No. 18-3329
UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

PRETERM-CLEVELAND; PLANNED PARENTHOOD OF SOUTHWEST OHIO REGION; WOMEN'S MEDICAL PROFESSIONAL CORPORATION; DOCTOR ROSLYN KADE; PLANNED PARENTHOOD OF GREATER OHIO,
Plaintiffs-Appellees,

v.

LANCE HIMES, DIRECTOR, OHIO DEPARTMENT OF HEALTH, KIM G. ROTHERMEL, SECRETARY, STATE MEDICAL BOARD OF OHIO, BRUCE R. SAFERIN, SUPERVISING MEMBER, STATE MEDICAL BOARD OF OHIO,
Defendants-Appellants,

JOSEPH T. DETERS, HAMILTON COUNTY PROSECUTOR; MICHAEL C. O'MALLEY, CUYAHOGA COUNTY PROSECUTOR; MATT HECK, JR., MONTGOMERY COUNTY PROSECUTOR; RON O'BRIEN, FRANKLIN COUNTY PROSECUTOR,
Defendants.

On Appeal from the United States District Court
for the Southern District of Ohio, No. 1:18-cv-00109

AMICI CURIAE BRIEF OF BIOMEDICAL ETHICISTS IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

Brandon D. Harper
O'MELVENY & MYERS LLP
7 Times Square
New York, NY 10036
Telephone: (212) 326-2000

Allison B. Smith
O'MELVENY & MYERS LLP
1625 I Street NW
Washington, DC 20006
Telephone: (202) 383-5300

Chris A. Hollinger
David S. Almeling
O'MELVENY & MYERS LLP
Two Embarcadero Center, 28th Floor
San Francisco, CA 94111-3823
Telephone: (415) 984-8700

Attorneys for Amici Curiae Biomedical Ethicists

UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

Disclosure of Corporate Affiliations and Financial Interest

Sixth Circuit
Case Number: 18-3329 Case Name: Preterm-Cleveland v. Himes

Name of counsel: Brandon D. Harper

Pursuant to 6th Cir. R. 26.1, Amici Curiae Biomedical Ethicists
Name of Party
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No.

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s/Brandon D. Harper

This statement is filed twice: when the appeal is initially opened and later, in the principal briefs, immediately preceding the table of contents. See 6th Cir. R. 26.1 on page 2 of this form.

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STATEMENT OF INTEREST[1]

Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(D), *amici curiae* (listed in the Appendix hereto) state that they are a group of physicians, other health care practitioners, and professors in various fields – including law, medicine, and public health – from universities across the United States, who teach and/or write about biomedical ethics.[2] Collectively, *amici* hold a multitude of degrees, including JDs, MDs, PhDs, and MPHs, and have decades of experience in this field. Several *amici* serve or have served on national biomedical ethics committees and/or lead university centers and institutes devoted to this subject. All *amici* have made contributions to the scholarship and thoughtful practice of medical ethics.

Amici offer this brief in support of Plaintiffs-Appellees to discuss the application of medical ethics to Ohio's H.B. 214 (the "Ohio Ban"), which amended Ohio Revised Code § 3701.79, enacted Ohio Revised Code §§ 2919.10 and 2919.101, and criminalizes the performance of an abortion where the physician has

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[1] This brief is submitted pursuant to Federal Rule of Appellate Procedure 29(a) and Sixth Circuit Rule 29 with the consent of all parties. Undersigned counsel certify that: this brief was not authored in whole or in part by counsel for any of the parties; no party or party's counsel contributed money for this brief; and no one other than *amici* and their counsel have contributed money for this brief.

[2] Institutional affiliations are provided for identification purposes only. The views expressed in this brief do not necessarily reflect the views of *amici*'s institutions.

knowledge that the woman is seeking an abortion, in whole or in part, because of an indication of fetal Down syndrome. Plaintiffs-Appellees brought suit in the Southern District of Ohio, raising a challenge to the Ohio Ban as unconstitutionally restricting a woman's right to a pre-viability abortion. The District Court issued a preliminary injunction against implementation and enforcement of the Ohio Ban.

Amici seek to advise this Court that the requirements of the Ohio Ban are inconsistent with the foundational principles of biomedical ethics. *Amici* unite in this brief to share their views based on their experience, knowledge, and teachings, in the hope they will assist this Court in its decision-making process. *Amici* all have a strong interest in ensuring that the Court's decision accurately describes the principles of medical ethics implicated by the Ohio Ban and how those principles should be applied in this case.

A number of the *amici curiae* listed in the Appendix to this brief also served as *amici curiae* in *Planned Parenthood of Indiana and Kentucky, Inc. v. Commissioner of Indiana State Department of Health*, No. 17-3163 (7th Cir. 2017), in which they submitted a brief explaining how an Indiana ban on pre-viability abortions based on a prenatal diagnosis of a fetal disability violated principles of medical ethics and threatened the patient-physician relationship. The Court of Appeals for the Seventh Circuit affirmed the district court's grant of

summary judgment for plaintiffs in that case, holding that the Indiana ban was unconstitutional.[3]

STATEMENT OF ISSUE

Whether it is consistent with medical ethics to criminalize performing a pre-viability abortion if the physician has knowledge that the woman is seeking the abortion, in whole or in part, because of an indication of fetal Down syndrome.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Ohio Ban violates four long-established and widely-accepted principles of medical ethics: patient autonomy, beneficence and non-maleficence, and justice. The ethical violations imposed by the Ohio Ban are foundational and also undermine a physician's ability to "regard responsibility to the patient as paramount."[4]

Autonomy. By prohibiting abortions based on a woman's reason for seeking the procedure, the Ohio Ban interferes with an individual woman's autonomous right, consistent with the informed-consent decision-making process and other standards of sound medical care, to make her own healthcare choices for the

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[3] *Planned Parenthood of Ind. & Ky., Inc. v. Comm'r of Ind. State Dep't of Health*, 888 F.3d 300 (7th Cir. 2018).

[4] *See* Am. Med. Ass'n, *AMA Code of Medical Ethics*, *AMA Principles of Medical Ethics*, ¶ VIII ("AMA Code of Medical Ethics"), *available at* https://www.ama-assn.org/sites/default/files/media-browser/principles-of-medical-ethics.pdf.

reasons she deems appropriate.

Beneficence and Nonmaleficence. Once a woman has consulted with her physician and made an informed decision about her health care, prohibiting the woman from having an abortion will cause hardship and an increased risk of medically-adverse consequences with no therapeutic benefit to the woman and thus no medical justification. The Ohio Ban could compel physicians to provide care in a manner that deviates from generally-accepted clinical guidelines by failing to discuss and/or discouraging the use of prenatal assessments, and it definitely would prevent physicians from acting for the benefit of their patients by providing otherwise-permissible medical services the patients seek.

Justice. Medical ethics instructs that the benefits and costs of the health care system should be equitably distributed. The Ohio Ban violates this ethical principle by requiring women to continue a pregnancy and give birth (and incur the related medical expenses) after they have concluded they are not in a position to raise a child with Down syndrome. Further, the Ohio Ban violates the principle of justice by requiring physicians to deny certain women access to an otherwise medically-appropriate procedure based on nothing more than the State's moral judgment about the results of a woman's decision-making process.

Physician-Patient Relationship. In how it undermines the principles of autonomy, beneficence and nonmaleficence, and justice, the Ohio Ban impairs

physicians' ability to carry out their obligations to their patients. Moreover, by prohibiting abortions based on patients' reasons for choosing the procedure, the Ohio Ban incentivizes both patients and physicians to withhold information from each other and thereby subverts the trust and open communication that is essential to the physician-patient relationship.

ARGUMENT

H.B. 214 makes it a fourth-degree felony to perform an abortion if the physician has knowledge that the woman is seeking the abortion, in whole or in part, because of "any . . . reason to believe that an unborn child has Down syndrome."[5] The physician will also lose his or her license to practice medicine in Ohio.[6]

Ohio asserts that its Ban will effectuate its "strong interest in safeguarding the integrity of the medical profession."[7] This assertion is incorrect because, *inter alia*, the Ohio Ban prevents physicians from respecting their patients' decisions on account of the State's moral belief that abortion is wrong in the specific situation at

[5] Ohio Rev. Code § 2919.10. Under Ohio law, a fourth-degree felony is punishable by a prison term of six to eighteen months and a maximum fine of $5,000. *Id.* §§ 2929.14(A)(4), 2929.18(A)(3)(d).

[6] Ohio Rev. Code § 2919.10(D). The State monitors compliance by requiring physicians to complete an "abortion report" for each procedure they perform, certifying that they do not have knowledge that the woman sought the abortion in whole or in part because of an indication of Down syndrome. *Id.* § 2919.101(A).

[7] *See* Defs.-Appellants Br. at 53-55.

issue. To the contrary, if the State claims to be legislating with the purpose of "safeguarding the integrity of the medical profession," its efforts must be evaluated with reference to the four basic principles of biomedical ethics, *i.e.*, patient autonomy, beneficence, nonmaleficence, and justice. As will be demonstrated below, analysis of each of these principles leads to the conclusion that the Ohio Ban does not "safeguard[]" – but rather undermines – the integrity of the medical profession.

I. The Ohio Ban Violates The Ethical Principle Of Respect For Patient Autonomy.

Respect for a patient's right to make her own decisions about her medical care, within the framework of informed consent, is a foundational principle of contemporary medical ethics and medical practice. Physicians have "the duty to protect and foster a patient's free, uncoerced choices."[8]

Patient autonomy is safeguarded by the ethical practice of informed consent, which requires comprehension (or understanding) and free consent.[9] Informed

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[8] Lois Snyder, Am. Coll. of Physicians Ethics, Professionalism, & Human Rights Comm., *American College of Physicians Ethics Manual*, 156 Annals Internal Med. 73, 74 (6th ed. 2012) ("ACP Ethics Manual"), *available at* http://annals.org/aim/fullarticle/1033289/american-college-physicians-ethicsmanual-sixth-edition.

[9] *See* Am. Coll. of Obstetricians & Gynecologists ("ACOG"), Comm. on Ethics, *Committee Opinion No. 439: Informed Consent*, at 2 (Aug. 2009, reaffirmed 2015) ("ACOG Opinion 439"), *available at* https://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co439.pdf?dmc=1&ts=20180827T1939047370. ACOG Committee Opinions represent a committee's

consent "includes freedom from external coercion, manipulation, or infringement of bodily integrity" and "freedom from being acted on by others when they have not taken account of and respected the individual's own preference and choice."[10] The physician's role is to provide the patient with accurate information in a manner sufficient for the patient to comprehend her situation and her medical options, and then to allow the patient to make a voluntary choice as to the medical intervention (or non-intervention) that is right for her.[11] That is, the physician provides adequate information to empower the patient to make informed and voluntary decisions about her medical care.[12]

To meet the standard for informed consent, a physician generally provides the patient with the diagnosis and description of the medical condition and a description of the proposed treatments or medical courses of action.[13] Within this framework, the physician ethically may provide medical recommendations

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assessment of emerging issues in obstetric and gynecologic practice and are reviewed regularly for accuracy. *See* ACOG, Clinical Guidance & Publications, *available at* https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance.

[10] ACOG Opinion 439 at 5.

[11] *See id.* at 2-3; *see also* Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* 110 (7th ed. 2013) ("*Principles of Biomedical Ethics*").

[12] *See* ACOG Opinion 439 at 2-3, 5; Jessica W. Berg et al., *Informed Consent: Legal Theory and Clinical Practice* 11, 14-18 (2d ed. 2001).

[13] *See* ACOG Opinion 439 at 3.

(without coercion or deception) and may discuss the reasons animating a patient's decision making.[14] But ultimately, the patient's autonomous decision about her medical care must be respected.[15]

Respect for a patient's autonomy is especially important when she is deciding whether to continue a pregnancy. "The physician's professional role is . . . to pursue options that comport with ***the patient's unique health needs, values, and preferences***."[16] A woman's values and preferences are particularly germane to the decision whether to terminate or continue a pregnancy, resulting in "special ethical questions in the implementation of informed consent."[17]

Physicians must ensure that their own beliefs do not unduly influence patients' decision making.[18] A physician who objects to certain reproductive

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[14] *See id.*

[15] *See* World Med. Ass'n, *WMA International Code of Medical Ethics*, *available at* https://www.wma.net/policies-post/wma-international-code-of-medical-ethics/ ("A physician shall respect a competent patient's right to accept or refuse treatment. . . . A physician shall respect the rights and preferences of patients . . . ."). The World Medical Association's central objective is to "establish and promote the highest possible standards of ethical behavior and care by physicians." World Med. Ass'n, *What We Do / Medical Ethics*, *available at* https://www.wma.net/what-we-do/medical-ethics/.

[16] ACP Ethics Manual at 86 (emphasis added).

[17] ACOG Opinion 439 at 4; *see also* Anthony R. Gregg et al., *Noninvasive Prenatal Screening for Fetal Aneuploidy, 2016 Update: A Position Statement of the American College of Medical Genetics and Genomics*, 18 Genetics in Med. 1056, 1058 (Oct. 2016) ("*Noninvasive Prenatal Screening*").

[18] ACOG Opinion 439 at 3.

services is not ethically obligated to recommend or perform them, but ***is obligated*** to inform the patient about her medical options and, if necessary, to refer the patient elsewhere to receive her chosen reproductive services "so that the patient's rights are not constrained."[19] The Ohio Ban turns this ethical obligation on its head.

The Ohio Ban imposes one particular set of values on patients and physicians, and restricts the medically-appropriate care a physician can lawfully provide. The Ban is an attempt by the State to mandate the appropriate reasons for a woman to have a pre-viability abortion, without regard to the woman's own values. By forcing a woman to continue a pregnancy against her wishes, the Ohio Ban forces the woman to take on the physical burdens and risks of pregnancy and childbirth, as well as the mental harm from compelled pregnancy, after the woman has determined she does not wish to carry her pregnancy to term.[20] In doing so, the State impairs a physician's ability to comply with the fundamental ethical principle of respect for patient autonomy.

The Supreme Court similarly has described personal choices concerning

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[19] ACP Ethics Manual at 78; *see also* ACOG Opinion 439 at 7 ("Even in the context of justified conscientious refusal, physicians must provide the patient with accurate and unbiased information about her medical options and make appropriate referrals.").

[20] As discussed in Section II, this situation is exacerbated by the Ohio Ban's failure to provide an exception when the health of the woman is at risk.

procreation and contraception as "central to personal dignity and autonomy" and therefore protected from governmental interference.[21] In *Roe v. Wade*, the Supreme Court recognized the right of a physician to consult with his patient and determine that an abortion is in the patient's medical interests, without interference from the State (when the abortion is sought prior to viability of the fetus).[22] Put differently, individuals have a right "to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[23]

In *Planned Parenthood of Southeast Pennsylvania v. Casey,* the Supreme Court likewise concluded that, with pregnancy, the "liberty of the woman is at stake in a sense unique to the human condition."[24] This finding built on the *Roe* Court's recognition of a woman's right to choose to terminate her pregnancy based on a number of factors she and her physician "will consider in consultation," including: psychological harm; burdens on mental and physical health from child care; distress from having an unwanted child; a family's inability to care for a child

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[21] *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 851 (1992).

[22] 410 U.S. 113, 163 (1973). After the first trimester, the State may regulate the abortion procedure in ways that are reasonably related to the woman's health. *Id.*

[23] *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

[24] 505 U.S. at 852 (remarking on the anxieties, physical constraints, and pain that only a woman must bear in carrying a child).

– psychologically or otherwise; and the additional difficulties of being a single mother.[25]

The Ohio Ban contravenes medical ethics by barring physicians from respecting patient autonomy for every patient who seeks to terminate her pregnancy on account of an indication that the fetus may have Down syndrome. In the district court, Ohio submitted a declaration from Dr. Dennis Sullivan, a professor at Cedarville University and Director of Trinity International University's Center for Bioethics & Human Dignity, who acknowledged that respect for patient autonomy is a core principle of medical ethics and agreed that personal autonomy means "self-rule that is free from both controlling interference by others and from limitations, such as inadequate understanding, that prevent meaningful choice."[26] Yet, freedom of self-rule is exactly what the Ohio Ban ***eliminates*** for pregnant women after a prenatal indication of Down syndrome.[27]

Ohio claims that its restraints on patient autonomy are necessary to counteract systemic bias in favor of abortion after a prenatal indication of fetal

[25] *Roe*, 410 U.S. at 153.

[26] Sullivan Decl. ¶ 21, R.25-1, PageID#154 (quotation omitted).

[27] A discussion of personal autonomy is noticeably, but perhaps not surprisingly, absent from Ohio's appellate briefing. *See* Defs.-Appellants Br. at 54 (listing beneficence, nonmaleficence, and distributive justice as principles of medical ethics, but omitting patient autonomy).

Down syndrome.[28] The State discusses government-sponsored "propaganda" from foreign countries such as Iceland, the Netherlands, and France, but cites no evidence of any such campaign in Ohio or in the United States as a whole.[29] To the contrary, according to the State, Ohio is a particularly supportive place for people with Down syndrome and their families.[30] In any event, if the State is truly concerned about the veracity of information women receive from society at large, it can use its resources to mount a public campaign that is neutral toward, or supportive of, raising a child with Down syndrome.[31] Ohio also can inform pregnant women and their families of the public resources available to assist families raising a child with Down syndrome.[32] But what the State cannot do,

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[28] *See id.* at 18-25.

[29] *See id.* at 13-18.

[30] *See id.* at 5-6.

[31] *See id.* at 50-53 (arguing that the State has a compelling interest in eliminating discrimination, including when caused by "incomplete, inaccurate, and, sometimes, offensive information," against people with Down syndrome) (quotation omitted); *see also Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2376 (2018) (noting that State of California could undertake a public-information campaign to inform women of public programs providing free or low-cost access to family planning services, prenatal care, and abortion – rather than requiring private clinics to distribute government-prescribed information on the same subjects).

[32] Indeed, this is exactly what the record below shows that physicians at Plaintiffs-Appellees' clinics already do. *See* Lappen Decl. ¶ 34, R.3-1, PageID#44. Additionally, Ohio's Department of Health creates a "Down syndrome information sheet" that must be distributed to a patient after "a test result indicating Down syndrome or a prenatal or postnatal diagnosis of Down syndrome." Ohio Rev.

under accepted principles of medical ethics, is to make the childbirth/abortion choice for the woman.

Ohio also claims its restraints on patient autonomy are necessary to counteract "pro-abortion" bias by health care professionals after a prenatal diagnosis of fetal Down syndrome – but, again, it cites no substantial evidence of any such bias in Ohio.[33] In contrast, Plaintiffs-Appellees presented specific evidence of professionally- and ethically-appropriate, non-directive discussions between Ohio health care providers and patients seeking an abortion.[34] Moreover, the American College of Medical Genetics and Genomics specifies that genetic

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Code § 3701.69. This document includes information on Down syndrome, screening and testing, and local, state, and national resources for additional information and support services. Ohio Dep't Health, Down Syndrome Fact Sheet for New and Expectant Mothers, *available at* https://www.odh.ohio.gov/~/media/ODH/ASSETS/Files/cmh/dsyndrome/Down%20Syndrome%20Fact%20Sheet%20072015.pdf (last updated Dec. 4, 2015). *See also Noninvasive Prenatal Screening* at 1062-63 (listing "available patient resources . . . that have resulted from collaborations between healthcare professional groups and advocacy organizations").

[33] *See* Defs.-Appellants Br. at 18-25. The State cites: a statistic on pregnancy terminations after prenatal detection of Down syndrome; one study (of unspecified size) that found mothers of children with Down syndrome encountered "biases" from medical professionals and caseworkers; and anecdotes of women who received incomplete information on Down syndrome. None of these show systemic bias by health care professionals in Ohio against women's choices to complete pregnancies after prenatal testing indicates Down syndrome.

[34] *See* Harvey Decl. ¶¶ 6-7, R.3-2, PageID#50; France Decl. ¶¶ 9-10, R.3-3, PageID#55-56; Kade Decl. ¶¶ 8-9, R.3-4, PageID#59.

counseling should be "client-centered and non-directive,"[35] and the National Society of Genetic Counselors likewise "supports the right of all individuals and couples to make reproductive choices," including "using information from genetic counseling and/or testing to decide whether to pursue a pregnancy."[36]

Notwithstanding these professional standards, and purportedly due to its unsubstantiated concern that some doctors in Ohio might steer patients toward a certain choice, the State of Ohio seeks to impose its moral judgment on ***all*** women who receive a prenatal indication of fetal Down syndrome – even where the patient has undeniably received accurate and complete information about the childbirth/abortion decision.[37] The Ohio Ban thus compels pregnancy for all women who, with appropriate informed consent, otherwise would not complete their pregnancy if allowed to make their own health care choices. There can be no doubt that, even if some minority of Ohio physicians might depart from applicable professional standards with respect to the counseling of women who have received

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[35] *Noninvasive Prenatal Screening* at 1057.

[36] National Society of Genetic Counselors, *Position Statements: Reproductive Freedom*, *available at* https://www.nsgc.org/p/bl/et/blogaid=35 (2010, reaffirmed May 2014).

[37] Ohio assumes, in effect, that a woman would choose to terminate a pregnancy after a prenatal indication of fetal Down syndrome only if she were unduly influenced by biased information and pressure from a health care professional. But, certainly, a woman can "rationally" decide to terminate a pregnancy in such a circumstance based on various factors, including her and her family's financial situation and support structure.

a prenatal indication of fetal Down syndrome, the Ohio Ban is not the ethically-appropriate way to address such lapses.[38]

The seriousness of criminal liability, and loss of one's license to practice medicine, for performing an abortion if a woman's choice is even minimally based on a prenatal diagnosis of fetal Down syndrome cannot be overstated. To avoid these consequences, a physician might assume that a patient's decision to abort after a prenatal indication of possible Down syndrome is, at least in part, because of that indication – even though a patient's decision to terminate a pregnancy can be animated by a number of considerations, which can also evolve over time – and refuse to perform the patient's chosen procedure as a result.[39] This is true even if the physician does not object to performing abortions, including in the case of an abortion after a prenatal diagnosis of Down syndrome, but is motivated to deny the reproductive option solely out of fear of criminal and professional liability.

By prohibiting pre-viability abortions based on the patient's reason for

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[38] As described above, there are alternative ways to address Ohio's stated concerns about "patient steering" that are consistent with the ethical principle of patient autonomy. *See supra* notes 30-31 and accompanying text. The State also can require better education of physicians regarding Down syndrome, which would facilitate unbiased decision making by patients. *See Noninvasive Prenatal Screening* at 1063 (describing resources that have been "created by respected medical organizations or medical expert consensus and can serve as useful references for medical providers").

[39] *See* Harvey Decl. ¶ 5, R.3-2, PageID#50; France Decl. ¶ 5, R.3-3, PageID#54; Lappen Decl. ¶¶ 8, 12, 37, R.3-1, PageID#38-40, 46.

seeking an abortion, the Ohio Ban denies the patient the right to act on her wishes, even when her decision is consistent with the informed consent process, and undermines the basic bioethical principle of respect for patient autonomy.

II. The Ohio Ban Violates The Ethical Principles Of Beneficence And Nonmaleficence.

As demonstrated below, threatening criminal liability and loss of one's medical license for physicians who provide the medical care their patients select through an informed-consent decision-making process, and that is otherwise compatible with accepted standards of medical practice, compels physicians to violate their ethical duties of beneficence and nonmaleficence.[40]

Physicians' duty of nonmaleficence "is the obligation not to harm or cause injury" to the patient, and dates back to the Hippocratic injunction to "do no harm."[41] The closely-related duty of beneficence is the "obligation to promote the well-being of others."[42] Beneficence, meaning to do or produce good, requires

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[40] *See* ACOG, *Statement on Abortion Reason Bans* (Mar. 10, 2016) ("*Statement on Abortion Reason Bans*"), *available at* https://www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statement-on-Abortion-Reason-Bans ("Restricting abortions on the basis of a woman's reason for needing one is not medically appropriate and endangers the health of women.").

[41] ACOG, Comm. on Ethics, *Committee Opinion No. 390: Ethical Decision Making in Obstetrics and Gynecology* at 3 (Dec. 2007, reaffirmed 2016) ("ACOG Opinion 390"), *available at* https://www.acog.org/-/media/Committee-Opinions/Committee-on-Ethics/co390.pdf?dmc=1&ts=20180827T1941166591; *see also Principles of Biomedical Ethics* at 150.

[42] ACOG Opinion 390 at 3; *see also Principles of Biomedical Ethics* at 202

physicians "to act in a way that is likely to benefit the patient."[43] The Ohio Ban impedes physicians' ability to comply with both of these duties.

Although all courses of medical treatment and care involve some degree of risk, the duty of nonmaleficence requires that physicians take due care and thereby ensure that "the goals pursued justify the risks that must be imposed to achieve those goals."[44] The ethical standard for due care is informed by the standards of care established by the medical profession, including standards for the physician's specialty.[45] As applicable here, professional standards in obstetrics and gynecology instruct that physicians should offer prenatal assessment, by screening or diagnostic testing, to all pregnant women. The American College of Obstetricians and Gynecologists explains in its clinical guidelines that "[t]he objective of prenatal genetic testing is to detect health problems that could affect the woman, fetus, or newborn and provide the patient and her obstetrician-gynecologist . . . with enough information to allow a fully informed decision about pregnancy management."[46] The guidelines also state that "[a]ll pregnant women

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("Morality requires not only that we treat persons autonomously and refrain from harming them, but also that we contribute to their welfare.").

[43] ACOG Opinion 390 at 3.

[44] *Principles of Biomedical Ethics* at 154-55.

[45] *See id.* at 155 ("By entering into the profession of medicine, physicians accept a responsibility to observe the standards specific to their profession.").

[46] ACOG, *Practice Bulletin No. 162: Prenatal Diagnostic Testing for Genetic*

should be offered prenatal assessment for aneuploidy [*i.e.*, an abnormal number of chromosomes] by screening or diagnostic testing regardless of maternal age or other risk factors," and that "[t]he option of pregnancy termination should be discussed" when the patient indicates it is an option she wants to consider.[47] It is, of course, the patient's decision to have prenatal screening or diagnostic tests, but the established standard of care is for physicians to offer them to all pregnant women.

The Ohio Ban militates against physicians' duties of beneficence and nonmaleficence by creating exceptionally powerful incentives for physicians to provide medical care below the accepted clinical standards. For instance, doctors may be discouraged from offering the recommended prenatal screening so as to avoid potentially gaining the knowledge that a woman's decision to terminate a pregnancy might be due, in however minimal part, to the results of the screening or diagnostic testing. Women may – at risk to themselves and the fetus – also be driven away from prenatal health services, to likewise prevent gaining any knowledge that could constrain their reproductive options.[48] Further, even if a

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Disorders, 127 Obstetrics & Gynecology e108 (May 2016).

[47] *Id.* at e112, e115.

[48] Rebecca B. Reingold & Lawrence O. Gostin, *Banning Abortion in Cases of Down Syndrome: Important Lessons for Advances in Genetic Diagnosis*, 319 J. Am. Med. Ass'n 2375, 2376 (2018).

woman is informed about and opts for prenatal screening/testing, physicians in Ohio might be extremely unlikely to advise their patients that terminating a pregnancy is one option after a diagnosis or indication of fetal Down syndrome because, without exception, termination based in any part on such a diagnosis or indication will result in criminal and professional liability. The Ohio Ban thus forces physicians into an untenable Hobson's Choice: either violate the widely accepted standards of prenatal medical care in their field, or risk violating Ohio law.

The Ohio Ban undermines the ethical principles of beneficence and nonmaleficence for the additional reason that it can force women to complete pregnancies against their will, leading to an increase in women's health risk (childbirth presents a greater health risk than abortion) and, potentially, emotional harm as well.[49] Remarkably, the Ohio Ban does not even have a maternal health exception that would allow a physician to perform the abortion if the primary

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[49] *See Statement on Abortion Reason Bans* ("By forcing women to carry pregnancies to term . . . these bans will compel high-risk women to endanger their lives, increasing maternal mortality. . . . And by restricting the termination of pregnancies with genetic anomalies, the bill would cause additional severe emotional pain for women and their families."). The risk of death associated with childbirth is 14 times higher than that of abortion, and the overall morbidity associated with childbirth exceeds that associated with abortion. Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215, 217 (2012).

reason was to protect the woman's health. Forcing women to forgo a safe, medically-supervised procedure and instead to pursue a medically-riskier course of action – without any therapeutic benefit for the woman – is a paradigmatic breach of the duties of nonmaleficence and beneficence.[50] And finally, "When a State severely limits access to safe and legal procedures, women in desperate circumstances may resort to unlicensed rogue practitioners, *faute de mieux*, at great risk to their health and safety."[51]

In sum, the Ohio Ban violates the ethical principles of beneficence and nonmaleficence by coercing physicians to deviate from well-accepted clinical standards in obstetrics and gynecology, preventing physicians from providing medical services that would advance the welfare of their patients, and requiring patients to continue pregnancies against their will.

III. The Ohio Ban Violates The Ethical Principle Of Justice.

In medical ethics, the principle of justice demands that physicians do their part to address inequalities in access to and quality of health care.[52] The goal of this principle is to ensure an equitable distribution of the benefits of care.[53] The

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[50] *See* Susan S. Mattingly, *The Maternal-Fetal Dyad*, Hastings Ctr. Rep., Jan.-Feb. 1992, at 13, 14, 16.

[51] *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2321 (2016) (Ginsburg, J., concurring).

[52] *See Principles of Biomedical Ethics* at 249.

[53] *Id.* at 250; *see also* ACOG Opinion 390 at 4 (describing the principle of

Ohio Ban violates the ethical principle of justice by preventing women from acting upon their assessment of their own financial, physical, and emotional abilities to raise a child with Down syndrome when making a decision as to whether or not to continue a pregnancy, and instead forcing all women who receive a prenatal diagnosis of fetal Down syndrome to carry the pregnancy to term. The Ohio Ban also violates the principle of justice by limiting access to medically-appropriate health care for certain women based on the State's moral judgment, thereby directly contradicting the medical community's commitment to ensuring equal access to care.

Raising a child with Down syndrome can, in fact, require greater financial resources than raising a child without Down syndrome. The medical costs alone for children with Down syndrome are 12-13 times higher than for children without Down syndrome.[54] Children with Down syndrome are also at greater risk for a wide range of other medical conditions, and about 50% are born with a congenital heart defect.[55] Moreover, because children with Down syndrome often need a full-

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justice as dealing with "the physician's obligation to render to a patient what is owed," and "the physician's role in the allocation of limited medical resources in the broader community").

[54] *See* Ctr. Disease Control & Prevention, *Data and Statistics: Down Syndrome*, *available at* https://www.cdc.gov/ncbddd/birthdefects/downsyndrome/data.html (updated June 27, 2017).

[55] *Id.*

time caregiver at home, one parent or family member may be prevented from working outside the home: more than 40% of families of children with Down syndrome have a family member who stopped working because of the child's needs.[56] These are facts.

Of course, children with Down syndrome, like all children, may bring great joy to their families. To repeat, children with Down syndrome may bring great joy to their families. But this does not provide ethical license for the State to make major life decisions for pregnant women and to create different rules on access to health care depending on women's reasons for their reproductive choices. Furthermore, by restricting access to abortion procedures, the Ohio Ban will no doubt lead some women to travel to other states to obtain the procedure.[57] This imposes a disproportionate burden on women who are less able to undertake such travel, due to financial constraints, limited access to transit options, and existing obligations at home and work, to name but a few factors that have no place in an equitable distribution of the benefits of the health care system.[58]

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56 *Id*.

57 *See, e.g.*, Harvey Decl. ¶ 12, R.3-2, PageID#51 (stating that Planned Parenthood of Greater Ohio will have to refer patients to an out-of-state health center if the Ohio Ban takes effect).

58 *See* Kade Decl. ¶ 11, R.3-4, PageID#60 (explaining that raising the necessary funds to travel out-of-state will "cause extreme hardship" for some patients, and will be impossible for others); France Decl. ¶ 12, R.3-3, PageID#56 (expressing concern that Preterm-Cleveland's patients, the majority of whom are

In addition, the increased caregiving required to raise a child with Down syndrome (as with any other reason for increased caregiving responsibilities on the part of a family member) can often take a significant emotional toll on families. Research has shown that the mental health of mothers is strongly influenced by their child's behavior and caregiving needs, resulting in below-average mental health scores for mothers of children with Down syndrome.[59] Although Ohio correctly notes that medical advances now provide better health outcomes for people with Down syndrome,[60] it ignores the fact that not every family is able to dedicate the time, resources, and energy that raising a child with Down syndrome continues to require, even with improved medical care.

Women who choose to continue pregnancies with a fetal diagnosis of Down syndrome should – indeed, must – be respected and supported for their choice. But it is unjust to prevent women from exercising the opposite choice based on their own assessment of their ability to bear the financial and emotional costs of raising

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low-income, will not be able to afford a trip out-of-state to get an abortion, may go to "extreme measures" to raise the necessary money for the out-of-state trip, or may resort to unsafe methods to end their pregnancies).

[59] *See* Jenny Bourke et al., *Maternal Physical and Mental Health in Children with Down Syndrome* (manuscript), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2586647/ ("Mothers of children with Down syndrome appear to experience poorer mental health and may require greater support and services to improve behaviour management skills for their child and their own psychological well-being.").

[60] *See* Defs.-Appellants Br. at 5.

a child with Down syndrome, given that they retain the right to terminate their pregnancy, pre-viability, for any other reason.

IV. The Ohio Ban Undermines The Patient-Physician Relationship.

The Ohio Ban infringes on the physician-patient relationship, a relationship of paramount importance in medical ethics[61] and the value of which has frequently been recognized by the courts.[62] An ethically-sound physician-patient relationship should involve: open and honest communication between the physician and patient; commitment of the physician to advocate for the patient and to act in the patient's best interest; provision by the physician of care that is necessary and appropriate for the health of the patient; and respect for the autonomy, privacy, and dignity of the patient.[63]

The Ohio Ban encroaches upon the physician-patient relationship because it

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[61] *See* ACP Ethics Manual at 75 ("The physician's primary commitment must always be to the patient's welfare and best interests, whether in preventing or treating illness or helping patients to cope with illness, disability, and death.").

[62] *See, e.g.*, *Roe*, 410 U.S. at 163 (ruling that, pre-viability, "the attending physician, in consultation with his patient, is free to determine, without regulation by the State, that, in his medical judgment, the patient's pregnancy should be terminated. If that decision is reached, the judgment may be effectuated by an abortion free of interference by the State."); *N.Y.C. Health & Hosps. Corp. v. N.Y. State Comm'n of Corr.*, 969 N.E.2d 765, 768 (N.Y. 2012) ("The physician-patient privilege exists to protect important policies–namely, uninhibited and candid communication between patients and medical professionals, the accurate recording of confidential information and the protection of patients' reasonable privacy expectations.")

[63] *See, e.g.*, AMA Code of Medical Ethics.

interferes with the process by which physicians advise, counsel, and assist their patients. Ethical standards dictate that a physician must use professional judgment with individualized consideration that enables each patient to make well-considered decisions about her health care. Physicians must "inform the patient about care options and alternatives, or refer the patient for such information, so that the patient's rights are not constrained."[64]

The Ohio Ban prevents physicians from fulfilling their ethical duties by disrupting the trust and open communication that is essential to the physician-patient relationship. Because the Ohio Ban prohibits physicians, on pain of criminal liability and revocation of their medical licenses, from providing abortion services to a woman if she is motivated in part by a belief that the fetus might have Down syndrome, it will inevitably make physicians hesitant to discuss all available treatment options with their patients. Physicians may decline to mention or discourage prenatal testing for reasons that have nothing to do with medical treatment, solely to minimize their own risk of criminal and professional liability if a patient gains information that leads her to choose abortion: the less physicians know about the reasons a patient chooses abortion, the less likely they are to be exposed to liability. Incentivizing the withholding of information which is

[64] ACP Ethics Manual at 78.

clinically relevant and germane to a woman's decision-making about her own medical treatment is ethically unacceptable and it undermines the physician-patient relationship.[65]

The Ohio Ban is also dangerous to the physician-patient relationship because it impedes open communication from a patient to her physician. By imposing criminal and professional liability on physicians, the Ohio Ban puts patients in a very difficult bind. If a physician advises her of the Ohio Ban, the patient interested in choosing an abortion is forced to consider withholding information from her physician.[66] Alternatively, the patient is forced to consider avoiding her regular doctors altogether and seeking treatment outside of the state, where the Ohio Ban would not apply.

In sum, by erecting a wall of distrust and reduced information-sharing

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[65] The Ohio Ban also would operate to distort the proper bounds of the physician-patient relationship if it resulted in physicians interrogating their patients on their reasons for seeking an abortion, because ethical standards require that physicians refrain from skeptically critiquing patients' reasons for choosing a procedure when the procedure itself is medically appropriate. *See* Mattingly, *supra* note 49, at 13, 15-16; ACP Ethics Manual at 75; ACOG Opinion 390 at 5-6.

[66] Creating an environment where physicians and patients cannot speak truthfully could also undermine Ohio's stated desire to discourage discrimination based on Down syndrome. For example, a woman may be coerced against her wishes to abort a fetus with indications of Down syndrome, or she might initially be inclined toward abortion based on outdated, incorrect or incomplete information about what it is like to raise a child with Down syndrome. Without an open conversation with her physician, the woman's true choice to complete the pregnancy could not be effectuated.

between physician and patient, the Ohio Ban seriously interferes with the physician-patient relationship. Medical decision-making based on lies, forbidden discussions, or a "wink and a nod" is not sound medical decision-making. As the President of the American Congress of Obstetricians and Gynecologists has said, abortion bans (like the Ohio Ban) based on the patient's reason for choosing the procedure:

> represent gross interference in the patient-physician relationship, creating a system in which patients and physicians are forced to withhold information or outright lie in order to ensure access to care. In some cases, this will come at a time when a woman's health, and even her life, is at stake, and when honest, empathetic health counseling is in order.[67]

CONCLUSION

For the foregoing reasons, *amici* join Plaintiffs-Appellees in urging this Court to affirm the district court's decision.

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[67] *Statement on Abortion Reason Bans*.

Dated: August 29, 2018

Respectfully submitted,

/s/ Brandon D. Harper

Brandon D. Harper
O'MELVENY & MYERS LLP
7 Times Square
New York, NY 10036
Telephone: (212) 326-2000
Facsimile: (212) 326-2061
bharper@omm.com

Chris A. Hollinger
David S. Almeling
O'MELVENY & MYERS LLP
Two Embarcadero Center, 28th Floor
San Francisco, CA 94111-3823
Telephone: (415) 984-8700
Facsimile: (415) 984-8701
chollinger@omm.com
dalmeling@omm.com

Allison B. Smith
O'MELVENY & MYERS LLP
1625 I Street NW
Washington, DC 20006
Telephone: (202) 383-5300
Facsimile: (202) 383-5414
allisonsmith@omm.com

Counsel for Amici Curiae Biomedical Ethicists

CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitations of Fed. R. App. P. 29(a)(5) and Fed. R. App. P. 32(a)(7)(B)(i) because it contains 6,487 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f) and Circuit Rule 32(b)(1).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared using a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14-point font.

Dated: August 29, 2018

By: *<u>/s/ Brandon D. Harper</u>*
Brandon D. Harper

Counsel for Amici Curiae Biomedical Ethicists

CERTIFICATE OF SERVICE

I, Brandon D. Harper, a member of the Bar of this Court, hereby certify that on August 29, 2018, I caused a true and correct copy of

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Dated: August 29, 2018

By: */s/ Brandon D. Harper*
Brandon D. Harper

Counsel for Amici Curiae Biomedical Ethicists

APPENDIX: *AMICI CURIAE*[1]

Paul S. Appelbaum, MD
Dollard Professor of Psychiatry, Medicine, & Law
Director, Division of Law, Ethics, and Psychiatry
Director, Center for Research on Ethical, Legal & Social Implications of Psychiatric, Neurologic & Behavioral Genetics
Department of Psychiatry
Columbia University College of Physicians & Surgeons

Alison Bateman-House, PhD, MPH, MA
Assistant Professor, Division of Medical Ethics
NYU Langone Health

Amy E. Caruso Brown, MD, MSc, MSCS
Assistant Professor of Pediatrics, Bioethics and Humanities
Center for Bioethics and Humanities
Department of Pediatrics, Division of Pediatric Hematology/Oncology
SUNY Upstate Medical University

Stephen D. Brown, MD
Associate Professor of Radiology
Director, Institute for Professionalism and Ethical Practice
Boston Children's Hospital and Harvard Medical School

Mara Buchbinder, PhD
Associate Professor
Department of Social Medicine
University of North Carolina at Chapel Hill

Alyssa M. Burgart, MD, MA
Clinical Assistant Professor
Department of Anesthesiology, Perioperative, and Pain Management
Medical Director, Clinical Ethics at Lucile Packard Children's Hospital Stanford
Stanford Center for Biomedical Ethics

---

[1] Institutional affiliations are provided for identification purposes only. The views expressed in this brief do not necessarily reflect the views of *amici*'s institutions.

Stanford University

Arthur L. Caplan, PhD
Drs. William F. and Virginia Connolly Mitty Professor of Bioethics,
Department of Population Health
Director Division of Medical Ethics
NYU Langone Health

Mildred Cho, PhD
Professor (Research) of Pediatrics (Center for Biomedical Ethics) and of
Medicine (General Medical Disciplines)
Stanford School of Medicine

Ellen Wright Clayton, MD, JD
Craig-Weaver Professor of Pediatrics
Professor of Law
Professor of Health Policy
Center for Biomedical Ethics and Society
Vanderbilt University Medical Center

Thomas I Cochrane MD, MBA
Assistant Professor of Neurology
Center for Bioethics
Harvard Medical School

Christopher Daugherty, MD
Professor of Medicine
Chair, Biological Sciences Division Institutional Review Board
The University of Chicago Medicine

Nicole M. Deming, JD, MA
Assistant Professor of Bioethics
CWRU School of Medicine

Brownsyne Tucker Edmonds, MD, MPH, MS
Associate Professor of Obstetrics & Gynecology
Indiana University School of Medicine

Ezekiel J. Emanuel, MD, PhD
Vice Provost of Global Initiatives

Chair, Department of Medical Ethics and Health Policy
Levy University Professor
Perelman School of Medicine and The Wharton School
University of Pennsylvania

Eric A. Feldman, JD, PhD
Professor of Law
Professor of Medical Ethics & Health Policy
University of Pennsylvania Law School

Robert I. Field, JD, PhD, MPH
Professor of Law and Professor of Health Management and Policy
Drexel University
Thomas R. Kline School of Law and Dornsife School of Public Health

Leonard H. Glantz, JD
Emeritus Professor of Health Law, Bioethics and Human Rights
Boston University School of Public Health

Kenneth W. Goodman, PhD, FACMI
Professor of Medicine
Director, Institute for Bioethics and Health Policy
University of Miami Miller School of Medicine

Michele Bratcher Goodwin, JD, LLM
Chancellor's Professor of Law
Director, Center for Biotechnology & Global Health Policy
University of California, Irvine School of Law

Moti Gorin, PhD, MBE
Assistant Professor
Director of Jann Benson Ethics Center
Colorado State University

Henry T. Greely, JD
Deane F. and Kate Edelman Professor of Law
Professor (by courtesy) of Genetics
Director, Center for Law and the Biosciences
Stanford University

Laura Hermer, JD LLM
Professor of Law
2017-2018 John H. Faricy Jr. Professor for Empirical Research in the Law
Mitchell Hamline School of Law

Pamela S. Hinds, PhD, RN, FAAN
The William and Joanne Conway Chair in Nursing Research
Executive Director, Department of Nursing Science, Professional Practice, and Quality Outcomes
Research Integrity Officer
Children's National Health System

Allison K. Hoffman, JD
Professor of Law
University of Pennsylvania Law School

Peter D. Jacobson, JD, MPH
Professor Emeritus of Health Law and Policy
Director, Center for Law, Ethics, and Health
University of Michigan School of Public Health

Steven Joffe, MD, MPH
Emanuel and Robert Hart Professor
Chief, Division of Medical Ethics
Department of Medical Ethics and Health Policy
Perelman School of Medicine, University of Pennsylvania

Jeffrey Kahn, PhD, MPH
Andreas C Dracopoulos Director
Johns Hopkins Berman Institute of Bioethics

Nancy E. Kass, ScD
Vice Provost for Graduate and Professional Education
Johns Hopkins University
Phoebe R. Berman Professor of Bioethics and Public Health
Johns Hopkins Berman Institute of Bioethics and
Johns Hopkins Bloomberg School of Public Health

Eric Kodish, MD
Program Director, Cleveland Clinic Fellowship in Pediatric Hematology and Oncology
Professor of Pediatrics, Lerner College of Medicine of Case Western Reserve University

Emily Largent, JD, PhD, RN
Assistant Professor of Medical Ethics and Health Policy
Perelman School of Medicine, University of Pennsylvania

Sana Loue, JD, PhD, MPH, MSSA
Vice Dean, Faculty Development and Diversity, School of Medicine
Professor, Department of Bioethics, School of Medicine
Professor, Department of Population and Quantitative Health Sciences, School of Medicine
Professor, Department of Psychiatry, School of Medicine
Professor, Center for Global Health, School of Medicine
Professor, Mandel School of Applied Social Sciences (MSASS)
Case Western Reserve University

Holly Fernandez Lynch, JD, MBe
John Russell Dickson, MD Presidential Assistant Professor of Medical Ethics
Assistant Faculty Director of Online Education
Department of Medical Ethics and Health Policy
Perelman School of Medicine, University of Pennsylvania

Karen J. Maschke, PhD
Research Scholar
The Hastings Center

Thomas Wm. Mayo, JD
Altshuler University Distinguished Teaching Professor
Professor of Law, SMU/Dedman School of Law
Adjunct Assoc. Prof., Internal Medicine,
UT-Southwestern Medical School

Michelle L. McGowan, PhD
Research Associate Professor
Ethics Center and Division of General and Community Pediatrics

Cincinnati Children's Hospital Medical Center
Departments of Pediatrics and Women's, Gender & Sexuality Studies
University of Cincinnati

Maria W. Merritt, PhD
Associate Professor
Berman Institute of Bioethics and Bloomberg School of Public Health
Johns Hopkins University

Jon F. Merz, MBA, JD, PhD
Associate Professor
Department of Medical Ethics & Health Policy
Perelman School of Medicine, University of Pennsylvania

Marsha Michie, PhD
Assistant Professor of Bioethics
Case Western Reserve University School of Medicine

Steven H. Miles, MD
Professor Emeritus of Medicine and Bioethics
University of Minnesota Medical School

Christine Mitchell RN, MS, MTS
Executive Director
Center for Bioethics
Harvard Medical Center

Stephanie Morain, PhD, MPH
Assistant Professor
Center for Medical Ethics and Health Policy
Baylor College of Medicine

Jonathan D. Moreno, PhD
David and Lyn Silfen University Professor
Department of Medical Ethics and Health Policy
Department of History and Sociology of Science
Department of Philosophy (by courtesy)
University of Pennsylvania

Thomas H. Murray, PhD
President Emeritus
The Hastings Center

Thaddeus Mason Pope, JD, PhD
Director of the Health Law Institute
Professor of Law
Mitchell Hamline School of Law

Michelle Oberman, JD, MPH
Katharine and George Alexander Professor of Law
Santa Clara University School of Law

Govind Persad, JD, PhD
Assistant Professor
University of Denver Sturm College of Law

Reed E. Pyeritz, MD, PhD
William Smilow Professor
Department: Medicine
Perelman School of Medicine, University of Pennsylvania

Steven J. Ralston, MD, MPH
Chair, Department of OB/GYN
Pennsylvania Hospital

Jessica L. Roberts, JD
Professor
Alumnae College Professor in Law
Director, Health Law & Policy Institute
University of Houston Law Center

Lainie Friedman Ross, MD, PhD
Carolyn and Matthew Bucksbaum Professor of Clinical Ethics Professor,
Departments of Pediatrics, Medicine, and Associate Director,
MacLean Center for Clinical Medical Ethics University of Chicago

Karen Rothenberg, JD, MPA
Marjorie Cook Professor of Law
University of Maryland Francis King Carey School of Law

Visiting Core Faculty
Berman Institute of Bioethics
Johns Hopkins University

Mark Rothstein, JD
Herbert F. Boehl Chair of Law and Medicine
Founding Director, Institute for Bioethics, Health Policy and Law
University of Louisville School of Medicine

Margaret L. (Gretchen) Schwarze, MD, MPP, FACS
Associate Professor of Surgery, Department of Surgery
University of Wisconsin School of Medicine and Public Health

Lois Shepherd, JD
Peter A. Wallenborn, Jr. and Dolly F. Wallenborn Professor of Biomedical Ethics
Professor of Public Health Sciences
Professor of Law
University of Virginia

Ronit Y. Stahl, PhD, MA
Assistant Professor of History
University of California, Berkeley

Robert D. Truog, MD
Frances Glessner Lee Professor of Medical Ethics, Anaesthesia, & Pediatrics
Director, Center for Bioethics, Harvard Medical School
Department of Global Health and Social Medicine
Senior Associate in Critical Care Medicine,
Department of Anesthesiology, Critical Care, and Pain Medicine, Boston Children's Hospital

Yoram Unguru, MD, MS, MA
Attending Physician
Division of Pediatric Hematology/Oncology
The Herman & Walter Samuelson Children's Hospital at Sinai
Chairman, Sinai Hospital Ethics Committee
Core Faculty, Johns Hopkins Berman Institute of Bioethics
Assistant Professor, Johns Hopkins School of Medicine

Stuart Youngner, MD
Professor, Department of Bioethics
Professor, Department of Psychiatry
Case Western Reserve University School of Medicine