay Whitehurst, *Tennessee Moves to the Forefront with Anti-Transgender Laws*, Associated Press (May 23, 2021), <https://apnews.com/article/tennessee-transgender-laws-b8d81d56287d6ed9d56c5da2203596b0>.

This politicized understanding of the phrase “biological sex” as contrasted with a transgender person’s gender identity is inconsistent with the medical consensus that gender identity itself has a biological basis. *See* Taylor Decl. ¶¶ 15–16; Editorial, *Anatomy Does Not Define Gender*, 365 *Nature* 5 (Oct. 30, 2018), at <https://www.nature.com/articles/d41586-018-07238-8>.

As a matter of scientific consensus, the terms “[b]iological sex, biological male or female” “refer to physical aspects of maleness and femaleness. As these may not be in line with each other (*e.g.*, a person with XY chromosomes may have female-appearing genitalia), the terms biological sex and biological male or female are imprecise and should be avoided.” Wylie C. Hembree, et al., *Endocrine Treatment of Gender-Dysphoric/Gender Incongruent Persons: An Endocrine Society Clinical Practice Guideline* 102 *J. of Clinical Endocrinology & Metabolism* 3869, 3875 Table 1, <https://doi.org/10.1210/jc.2017-01658>. A person’s sex encompasses a number of different biological attributes, including sex chromosomes, certain genes, gonads, sex hormone levels, internal and external genitalia, other secondary sex characteristics, and gender identity. *See* Taylor Decl. ¶ 13. These components of sex do not all align neatly in every human being. Where they do not, best practice for medical care recognizes that, for purposes of social and legal recognition, a person’s gender identity should be the basis for their sex classification. *See id.* at ¶ 17.

There is a medical consensus that there is a significant biological component underlying gender identity. *See id.* at ¶¶ 15–16; *see also* Att’y Decl. Exh. B., Joshua D. Safer & Vin Tangpricha, *Care of the Transgender Patient*, 171 *Annals of Internal Med.* 171:ITC1 (July 2, 2019), <https://doi.org/10.7326/AITC201907020>; Denise Grady, *Anatomy Does Not Determine Gender, Experts Say*, *N.Y. Times* (Oct. 28, 2018), <https://www.nytimes.com/2018/>

10/22/health/transgender-trump-biology.html. While the Act targets transgender people in public spaces, it also erases entirely the existence of intersex people, by suggesting that there are only two possible sexes with the use of the mandated phrase “*either* biological sex.”⁵

The Act takes as a given that the term “biological sex” excludes transgender people, while ignoring that gender identity itself has a biological component. In this political moment, the term carries an anti-transgender connotation that reflects the Tennessee legislature’s political viewpoint that transgender people are a different sex than the sex they know themselves to be, and that allowing transgender people to use the restroom is sufficiently controversial to require a special warning notice. The Act further requires Plaintiffs to appear to endorse this statement by characterizing their own policy in the legislature’s controversial language (“THIS FACILITY MAINTAINS A POLICY . . .”). Plaintiffs do not want to be forced to communicate this viewpoint on the walls of their businesses.

C. Plaintiffs’ Restroom Policies

Plaintiff Bongo Productions, LLC (“Bongo”) owns several restaurants, coffee shops, and a coffee roasting company all located in Nashville, Tennessee. Plaintiff Robert M. Bernstein is Bongo’s founder and chief manager. He is responsible for decisions regarding compliance with state and local building codes for Bongo’s establishments. *See* Exh. A, Decl. of Robert Bernstein (Bernstein Decl.) ¶¶ 1–2.

⁵ “Sex related characteristics do not always align as either completely male or completely female. For example, many children are born with ambiguous genitalia, and as a result it is difficult to assign these infants as either male or female at birth.” Taylor Decl. ¶ 14. “Intersex is an umbrella term for unique variations in reproductive or sex anatomy.” InterAct, *Intersex Definition*, <https://interactadvocates.org/intersex-definitions/> (last visited Jun. 24, 2021).

Mr. Bernstein opened Fido, one of the Bongo businesses, in 1996. Fido is a restaurant located in the Hillsboro Village neighborhood of Nashville. Fido has twenty-five employees currently on staff and has employed hundreds of people over the years. *Id.* at ¶¶ 3–5.

Bongo and Mr. Bernstein have worked over the years to create a welcoming environment in their businesses for the LGBTQ community. Bongo has employed transgender individuals in the past, and its patrons include members of the transgender community. *Id.* at ¶¶ 6–7. In reaction to the rash of anti-transgender laws that passed this year and to show their support for transgender people, Fido’s staff decorated one of their drink menu blackboards with transgender and LGBTQ pride flag colors. *Id.* at ¶ 8.

Fido has three restrooms. One is a single-user unisex restroom, which is not subject to the Act. *Id.* at ¶ 9. The other two restrooms have multiple stalls and/or urinals and bear sex designations. *Id.* Prior to the passage of the Act, Fido’s management and Mr. Bernstein had never thought about a formal policy as to who could use which restroom. *Id.* at ¶ 11. Their informal policy was to allow people to use the sex-designated restroom that aligned with their gender identity. *Id.* Mr. Bernstein has never received any complaints or concerns about their restroom policy. *Id.* at 12.

Plaintiff Sanctuary Performing Arts LLC (“Sanctuary”) is a performing arts venue, community center, and safe haven located in Chattanooga, Tennessee. Exh. B, Decl. of Kye Sayers (Sayers Decl.) Decl. ¶ 3. Sanctuary was founded by members of the transgender community in December 2020 to serve the needs of transgender and intersex people of all ages, as well as other LGBTQ people and allies. *Id.* at ¶ 4.

Sanctuary has two employees on staff, as well as many volunteers. The majority of the people working there and who attend their programs are transgender. Since Sanctuary opened its

doors in late 2020, approximately 400 people have been involved with Sanctuary as volunteers or participants. *Id.* at ¶ 5.

Sanctuary has three restrooms. One is a single user unisex restroom, which is not subject to the Act. *Id.* at ¶ 7. Its other two restrooms both have multiple stalls and do not have a sex designation at this time. *Id.* Next month, Sanctuary intends to begin operating a full-service café and will post a sex designation on each restroom as required by local building codes. *Id.* at ¶ 8. It will allow transgender people to use the restroom that accords with their gender identity. Sanctuary has never received any complaints about its restroom policies. *Id.*

D. The Impact of the Act on Plaintiffs

Robert Bernstein, Bongo, and Bongo’s staff are supportive of the LGBTQ community and have transgender patrons. They are concerned that the warning notice mandated by the Act is offensive and will alienate or offend their customers and employees. Bernstein Decl. ¶ 14. The Act will also mischaracterize their policy by suggesting they do not have sex-designated restrooms despite the designation on the restrooms. *Id.* at ¶¶ 10–11, 15.

Sanctuary and its staff have worked hard to create a safe space for transgender and intersex people and their families in a state that is frequently perceived as unwelcoming to LGBTQ people. Sanctuary recognizes that the phrase “either biological sex” on the Act’s required warning notice is offensive to transgender and intersex people, Sayers Decl. ¶ 11, because it suggests that transgender people are not the sex they know themselves to be, and ignores the existence of intersex people by suggesting that there are only two distinct “biological” sexes, *id.* at 12. Sanctuary believes that posting the warning notice required by H.B. 1182 would communicate to transgender and intersex people that they are not welcome, thereby directly contradicting the message Sanctuary tries to cultivate in everything it does. *Id.* at ¶ 13.

Sanctuary believes that it will lose the customers and supporters it has worked hard to bring to Sanctuary if it displays the warning notice. *Id.* at ¶ 14.

Accordingly, the Act requires Plaintiffs to communicate the legislature’s controversial viewpoint on sex and transgender people for the following reasons:

First, the Act requires Plaintiffs to post the required warning notice solely because they allow transgender people to use the appropriate restroom—yet the Act does not even allow Plaintiffs to describe their restroom policies in their own words. Instead, it requires them to use the legislature’s controversial and politically loaded terminology of “biological sex” to imply that transgender people are a different “biological sex” than their deeply held gender identity, and to characterize this fraught message as their own policy (“THIS FACILITY HAS A POLICY ALLOWING THE USE OF RESTROOMS BY EITHER BIOLOGICAL SEX . . .”).

Second, the Act forces Plaintiffs Bongo and Mr. Bernstein to communicate an inaccurate description of their restroom policies for an additional reason. Fido does not have all-gender multi-user restrooms. Allowing transgender people to use the restrooms that accord with their identity does not invalidate the sex-segregated nature of Fido’s sex-designated restrooms. Yet the Act requires them to post a notice saying that anyone can use their restrooms regardless of “biological sex.” Plaintiffs Bongo and Mr. Bernstein are concerned this will cause confusion for their staff, customers, or clients. *See* Bernstein Decl. ¶ 15.

Third, the Act forces all Plaintiffs to communicate the legislature’s viewpoint that allowing transgender people to use the restrooms that accord with their identity is so troubling as to require a red and yellow “NOTICE” sign in large block letters. All Plaintiffs object to this message because it is contrary to the welcoming culture they seek to create in their businesses.

III. ARGUMENT

A. Applicable Legal Standards

Plaintiffs seek a preliminary injunction to prevent the enforcement of H.B. 1182 from compelling them to speak a government-mandated, controversial, and confusing message that will harm Plaintiffs and their staff, customers, and clients. In ruling on this motion, this Court must balance four factors: “(1) whether the movant has a strong likelihood of success on the merits; (2) whether the movant would suffer irreparable injury absent the injunction; (3) whether the injunction would cause substantial harm to others; and (4) whether the public interest would be served by the issuance of an injunction.” *Am. C.L. Union Fund of Mich. v. Livingston Cnty.*, 796 F.3d 636, 642 (6th Cir. 2015) (internal quotation marks and citation omitted).

The Sixth Circuit has recognized that “in [] First Amendment case[s], ‘the crucial inquiry is usually whether the Plaintiff has demonstrated a likelihood of success on the merits.’” *Hamilton’s Bogarts, Inc. v. Michigan*, 501 F.3d 644, 649 (6th Cir. 2007) (citation and internal quotations omitted). This is because the public interest and harm to the parties will “largely depend on the constitutionality of the statute.” *Id.*

B. Plaintiffs Are Likely to Succeed on the Merits

Plaintiffs are likely to prevail on their First Amendment claims. The Act infringes on Plaintiffs’ First Amendment rights by requiring them to post a specific controversial message within their private establishments. This kind of compelled ideological speech is presumptively unconstitutional and subject to strict scrutiny. *Riley v. Nat’l Fed’n of the Blind of N.C., Inc.*, 487 U.S. 781, 798 (1988). H.B. 1182 fails strict scrutiny because it is not rationally related to any legitimate government interest, let alone narrowly tailored to advance a compelling government interest.

I. The Act unconstitutionally compels controversial speech

H.B. 1182 requires Plaintiffs, and likely thousands of other similarly situated entities throughout Tennessee, to post a highly politicized notice on their premises, but the First Amendment prohibits such a requirement. It is long settled that the government may not require private entities “to participate in the dissemination of an ideological message by displaying it on his private property in a manner and for the express purpose that it be observed and read by the public.” *Wooley v. Maynard*, 430 U.S. 705, 713 (1977). The First Amendment protects “both the right to speak freely and the right to refrain from speaking at all,” *id.* at 714, and requires the presumption “that speakers, not the government, know best both what they want to say and how to say it,” *Riley*, 487 U.S. at 791. In recent years, the Supreme Court has further emphasized the “damage” done when “individuals are coerced into betraying their convictions” through compelled speech. *Janus v. Am. Fed’n of State, Cnty., & Mun. Emps. Council 31*, 138 S. Ct. 2448, 2464 (2018).

A statute that compels private entities “to speak a particular message” is considered a content-based regulation of speech. *Nat’l Inst. of Fam. Life Advocs. v. Becerra (NIFLA)*, 138 S. Ct. 2361, 2371 (2018). Such content-based restrictions are “presumptively unconstitutional.” *Reed v. Town of Gilbert*, 576 U.S. 155, 163 (2015). H.B. 1182’s compelled speech requirement is also viewpoint based, because it requires private actors to convey an idea they abhor. *See* Sayers Decl. ¶¶ 11–13; Bernstein Decl. ¶ 16. The Sixth Circuit has held that “the most aggressive form of viewpoint discrimination [is] compelling an individual ‘to utter what is not in [her] mind’ and indeed what she might find deeply offensive.” *Ward v. Polite*, 667 F.3d 727, 733 (6th Cir. 2012) (quoting *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 634 (1943) (second alteration in original)).

The legislature cannot force Plaintiffs or any other private entity to convey an anti-transgender viewpoint. There is no mistaking H.B. 1182 for a basic, factual notice requirement; Plaintiffs and their communities instantly recognized the viewpoint expressed in the notice language. *See* Sayers Decl. ¶ 11; Bernstein Decl. ¶ 14. The specific language dictated by the General Assembly was designed to distinguish between “biological sex,” a loaded term with anti-transgender connotations rejected by the medical and scientific community, and transgender people’s gender identity. As the sponsor himself stated on the record, the objective of the bill is to push back against advances in civil rights for transgender people at the Supreme Court and in society at large. Legislators may disagree with policies and decisions “coming out of Washington,”⁶ but they cannot require members of the public to disseminate the legislators’ view.

The Supreme Court has recognized narrow exceptions to this prohibition on compelled speech where a notice is limited to “purely factual and uncontroversial information about the terms under which [] services will be available.” *Zauderer v. Office of Disciplinary Counsel of the S. Ct. of Ohio*, 471 U.S. 626, 651 (1985). Likewise, in *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2012), the Sixth Circuit distinguished between different elements of required warning labels on cigarettes, holding that provisions that require the disclosure of “factual information” not “in dispute within the scientific or medical community” were subjected to a lower level of scrutiny than provisions that required “subjective” and “highly controversial” warnings, *id.* at 526. “While it is permissible for the government to require a product manufacturer to provide truthful information, even if perhaps frightening, to the public

⁶ *Debate of H.B. 1182 Before the H. State Gov’t Comm.* at 1:04:40, 112th Gen. Assemb. (Mar. 23, 2021), available at http://tnga.granicus.com/MediaPlayer.phpview_id=610&clip_id=24337&meta_id=575940.

in an effort to warn it of potential harms, it is less clearly permissible for the government to simply frighten consumers or to otherwise attempt to flagrantly manipulate the emotions of consumers as it seeks to do here.” *Id.* at 529. The notice required by H.B. 1182 is neither factual nor uncontroversial. It is not an attorney fees disclosure requirement like the one considered in *Zauderer*, nor is it like the abortion informed consent requirement contemplated in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), or the “mere health disclosure warnings” at issue in *Discount Tobacco City*, 674 F.3d at 526. Instead, the notice carries an inaccurate and highly controversial message at odds with the prevailing medical and scientific understanding of the nature of sex.

As described above in Section II.C, Plaintiffs have an informal policy of allowing people to use the restroom that accords with their gender identity. Since they make no inquiry into a person’s “biological sex” before allowing them to access the sex-designated restroom, they are undoubtedly covered by the statute and required to post the notice. Indeed, because it is hard to imagine any business or organization having a policy that requires confirming someone’s “biological sex” before they enter the restroom, it is likely that most businesses in Tennessee would be required to post the State’s notice, even if they do not in fact have a policy of letting people use any public restroom “regardless of the designation on the restroom.” H.B. 1182 § 1(b)(3). The language in the notice describes all-gender or unisex restrooms, but Fido maintains sex-designated restrooms.

The fact that transgender people are allowed to use the restroom that corresponds with who they know themselves to be does not eliminate the sex-designated nature of restrooms. To the contrary, having a policy based solely on a person’s sex assigned at birth, one possible definition of “biological sex,” would undermine a facility’s sex designation by forcing, for example, a

transgender man who lives and identifies as a man—and who may have had medical interventions such as hormone therapy that produce typically masculine physical features—to use the women’s restroom. “Warning[s] and disclaimer[s] might be appropriately required . . . in order to dissipate the possibility of consumer confusion or deception,” *Zauderer*, 471 U.S. at 651 (quoting *In re R.M.J.*, 455 U.S. 191 (1982)), but H.B. 1182 will only *create* confusion for Plaintiffs’ staff, customers, and clients.

The Act is also far from non-controversial. *Cf. NIFLA*, 138 S. Ct. at 2372 (more deferential *Zauderer* standard applies only to compelled disclosures of non-controversial information). To the contrary, H.B. 1182 is squarely aimed not at providing factual information, but at stigmatizing transgender people. It requires Plaintiffs to use a phrase that lacks scientific support, and perpetuates the misleading viewpoint that transgender people are not the sex they know themselves to be. Gender identity today is a political topic that is “undoubtedly [a] matter[] of profound ‘value and concern to the public.’” *Janus*, 138 S. Ct. at 2476 (quoting *Snyder v. Phelps*, 462 U.S. 443, 453 (2011)). “We have often recognized that such speech occupies the highest rung of the hierarchy of First Amendment values and merits special protection.” *Id.* In the current political context, Plaintiffs justifiably fear the notice will alienate their transgender staff and clientele by calling into question their identity and core being, and will further create confusion among people who had previously been using public restrooms without incident. Sayers Decl. ¶¶ 7, 10, 12–14; Berstein Decl. ¶¶ 12, 14–15; *see also* Taylor Decl. ¶¶ 28–29.

2. The Act cannot survive strict scrutiny

Where the government compels private actors to display an ideological message with which they disagree, strict scrutiny applies. *Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n of Cal.*, 475 U.S. 1, 18 (1986). Content-based restrictions are “presumptively unconstitutional and may

be justified only if the government proves that they are narrowly tailored to serve compelling state interests.” *Reed*, 576 U.S. at 163. While less stringent review is appropriate when the government compels non-controversial commercial speech such as factual disclosures in advertisements, *see Zauderer*, 471 U.S. 626, strict scrutiny applies when, as here, the government seeks to conscript a business into affirming ideological positions.

H.B. 1182 does not state a government interest it is designed to advance, but the bill’s sponsor offered three: public safety,⁷ clear restroom signage,⁸ and pushing back against expanding federal civil rights protections for transgender people.⁹ The third stated interest can be dispatched with quickly. Expressing frustration with federal policy is not a legitimate government interest that would justify infringing on Plaintiffs’ First Amendment rights, never mind a compelling one. And while public safety and clear restroom signage might be compelling state interests in certain circumstances, the notice requirement does nothing to advance those interests—and indeed would cut against them. As noted above, the required notice is factually inaccurate and will create confusion about what Plaintiffs’ restroom policy actually is. It applies to sex-designated restrooms, and then requires Plaintiffs to declare they have a policy of allowing anyone to use any restroom (which they do not), simply because they allow transgender people to use the restroom that aligns with their gender identity. Moreover, it does so with

⁷ *See Debate of H.B. 1182 Before the H. Pub. Serv. Comm.* at 21:00, 112th Gen. Assemb. (Mar. 10, 2021), available at https://tnga.granicus.com/MediaPlayer.php?view_id=610&clip_id=24150.

⁸ *See Debate of H.B. 1182 Before the H. State Gov’t Comm.* at 1:10:30, 112th Gen. Assemb. (Mar. 23, 2021), available at https://tnga.granicus.com/MediaPlayer.php?view_id=610&clip_id=24337.

⁹ *See Debate of H.B. 1182 Before the H. State Gov’t Comm.* at 1:04:40, 112th Gen. Assemb. (Mar. 23, 2021), available at http://tnga.granicus.com/MediaPlayer.phpview_id=610&clip_id=24337&meta_id=575940.

reference to the controversial and misleading term “biological sex.” Finally, the myth of transgender inclusion as a public safety issue has been thoroughly debunked, and the legislature did not consider a scintilla of evidence—nor could it have, because such evidence does not exist—supporting the specious safety concern.¹⁰

The Act further undermines public safety by stigmatizing transgender people, *see* Taylor Decl. ¶¶ 28–29, and by incentivizing businesses to attempt to exclude transgender individuals from the bathrooms that match their gender identity.¹¹ Anti-transgender dog-whistling signs do not protect public safety and instead create great harm.

H.B. 1182 is so untethered from advancing any legitimate government interest that it would fail even rational basis review, let alone the strict scrutiny that applies. Even under the relaxed standard from *Zauderer*, “a disclosure requirement cannot be ‘unjustified or unduly burdensome.’” *NIFLA*, 138 S. Ct. at 2377 (quoting *Zauderer*, 471 U.S. at 651). In considering a Florida mandatory disclosure requirement for accounting professionals in *Ibanez v. Florida Department of Business and Professional Regulation, Board of Accountancy*, 512 U.S. 136 (1994), the Supreme Court applied *Zauderer*, but found that based on “the failure of the [state] to point to any harm that is potentially real, not purely hypothetical—we are satisfied that the [state]'s action is unjustified,” *id.* at 146.

¹⁰ *See, e.g.*, Lou Chibbaro Jr., *Predictions of Trans Bathroom Harassment Unfounded*, Washington Blade (Mar. 31, 2016), <https://www.washingtonblade.com/2016/03/31/predictions-of-trans-bathroom-harassment-unfounded/>.

¹¹ *Cf.* Timothy Wang, et al., *State Anti-Transgender Bathroom Bills Threaten Transgender People’s Health and Participation in Public Life*, The Fenway Inst. (2016), https://fenwayhealth.org/wp-content/uploads/2015/12/COM-2485-Transgender-Bathroom-Bill-Brief_v8-pages.pdf (describing medical and psychological harms that result from barring transgender people from accessing restrooms that match who they are).

C. Absent an Injunction, Plaintiffs Will Suffer Irreparable Injury

“The loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.” *Elrod v. Burns*, 427 U.S. 347, 373 (1976). The Sixth Circuit has made clear that “if it is found that a constitutional right is being threatened or impaired, a finding of irreparable injury is mandated.” *Am. C.L. Union of Ky. v. McCreary Cnty.*, 354 F.3d 438, 445 (6th Cir. 2003). Without prompt relief, Plaintiffs will be required to post the notice on July 1, or within thirty days of a citation, or risk the threat of six months’ imprisonment and/or a civil penalty of up to \$500, as well as other enforcement actions or civil penalties under Title 68, Chapter 120.

D. An Injunction Would Not Harm Defendants and Would Serve the Public Interest

The balance of equities weighs heavily in favor of Plaintiffs. As set forth above, Plaintiffs will suffer significant harm without an injunction, whereas Defendants only stand to temporarily lose the ability to enforce a new law that does not advance any legitimate state interest and is likely to be held unconstitutional. *See Planned Parenthood Ass’n of Cincinnati, Inc. v. City of Cincinnati*, 822 F.2d 1390, 1400 (6th Cir. 1987) (finding it “questionable” whether state “has any ‘valid’ interest in enforcing” an unconstitutional law); *see also Chamber of Com. v. Edmondson*, 594 F.3d 742 (10th Cir. 2010) (noting that defendant “does not have an interest in enforcing a law that is likely constitutionally infirm”).

Finally, granting an injunction in this case will undoubtedly serve the public interest. As the Sixth Circuit has made clear, “[w]hen a constitutional violation is likely . . . the public interest militates in favor of injunctive relief because it is always in the public interest to prevent violation of a party’s constitutional rights.” *Am. C.L. Union Fund of Mich.*, 796 F.3d at 649 (alteration in original) (internal quotation marks omitted); *see also Planned Parenthood Ass’n of*

Cincinnati, 822 F.2d at 1400 (“[T]he public is certainly interested in the prevention of enforcement of ordinances which may be unconstitutional.”).

IV. CONCLUSION

For all of the foregoing reasons, Plaintiffs’ motion for a preliminary injunction should be granted. Defendants should be enjoined from enforcing the Act pending the final determination of Plaintiffs’ claims.¹²

Dated: June 25, 2021

Respectfully submitted,

/s/ Thomas H. Castelli
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**Pro hac vice* motions forthcoming

¹² Because Plaintiffs face a loss of constitutional rights, and Defendants are not faced with any monetary injury if a preliminary injunction is issued, this Court should exercise its discretion to waive the Fed. R. Civ. P. 65(c) bond requirement. *See Appalachian Reg’l Healthcare, Inc. v. Coventry Health and Life Ins. Co.*, 714 F.3d 424, 431 (6th Cir. 2013); *see also Moltan Co. v. Eagle-Picher Indus., Inc.*, 55 F.3d 1171, 1176 (6th Cir. 1995) (affirming district court decision to require no bond “because of the strength of [the plaintiff]’s case and the strong public interest involved”).

CERTIFICATE OF SERVICE

I, the undersigned, do hereby certify that on June 25, 2021, a true and correct copy of the foregoing has been served by e-mail according to the agreement and instructions from the Attorney General's Office to tnattygen@ag.tn.gov.

/s/ Thomas H. Castelli
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Attorney for Plaintiffs

EXHIBIT A

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

BONGO PRODUCTIONS, LLC, ROBERT)
BERNSTEIN, SANCTUARY PERFORMING)
ARTS LLC, and KYE SAYERS,)

Plaintiffs,)

v.)

CARTER LAWRENCE, Tennessee State Fire)
Marshal, in his official capacity,)
CHRISTOPHER BAINBRIDGE, Director of)
Codes Enforcement, in his official capacity,)
GLENN R. FUNK, District Attorney General)
for the 20th Judicial District, in his official)
capacity, and NEAL PINKSTON, District Attorney)
General for 11th Judicial District, in his official)
capacity,)

Defendants.)

Civ. Action

No. 3:21-cv-00490

Judge Trauger

DECLARATION OF ROBERT BERNSTEIN

1. Through my company, Bongo Productions, LLC (“Bongo”), I own and operate several coffeehouses or restaurants, Bongo Java, Bongo East, Fido, Game Point and Grins Vegetarian Cafe, in Nashville, Tennessee. I also operate a coffee roasting company that provides our cafes as well as restaurants, offices, and individual customers in Nashville and across the country with certified organic, specialty coffee. See <https://www.bongojava.com/>

2. I am the founder and chief manager of Bongo.

3. Of my businesses, only Fido has multi-user sex-designated restroom facilities. Grins Vegetarian Café is located inside the Hillel Center as part of the Vanderbilt University campus, which also has multiple stalls in their restrooms.

4. I opened Fido in 1996. Fido is restaurant located in the Hillsboro Village neighborhood of Nashville.
5. Fido has 25 employees currently on staff and has employed hundreds of people over the years.
6. In the past, Bongo has employed transgender people. Bongo's and Fido's patrons include members of the transgender community.
7. Bongo and I have worked over the years to create a welcoming environment for members of the LGBTQ community. I believe that many of our customer base supports LGBTQ rights.
8. In reaction to the rash of anti-transgender laws that passed this year and to show support for transgender people, Fido's staff decorated the restaurant's specialty drinks sign with transgender and LGBTQ pride flag colors.
9. Fido has three restrooms. One is a single user, unisex restroom, which I believe is not subject to H.B. 1182. The other two restrooms both have multiple stalls and/or urinals and bear sex-designations, and therefore I believe are subject to H.B. 1182's requirements.
10. I am concerned that I will be required to post the warning notice on Fido's restrooms because we allow all women, including transgender women, to use the women's restroom, and all men, including transgender men, to use the men's restroom.
11. Prior to the passage of H.B. 1182, Fido's management and I had never thought about a formal policy as to who could use which restroom. Our informal policy was to never tell any person that they could not use a particular sex-designated restroom, and to allow transgender people to use the restroom that matched their gender identity.

12. I have never received any complaints about our restroom policies or about transgender people using the restrooms that match their identity.

13. Fido's restroom are not in constant visual line of sight of our staff so we might have to put up cameras if we had to monitor who uses which restroom.

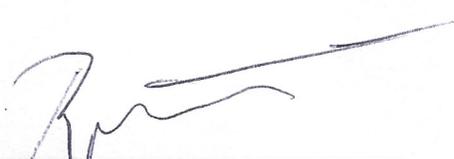
14. I believe that posting the warning notice required by H.B. 1182 will offend our staff, customers, friends, and family. I am worried I could lose staff and customers if forced to post this sign.

15. I am also concerned that the required warning notice could create confusion for our customers, clients and employees.

16. I am a former journalist and I believe strongly in freedom of speech. I find the message communicated by H.B. 1182 offensive, and I object to the government requiring me to post a controversial warning notice in my businesses that is ideologically motivated and inaccurate.

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

Dated: June 24, 2021



Robert M. Bernstein

EXHIBIT B

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

BONGO PRODUCTIONS, LLC, ROBERT)
BERNSTEIN, SANCTUARY PERFORMING)
ARTS LLC, and KYE SAYERS,)

Plaintiffs,)

v.)

CARTER LAWRENCE, Tennessee State Fire)
Marshal, in his official capacity,)
CHRISTOPHER BAINBRIDGE, Director of)
Codes Enforcement, in his official capacity,)
GLENN R. FUNK, District Attorney General)
for the 20th Judicial District, in his official)
capacity, and NEAL PINKSTON, District Attorney)
General for 11th Judicial District, in his official)
capacity,)

Defendants.)

Civ. Action
No. 3:21-cv-00490
Judge Trauger

DECLARATION OF KYE SAYERS

1. I am a resident of Chattanooga, Tennessee and am the owner and co-founder of Sanctuary Performing Arts LLC (“Sanctuary”).

2. I make decisions for Sanctuary, including with regard to compliance with state and local building codes.

3. Sanctuary is a performing arts venue, community center and safe haven located in Chattanooga, Tennessee. See www.Sanctuaryperformingarts.com.

4. Sanctuary was founded by me and other members of the transgender community in December 2020 to serve the needs of transgender and intersex people of all ages, as well as other LGBTQ people and allies.

5. Sanctuary has two employees on staff, and many volunteers. The majority of the people who work and volunteer there and the majority of those who participate in Sanctuary's programs are transgender. Since Sanctuary opened its doors in late 2020, approximately 400 people have been involved with Sanctuary as volunteers or participants.

6. Sanctuary's founders and staff have worked hard to create a safe space for transgender and intersex people and their families in a state that is frequently perceived as unwelcoming to LGBTQ people.

7. Sanctuary has three restrooms. One is a single user unisex restroom. The other two restrooms have multiple stalls and/or urinals and do not have a sex designation at this time. Anyone is welcome to use any of Sanctuary's restrooms. No one has ever complained about Sanctuary's restroom policies.

8. Next month, Sanctuary intends to begin operating a full-service café and will be required by the local building code to post a sex-designation on its two multi-user restrooms. Sanctuary will continue to allow transgender people to use the restroom that accords with their gender identity.

9. I am concerned that H.B. 1182 applies to Sanctuary now because its multi-user facilities are not "excluded" under the Act's definition of covered entities, and am also concerned that the Act will apply to it in the future once it adds a sex designation on its multi-user restrooms.

10. I am concerned that the warning notice will make transgender and intersex people will feel that their presence is viewed as alarming, and that they will be offended by the term "biological sex" because of the political controversy and anti-transgender animus surrounding that phrase.

11. I immediately understood the term “biological sex” to be stigmatizing to transgender people and believe our clients will as well.

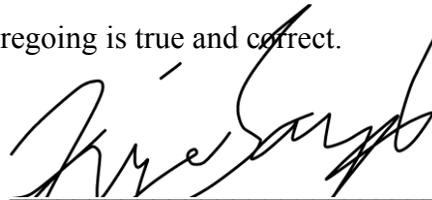
12. I further believe that the notice required by H.B. 1182 will send a message that erases the existence of intersex people by suggesting that there are only two “biological sexes.”

13. I believe that posting the warning notice required by H.B. 1182 would send a message to transgender and intersex people that they are not welcome, which would undermine Sanctuary’s mission and is the exact opposite of the message we try to send in everything we do.

14. I fear that Sanctuary will lose staff, community members and supporters if we display the warning notice.

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

Dated: June 23, 2021

A handwritten signature in black ink, appearing to read "Kye Sayers", written over a horizontal line.

Kye Sayers

EXHIBIT C

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

BONGO PRODUCTIONS, LLC, ROBERT)
BERNSTEIN, SANCTUARY PERFORMING)
ARTS LLC, and KYE SAYERS,)

Plaintiffs,)

v.)

CARTER LAWRENCE, Tennessee State Fire)
Marshal, in his official capacity,)
CHRISTOPHER BAINBRIDGE, Director of)
Codes Enforcement, in his official capacity,)
GLENN R. FUNK, District Attorney General)
for the 20th Judicial District, in his official)
capacity, and NEAL PINKSTON, District)
Attorney General for 11th Judicial District, in)
his official capacity,)

Defendants.)

Civ. Action
No. 3:21-cv-00490
Judge Trauger

DECLARATION OF SHAYNE SEBOLD TAYLOR, MD

Preliminary statement

1. My name is Shayne Sebold Taylor, MD. I have been retained by counsel for Plaintiffs as an expert in connection with the above-mentioned litigation. I have actual knowledge of the matters stated herein.
2. I am an Assistant Professor of Internal Medicine and Pediatrics at Vanderbilt University Medical Center and the Monroe Carrell Jr. Children’s Hospital at Vanderbilt in Nashville, Tennessee.
3. I am licensed in the state of Tennessee to practice medicine (TN License #55151).

4. I am board certified in both Internal Medicine and Pediatrics by the American Board of Internal Medicine and the American Board of Pediatrics, respectively.
5. I obtained my undergraduate degree at Emory University with a BS in Biology and a BA in Women and Gender Studies. I received my medical degree from Drexel University College of Medicine and completed my Internal Medicine and Pediatrics residencies at Vanderbilt University Medical Center.
6. I have lived and practiced medicine in the state of Tennessee since 2014.
7. Additional information about my professional background and experience is outlined in my curriculum vitae, a true and accurate copy of which is attached as Exhibit A to this report. In conjunction with serving as an Assistant Professor of Internal Medicine and Pediatrics at Vanderbilt, I am the creator and Lead Clinician of the Vanderbilt Clinic for Transgender Health, a multi-disciplinary patient-centered medical home for transgender adults. My clinical duties include providing primary care and transition-related care (particularly hormone therapy), as well as providing care navigation with specialists across the Vanderbilt medical community. I have over 700 transgender patients under my care with a 3-6 month waitlist to be seen for services. The majority of my patients reside in Middle TN, however I have patients traveling 3-4 hours to come to the clinic spanning from Memphis to the west and Kingsport to the east.
8. In addition to my clinical work, I provide guidance to physicians throughout Vanderbilt and Middle Tennessee who care for transgender patients. I do this by giving grand rounds, presentations to medical students and residents, and training to various community providers on the importance of culturally competent care for the transgender patient.

9. As part of my practice, I stay current on medical research and literature relating to the care of transgender persons and patient's suffering with gender dysphoria.
10. I am a member of the World Professional Association of Transgender Health (WPATH), American Academy of Pediatrics (AAP), American College of Physicians (ACP), Alpha Omega Alpha (AOA) medical honor's society, and the Gay and Lesbian Medical Association (GLMA).
11. I am being compensated \$350/hour for my time preparing this testimony. My compensation does not depend on the outcome of the litigation, the opinions I express, or the testimony I provide.

Sex, Gender, and Gender Identity

12. The sex of a child is most often determined after delivery based on the visual appearance of an infant's external genitals.
13. Research has identified that determination of sex is far more complex than what is seen on genital exam. Instead, sex is a complex compilation of multiple factors including one's chromosomal make up (XX for those assigned female at birth, XY for those assigned male at birth), gonadal sex (presence of ovaries or testes), fetal hormonal sex (production of sex hormones *by* the fetus or exogenous exposure of sex hormones *to* the developing fetus), pubertal hormonal sex (the change in hormonal milieu that results in the development of secondary sexual characteristics- facial hair and deep voice for those assigned male at birth, breasts and menstrual cycles for those assigned female), hypothalamic sex (variations in brain structure and function as a result of embryonal exposure of sex hormones), and gender identity.

14. For each of the above factors that contribute to the development of sex, there can be variations. Sex related characteristics do not always align as either completely male or completely female. For example, many children are born with ambiguous genitalia, and as a result it is difficult to assign these infants as either male or female at birth. These patients are often identified as intersex, which is one of many disorders of sexual development (DSD). These children often see multiple specialists throughout their lifespan. Other examples of DSDs are those of chromosomal differences. The typical human chromosomal make up includes 46XY for males and 46XX for females. However, in male patients with Klinefelter's syndrome their chromosomal makeup is 47XXY. These chromosomal male individuals have an extra X chromosome. The results include breast development and small testes, in addition to other physical findings. Patients with Turner Syndrome are 45XO. These female individuals are missing an X chromosome, and as such many of them do not develop normal female puberty and are often infertile. These variations are common. The Monroe Carrell Children's Hospital at Vanderbilt has an entire clinic to cater to the medical needs of this patient population.
15. Gender identity is a person's inner sense of belonging to a particular gender. Identifying as male or female is a core component of one's overall identity. Every person has a gender identity. Research has shown that children begin to develop and express their gender identity during their toddler years, at around the age of 3 years old. It has a strong biological basis and cannot be changed.
16. Scientific research has discovered many biological reasons for how an individual develops a gender identity. Complex interactions between hormones, chromosomes, and the developing embryo in utero are at the center of these theories.

17. From a medical perspective, in the event that one's gender identity does not match their sex assigned at birth, i.e. in transgender people, one's gender identity should be the determining factor of their sex. The medical consensus recognizes that when one's sex related-characteristics are not in alignment, a person's gender identity is the determining factor, more important than the presence of their genitals, their chromosomal analysis, or their hormone levels.

Gender Dysphoria and its Treatment

18. Transgender people have a gender identity that differs from the sex that was assigned to them at birth.
19. This lack of alignment of assigned sex and gender identity can result in severe distress, depression, anxiety. This constellation of symptoms is termed gender dysphoria.
20. Treating gender dysphoria results in significant improvement in the quality of life, mental and physical health of transgender persons. Transgender people undergoing treatment for their gender dysphoria can live long, happy, productive and meaningful lives.
21. Gender transition for those that suffer from Gender Dysphoria is a lengthy process with multiple components. These components may include social transition, medical transition, and surgical transition. Each transgender individual approaches transition differently, as the decision to undergo any aspect of transition is deeply personal and depends on the degree and type of dysphoria the patient is experiencing.
22. The social transition is a formative aspect of a transgender person's experience. Social transition can include going by a different name, using different pronouns, or changing one's haircut, or clothing to match one's gender identity.

23. As part of the social transition, a transgender individual will make changes that will allow them to seamlessly incorporate into their communities with a presentation that matches with their gender identity. This may mean using a restroom facility that matches their gender identity, in the same way that a non-transgender person uses the bathroom that matches their gender identity.
24. In addition to social transition, transgender individuals often interface with a healthcare setting for medical or surgical intervention. Medical transition often includes the prescription of hormones so that the transgender person can develop secondary sexual characteristics of the sex with which they identify. This may mean that a transgender man (or someone who was assigned female at birth) may grow facial hair and develop a much deeper voice as a result of testosterone treatment. Alternatively, transgender women (assigned male at birth), may develop breast tissue and a more feminine body fat distribution as a result of estrogen that may be prescribed by a clinician.
25. Some transgender patients seek surgical transition. These surgical procedures further change the patient's anatomy so that their outward appearance matches more closely with their gender identity.
26. Given the medical and surgical treatments that transgender patients may encounter, they are often no longer presenting as their sex assigned at birth. This will further create stress and anxiety for bathroom users, both transgender and otherwise. An example is as follows: a transgender man has been on testosterone therapy for many years. As a result, he has a full-grown beard. He has also had surgical removal of his breast tissue. He wears men's clothing and speaks in a deep voice. It is harmful for that man to have to use a woman's restroom.

Transgender in Tennessee

27. According to a Williams Institute study in 2016, there are approximately 1.6 million people in the United States that identify as transgender. In this same study, it was revealed that an estimated 31,000 transgender people (or 0.6% of the state's population) live in the state of Tennessee. Tennessee is ranked 10th in the nation for its percentage of transgender individuals (Hawaii being the highest and North Dakota with the lowest).
28. H.B. 1182 requires a sign that specifically mentions the term "biological sex." This term has no place or meaning in either science or medicine, because experts who study sex and gender understand that the biology and identity of a human being is far more complex than what can be identified on an individual's genital anatomy or chromosomal evaluation. Having this controversial political term, one that has no value or meaning in medicine or science, posted on every public bathroom in the state of Tennessee is dangerous and distressing, further running the risk of worsening gender dysphoria for those that suffer from the condition.
29. The 31,000 transgender individuals in Tennessee work in Tennessee businesses, go to Tennessee schools and are active members of their families, communities and churches to name a few. Transgender Tennesseans deserve privacy when they use the restroom. Using the restroom at a business is often necessary and should be routine. A transgender patron should not have to effectively disclose their transgender status by using the designated restroom that matches their sex assigned at birth. A transgender person should be able to use the restroom that matches with their gender identity. A large posted sign referencing "biological sex" on every business is stigmatizing and isolating for

transgender Tennesseans. The Act that goes into law on July 1, 2021 is harmful and dangerous for these members of our community.

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

Dated: June 21, 2021


Shayne Sebold Taylor, MD

HOSPITAL APPOINTMENTS

Active Medical Staff

VANDERBILT UNIVERSITY SCHOOL OF MEDICINE, Nashville, TN

August 2018 – present

PROFESSIONAL ORGANIZATIONS

- American Academy of Pediatrics (AAP)
- American College of Physicians (ACP)
- Alpha Omega Alpha (AOA)
- Cumberland Pediatrics Foundation (CPF)
- National Med-Peds Residency Association (NMPRA)
- Gay and Lesbian Medical Association (GLMA)
- World Professional Association for Transgender Health (WPATH)

PROFESSIONAL ACTIVITIES

- Vanderbilt University, Med-Ped Residency Program
 - Physicians for Reproductive Health Board Member, 2014-2017
 - LGBTI Health Provider, 2015-present
 - World Professional Association for Transgender Health (WPATH) Conference Attendee, February 2016
 - Nexplanon Resident Education Organizer, 2016-2017
 - Vanderbilt Gender Clinic Committee Member, 2016-present
 - Page Campbell Moonlighter, 2016-2018
 - Bioethics Certificate Program Participant, 2017-2018
 - Med-Peds Wellness Chief, 2017-2018
- Vanderbilt University Medical Center
 - Lead clinician, Vanderbilt Clinic for Transgender Health 2018-present
 - Providing direct clinical care to >600 transgender patients in the Southeast region
 - Coordinating care between all specialties at VUMC for transgender care
 - Regional consultant to local primary care physicians
- Expert witness to Lambda Legal 2020-present

AWARDS AND SPECIAL RECOGNITION

- Writer's Award from The Emory University President's Commission on the Status of Women, "*Young Venuses and Old Hags: a feminist critique on the media's portrayal of aging women,*" 2009
- Pathology Honor Society at Drexel University, 2010
- The Lila Kroser Scholarship at Drexel University, 2013
- The Drexel University Peer Commendation for Professional Behavior, 2014
- Alpha Omega Alpha, Drexel University College of Medicine, 2014

- Excellence in Patient Experience, VUMC 2020

TEACHING ACTIVITIES

- Creator for the LGBTQ Health Curriculum for Residents, 2017-present
- Research mentor to Mollie Limb, VUSM student, 2018-present
- QI research mentor to Kalin Wilson, VUSM student, 2018-present
- Faculty partner with Internal Medicine Residency Social Medicine Club 2019
- Contributor to Internal Medicine Resident Handbook 2019
- Foundations of Healthcare Delivery faculty
- Integrated Science Course faculty
- ACE primary care rotation faculty

PUBLICATIONS AND PRESENTATIONS

Presentations:

“Caring for the Transgender Patient: With little evidence, but a lot of love.” Vanderbilt University Division of Infectious Disease Grand Rounds and Division of General Internal Medicine Grand Rounds, 4/4/2019 and 5/22/2019.

“A Primer for Transgender Health.” Southeast/TN AIDS Education and Training Center, webcast 1/30/2019.

“The Clinic for Transgender Health: A Passion Project for our Patients.” Vanderbilt University Program for LGBTQ Health Grand Rounds, 11/14/2018.

“Caring for the Transgender Patient.” Vanderbilt University School of Nursing, 10/23/19.

“Caring for the transgender patient, with little evidence but a lot of love. Lessons learned creating a Transgender Health Clinic in the South.” American College of Osteopathic Obstetricians and Gynecologists. Virtual Presentation 3/20/2020.

Articles in Refereed Journals:

Taylor, S.S., Ehrenfeld, J.M. “Electronic Health Records and Preparedness: Lessons from Hurricanes Katrina and Harvey” *Journal of Medical Systems*. (2017) 41:173.

Gamble, R, **Taylor SS**, Ehrenfeld J.M., Huggins, A. “Trans-specific Geriatric Health Assessment (TGHA): An inclusive clinical guideline for the geriatric transgender patient in a primary care setting.” *Maturitas*, Volume 132, 70 - 75

RESEARCH PROJECTS

Healthcare Needs and Barriers Among New Patients at a Clinic for Transgender Health

IRB NUMBER: 192299

PI: Shayne Taylor

Assessing LGBTQ+/Racial Minority Trainee's Experiences with Social Support, Loneliness, and Feelings of Anxiety or Depression During Training

IRB #210225

PI: Hannah Lomzenski

Faculty Advisor: Shayne Taylor

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

BONGO PRODUCTIONS, LLC, ROBERT)
BERNSTEIN, SANCTUARY PERFORMING)
ARTS LLC, and KYE SAYERS,)

Plaintiffs,)

v.)

Civ. Action
No. 3:21-cv-00490
Judge Trauger

CARTER LAWRENCE, Tennessee State Fire)
Marshal, in his official capacity,)
CHRISTOPHER BAINBRIDGE, Director of)
Codes Enforcement, in his official capacity,)
GLENN R. FUNK, District Attorney General)
for the 20th Judicial District, in his official)
capacity, and NEAL PINKSTON, District)
Attorney General for 11th Judicial District, in)
his official capacity,)

Defendants.)

DECLARATION OF THOMAS H. CASTELLI

1. I am one of the attorneys for Plaintiffs Bongo Productions, LLC, Robert Bernstein, Sanctuary Performing Arts LLC, and Kye Sayers.

2. I submit this declaration to provide copies of materials referenced in the memorandum of law in support of Plaintiffs' motion for preliminary injunction that are not readily available online. All other materials referenced in Plaintiffs' memorandum of law are available in reporters or other legal databases, or include a URL in the citation for ease of access.

3. A true and accurate copy of Joshua D. Safer & Vin Tangpricha, *Care of the Transgender Patient*, 171 *Annals of Internal Med.* 171:ITC1 (July 2, 2019) is attached as Exhibit A.

4. A true and accurate copy of Katrina Kazarkis, *The Misuses of 'Biological Sex,'* *The Lancet* 1898 (Nov. 23, 2019) is attached as Exhibit B.

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

Dated: June 25, 2021

/s/ Thomas H. Castelli
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EXHIBIT A



The art of medicine The misuses of “biological sex”

Whether one is entering into military service, seeking identity documents, or participating in sports, the categorisation of bodies according to “sex” is central to the organisation of society. Who is categorised as a woman and who is categorised as a man may seem like simple questions, but making a determination of sex has long been understood as far from straightforward.

For a century, scientists studied an array of human characteristics that inform our ideas of what makes someone a woman or a man, seeking to pin down a single, definitive biological indicator of sex. Bodies troubled these schemes and socially untenable categorisations ensued. If gonads were understood as the essence of sex, women who were phenotypically female but who had testes were men. This seemed illogical, so scientists proposed yet other traits. Even as they debated which biological trait or combination of traits signalled its essence, scientists understood sex as biological and involving multiple, if contested, factors.

Contemporary scientific understanding of sex and its relation to gender was greatly influenced by the work of psychologist John Money, at Johns Hopkins University, USA, beginning in the 1950s. With colleagues, Money further complicated approaches to sex by identifying a range of biological and social factors. Chromosomes, gonads, hormones, and internal and external genital morphology were considered alongside social factors such as assigned sex and rearing, and gender role and sexual orientation. His ideas gained traction, and scientists and medical professionals came to accept sex as inherently knotty: that its “variables” are multiple, come in far more than two versions, and that no single biological factor is determinative.

Research since has expanded the range of variables that produce sex. As one example, the Y chromosome was once

said to trigger testes development in fetuses. Later research showed a gene called *SRY*, located on the Y chromosome, “pushed” primordial germ cells in the embryo to become testes. We now know there are active genes involved in both ovary and testis determination across the genome, and not restricted to the X and Y chromosomes. As biologist Anne Fausto-Sterling has observed, “[T]hose looking to biology for an easy-to-administer definition of sex and gender can derive little comfort from the most important of these [research] findings.”

If what we know of sex is its multiplicity, this introduces a conundrum: which factors to use in categorising and defining sex? Policy makers who formulate sex categorisations and definitions overwhelmingly rely on biological features to ground membership. Biological factors hold appeal and power since reference to “biology” and “science” lends any suggested trait or combination of traits the appearance of neutrality and thus objectivity. But biological definitions of sex are at odds with the understanding that sex involves multiple biological and social factors. They are also at odds with social scientific work that complicates the idea that sex is biological whereas gender is cultural; sex, as much as gender, is culturally contingent and produced. As J R Latham notes, “sex” is not a static, discrete, or even strictly biological characteristic that exists prior to the relations and practices that produce it. Historian of science Sarah Richardson, for example, has shown how scientists “sexed” the X and Y chromosomes by glossing over inconsistencies and ambiguities between the two in their research to elevate findings that align with gendered ideas about biological sex differences.

Decisions about which traits or sets of traits are used, in what combination, and for what purpose are inextricably tied to why sex categorisation exists and whom or what it serves. Far from neutral or objective, sex classification and definition rely on cultural norms about the “appropriate” relationships between sex, gender, and sexuality, and work in tandem with power to support social norms and goals as well as sociopolitical hierarchies that determine opportunities, rights, and privileges.

Not surprisingly, there is a long history of using—and misusing—discrete biological criteria to determine sex and thereby include or exclude certain people from categories. Just this year, the administration of US President Donald Trump began requiring military personnel to serve “in their biological sex”, which they define as “a person’s biological status as male or female based on chromosomes, gonads, hormones, and genitals” (treating these as congruent). Meanwhile, in a leaked memo, the US Department of Health and Human Services (HHS) proposed establishing a federal legal definition of sex “on a biological basis that is clear,



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grounded in science, objective and administrable". Using early 20th-century criteria, HHS suggested defining individuals as "either male or female, unchangeable, and determined by the genitals that a person is born with", and in yet another definition, "male or female based on immutable biological traits identifiable by or before birth".

For many, these proposed methods for categorisation suggest a commonsense and clear-cut assessment. The US military definition of sex relies on the sex designation on a birth certificate, which is likely based on a glance at the genitals at birth. But its definition of biological sex includes "chromosomes, gonads, hormones, and genitals"—that is, all four characteristics. Someone with what are understood as female-typical genitals and 46,XY chromosomes would be classified as female if genitals are used as the indicator but male if chromosomes are used. The HHS-suggested definition appears to directly prioritise genitals yet gives chromosomes a role too.

Science does not drive these policies; the desire to exclude does. This intentional gerrymandering of sex opportunistically uses the idea of "biological sex"—which lends a veneer of science and thus rationality to any definition—to remove certain individuals from a category based on intolerance. One result is the nullification of the Title IX protections that were expanded under the Obama administration—laws applicable to transgender individuals and people with certain differences of sex development who serve in the military or otherwise seek to be safeguarded from discrimination.

The Trump administration's appeal to "biological sex" has parallels in international elite sport. "The biological sex... must prevail", thundered an official for the International Association of Athletics Federations (IAAF), in the context of a rancorous decades-long battle over sex-testing policies used to determine which women are allowed to compete in the female category. The IAAF's appeal to biological sex is an example of how power, not science, comes to shape sex categorisation. In the 1960s, athletes were sex tested using physical examinations; in the 1970s, chromosomal testing was used. By 2011, sex testing regulations focused exclusively on testosterone (T), and any woman with higher than typical levels of naturally occurring T could not compete in the female category. The rationale for this hinged on T's purported role in athletic performance: high levels of T were said to give some women an unfair "masculine" advantage over their competitors. Their solution: women can lower their T levels or forego sport competition. However, the data didn't support the claim underpinning the regulations: that higher T necessarily improves athletic performance. The IAAF scrambled for a new biological indicator, seizing on a combination of chromosomes and internal reproductive organs, and announced a new, special type of categorisation that was designated "sport sex". This is a category of sex relevant to one unique context: elite sport. Women with

high endogenous T could now compete—if they had a specific combination of chromosomes and reproductive organs. Exclusion is based on a woman's primary source of endogenous T, rather than her T level per se.

The newest T regulations were designed by policy makers as an end-run around strict and deterministic criteria for inclusion in the female category—that is, sex testing. But once T couldn't be shown to have the role in athleticism they claimed, they turned to their own idiosyncratic definition of biological sex to keep women with atypical sex traits out of the female category. While the IAAF's focus on women's chromosomes and gonads was a method of calling out certain women as not "really" women, they attempted to cement this notion by then also inaccurately deeming them "biological males".

Debates about sex are often framed falsely as scientific versus cultural arguments, whereby the former by virtue of being grounded in biology are seen as tied to nature and thus truth, whereas the latter are seen as hectoring from a postmodern gender La La Land. T regulation supporters, for example, have argued that critics of the policy misunderstand, or worse, obscure the scientific facts of sex. Yet this profoundly misconstrues who is hewing to science. Those questioning simplistic understandings of sex—scientists among them—are hardly unscientific, but rather keen observers of the science of sex biology and the peculiar categorical gatekeeping of, say, soldiers and elite women athletes. This is not a case of science versus social constructionism as some argue; it's about the calculated use of "biological sex" to buttress obsolete thinking about sex.

Years ago I wondered, "if one postulates bodies (including genitals, gonads, chromosomes, and hormones), what more does the word sex buy us?...The body as a material fact is given, but sex is not." It is long overdue that we understand sex not as an essential property of individuals but as a set of biological traits and social factors that become important only in specific contexts, such as medicine, and even then complexity persists. If we are concerned with certain cancers, for example, knowing whether someone has a prostate or ovaries is what's important, not their "sex" per se. If reproduction is the interest, what matters is whether one produces sperm or eggs, whether one has a uterus, a vaginal opening, and so on. For those arenas where it's not clear what purpose sex designation serves, we might question whether we need it at all. Doing so could lead to better science and health care, and, crucially, less harm.

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I am co-author, with Rebecca M Jordan-Young, of *Testosterone: an Unauthorized Biography* (Harvard University Press, 2019).

Further reading

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- Oudshoorn N. *Beyond the natural body: an archeology of sex hormones*. London and New York: Routledge, 1994
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- Ritz SA. Complexities of addressing sex in cell culture research. *Signs* 2017; **42**: 307–27

EXHIBIT B

In the Clinic®

Care of the Transgender Patient

Terminology and Initial Evaluation

Medical Management

Transgender-Specific Surgeries

Medicolegal and Societal Issues

Practice Improvement

Transgender persons are a diverse group whose gender identity differs from their sex recorded at birth. Some choose to undergo medical treatment to align their physical appearance with their gender identity. Barriers to accessing appropriate and culturally competent care contribute to health disparities in transgender persons, such as increased rates of certain types of cancer, substance abuse, mental health conditions, infections, and chronic diseases. Thus, it is important that clinicians understand the specific medical issues that are relevant to this population.

CME/MOC activity available at [Annals.org](https://annals.org).

Physician Writers
Joshua D. Safer, MD
Vin Tangpricha, MD, PhD
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doi:10.7326/AITC201907020

CME Objective: To review current evidence for terminology, initial evaluation, medical management, transgender-specific surgeries, medicolegal and societal issues, and practice improvement of transgender patient care.

Funding Source: American College of Physicians.

Disclosures: Dr. Safer, ACP Contributing Author, reports that he is employed at Icahn School of Medicine at Mount Sinai, served on an advisory panel for Endo Pharmaceuticals, and has given invited lectures for various academic institutions and professional organizations. His spouse is employed by Parexel. Dr. Tangpricha, ACP Contributing Author, has nothing to disclose. Disclosures can also be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M19-0182.

With the assistance of additional physician writers, the editors of *Annals of Internal Medicine* develop **In the Clinic** using **MKSAP** and other resources of the American College of Physicians.

In the Clinic does not necessarily represent official ACP clinical policy. For ACP clinical guidelines, please go to https://www.acponline.org/clinical_information/guidelines/.

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2. Chan KJ, Jolly D, Liang JJ, et al. Estrogen levels do not rise with testosterone treatment for transgender men. *Endocr Pract*. 2018; 24:329-33. [PMID: 29561193]
3. Reisner SL, Poteat T, Keatley J, et al. Global health burden and needs of transgender populations: a review. *Lancet*. 2016; 388:412-36. [PMID: 27323919]
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Transgender and gender-incongruent persons have gender identities that differ from their sex recorded at birth (typically determined by examination of external genitalia). Studies estimate that 0.6% of U.S. adults, or 1.4 million persons, are transgender (1). This population faces disproportionate challenges in accessing health care services and may experience medical mistreatment (2-5). The largest barrier to care reported by transgender persons is a lack of knowledgeable providers (6). Bar-

riers to accessing appropriate and culturally competent care play a significant role in health disparities among transgender persons, such as increased rates of certain types of cancer, substance abuse, mental health conditions, infections, and chronic diseases (3, 4, 7-13). Historically, care was largely limited to select facilities. Improving access to medically and culturally competent care requires involvement of primary care providers outside such specialized settings (14).

Terminology and Initial Evaluation

What does “transgender” mean?

Gender identity refers to a person's sense of being male, female, neither, or a combination of both (**Box**). The terms “transgender,” “transsexual,” “trans,” “gender nonbinary,” “gender incongruent,” and “genderqueer” are used to describe persons whose gender identity does not align with the sex recorded at birth. Previously, the term “transsexual” indicated that the person had received medical and surgical treatment to align their appearance and gender identity. However, “transgender” has become the preferred term because it also includes those who have had no treatment. “Cisgender” refers to persons who are not transgender—that is, those whose sex recorded at birth aligns with their gender identity.

Transgender men have a male gender identity but were identified as female at birth, and transgender women have a female gender identity but were identified as male at birth. Gender-nonbinary and genderqueer persons may identify with a gender that is neither male nor female or has features of both. Gender expression relates to how a person signals gender identity to others via clothing, hairstyle, actions, and mannerisms. Alignment of physical characteristics with gender identity is referred to as “trans-

ition,” “gender affirmation,” or “gender confirmation.”

Gender dysphoria is a mental health diagnosis that describes the discomfort of misalignment of gender identity and the sex recorded at birth. Not all transgender persons have dysphoria, but many U.S. insurance companies require this diagnosis for reimbursement for transgender medical and surgical interventions (15). Although transgender identity does not equate with a mental health condition, the only codes for a transgender diagnosis in the International Classification of Diseases, 10th Revision (ICD-10), are in the mental health section. A tentative plan for ICD-11 is to add gender incongruence to the sexual health section and remove gender dysphoria entirely (16).

What is known about the natural history of transgender identity development?

Although the mechanisms are not known, data suggest a biological underpinning to gender identity that is present at birth (17, 18). Investigators report an inability to manipulate gender identity by external means (19, 20). Twin studies indicate that identical twins have greater concordance with regard to transgender identity than fraternal

Common Terminology

Gender/sex: Broad terms describing the entire category of relevant biological characteristics, self-identification, and stereotypical behaviors that might be considered male, female, or some variation.

Gender identity: The internal sense of being male, female, or neither.

Transgender, transsexual, trans, gender nonbinary, gender incongruent, genderqueer: Adjectives used to refer to persons whose gender identity does not align with their sex recorded at birth (the latter primarily based on visible physical anatomy).

Cisgender, nontransgender: Adjectives used to refer to persons whose gender identity aligns with their sex recorded at birth.

Gender expression: How a person communicates gender identity through appearance, dress, name, pronouns, mannerisms, and speech.

Gender-affirming hormone treatment and surgeries: Broad categories of medical interventions that transgender persons might consider to align their appearance and their gender identity.

Gender transition, gender affirmation, gender confirmation: An overall process of alignment of physical characteristics and/or gender expression with gender identity.

Gender dysphoria: Discomfort felt by some persons due to lack of alignment between gender identity and the sex recorded at birth. Not all transgender persons have dysphoria, but many U.S. insurance companies require this diagnosis for payment for transgender medical and surgical interventions.

twins (21). Further, evidence shows increased rates of male gender identity among some persons with congenital adrenal hyperplasia who were exposed to excess androgen in utero (22), whereas those with complete androgen insensitivity syndrome have female gender identity (23).

Children demonstrate an ability to articulate a gender identity as early as age 2 years and develop facility with gender labeling, including pronouns, by school age (24). High-quality epidemiologic studies and consistent definitions of gender identity among children are lacking. Depending on the ages included in the study and the definitions used, 0.6%–2.7% of children may report some degree of gender incongruence (25). Not all such children seek medical intervention later in life (26). By adolescence, children are increasingly able to articulate gender identity. Puberty can be distressing for gender-incongruent children. The desire to avoid the “wrong puberty” may prompt some adolescents to report their gender incongruence to their parents, health care providers, and others (27).

Most transgender persons present to clinicians in late adolescence or adulthood. Whether this represents delayed recognition of gender incongruence, inability to articulate gender identity, or outside pressure to conform is not known. Despite the late presentation, many transgender persons report becoming aware of their gender incongruence well before puberty.

What is the initial approach for a patient who presents with gender incongruence?

Transgender persons present in myriad ways (14). Some may be confident in their gender identity and have clear treatment goals. Others may be less able to articulate their gender identity and may benefit from greater support from mental health providers. Finally, some are clear about their gender identity but less clear about their desire for medical intervention to align their identity and appearance. This last group may benefit from guidance from both mental health providers and providers who can help set expectations about medical interventions.

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15. Lambda Legal. Accessing Coverage for Transition-Related Health Care. Accessed at www.lambdalegal.org/know-your-rights/article/trans-health-care on 27 December 2018.
16. World Health Organization. ICD-11: Classifying disease to map the way we live and die. Geneva: World Health Organization; 2018. Accessed at www.who.int/health-topics/international-classification-of-diseases on 27 December 2018.
17. Saraswat A, Weinand JD, Safer JD. Evidence supporting the biologic nature of gender identity. *Endocr Pract.* 2015;21:199-204. [PMID: 25667367]
18. Safer JD, Tangpricha V. Out of the shadows: it is time to mainstream treatment for transgender patients. *Endocr Pract.* 2008;14:248-50. [PMID: 18308667]
19. Meyer-Bahlburg HF. Gender identity outcome in female-raised 46,XY persons with penile agenesis, cloacal extrophy of the bladder, or penile ablation. *Arch Sex Behav.* 2005;34:423-38. [PMID: 16010465]
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Criteria for Establishing That a Patient Is Transgender or Gender Incongruent*

Persistent gender identity that does not align with sex recorded at birth

Capacity to make medical decisions

Potential confounding mental health conditions are addressed

*From reference 28.

21. Heylens G, De Cuypere G, Zucker KJ, et al. Gender identity disorder in twins: a review of the case report literature. *J Sex Med.* 2012;9:751-7. [PMID: 22146048]
22. Dessens AB, Slijper FM, Drop SL. Gender dysphoria and gender change in chromosomal females with congenital adrenal hyperplasia. *Arch Sex Behav.* 2005;34:389-97. [PMID: 16010462]
23. Mazur T. Gender dysphoria and gender change in androgen insensitivity or micropenis. *Arch Sex Behav.* 2005;34:411-21. [PMID: 16010464]
24. Zosuls KM, Ruble DN, Tamis-Lemonda CS, et al. The acquisition of gender labels in infancy: implications for gender-typed play. *Dev Psychol.* 2009;45:688-701. [PMID: 19413425]
25. Rider GN, McMorris BJ, Gower AL, et al. Health and care utilization of transgender and gender nonconforming youth: a population-based study. *Pediatrics.* 2018;141. [PMID: 29437861]
26. Steensma TD, Biemond R, de Boer F, et al. Desisting and persisting gender dysphoria after childhood: a qualitative follow-up study. *Clin Child Psychol Psychiatry.* 2011;16:499-516. [PMID: 21216800]
27. Rosenthal SM. Approach to the patient: transgender youth: endocrine considerations. *J Clin Endocrinol Metab.* 2014;99:4379-89. [PMID: 25140398]
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29. Brown GR, Jones KT. Mental health and medical health disparities in 5135 transgender veterans receiving healthcare in the Veterans Health Administration: a case-control study. *LGBT Health.* 2016;3:122-31. [PMID: 26674598]
30. Safer DL, Bullock KD, Safer JD. Obsessive-compulsive disorder presenting as gender dysphoria/gender incongruence: a case report and literature review. *AAACE Clin Case Rep.* 2016;2:e268-e271.

In the clinical setting, transgender identity can be established on the basis of history alone (**Box**). The patient should have persistent gender incongruence and the capacity to make treatment decisions (28). The clinician should also address mental health conditions that may confound the determination. The requirement for persistence does not have a specific time frame, but multiyear histories extending as far back as childhood are typical. Development of gender incongruence over shorter periods (for example, not measured in years) should prompt further exploration of underlying factors and individual goals. Transgender persons have higher rates of anxiety, depression, and suicidality (29), so clinicians should be alert to signs and symptoms of these conditions.

For assessment, relevant mental health conditions are those that would interfere with reliable history taking. For example, there have been reports of patients presenting as transgender who had obsessive compulsive disorder (30) or well-masked psychoses rather than true gender incongruence. Transgender per-

sons can certainly experience obsessions, compulsions, and psychoses, and in such instances, a multidisciplinary approach to assessment and care that involves a mental health provider would be prudent.

Although the Endocrine Society guidelines (31) state a preference for involvement of mental health providers in transgender determination for adults, they acknowledge that any sufficiently knowledgeable provider can make this determination. The provider should be knowledgeable enough to be able to identify mental health conditions that might confound the assessment or should refer the patient to a mental health provider who can help address this. Although the criteria for determining whether someone is transgender are the same for children and adolescents as for adults, children may articulate their gender identity in a more heterogeneous fashion. Thus, the Endocrine Society guidelines (31) recommend that assessment of children and adolescents involve a team of clinicians, including mental health professionals.

Terminology and Initial Evaluation... "Transgender" describes persons whose gender identity does not align with their sex recorded at birth, which is usually based on visible anatomy at the time. In the clinical setting, determination of transgender identity is based entirely on history. In making this determination, the provider should establish that the patient has persistent gender incongruence. The patient should be competent to make an informed decision about transgender medical interventions. For children and adolescents, a qualified pediatric or adolescent mental health provider should be involved in the assessment. For adults, the determination may be made by any provider who is sufficiently knowledgeable in transgender medicine and potential confounding mental health conditions.

CLINICAL BOTTOM LINE

How should clinicians manage transgender patients considering medical intervention?

Although precise estimates are not available, not all transgender persons seek medical intervention (32). Further, some who want intervention may postpone it because of family circumstances, work environment, insurance coverage, or other barriers. With appropriate knowledge, primary care clinicians can initiate and manage transgender medical interventions, including hormone therapy and other agents that affect hormone levels, with involvement of an endocrinologist if needed.

Before initiating hormone therapy, clinicians should confirm the patient's transgender identity and assess the appropriate timing of therapy, with consideration of both social and health issues. Patients should be informed of the potential risks and benefits of hormone therapy and the time frame for expected changes. Selected laboratory tests are recommended before initiation of therapy (such as serum potassium measurement for spironolactone treatment or complete blood count for testosterone treatment). Clinicians should be knowledgeable about routine monitoring of hormone levels and potential adverse outcomes. In the absence of transgender-specific data, routine cancer screening should be done on the basis of the tissues and organs present and guidelines for the general population.

What is the role of hormone therapy?

Transfeminine (male-to-female) hormone therapy

Many transgender women seek hormone treatment to reduce

facial hair growth, induce breast growth, and change fat and muscle to a more classically feminine distribution. Prior effects of androgens on the skeleton (height and size and shape of the hands, feet, jaw, and pelvis) and voice (including visible laryngeal prominence) will not be altered if treatment is initiated after puberty. Many transgender women require electrolysis or laser hair removal, especially if they begin hormone therapy later in life after substantial androgen exposure. Terminal facial hair continues to grow even without continued androgen stimulation. Also, some report a decrease in sexual desire with initiation of transfeminine hormone therapy.

The conventional approach is to decrease testosterone levels from the male range (10.4–34.7 nmol/L [300–1000 ng/dL]) to the female range (<1.7 nmol/L [<50 ng/dL]). Supraphysiologic doses of estrogens alone suppress androgen production via central feedback but may be associated with increased risk for thrombosis. Thus, typical regimens also include other testosterone-lowering agents so that lower estrogen doses can be administered.

Oral 17- β -estradiol is the most commonly prescribed estrogen (**Table**). The Endocrine Society does not list oral conjugated estrogens as first-line agents because they cannot be monitored with routine blood testing, a situation that may lead to unintentional supraphysiologic levels and increased thromboembolic risk. Evidence shows that the excess risk for thrombosis can be mitigated by using lower doses of oral estrogen or by using transdermal or injectable estrogen products, thus avoiding the drug's initial metabolism by the

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36. Moore E, Wisniewski A, Dobs A. Endocrine treatment of transsexual people: a review of treatment regimens, outcomes, and adverse effects. *J Clin Endocrinol Metab*. 2003;88:3467-73. [PMID: 12915619]
37. Tangpricha V, Ducharme SH, Barber TW, et al. Endocrinologic treatment of gender identity disorders. *Endocr Pract*. 2003; 9:12-21. [PMID: 12917087]
38. Manson JE, Chlebowski RT, Stefanick ML, et al. Menopausal hormone therapy and health outcomes during the intervention and extended poststopping phases of the Women's Health Initiative randomized trials. *JAMA*. 2013;310: 1353-68. [PMID: 24084921]
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Table. Hormone Regimens Used in Treatment of Transgender Patients

Category	Dosing	Mechanism of Action	Adverse Effects	Notes
Transfeminine (male-to-female) hormone therapy				
Estrogens		Direct estrogen action, and central suppression of reproductive axis to decrease testosterone levels for persons with intact testes	Increased rates of venous thromboembolism	For estrogen therapy, measure total testosterone and estradiol levels approximately every 3 mo (i.e., with dose changes) initially and approximately annually when at steady state
Oral	Initial: 1-2 mg/d Maintenance: 2-6 mg/d			
Estradiol	Initial: 1.25-2.5 mg/d Maintenance: 5-7.5 mg/d			
Conjugated estrogens	0.025-0.2 mg/d (new patch placed every 3-5 d)			Note that the Endocrine Society does not consider conjugated estrogens as first-line therapy because they contain estrogens that cannot be monitored
Transdermal: Estradiol patch	2-10 mg IM weekly or 5-30 mg IM every 2 wk			Start at low end of dose range and titrate to lowest effective dose (i.e., that achieves total testosterone level in female range)
Parenteral: Estradiol valerate				
Androgen-lowering agents				
Spironolactone	100-300 mg/d orally	Inhibition of the androgen receptor decreased testosterone and production	Hyperkalemia risk	Start with 50 mg/d and verify safety of potassium level before each dose increase
Cyproterone acetate	25-50 mg/d orally	Central suppression of reproductive axis to decrease testosterone levels for persons with intact testes	Prolactin elevation	Start at low end of dose range and titrate to lowest effective dose (i.e., that achieves total testosterone level in female range)
Leuprolide	3.75-7.5 mg IM or SQ monthly or 11.25-22.5 mg IM or SQ depot every 3 mo	Central suppression of reproductive axis to decrease testosterone levels for persons with intact testes		Second-line agent for adults
Transmasculine (female-to-male) hormone therapy				
Androgen (testosterone)		Direct action on tissues	Erythrocytosis, acne	Start at low end of dose range and titrate to physiologic total testosterone level
Parenteral				Increase dose if menses persist for >3 mo at steady state
Testosterone enanthate or cypionate	50-100 mg IM or SQ weekly or 100-200 mg IM or SQ every 2 wk			Consider dose decrease for severe acne
Testosterone undecanoate	1000 mg every 12 wk			
Transdermal or transbuccal				
Gel	50-100 mg/d			
Transdermal patch	2-8 mg/d			
Transbuccal patch	30 mg to gums every 12 h			

IM = intramuscularly; SQ = subcutaneously.

liver (33). The Endocrine Society guidelines recommend against use of ethinyl estradiol (31) because data suggest that it is especially thrombogenic (34).

Orchiectomy is the most effective means of decreasing testosterone levels, but many transgender women choose medical treatment only, particularly early in their presentation. Thus, many have intact testes and may require relatively high estrogen doses to suppress testosterone into the female range, even with an adjunct antiandrogen agent (35). The usual approach is to start the estrogen and antiandrogen therapies concurrently. Typical estrogen regimens include oral estradiol, trans-

dermal estradiol, or parenteral estradiol valerate. Patients should take only 1 estradiol formulation at a time but may switch formulations if the response in hormone levels is inadequate, if they have adverse outcomes (such as skin irritation), or if they prefer another formulation.

The 3 most commonly used adjunctive androgen-lowering agents (**Table**) are spironolactone (a potassium-sparing diuretic that blocks androgen action at its receptor and also decreases testosterone levels) (36, 37), cyproterone acetate (a progestin that is especially popular in Europe), and gonadotropin-releasing hormone (GnRH) agonist therapy. Spirono-

40. Spratt DJ, Stewart II, Savage C, et al. Subcutaneous injection of testosterone is an effective and preferred alternative to intramuscular injection: demonstration in female-to-male transgender patients. *J Clin Endocrinol Metab.* 2017;102:2349-55. [PMID: 28379417]
41. Perrone AM, Cerpolini S, Maria Salfi NC, et al. Effect of long-term testosterone administration on the endometrium of female-to-male (FtM) transsexuals. *J Sex Med.* 2009;6:3193-200. [PMID: 19570144]
42. Getahun D, Nash R, Flanders WD, et al. Cross-sex hormones and acute cardiovascular events in transgender persons: a cohort study. *Ann Intern Med.* 2018;169:205-13. [PMID: 29987313]

lactone dosing for testosterone lowering is typically higher than for control of hypertension. Cyproterone acetate suppresses gonadotropins and may serve as an androgen-receptor antagonist. GnRH agonists are effective in suppressing testosterone levels but are second-line therapy in the United States because of their high cost.

Although not recommended by the Endocrine Society, progestins, such as medroxyprogesterone acetate and micronized progesterone, can suppress gonadotropins and, therefore, testosterone secretion. Medroxyprogesterone acetate has been associated with excess cardiovascular and breast cancer risk in older postmenopausal women receiving conjugated estrogens (38).

Finasteride inhibits 5- α -reductase-2 activity and, therefore, partially inhibits conversion of testosterone to the more potent dihydrotestosterone, which targets some tissues, including the prostate and the scalp. Finasteride has little utility if testosterone levels are already in the female range (providing no substrate to generate dihydrotestosterone) and is not routinely needed in transgender women. However, it may be an option for those with higher testosterone levels who are experiencing male pattern hair loss.

After treatment for approximately 6–18 months, transgender women often report breast growth, decreased muscle mass, softer skin, decreased sexual desire, and fewer erections.

Similar to the approach used for prescribing hormone replacement for postmenopausal women, clinicians should consider the relative contraindications for estrogen therapy, such as history of breast cancer, venous thromboembolic disease, cardiovascular disease, or cerebrovascular disease. Hyperprolactinemia should be ad-

ressed before estradiol therapy is started to avoid confusion, although data do not show that the common estrogen-spirolactone regimen stimulates increased prolactin production outside the normal range (39).

Transmasculine (female-to-male) hormone therapy

Similar to transfeminine therapy, the goal for transmasculine hormone therapy is to induce physical changes in patients to match their gender identity. Testosterone is usually administered at an appropriate dose to achieve and maintain hormone levels in the normal physiologic range for men (10.4–34.7 nmol/L [300–1000 ng/dL]). Typical testosterone regimens include esters, gels, or patches (**Table**). In the United States and Europe, a long-acting testosterone (testosterone undecanoate) is available but is associated with pulmonary oil microembolism and anaphylaxis. Thus, certification via a Risk Evaluation and Mitigation Strategy is required to administer this drug in the United States. Buccal testosterone patches are also available but are not commonly prescribed because they are difficult to apply. Injectable testosterone esters may be administered subcutaneously rather than intramuscularly, and good levels are achieved with greater patient comfort (40).

For patients interested in modified regimens, possibly because they have a nonbinary identity, maximum dosing is not required. The chief concern is avoiding hypogonadism and its associated risk to bone health.

Among available testosterone preparations and routes of administration (injectables, gels, skin patches, and buccal patches), no data suggest superiority of 1 form of treatment. However, higher testosterone levels are more easily achieved with

43. Nota NM, Wiepjes CM, de Blok CJM, et al. Occurrence of acute cardiovascular events in transgender individuals receiving hormone therapy [Letter]. *Circulation*. 2019;139:1461-2. [PMID: 30776252]
44. De Sutter P. Gender reassignment and assisted reproduction: present and future reproductive options for transsexual people. *Hum Reprod*. 2001;16:612-4. [PMID: 11278204]
45. Wierckx K, Van Caenegem E, Pennings G, et al. Reproductive wish in transsexual men. *Hum Reprod*. 2012;27:483-7. [PMID: 22128292]
46. Becerra-Culqui TA, Liu Y, Nash R, et al. Mental health of transgender and gender nonconforming youth compared with their peers. *Pediatrics*. 2018;141. [PMID: 29661941]
47. Habarta N, Wang G, Mulatu MS, et al. HIV testing by transgender status at Centers for Disease Control and Prevention-funded sites in the United States, Puerto Rico, and US Virgin Islands, 2009–2011. *Am J Public Health*. 2015;105:1917-25. [PMID: 26180964]
48. Kailas M, Lu HMS, Rothman EF, et al. Prevalence and types of gender-affirming surgery among a sample of transgender endocrinology patients prior to state expansion of insurance coverage. *Endocr Pract*. 2017;23:780-6. [PMID: 28448757]
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51. Salim A, Poh M. Gender-affirming penile inversion vaginoplasty. *Clin Plast Surg*. 2018;45:343-50. [PMID: 29908622]
52. Schechter LS, Safa B. Introduction to phalloplasty. *Clin Plast Surg*. 2018;45:387-9. [PMID: 29908627]
53. Deebel NA, Morin JP, Autorino R, et al. Prostate cancer in transgender women: incidence, etiology, pathogenesis, and management challenges. *Urology*. 2017;110:166-71. [PMID: 28882782]

parenteral therapy. Serum testosterone can be measured either with peaks (24-48 hours after injection) and troughs (immediately before injection) or midway between injections. Some clinicians start with lower testosterone doses because transgender men are often smaller than other men. Testosterone gel may also be used. Because skin patches often induce pruritus, they are rarely used in practice.

After approximately 3-6 months of treatment, transgender men often report cessation of menses, deepening voice, increased muscle mass, increased acne (at least initially), and increased sexual desire. Other changes may become apparent over longer periods, such as male hair pattern (including balding depending on age and family genetic background) and clitoral enlargement. Height is not affected by hormone treatment administered after puberty.

Although guidelines (31) have suggested that practitioners consider hysterectomy for transmasculine patients to avoid cancer risk from endometrial exposure to androgen, there are no data documenting this risk (41).

How should patients receiving hormone therapy be monitored?

Transfeminine patients

The Endocrine Society guidelines suggest monitoring transgender women receiving hormone therapy approximately every 3 months during the first year (that is, with each dose adjustment). The first year of medication adjustments and monitoring should focus on achieving hormone levels in the female range (testosterone levels <1.7 nmol/L [<50 ng/dL] and estradiol levels of approximately ≤ 734 pmol/L [≤ 200 pg/mL]). Medications should be adjusted to correct the specific sex-steroid hormone level that is out of range.

For example, the testosterone-lowering medication dose should be increased for testosterone levels that remain above the female range. Likewise, for estradiol levels that are not in the female range, the estrogen dose should be altered as needed or changed to another preparation. For transgender women receiving spironolactone, potassium levels should be checked along with hormone levels to ensure that the patient is not hyperkalemic. Once the ideal concentrations of testosterone and estradiol are achieved, the Endocrine Society suggests monitoring sex-steroid hormone concentrations 1-2 times a year or whenever the dose is changed. In addition, the clinician should ask whether the patient is comfortable with the regimen or is experiencing adverse events, including mood changes.

Some practitioners also monitor estrogen-sensitive laboratory values, including triglycerides and serum prolactin. However, as previously noted, there is no evidence that the common estrogen-spironolactone regimen stimulates a clinically significant increase in prolactin production (39). Further, estradiol measurements do not reflect other estrogens that may be present (such as the multiple estrogens present in conjugated estrogen preparations as noted earlier or estrone produced hepatically after oral ingestion of estradiol).

Transmasculine patients

The Endocrine Society guidelines suggest monitoring serum testosterone levels in transmasculine patients every 3 months during the first year (with testosterone dose adjustment) and then 1-2 times per year once the patient is receiving a stable dose (31). Additional typical laboratory testing includes hematocrit, given that erythropoiesis is stimulated by testosterone.

54. Deutsch MB, Green J, Keatley J, et al; World Professional Association for Transgender Health EMR Working Group. Electronic medical records and the transgender patient: recommendations from the World Professional Association for Transgender Health EMR Working Group. *J Am Med Inform Assoc.* 2013;20:700-3. [PMID: 23631835]
55. Daniel H, Butkus R; Health and Public Policy Committee of American College of Physicians. Lesbian, gay, bisexual, and transgender health disparities: executive summary of a policy position paper from the American College of Physicians. *Ann Intern Med.* 2015;163:135-7. [PMID: 25961598] doi:10.7326/M14-2482

What adverse effects are related to hormone therapy?

Transgender hormone therapy is generally safe when prescribed under medical supervision (17). However, reports suggest that transgender women who receive hormone therapy may have increased risk for deep venous thrombosis, pulmonary embolism, stroke, and potentially myocardial infarction (42, 43). Data are insufficient to determine whether the cardiac and vascular risks are related to dose, duration of therapy, or another factor unique to transgender persons.

Clinicians should advise tobacco cessation and ensure that estradiol levels are not significantly supraphysiologic. Data from surrogate populations (33, 38) may favor reductions in estrogen dose with age along with a change to cutaneous estrogen preparations (presuming that the first pass of oral estrogens through the liver is more thrombogenic), although there are no data in transgender women.

Androgens stimulate erythropoiesis and explain the difference in hematocrit ranges between men and women. The result is that exogenous androgens can unmask polycythemic states in persons with other reasons for an increased hematocrit, such as sleep apnea. Hematocrit should be monitored with exploration of alternative explanations or treatments if it is found to be elevated. The androgen dose can be decreased as long as levels remain in the normal range and the lower dose has no adverse consequences.

How should clinicians discuss fertility with transgender patients?

Transgender patients who use hormone therapy may have limited fertility unless therapy is stopped. Those who have

gender-affirming genital reconstruction surgery that includes removal of gonads lose their reproductive potential altogether. Thus, before starting any treatment, patients should be encouraged to consider fertility issues. Before hormone treatment or surgery, transgender women may consider sperm cryopreservation (44), and transgender men may have the option of cryopreservation of oocytes or embryos (44, 45). Embryo preservation is better established, but the associated costs are high, including ovarian stimulation along with oocyte retrieval, in vitro fertilization, and storage fees.

How do treatment approaches differ for prepubescent versus older persons?

Parents of prepubescent children should seek a multidisciplinary team with expertise in assessment and management of gender-incongruent children (31). If such a team is not available, a mental health provider with expertise in this topic should be identified. No medical intervention is indicated for prepubescent youth. Because male and female youth do not have appreciable levels of either estrogen or testosterone before puberty, puberty-blocking medication would not add benefit in a prepubescent child. The child should be assessed and managed for coexisting mood disorders during this period because risk for suicide is higher than in their cisgender peers (46). A mental health provider can assist the child and family with identifying an appropriate time for a social transition (gender presentation in public). At the earliest signs of puberty (Tanner stage 2), a transgender child may start receiving relatively reversible puberty blockers, such as GnRH agonists. Under the care of a

multidisciplinary team, an adolescent with well-established gender identity may begin hormone therapy. Adolescents presenting after puberty may have little benefit from GnRH agonists and may be treated with sex-steroid hormones at the same doses as adults. Before any medical intervention, the clinician should discuss with the patient the effect of these therapies on fertility and potential approaches for preserving reproductive capability later in life.

Are there HIV-related issues that are specific to transgender patients?

Transgender persons are overrepresented among persons with HIV (47). Risk assessment must be customized rather than a single approach being applied to all transgender persons. Clinicians should counsel safe sex practices and screen for HIV, especially in transgender persons whose sexual behaviors place them at higher risk. Preexposure prophylaxis should also be provided to those at high risk.

What is the role of the psychologist or psychiatrist?

Many transgender persons have mental health conditions, such as depression and anxiety, with associated increased risk for suicide and self-harm. A psychologist or psychiatrist is often needed to manage the patient's mental health issues. In addition, some transgender patients receiving medical interventions (even those without a history of mental health issues) may require mental health support to manage the stress associated with treatment. Although there are no data to demonstrate utility, most payers require that persons who seek gender-affirming genital reconstruction surgeries have referral

letters from qualified mental health providers.

How should clinicians handle screening and disease prevention?

Clinicians should pay attention to all tissues and organs present, regardless of gender identity (for example, prostate, breast, uterus, and cervix). Absent transgender-specific data, guidelines (28, 31) suggest preventive screening based on established guidelines for the general population. Screening for osteoporosis according to established recommendations by national professional associations seems appropriate, with particular attention paid to persons who have had prolonged periods of hypogonadism. The International Society for Clinical Densitometry recommends use of the cisgender female reference range for bone density T-scores to assess fracture risk in both cisgender men and cisgender women.

Thus, no adjustment is required for transgender persons. For relative bone density Z scores, reference ranges consistent with gender identity may be used. For the latter, the reviewing clinician should consider hormone status and history for the overall bone density assessment.

When should clinicians refer transgender patients to specialists?

For adolescent patients, assessment by a multidisciplinary team

is the standard of care, and providers should refer these patients to health care providers with the appropriate training. For adult patients, primary care providers with fewer patients on their panels may find it useful to refer transgender patients to qualified mental health providers for assistance with transgender assessment and to endocrinologists for guidance on initiation of hormone therapy (if desired by the patient).

Medical Management... Primary care clinicians with sufficient knowledge of transgender medicine can determine whether patients are transgender. Although hormones are reasonably safe when monitored, clinicians should be aware of potential adverse effects. Qualified mental health providers can assist with the initial assessment as well as comanagement of any mental health conditions. Clinicians may ask for guidance from endocrinologists on prescribing and managing hormone therapy. Absent transgender-specific data, cancer surveillance and other disease prevention strategies should follow general guidelines for all tissues and organs present in the patient, regardless of gender identity.

CLINICAL BOTTOM LINE

Transgender-Specific Surgeries

Approximately half of medically treated transgender persons also seek transgender-specific surgeries (32, 48). Transgender patients typically but not always seek surgical interventions after hormone therapy. Hormone therapy before transgender-specific surgeries is not obligatory. For patients seeking transgender-specific surgeries, clinicians should have a rudimentary understanding of the options and their limitations. They should also understand the usual preparation required for these surgeries.

At the initial encounter, clinicians should discuss potential surgical plans and medical interventions. Surgical plans may shift over time, so providers should plan to

revisit surgical options with transgender patients periodically. Hormone therapy and surgery can significantly affect fertility, and patients may require time to address fertility concerns. Most surgeons follow World Professional Association for Transgender Health (WPATH) and Endocrine Society guidelines, which suggest that surgeries take place only after a year of hormone treatment (28, 31). The rationale is that patients should have a stable treatment regimen before undergoing more invasive interventions. For the rarer patients who seek surgery without hormone treatment, a different surrogate for a stable regimen might be considered, such as living in the gender role that matches the identity for a year.

As with other operations, providers should refer their patients to experienced surgeons with good outcomes in gender-affirmation procedures. Unfortunately, standards for evaluating surgeons' qualifications (such as number of surgeries) or quality of surgical outcomes do not exist. Surgical quality measures should include assessment of appearance and function. For genital surgery, quality measures should evaluate sexual and urinary function.

What surgical options are available?

Transfeminine surgeries

There are 3 categories of transgender-specific surgeries for transgender women (**Box**). Facial feminization surgeries are sometimes performed to create

more feminine features (49). Breast augmentation is another surgical option chosen by some transgender women, but there is no consensus on the optimal timing (50). Finally, some transgender women may desire genital reconstruction surgery (51).

Because facial feminization surgeries have historically been considered cosmetic, they remain uncovered by some payers even when other transgender-specific surgeries are covered. For many transgender women, especially those having medical intervention later in life when their faces show more signs of androgen exposure, facial feminization procedures are a necessary component of their care. Matching their gender identity with their anatomy that is visible to the public (for example, face and chest) can be a higher priority for some patients than anatomical changes that only the patient and his or her intimate contacts can appreciate. In addition to improving the patient's quality of life, such surgery can be necessary for their safety. Facial feminization surgeries are typically done by plastic surgeons with experience in transfeminine procedures.

Breast augmentation surgery can be more important than some realize for the same reasons as facial feminization surgery. Because breast augmentation is available to cisgender women, there are larger numbers of experienced surgeons and transgender women can anticipate fewer access barriers than with other transgender-specific surgeries.

Although some transgender women seek complete genital reconstruction, others seek more intermediate genital surgeries due to ease of care or preference. Elements of genital reconstruction surgery include bilateral orchiectomy,

Surgical Options for Transgender Patients

Transgender Women

Facial feminization surgeries
Breast augmentation
Genital reconstruction surgeries: vaginoplasty, orchiectomy

Transgender Men

Chest reconstruction surgery
Oophorectomy and/or hysterectomy
Genital reconstruction surgeries: vaginectomy, metoidioplasty, phalloplasty

penectomy, and vaginoplasty (the last of which typically involves surgical construction of a vagina, a clitoris, and labia, often using the penile skin for the vaginal lining). Genital reconstruction surgeries are highly specialized. Patients should be advised to seek specialized surgical centers with both wide transgender-specific experience and good outcomes.

Transmasculine surgeries

For transgender men, the most common transgender-specific surgery is chest reconstruction surgery (50). In one report, 93% of transgender men seeking gender-affirming surgery at a single center sought chest masculinization surgery (48). Because of the substantial overlap with other chest masculinization surgeries (for example, for gynecomastia), more surgeons are able to perform these types of surgeries than other transgender-specific surgeries. Still, providers should seek surgeons with transgender-specific experience who can address the greater volume of mammary tissue that is present in a high-quality fashion as well as the occasionally different priorities expressed by transgender men relative to cisgender men with gynecomastia.

Some transgender men choose to have some combination of oophorectomy, hysterectomy, and vaginectomy. The first 2 are the most widely available transgender-related surgeries because they follow standard gynecologic pro-

cedures. Although data are limited, a minority of transgender men are reported to undergo oophorectomy or hysterectomy in the United States (48). Most report satisfaction with cessation of menses from testosterone treatment alone.

Genital reconstruction surgeries are the least common gender-affirming surgeries because of their relatively high morbidity (52). The 2 major procedures are phalloplasty (creation of a neophallus) and metoidioplasty.

For phalloplasty, tissue from elsewhere on the body (often the forearm) is used to create a phallus to attach to the body. The scar at the donor site can be disfiguring. The neophallus may have sensation but will not have erectile function. A prosthesis can be placed for vaginal penetration if desired. Sexual function is maintained by preserving the clitoral tissue in various locations. Harvesting tissue to extend the urethra through the neophallus is common, although current techniques are often associated with urethral strictures, which require additional operations.

The classic metoidioplasty involves release of ligaments surrounding the clitoris. When coupled with extensive androgen exposure, a microphallus up to several centimeters in length can be achieved. The clitoral release should preserve sensation for good sexual function. A version of

metoidioplasty includes urethral lengthening, which increases risk for urethral strictures.

Because of the substantial complexity and the likelihood of subsequent procedures, genital reconstruction surgeries for transgender men are best performed in centers with specific expertise.

How can clinicians help with decision making regarding surgery?

Primary care providers play an important role in counseling patients about gender-affirming surgeries. They must ascertain fertility plans in advance and must also set appropriate expectations with regard to sexual function and risk for additional procedures. Chest reconstruction surgeries, hysterectomy, and oophorectomy are widely available, even outside dedicated centers. Facial feminization surgeries and feminizing genital reconstruction surgeries are well established but require experienced surgeons with specific training and focus. Masculinizing genital reconstruction surgeries carry higher risk for morbidity and revisions, and the number of qualified surgeons practicing at regional centers is limited.

What preoperative evaluations need to be done?

As with most major surgeries, any medical and mental health conditions should be optimized to the degree needed for safe surgery and recovery. In addition, for genital reconstruction surgeries, hair must be removed from the relevant body regions. Laser hair removal or electrolysis may require several sessions over multiple months. Time for such treatment must be factored into preoperative planning.

For many gender-affirming surgeries, U.S. payers require

letters from both medical and mental health providers to support the patient's plans, although there are no data showing the need for such a requirement. For surgeries that compromise fertility (such as gonadectomy or genital reconstruction surgeries), it is common for payers to require letters from 2 mental health professionals. Some payers stipulate that at least 1 of the letters come from a doctorate-level provider (such as a psychiatrist or clinical psychologist).

How should the patient's medications be managed before surgery?

Although neither data nor similar protocols exist for other operations, some surgeons require transgender women to stop estrogen treatment for several weeks immediately before and after surgery to decrease risk for perioperative thromboses. Surgical practice varies, but stopping treatment for 2-4 weeks is common.

How will the medication regimen change after surgery?

For transgender women who have had surgery that includes gonadectomy (for example, orchiectomy or vaginoplasty), the primary postoperative medication change is discontinuation of androgen-lowering medical treatment. Many providers typically decrease the estrogen dose by half with the thought that pharmacologic estrogen dosing serves in part as a testosterone-lowering method through central feedback. Absent testes, such therapy may no longer be necessary. There are no data to guide practitioners, and positions remain ad hoc.

How should patients be monitored after surgery?

Beyond monitoring hormone treatments in the usual fashion, transgender persons who have had gender-affirming surgeries may require specific follow-up.

Facial feminization and chest reconstruction surgeries do not have transgender-specific monitoring requirements. Given their complexity, genital reconstruction has postoperative practices and potential issues that should be monitored.

Transgender women who have had vaginoplasty need to use vaginal dilators regularly to maintain the patency of the neovagina. Daily use of dilators may be required during the early postoperative period, with frequency decreasing modestly over time. It also should be noted that standard vaginoplasty procedures leave the prostate in place. With substantially lower levels of circulating androgens, the prostate shrinks in transgender women, so most prostate morbidity (such as benign prostatic hypertrophy) is unlikely. However, transgender women with vaginoplasty continue to have the potential for medical conditions involving the prostate, including cancer (53). Absent transgender-specific data, surveillance and screening for prostate cancer should follow general population guidelines.

Transgender men who have had phalloplasty are at significantly increased risk for urethral stricture. Awareness of this and the potential need for urgent intervention must be part of ongoing health care.

Do patients who have had transgender-specific surgeries have special health care needs?

Providers should follow usual practice, including monitoring of hormone treatment regimens. In addition, providers should perform cancer surveillance based on the organs that are present rather than gender identity. For example, a transgender man with a uterus and cervix requires appropriate cervical cancer screening.

Transgender-Specific Surgeries... Transgender persons have many surgical options, including facial, chest, and genital procedures. Chest reconstruction surgeries, hysterectomy, and oophorectomy are widely available. Facial feminization operations and feminizing genital reconstruction surgeries are well established but require surgeons with transgender-specific experience. Masculinizing genital reconstruction procedures carry high risk for morbidity. Facial and chest operations do not have transgender-specific monitoring requirements; however, clinicians should be aware that genital reconstruction procedures carry several postoperative risks. Transgender persons require medical surveillance of tissues that are present in the body regardless of gender identity.

CLINICAL BOTTOM LINE

Is it ethical or legal for clinicians to decline to care for a patient on the basis of gender identity?

Targeting specific medical conditions for discriminatory behavior is a straightforward violation of standard professional practice. Most major medical societies are developing best practices related to transgender health care.

How should clinicians document the patient's identity in the medical record?

For many institutions in the United States, the electronic medical record (EMR) presents a barrier to optimal documentation for transgender patients (54). In order to provide a safe, respectful environment, the EMR should have the capacity to record the pronouns used by the patient in addition to their used name, their gender identity, and the organs and tissues present.

Medicolegal and Societal Issues

Typically, the gender marker (in most states, the legal sex ["F" for female and "M" for male]) and the legal name require formal government-approved changes, with processes varying widely among states. Transgender persons may present according to their gender identity long before such documentation has occurred, including using names to match their identity. In addition, they may report their gender identity as male, female, or something else (including nonbinary), requiring further flexibility for appropriate data collection. Thus, relevant demographic characteristics to collect would be legal name, used name (if different), legal sex, sex recorded on the birth certificate, gender identity, and pronoun. In addition, providers should record organs and tissues that are and have ever been present to set

the correct reminders in the system.

Organs and tissues that are present may change over time, and the medical record may need to be updated. Similarly, legal name and gender marker may be changed formally to match the used name over time, with analogous updating needed.

Are transgender medical and surgical interventions covered by insurance?

Approximately 20 states consider insurance for transgender care obligatory, with coverage details influenced by the evidence base and recommendations from established medical societies. The Patient Protection and Affordable Care Act made the obligation to provide transgender care nationwide.

Medicolegal and Societal Issues... National medical societies are unified with regard to the professional obligation of physicians to provide high-quality care to transgender persons according to current guidelines and practice. EMRs will need to be updated to correctly, safely, and respectfully record relevant medical and social details for transgender patients.

CLINICAL BOTTOM LINE

Practice Improvement

What are the elements of a successful care environment for transgender patients?

A successful care environment requires training of staff in addition to providers (**Box**). Staff should be comfortable with potential changes in names, pronouns, and physical appearance among transgender patients. Such changes may result in some identifiers not matching the older record or the insurance demographic information. Staff should be aware of these typical circumstances for transgender patients and should maintain an environment that is respectful and helpful. Part of the environment includes a change in the EMR to accommodate such shifts along with facilitating care for tissues present in patients regardless of their gender identity (54).

Clinic operations may require upgrades to improve the patient experience and to model good transgender-inclusive practice. Accommodations may require changes, including efforts to make restrooms inclusive of all gender identities.

Extra attention may be required to navigate certain circumstances to maintain respect but avoid confidentiality breaches for patients visiting the

Elements of a Successful Care Environment

Transgender-specific staff training, with annual refreshers
Transgender-specific provider training as required
Transgender-friendly environment (e.g., inclusive bathroom use policies)
EMR updated to collect legal name, used name, sex on birth certificate, gender identity, and pronouns

clinic with relatives who are unaware of certain medical details (for example, transgender adolescents whose parents are not aware of the child's gender identity).

Because transgender medicine has not been part of conventional medical training, many providers will feel more comfortable if they receive specific training, such as society-specific sessions at national meetings and formal courses provided by WPATH, before providing care to transgender patients. A near-term goal must be to integrate transgender medical care into relevant specialty training, which will eventually obviate the need for independent transgender-specific training.

What do professional organizations recommend with regard to management of transgender patients?

In its most recent position statement, the American College of

Physicians advocated for complete insurance coverage for transgender-specific health care and EMR improvements for appropriate collection of demographic data on transgender patients (55). The Endocrine Society and WPATH provide straightforward approaches to medical care for transgender patients (28, 31). For children and adolescents, the latter 2 organizations promote a multidisciplinary approach that includes both mental health professionals for assessment and medical professionals for medical interventions. For adults, clinical providers must determine that patients are persistent in their gender identity and must be versed in mental health conditions that might confound the determination. When desired, medical intervention should be managed by qualified providers who can address primary care, hormone regimens, and surgical procedures as appropriate with corresponding monitoring.

In the Clinic Tool Kit

Care of the Transgender Patient

Patient Information

www.hormone.org/diseases-and-conditions/transgender-health
Patient resources from the Endocrine Society's Hormone Health Network.

<http://transhealth.ucsf.edu/trans?page=lib-00-00>
Transgender Health Learning Center from the University of California, San Francisco, Center of Excellence for Transgender Health.

<http://transhealth.ucsf.edu/trans?page=lib-00-05>
Transgender Health Fact Sheets from the University of California, San Francisco, Center of Excellence for Transgender Health in English and Spanish.

www.glma.org/index.cfm?fuseaction=Page.viewPage&pageID=692
Ten Things Transgender Persons Should Discuss with Their Health Care Provider from the GLMA: Health Professionals Advancing LGBTQ Equality.

www.cdc.gov/lgbthealth/Transgender.htm
Patient resources from the Centers for Disease Control and Prevention.

Information for Health Professionals

www.endocrine.org/guidelines-and-clinical-practice/clinical-practice-guidelines/gender-dysphoria-gender-incongruence
2017 Clinical Practice Guideline on the Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons from the Endocrine Society.

<http://transhealth.ucsf.edu/protocols>
Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People from the University of California, San Francisco, Center of Excellence for Transgender Health.

www.wpath.org/publications/soc
Standards of Care, Version 7, from the World Professional Association for Transgender Health; free download available in 18 languages.

www.mayoclinic.org/medical-professionals/endocrinology/news/addressing-the-challenges-of-transgender-health-care/mac-20429315
Addressing the Challenges of Transgender Health Care information page from the Mayo Clinic.

In the Clinic

WHAT YOU SHOULD KNOW ABOUT CARE OF THE TRANSGENDER PATIENT

In the Clinic
Annals of Internal Medicine

What does it mean to be transgender?

Being transgender means that your gender identity differs from the sex recorded on your birth certificate. Gender identity is an internal sense of being male, female, or neither. Other common terms for this include "gender nonbinary," "gender incongruent," or "genderqueer."

Do transgender persons have special health considerations?

As a transgender man or woman, you may face challenges in accessing high-quality health care. It may be hard to find a provider who knows about transgender health issues and feels comfortable providing culturally sensitive care.

Transgender persons are at higher risk for:

- Substance abuse
- Anxiety, depression, and suicide
- Certain types of cancer
- Infections

What is gender transition?

Transitioning is the process of making physical traits match gender identity, which may occur through clothing, hairstyle, or actions and mannerisms. Some transgender persons have medical treatment to make their physical appearance match their gender identity.

What can I expect when talking to my health care provider about my gender identity?

Maybe you feel confident in your gender identity and know which steps you want to take next. Or, maybe you feel clear about your gender identity but less sure about what, if any, medical intervention you want to align your gender identity and appearance.

Either way, it is important to find a trusted health care provider who can help you manage what comes next. During your first visit, your provider will:

- Take a detailed medical history
- Ask questions to find out how long your gender identity has differed from the sex recorded on your original birth certificate
- Assess your ability to make medical decisions

Transgender persons often have mental health issues, such as depression and anxiety. If your primary care provider believes you would benefit from seeing a mental health professional, they will refer you to one.



What medical options are available to transgender persons?

Hormone therapy is often the first approach. It can be used on its own or before surgical interventions. Talk to your health care provider about the risks and benefits of hormone therapy and the time frame of expected changes.

What are the risks and considerations of hormone therapy?

Hormone therapy is generally safe when it is medically supervised. Your provider will monitor you regularly during the first year and periodically thereafter. Let your provider know if you have any serious adverse effects, including mood changes.

What surgical options are available to transgender persons?

Surgical options for transgender men include:

- Chest reconstruction surgery
- Removal of the ovaries and/or uterus
- Genital reconstruction surgery

Surgical options for transgender women include:

- Surgery to make the face appear more feminine
- Breast augmentation
- Removal of 1 or both testicles
- Genital reconstruction surgery

Surgical interventions have risks. Talk to your provider about finding a surgeon who specializes in transgender-specific surgery and any preoperative and postoperative considerations.

Questions for My Doctor

- Do you have experience caring for transgender patients?
- Are transgender medical and surgical interventions covered by my insurance?
- What are the risks and benefits of hormone therapy?
- When will I start to see changes in my body after starting hormone therapy?
- I would like to have children one day. How can I preserve my fertility?

For More Information



American College of Physicians
Leading Internal Medicine, Improving Lives

Centers for Disease Control and Prevention
www.cdc.gov/lgbthealth/transgender.htm

National LGBT Health Education Center
www.lgbthealtheducation.org/topic/transgender-health

Patient Information