# **Attachment 16**

# IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF OKLAHOMA

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Plaintiffs,

v.

Case No. 23-cv-00177-JFH-SH

GENTNER DRUMMOND, et al.,

Defendants.

# EXPERT DECLARATION OF ARMAND H. MATHENY ANTOMMARIA, MD, PhD, FAAP, HEC-C

I, Armand H. Matheny Antommaria, hereby declare and state as follows:

- 1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. I am over 18 years old, of sound mind, and in all respects competent to testify.
  - 2. I have actual knowledge of the matters stated herein.
- 3. In preparing this declaration, I reviewed Oklahoma Senate Bill No. 613 (hereafter "the ban"). In addition to this legislation and the materials cited herein, I have also relied on my years of research and other experience, as set out in my curriculum vitae (Exhibit A), in forming my opinions. The materials I have relied upon in preparing this declaration are the same types of materials that experts in my fields of study regularly rely upon when forming opinions on subjects. I may wish to supplement these opinions or the bases for them as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

#### **OVERVIEW**

- 4. I am a pediatrician and bioethicist with extensive clinical and research experience. I am the author of 41 peer-reviewed articles, which have been published in high-impact journals including the *Journal of the American Medical Association* and *Annals of Internal Medicine*, and I direct the Ethics Center at Cincinnati Children's Hospital Medical Center. I have reviewed the ban and submit this declaration to explain my disagreement with and concerns about its conclusions.
- 5. The ban singles out "[g]ender transition procedures" on children for anomalous treatment. I will refer to these procedures as gender-affirming medical care and the individuals to whom they are provided as minors or adolescents. Gender-affirming medical care is only provided to individuals who have begun puberty. <sup>1</sup> The ban prohibits healthcare professionals from providing gender-affirming medical care to minors under the threat of administrative, criminal, and civil penalties.
- 6. There is no sound medical or ethical basis for such a ban. Gender-affirming medical care is evidence-based and the evidence for it is comparable to the evidence for many other treatments in pediatrics. The potential benefits and risks of gender-affirming medical care are comparable to those of other forms of medical treatment, treatment for which parents or legal guardians are capable of providing informed consent and minor adolescents are capable of providing assent.
- 7. As a result, the ban puts clinicians in the untenable position of either following state law and violating their ethical duties to promote their patients' well-being and protect them from

<sup>&</sup>lt;sup>1</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

harm, or facing administrative, criminal, and civil penalties. Either outcome results in harm to patients.

#### **BACKGROUND AND QUALIFICATIONS**

- 8. I am the Director of the Ethics Center, the Lee Ault Carter Chair of Pediatric Ethics, and an Attending Physician in the Division of Hospital Medicine at Cincinnati Children's Hospital Medical Center ("Cincinnati Children's"). I am also a Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.
- 9. I received my medical degree from Washington University School of Medicine in St. Louis, Missouri in 2000. I received my PhD in Religious Ethics from The University of Chicago Divinity School in 2000. I completed my pediatrics residency at the University of Utah in 2003.
- 10. I have been licensed to practice medicine since 2001 and am currently licensed to practice medicine in Ohio. I have been Board Certified in General Pediatrics since 2004 and in Pediatric Hospital Medicine since the inception of this certification in 2019. I have been certified as a Healthcare Ethics Consultant since the inception of this certification in 2019.
- 11. I have extensive experience as a pediatrician and as a bioethicist. I have been in clinical practice since 2003 and 30% of my current effort is dedicated to caring for hospitalized patients. I was Chair of the Ethics Committee at Primary Children's Medical Center in Salt Lake City, Utah from 2005 to 2012 and have been Director of the Ethics Center at Cincinnati Children's since 2012. I regularly consult on the care of patients in the Transgender Health Clinic at Cincinnati Children's and participate in the Clinic's monthly multidisciplinary team meetings. I remain current with the medical and bioethics literature regarding the treatment of minors with gender dysphoria. I am also part of Cincinnati Children's team that cares for patients born with differences or disorders of sex development (DSD), also known as intersex traits. I chair Cincinnati Children's

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Fetal Care Center's Oversight Committee, which provides the Center recommendations on the use of innovative treatments and experimental interventions.

- 12. I am a member of the American Academy of Pediatrics (AAP), the American Society for Bioethics and Humanities (ASBH), the Association of Bioethics Program Directors, and the Society for Pediatric Research. I was a member of the AAP Committee on Bioethics from 2005 to 2011. I have also served as a member of ASBH's Clinical Ethics Consultation Affairs Committee from 2009 to 2014 and currently serve on its Healthcare Ethics Consultant Certification Commission.
- 13. I am the author of 41 peer-reviewed journal articles, 11 non-peer-reviewed journal articles, 6 book chapters, and 28 commentaries. My peer-reviewed journal articles have been published in high-impact journals, including the *Journal of the American Medical Association* and *Annals of Internal Medicine*. I am also an author of 17 policy statements and technical reports, including 4 as lead author, by the AAP.
- 14. I am a member of *Pediatrics*' Executive Editorial Board and its Associate Editor for Ethics Rounds. I am an active peer reviewer for many medical journals, including the *American Journal of Bioethics* and the *Journal of Pediatrics*. I am chair of the National Library of Medicine's Literature Selection Technical Review Committee. I also review abstracts for meetings of professional organizations, including the Pediatric Academic Societies and ASBH. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities*.
- 15. I have previously testified at deposition and trial in *Dylan Brandt, et al.*, v. *Leslie Rutledge, et al.*, United States District Court, Eastern District of Arkansas, Case No. 5:21-CV-00450-JM-1; at deposition in *August Dekker, et al.*, v. *Jason Weida, et al.*, United States District

Court, Northern District of Florida, Case No. 4:22-cv-00325-RH-MAF; and at deposition in *Brianna Boe, et al., and United States v. Marshall, et al.*, United States District Court, Middle District of Alabama Northern Division, Case No. 22-cv-184-LCB-CWB. I have also previously testified in the preliminary injunction phase in *Jane Doe, et al., v. Greg Abbott, et al.*, District Court of Travis County, Texas 353<sup>rd</sup> Judicial District, Case No. D-1-GN-22-000977. I am being compensated at a rate of \$400 per hour for preparation of expert declarations and reports, and for time spent preparing for or giving deposition or trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

# THE TREATMENT OF GENDER DYSPHORIA IS SUPPORTED BY EVIDENCE COMPARABLE TO THE EVIDENCE FOR MANY OTHER MEDICAL TREATMENTS

#### **Clinical Practice Guidelines**

- 16. Medical professional organizations develop clinical practice guidelines to provide clinicians with helpful, evidence-based recommendations and improve patient care and outcomes. Clinical practice guidelines are developed using systematic processes to select and review scientific evidence. Guidelines typically rate the quality of the evidence and grade the strength of recommendations.<sup>2</sup>
- 17. Clinical practice has different goals and methods from research or experimentation. Clinical practice's goal is to benefit individual patients and its method is individualized decision-making. Research's goal is to contribute to generalizable knowledge and research is conducted using formal protocols that describe its objectives and procedures.<sup>3</sup> For example, a research study

<sup>&</sup>lt;sup>2</sup> American Academy of Pediatrics Steering Committee on Quality Improvement and Management. Classifying recommendations for clinical practice guidelines. *Pediatrics*. 2004;114(3):874-877; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

<sup>&</sup>lt;sup>3</sup> National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*. The Commission; 1978.

may have restrictive inclusion and exclusion criteria for participants in order to increase the investigators' ability to draw scientifically valid conclusions. A clinician may, however, recommend a treatment to a patient who would not have been eligible for the study because the clinician believes the treatment will benefit the patient. The clinician will subsequently make recommendations about whether to modify or discontinue the treatment based on the patient's response to it.

- 18. In clinical practice guidelines, the quality of evidence has been defined as "the extent to which one can be confident that an estimate of effect is correct." Quality of evidence is based on 4 factors: study design, study quality, consistency, and directness. The Grades of Recommendation Assessment, Development and Evaluation (GRADE) system, one widely used method of grading the quality of the evidence and the strength of recommendations, distinguishes 4 levels of evidence: "high," "moderate," "low," and "very-low." These levels are relative to one another and "low" does not necessarily mean poor or inadequate. As discussed below, a recommendation in a clinical practice guideline may be based on "low" or "very low" quality evidence, not just "high" or "moderate" quality evidence.<sup>5</sup>
- 19. With respect to study design, randomized trials generally provide "high" quality evidence.<sup>6</sup> In a randomized trial, participants are randomly assigned to a treatment or a comparison group. The major benefit of a randomized trial is that it decreases the likelihood that any

<sup>&</sup>lt;sup>4</sup> Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

<sup>&</sup>lt;sup>5</sup> Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

<sup>&</sup>lt;sup>6</sup> Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

differences in the outcomes between the groups is the result of baseline differences between the groups rather than the result of the intervention.<sup>7</sup>

- Observational studies include cross-sectional and longitudinal studies. In cross-sectional studies, investigators collect data at a single point in time. A cross-sectional design permits investigators to examine potential associations between factors, but it cannot prove one factor caused the other. An example of a cross-sectional study related to gender-affirming medical care is Jack L. Turban and colleagues' analysis of data from the 2015 United States (US) Transgender Survey. The survey asked transgender adults, who were recruited through community outreach, about their demographics, past gender-affirming medical care, family support, and mental health outcomes. The investigators found that those who received pubertal suppression had lower odds of lifetime suicidal ideation compared to those who wanted treatment with pubertal suppression but did not receive it. In longitudinal studies, researchers follow individuals over time, making continuous or repeated measures. Examples of longitudinal studies include the studies of the associations between gender-affirming medical care and psychological outcomes discussed below.
- 21. The labels "high" and "low" quality evidence can be misleading if the latter is used in the colloquial sense of poor or inadequate. While randomized controlled trials are described in

<sup>&</sup>lt;sup>7</sup> Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.

<sup>&</sup>lt;sup>8</sup> Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

<sup>&</sup>lt;sup>9</sup> Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal suppression for transgender youth and risk of suicidal ideation. *Pediatrics*. 2020;145(2):e20191725.

<sup>&</sup>lt;sup>10</sup> Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023.

<sup>&</sup>lt;sup>11</sup> See, for example, de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex* 

the medical literature as "high" quality evidence and observational studies as "low" quality evidence, randomized controlled trials may not be feasible or ethical, may have intrinsic methodological limitations, or may be unavailable in some contexts. "Low" quality evidence can be sufficient to justify treatment recommendations. <sup>12</sup>

- 22. At times, it may be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; there must be uncertainty about whether the efficacy of the intervention or the control is greater. Otherwise, it would be unethical to knowingly expose trial participants to an inferior intervention or control. Trials must also be feasible; it would also be unethical to expose individuals to the risks of trial participation without the benefit of the trial generating generalizable knowledge. A randomized trial that is unlikely to find enough people to participate because they believe they might be randomized to an inferior intervention would be unethical because it could not produce generalizable knowledge due to an inadequate sample size. <sup>13</sup>
- 23. Clinical research focusing on children is less likely to use randomized trials than is clinical research for adults. Potential reasons for this disparity include the low prevalence of

Med. 2011;8(8):2276-2283.

<sup>&</sup>lt;sup>12</sup> Swiglo BA, Murad MH, Schunemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the Grading of Recommendations, Assessment, Development, and Evaluation System. *J Clin Endocrinol Metab*. 2008:93(3):666-673.

<sup>&</sup>lt;sup>13</sup> Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-2711.

childhood disease, small market share for therapeutic agents in children, low level of National Institutes of Health funding, and difficulty enrolling children in research.<sup>14</sup>

- 24. When making recommendations, the authors of guidelines consider a variety of factors; the quality of the evidence is only one factor considered in making recommendations. Other considerations include the balance between desirable and undesirable outcomes, confidence and variability in patients' values and preferences, and resource use. <sup>15</sup> The GRADE system distinguishes "strong" and "weak" recommendations; if the authors are highly confident in the balance between desirable and undesirable consequences, they make a "strong" recommendation and, if they are less confident, a "weak" recommendation. <sup>16</sup> The larger the differences between the desirable and undesirable consequences and the smaller the variability in patient values and preferences, the more likely a "strong" recommendation is warranted. "Low" quality evidence may be sufficient to make a "strong" recommendation. <sup>17</sup>
- 25. Recommendations for pediatric care made by professional associations in clinical practice guidelines are seldom based on well-designed and conducted randomized controlled trials due to their rarity. Instead, recommendations are frequently based on observational studies or, if

<sup>&</sup>lt;sup>14</sup> Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in high quality study design. *Pediatrics*. 2008;122(1):52-57.

<sup>&</sup>lt;sup>15</sup> Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490; Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

<sup>&</sup>lt;sup>16</sup> Andrews J, Guyatt G, Oxman AD, et al. GRADE guidelines: 14. Going from evidence to recommendations: The significance and presentation of recommendations. *J Clin Epidemiol*. 2013;66(7):719-725.

<sup>&</sup>lt;sup>17</sup> Andrews JC, Schunemann HJ, Oxman AD, et al. GRADE guidelines: 15. Going from evidence to recommendation-determinants of a recommendation's direction and strength. *J Clin Epidemiol*. 2013;66(7):726-735.

such studies are unavailable, expert opinion. The medical use of the term "expert opinion" in this context refers to the consensus of experts when studies are not available.

26. For example, of the 130 recommendations in the American Heart Association's guideline for Pediatric Basic and Advanced Life Support, only 1 (0.8%) is based on "high-quality evidence from more than 1 [randomized clinical trial]" and 3 (2.3%) on "moderate-quality evidence from 1 or more [randomized clinical trials]." The remainder of the recommendations were based on lower quality evidence. Among its 57 "strong" recommendations (both Class 1 and Class 3 Harm), 48 (84%) are based on "limited data" or "expert opinion." Table 1 (Exhibit B).

# **Clinical Practice Guidelines for Gender-Affirming Medical Care for Minors**

- 27. Gender-affirming medical care is not experimental in either the colloquial or the technical sense. The level of evidence supporting clinical practice guidelines recommendations regarding gender-affirming medical care for adolescents is comparable to the level of evidence supporting many other pediatric medical treatments.
- 28. Gender-affirming care for minors is not experimental in the colloquial sense of new, novel, or unproven. The first reference to the use of puberty blockers for the treatment of gender dysphoria in the medical literature was in 1998, 25 years ago. <sup>19</sup> Prospective observational trials of puberty blockers began recruiting participants in 2000. <sup>20</sup> Evidence for this this medical care will

<sup>&</sup>lt;sup>18</sup> Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. *Circulation*. 2020;142(16\_suppl\_2):S469-S523. These clinical practice guidelines use different terminology than the GRADE approach for describing the quality of the evidence and the strength of recommendations.

<sup>&</sup>lt;sup>19</sup> Cohen-Kettenis PT, van Goozen SH. Pubertal delay as an aid in diagnosis and treatment of a transsexual adolescent. *Eur Child Adolesc Psychiatry*. 1998;7(4):246-248. See also Gooren L, Delemarre-van de Waal H. The feasibility of endocrine interventions in juvenile transsexuals. *J Psychol Human Sex*. 1996;8(4):69-74.

<sup>&</sup>lt;sup>20</sup> de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*.

be discussed in greater detail below. Gender-affirming medical care is also not experimental in the technical sense; it is intended to benefit individual patients and is modified based on individual patients' responses.<sup>21</sup>

29. The Endocrine Society, an international medical organization of over 18,000 endocrinology researchers and clinicians, has published a clinical practice guideline for the treatment of gender-dysphoric/gender-incongruent persons, including pubertal suppression, sex hormone treatment, and surgery for gender confirmation. <sup>22</sup> Gender dysphoria is a medical diagnosis contained in the American Psychiatric Association's (APA's) *Diagnostic and Statistical Manual of Mental Disorders*, 5th ed, Text Revision. It is "a marked incongruence between one's experienced/expressed gender and their assigned gender" which is "associated with clinically significant distress or impairment in social, occupational, or other important areas of functioning." Gender-affirming medical care is also recommended by the World Professional Association for Transgender Health's (WPATH's) Standards of Care for the Health of Transgender and Gender Diverse People which is currently in its 8<sup>th</sup> version ("SOC-8"). <sup>24</sup> The treatments outlined in these guidelines are also endorsed by other medical professional

<sup>2011;8(8):2276-2283.</sup> 

<sup>&</sup>lt;sup>21</sup> National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research.* The Commission; 1978.

<sup>&</sup>lt;sup>22</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

<sup>&</sup>lt;sup>23</sup> American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed, Text Revision. American Psychiatric Publishing; 2022.

<sup>&</sup>lt;sup>24</sup> Coleman E, Radix AE, Bouman WP, et al. Standards of care for the health of transgender and gender diverse people, Version 8. *Int J Transgend Health*. 2022;23(Suppl 1):S1-S259.

associations including the American Academy of Family Physicians,<sup>25</sup> the AAP,<sup>26</sup> the American College of Obstetricians and Gynecologists,<sup>27</sup> the American Medical Association,<sup>28</sup> the APA,<sup>29</sup> the American Psychological Association,<sup>30</sup> and the Pediatric Endocrine Society.<sup>31</sup>

30. The Endocrine Society clinical practice guideline includes 28 recommendations: 3 (11%) are based on "moderate" and 19 (68%) are based on "low" or "very low" quality evidence.

American Academy of Family Physicians. Care for the transgender and gender nonbinary patient. Accessed January 8, 2023. Available at <a href="https://www.aafp.org/about/policies/all/transgender-nonbinary.html#:~:text=The%20American%20Academy%20of%20Family,patients%2C%20including%20children%20and%20adolescents.">https://www.aafp.org/about/policies/all/transgender-nonbinary.html#:~:text=The%20American%20Academy%20of%20Family,patients%2C%20including%20children%20and%20adolescents.</a>

<sup>&</sup>lt;sup>26</sup> Rafferty J, Committee on Psychosocial Aspects of Child and Family Health, Committee on Adolescence, et al. Ensuring comprehensive care and support for transgender and gender-diverse children and adolescents. *Pediatrics*. 2018;142(4): e20182162.

American College of Obstetricians and Gynecologists. ACOG Committee Opinion Number 823: Health care for transgender and gender diverse individuals. March 2021. Accessed January 8, 2023. Available at <a href="https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals/">https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2021/03/health-care-for-transgender-and-gender-diverse-individuals/</a>; American College of Obstetricians and Gynecologists' Committee on Gynecologic Practice and Committee on Health Care for Underserved Women. Health care for transgender and gender diverse individuals: ACOG Committee Opinion, Number 823. Obstet Gynecol. 2021;137(3):e75-e88.

<sup>&</sup>lt;sup>28</sup> American Medical Association. Removing financial barriers to care for transgender patients H-185.950. 2022. Accessed January 8, 2023. Available at <a href="https://policysearch.ama-assn.org/policyfinder/detail/H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml">https://policysearch.ama-assn.org/policyfinder/detail/H-185.950?uri=%2FAMADoc%2FHOD.xml-0-1128.xml</a>; Madara JL to McBride B. April 26, 2021. Accessed January 8, 2023. Available at <a href="https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-4-26-Bill-McBride-opposing-anti-trans-bills-Final.pdf">https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-4-26-Bill-McBride-opposing-anti-trans-bills-Final.pdf</a>.

<sup>&</sup>lt;sup>29</sup> American Psychiatric Association. Position statement on treatment of transgender (trans) and gender diverse youth. July 2020. Accessed January 8, 2023. Available at <a href="https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Position-Transgender-Gender-Diverse-Youth.pdf">https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Position-Transgender-Gender-Diverse-Youth.pdf</a>.

<sup>&</sup>lt;sup>30</sup> American Psychological Association. Transgender, gender identity, and gender expression non-discrimination. August 2008. Accessed January 8, 2023, Available at https://www.apa.org/about/policy/transgender.pdf.

<sup>&</sup>lt;sup>31</sup> Endocrine Society and Pediatric Endocrine Society. Transgender health: Position Statement. December 2020. Accessed January 8, 2023. Available at <a href="https://www.endocrine.org/advocacy/position-statements/transgender-health">https://www.endocrine.org/advocacy/position-statements/transgender-health</a>; Anton BS. Proceedings of the American Psychological Association for the legislative year 2008: Minutes of the annual meeting of the Council of Representatives. *Am Psychol.* 2009:64:372-453.

The remaining 6 (21%) recommendations are Ungraded Good Practice Statements.<sup>32</sup> Table 2 (Exhibit C).

- 31. The quality of the evidence supporting these recommendations is similar to the quality of the evidence supporting the recommendations in other Endocrine Society clinical practice guidelines for the pediatric population. For example, none of the Endocrine Society's 84 recommendations in its 2 other guidelines that focus on the pediatric population—guidelines on pediatric obesity and congenital adrenal hyperplasia—is based on "high" quality evidence. Twenty-four (29%) of the recommendations are based on "moderate," and 49 (58%) on "low" or "very low" quality evidence. The remaining recommendations (11, 13%) are Ungraded Good Practice Statements.<sup>33</sup> Table 2 (Exhibit C).
- 32. With respect to puberty-delaying medication, the Endocrine Society specifically "suggest[s] that adolescents who meet diagnostic criteria for [gender dysphoria]/gender incongruence, fulfill criteria for treatment, . . . and are requesting treatment should initially undergo treatment to suppress pubertal development."<sup>34</sup> The evidence for this recommendation includes a longitudinal study of a group of 70 transgender adolescents who were evaluated using objective measures prior to both pubertal suppression and sex hormone treatment. The mean length of time

<sup>&</sup>lt;sup>32</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

<sup>&</sup>lt;sup>33</sup> Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2018;103(11):4043-4088; Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.

<sup>&</sup>lt;sup>34</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

between the start of pubertal suppression and sex hormone treatment was 1.88 years and ranged from 0.42 to 5.06 years. The study showed statistically significant decreases in behavioral and emotional problems and depressive symptoms, and increases in general functioning.<sup>35</sup>

- treatment of central precocious puberty which the ban permits. Central precocious puberty is the premature initiation of puberty, before 8 years of age in people assigned female at birth and before 9 in people assigned male, by the central nervous system. The potential negative effects of precocious puberty include impairment of final adult height as well as antisocial behavior and lower academic achievement. There are no randomized trials evaluating the adult height of treated and untreated individuals. Most studies are observational and compare pretreatment predicted final height with actual final height. These studies have additional limitations including small sample sizes. This "low" quality evidence nonetheless is sufficient to support the use of gonadotrophin-releasing hormone agonists as treatment for central precocious puberty. The ban therefore subjects the use of puberty blockers to a double standard. There are no randomized clinical trials for the use of puberty blockers to treat precocious puberty or gender dysphoria, but the evidence is deemed sufficient for the former but not the latter.
- 34. The evidence supporting the guideline's recommendations regarding gender-affirming hormone treatment in adolescents include <u>Annelou L C de Vries</u> and colleagues' longer-term follow-up of individuals after pubertal suppression through sex hormone and gender-affirming surgical treatment. Participants' mean age at their initial assessment was 13.6 years and

<sup>&</sup>lt;sup>35</sup> See de Vries AL, Steensma TD, Doreleijers TA, Cohen-Kettenis PT. Puberty suppression in adolescents with gender identity disorder: A prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283.

<sup>&</sup>lt;sup>36</sup> Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol*. 2008;159 Suppl 1:S3-S8.

their mean age at their final assessment was 20.7 years. The researchers report the resolution of gender dysphoria and improvement in psychological functioning.<sup>37</sup>

- 35. As a result of these studies and healthcare providers' subsequent experience, randomized, placebo-controlled trials (trials that compare pharmacological treatment to no pharmacological treatment) of gender-affirming medical care are currently unethical. Potential investigators do not have equipoise between pharmacological treatment and no pharmacological treatment; they believe that pharmacological treatment is superior. It is also highly unlikely that a sufficient number of participants would enroll in randomized controlled trials for them to be informative.<sup>38</sup>
- 36. Even if such studies could be conducted ethically, they would provide a lower quality of evidence because of intrinsic limitations in their design. For example, it would be impossible to blind the investigators or the participants to whether the participants were receiving the active treatment or a placebo. They would know if participants were in the intervention or the

<sup>&</sup>lt;sup>37</sup> See de Vries AL, McGuire JK, Steensma TD, Wagenaar EC, Doreleijers TA, Cohen-Kettenis PT. Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics*. 2014;134(4):696-704. Additional longitudinal studies of the psychosocial effects of pubertal suppression to treat gender dysphoria include Costa R, Dunsford M, Skagerberg E, Holt V, Carmichael P, Colizzi M. Psychological support, puberty suppression, and psychosocial functioning in adolescents with gender dysphoria. *J Sex Med*. 2015;12(11):2206-2214 and Carmichael P, Butler G, Masic U, et al. Short-term outcomes of pubertal suppression in a selected cohort of 12- to 15-year old young people with persistent gender dysphoria in the UK. *PLoS One*. 2021;16(2):e0243894.

<sup>&</sup>lt;sup>38</sup> Chew D, Anderson J, Williams K, May T, Pang K. Hormonal treatment in young people with gender dysphoria: A systematic review. *Pediatrics*. 2018;141(4):e20173742; Reisner SL, Deutsch MB, Bhasin S, et al. Advancing methods for US transgender health research. *Curr Opin Endocrinol Diabetes Obes*. 2016;23(2):198-207.

control arm of the study due to the physical changes in their bodies, or the lack thereof, over time.

This might bias their perception of the outcomes and lower the rating of the study's quality. 39

#### OFF-LABEL USE DOES NOT SUPPORT A BAN

37. The fact that puberty blockers and gender-affirming hormone treatment are not approved by the US Food and Drug Administration (FDA) for the treatment of gender dysphoria does not support a ban. Off-label use of FDA-approved medications is legal, common, and often evidence-based. FDA approval is not required for all uses of a medication. Once the FDA has approved a medication for one indication, <sup>40</sup> thereby agreeing that it is safe (i.e., its benefits outweigh its potential risks) and effective for this intended use, as is the case with the medications at issue here, prescribers are generally free to prescribe it for other indications. <sup>41</sup> The AAP Committee on Drugs states, "[i]t is important to note that the term 'off-label' does not imply an improper, illegal, contraindicated, or investigational use" and "[t]he administration of an approved

<sup>&</sup>lt;sup>39</sup> Browner WS, Newman TB, Cummings SR, et al. *Designing Clinical Research*. 5th ed. Wolters Kluwer; 2023; Atkins D, Best D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.

<sup>&</sup>lt;sup>40</sup> According to the FDA, an indication includes several factors: the particular disease or condition or the manifestation or symptoms of the disease or condition for which the drug is approved; whether the drug is approved for treatment, prevention, mitigation, cure, or diagnosis; and the population, including age group, for which the drug is safe and effective. Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, Food and Drug Administration, U.S. Department of Health and Human Services. Indications and Usage Section of Labeling for Human Prescription Drug and Biological Products—Content and Format: Guidance for Industry. July 2018. Accessed April 29, 2022. Available at <a href="https://www.fda.gov/files/drugs/published/Indications-and-Usage-Section-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94-Content-and-Format-Guidance-for-Industry.pdf">https://www.fda.gov/files/drugs/published/Indications-and-Usage-Section-of-Labeling-for-Human-Prescription-Drug-and-Biological-Products-%E2%80%94-Content-and-Format-Guidance-for-Industry.pdf</a>. A medication approved for the treatment of asthma in adults would, for example, be prescribed off label if used to treat a different disease, like pneumonia, or a different age group, like children.

<sup>&</sup>lt;sup>41</sup> U.S. Food & Drug Administration. Understanding unapproved use of approved drugs "off label." February 5, 2018. Accessed March 23, 2022. Available at <a href="https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label">https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label</a>.

drug for a use that is not approved by the FDA is not considered research and does not warrant special consent or review if it is deemed to be in the individual patient's best interest." It further states "in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children." There are several reasons why, even if there is substantial evidence of safety and efficacy for a new indication, a sponsor may not seek FDA approval for it. These reasons include seeking approval may not be economically beneficial for the sponsor. 43

38. "Off-label" use of drugs is common in many areas of medicine, including pediatrics. For example, nafcillin, an antibiotic commonly used to treat children with invasive staphylococcal infections, such as lung or joint infections, lacks FDA approval in individuals under 18 years of age. 44 A recent study of children's hospitals found that in 28.1% of encounters, at least one off-label drug was prescribed. Examples of medications used off-label in this study included: albuterol, which is used to treat asthma; morphine, which is used to treat pain; and lansoprazole (Prevacid®), which is used to treat gastroesophageal reflux. 45 The rate of off-label use may be significantly higher in certain age groups, categories of drugs, and clinical settings. 46

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<sup>&</sup>lt;sup>42</sup> Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in children. *Pediatrics*. 2014;133(3):563-567.

<sup>&</sup>lt;sup>43</sup> Wittich CM, Burkle CM, Lanier WL. Ten common questions (and their answers) about off-label drug use. *Mayo Clin Proc.* 2012;87(10):982-990.

<sup>&</sup>lt;sup>44</sup> Nafcillin Injection, USP. February 2007. Accessed April 5, 2022. Available at https://www.accessdata.fda.gov/drugsatfda\_docs/label/2008/050655s017lbl.pdf.

<sup>&</sup>lt;sup>45</sup> See Yackey K, Stukus K, Cohen D, Kline D, Zhao S, Stanley R. Off-label medication prescribing patterns in pediatrics: An update. *Hosp Pediatr*. 2019;9(3):186-193.

<sup>&</sup>lt;sup>46</sup> Maltz LA, Klugman D, Spaeder MC, Wessel DL. Off-label drug use in a single-center pediatric cardiac intensive care unit. *World J Pediatr Congenit Heart Surg.* 2013;4(3):262-266.

# GENERALLY APPLICABLE PRINCIPLES OF INFORMED CONSENT APPLY TO PEDIATRIC GENDER-AFFIRMING MEDICAL CARE

# **Principles of Informed Consent**

- 39. Before performing any medical intervention, a healthcare provider must generally obtain an adult patient's informed consent. Informed consent is a process in which the provider discloses information, elicits the patient's preferences, offers medical advice, and seeks explicit authorization. In order to participate in the informed consent process, a patient must have medical decision-making capacity. If an adult patient lacks capacity, a proxy decision maker is generally appointed. The healthcare provider's disclosure should include the nature of the intervention and the reasons for it, as well as its potential benefits, risks, and alternatives, including the alternative of not undergoing the intervention. The patient or the patient's proxy must understand and appreciate this information and express a decision. For the informed consent to be valid, the authorization must be voluntary. Exceptions to the requirement to obtain informed consent exist, such as in the case of an emergency.<sup>47</sup>
- 40. Medical decision-making and informed consent in pediatrics is more complex than in adult medicine because it involves both minor patients and their parents or legal guardians. Parents and guardians are afforded substantial, but not unlimited, discretion in making medical decisions for their minor children based on their assessment of the individual child's best interest. They generally care about their children and best understand their children's unique needs. 48
- 41. Healthcare providers also have an ethical obligation to include children in medical decision-making to the extent that it is developmentally appropriate. For example, a provider

<sup>&</sup>lt;sup>47</sup> Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 6th ed. Oxford University Press; 2009.

<sup>&</sup>lt;sup>48</sup> Diekema DS. Parental refusals of medical treatment: The harm principle as threshold for state intervention. *Theor Med Bioeth.* 2004;25(4):243-264.

examining a toddler for a possible ear infection should not ask a toddler for permission to look in the child's ear because the provider intends to look even if the child says no. The provider could, however, ask the toddler which ear the child would like to have looked in first. As a minor becomes older, the minor should participate more actively in medical decision-making and the minor's assent should be sought. In early adolescence, individuals typically have developed a sense of identity, individual values and preferences, and are developing medical decision-making capacity. Capacity entails the ability to (i) understand the indications and the potential benefits, risks, and alternatives to a treatment, including declining treatment; (ii) appreciate the implications of a treatment decision for their own lives; (iii) evaluate the potential benefits and risks; and (iv) express a preference. Adolescents generally possess comparable medical decision-making capacity to adults. Louis A. Weithorn and Susan B. Campbell, for example, found that 14-year-olds performed similarly to adults with respect to their ability to understand and reason about treatment information.

42. The current treatment paradigm for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and assent. The Endocrine Society clinical practice guideline extensively discusses the potential benefits, risks, and alternatives to treatment, and its recommendations regarding the timing of interventions are based in part on the treatment's potential risks and the adolescent's decision-making capacity. The guideline recommends that the informed consent process for puberty

<sup>&</sup>lt;sup>49</sup> Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. *Pediatrics*. 2016;138(2):e20161485; Kon AA, Morrison W. Shared decision-making in pediatric practice: A broad view. *Pediatrics*. 2018;142(Suppl 3):S129-S132.

<sup>&</sup>lt;sup>50</sup> Weithorn LA, Campbell SB. The competency of children and adolescents to make informed treatment decisions. *Child Dev.* 1982;53(6):1589-1598.

blockers and sex hormones include a discussion of the implications for fertility and options for fertility preservation. The Endocrine Society clinical practice guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes, until an adolescent is developmentally capable of providing informed consent. Lieke Vrouenraets and colleagues found most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding puberty blockers. 52

# Gender-Affirming Medical Care's Benefits, Risks, and Alternatives

- 43. The potential benefits of gender-affirming medical care include improved physical and psychological outcomes. Starting pubertal suppression in early puberty prevents adolescents with gender dysphoria from developing secondary sex characteristics inconsistent with their gender identity, which can be extremely distressing for them, and that may be difficult, if not impossible, to eliminate once the characteristics have fully developed. Sex hormone therapy results in the development of secondary sex characteristics consistent with individuals' gender identity. Potential psychological benefits include increased quality of life and decreased depression, suicidal ideation and suicide attempts, and anxiety. <sup>53</sup>
- 44. As with all medical treatments, gender-affirming medical care entails risks. One of the potential risks is negative effects on fertility but this risk should not be overstated. Puberty blockers do not, by themselves, permanently impair fertility. Children with central precocious

<sup>&</sup>lt;sup>51</sup> See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2017;102(11):3869-3903.

<sup>&</sup>lt;sup>52</sup> Vrouenraets L, de Vries ALC, de Vries MC, van der Miesen AIR, Hein IM. Assessing medical decision-making competence in transgender youth. *Pediatrics*. 2021;148(6): e2020049643.

<sup>&</sup>lt;sup>53</sup> See, for example, Baker KE, Wilson LM, Sharma R, Dukhanin V, McArthur K, Robinson KA. Hormone therapy, mental health, and quality of life among transgender people: A systematic review. *J Endocr Soc.* 2021;5(4):1-16.

puberty are routinely treated with puberty blockers and have typical fertility in adulthood.<sup>54</sup> These medications are also used for fertility preservation in individuals being treated for cancer.<sup>55</sup>

- 45. While treatment for gender dysphoria with gender-affirming hormones may impair fertility, this is not universal and may also be reversible. There are transgender men who became pregnant while on or after discontinuing testosterone therapy. <sup>56</sup> Transgender men and women are also capable of producing eggs and sperm respectively both during and after the discontinuation of gender-affirming hormone treatment. <sup>57</sup>
- 46. Additionally, offering individuals considering gender-affirming medical care methods to potentially preserve their fertility is a component of the clinical practice guidelines discussed above.<sup>58</sup>
- 47. The risk of infertility is also not unique to treatment for gender dysphoria. For example, parents and legal guardians consent to the treatment of nonmalignant medical conditions

<sup>56</sup> Light AD, Obedin-Maliver J, Sevelius JM, Kerns JL. Transgender men who experienced

Vlahakis E, et al. Successful restoration of spermatogenesis following gender-affirming hormone therapy in transgender women. *Cell Rep Med.* 2023;4(1):100858.

<sup>&</sup>lt;sup>54</sup> Lazar L, Meyerovitch J, de Vries L, Phillip M, Lebenthal Y. Treated and untreated women with idiopathic precocious puberty: Long-term follow-up and reproductive outcome between the third and fifth decades. *Clin Endocrinol* (Oxf). 2014;80(4):570-576.

<sup>&</sup>lt;sup>55</sup> Valsamakis G, Valtetsiotis K, Charmandari E, Lambrinoudaki I, Vlahos NF. GnRH analogues as a co-treatment to therapy in women of reproductive age with cancer and fertility preservation. *Int J Mol Sci.* 2022;23(4):2287.

pregnancy after female-to-male gender transitioning. *Obstet Gynecol*. 2014;124(6):1120-1127. <sup>57</sup> Leung A, Sakkas D, Pang S, Thornton K, Resetkova N. Assisted reproductive technology outcomes in female-to-male transgender patients compared with cisgender patients: A new frontier in reproductive medicine. *Fertil Steril*. 2019;112(5):858-865; de Nie I, van Mello NM,

<sup>&</sup>lt;sup>58</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

for their minor children, including some rheumatologic disorders and hematologic conditions, which may impair fertility.<sup>59</sup>

- 48. While transgender adolescents have higher rates of depression, anxiety, suicidal ideation, and suicide attempts, there are no studies indicating that those higher rates are caused by, or exacerbated by, gender-affirming medical care. Rather, contributing factors include conflict between one's appearance and identity, stigma, and rejection. As discussed above, the available evidence indicates that gender-affirming care improves, rather than worsens, psychological outcomes.
- 49. Finally, not knowing all potential harmful effects associated with a medication is not a sufficient reason for the FDA to not approve a medication, let alone a state to ban it. The FDA requires post-marketing surveillance of medications' adverse effects because the clinical trials on which the approvals are based cannot identity all possible side effects.<sup>62</sup>
- 50. In determining whether the benefits of treatment outweigh the risks, medical providers and patients must also consider the potential alternatives including not providing or receiving the treatment. As stated above, prior to the initiation of gender-affirming medical care, many individuals with gender dysphoria have significant, unresolved symptoms that treatment

<sup>&</sup>lt;sup>59</sup> Hirshfeld-Cytron J, Gracia C, Woodruff TK. Nonmalignant diseases and treatments associated with primary ovarian failure: An expanded role for fertility preservation. *J Womens Health (Larchmt)*. 2011;20(10):1467-1477.

<sup>&</sup>lt;sup>60</sup> Haas AP, Eliason M, Mays VM, et al. Suicide and suicide risk in lesbian, gay, bisexual, and transgender populations: Review and recommendations. *J Homosex.* 2011;58(1):10-51.

<sup>&</sup>lt;sup>61</sup> Bauer GR, Scheim AI, Pyne J, Travers R, Hammond R. Intervenable factors associated with suicide risk in transgender persons: A respondent driven sampling study in Ontario, Canada. *BMC Public Health*. 2015;15:525.

<sup>&</sup>lt;sup>62</sup> U.S. Food & Drug Administration. Postmarketing Surveillance Programs. April 2, 2020. Accessed February 26, 2023. Available at

improves. Without medical treatment, these symptoms would persist. The assertion that psychotherapy alone is sufficient to treat gender dysphoria in adolescents is only supported by anecdotal evidence. <sup>63</sup>

# The Risks and Benefits of Gender-Affirming Medical Care are Comparable to Those of Other Medical Care to which Parents and Guardians May Consent

- 51. Medical care for minors can require weighing potential benefits and risks in the face of uncertainty. There is nothing unique about gender-affirming medical care that justifies singling out this medical care for prohibition and criminalization based on concern for adolescents' inability to assent or parents or guardians' inability to consent. Medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of adolescents, their parents or guardians, and their healthcare providers.
- 52. The potential risks of gender affirming medical care are comparable to the risks parents and adolescents are permitted to assume in numerous other treatment decisions, including decisions explicitly authorized by this legislation. Parents of children with some types of malignancies may choose treatments that may damage their children's gonads and result in infertility. <sup>64</sup> Individuals with some types of DSDs, such as complete androgen insensitivity syndrome, are treated with sex hormones, which have comparable risks to the use of these treatments in persons with gender dysphoria. <sup>65</sup> And, parents of children with some types of DSDs

<sup>&</sup>lt;sup>63</sup> See, for example, Levine SB. Transitioning back to maleness. *Arch Sex Behav*. 2018;47(4):1295-1300.

<sup>&</sup>lt;sup>64</sup> Delessard M, Saulnier J, Rives A, Dumont L, Rondanino C, Rives N. Exposure to chemotherapy during childhood or adulthood and consequences on spermatogenesis and male fertility. *Int J Mol Sci.* 2020;21(4):1454; Blumenfeld Z. Chemotherapy and fertility. *Best Pract Res Clin Obstet Gynaecol.* 2012;26(3):379-390.

<sup>&</sup>lt;sup>65</sup> Lanciotti L, Cofini M, Leonardi A, Bertozzi M, Penta L, Esposito S. Different clinical presentations and management in complete androgen insensitivity syndrome (CAIS). *Int J Environ Res Public Health*. 2019;16(7):2168.

may choose to have their children's gonads removed due to the possible elevated risk of malignancy, which causes infertility.<sup>66</sup> It is also my understanding that the ban permits gender-affirming medical treatment of individuals with DSDs, which has similar risks to the use of this treatment in individuals who do not have DSDs. The types of risks present for breast reduction surgery, which may be performed for cosmetic reasons or to reduce physical discomfort, are similar to those of chest surgery to treat gender dysphoria.<sup>67</sup>

### **Potential Regret Does Not Support a Ban**

- 53. Patients experiencing regret as a result of any medical treatment is profoundly unfortunate and such individuals should be provided support and additional treatment as needed. Patients expressing regret over having received a certain kind of medical care, gender-affirming or other medical care, however, does not justify banning that medical care.
- 54. While there are individuals who received gender-affirming medical care as minors who express regret, the available studies report that rates of regret are very low. For example, Chantal M. Wiepjes and colleagues report that 0.6% of transgender women and 0.3% of transgender men who had their gonads removed experienced regret. Similarly, R. Hall and colleagues report regret was specifically documented in 1.1% of adult gender-diverse patients. Banning gender-affirming medical care to prevent regret in a small minority of patients would

<sup>&</sup>lt;sup>66</sup> Abaci A, Catli G, Berberoglu M. Gonadal malignancy risk and prophylactic gonadectomy in disorders of sexual development. *J Pediatr Endocrinol Metab*. 2015;28(9-10):1019-1027.

<sup>&</sup>lt;sup>67</sup> Manahan MA, Buretta KJ, Chang D, Mithani SK, Mallalieu J, Shermak MA. An outcomes analysis of 2142 breast reduction procedures. *Ann Plast Surg.* 2015;74(3):289-292.

<sup>&</sup>lt;sup>68</sup> Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med*. 2018;15(4):582-590.

<sup>&</sup>lt;sup>69</sup> Hall R, Mitchell L, Sachdeva J. Access to care and frequency of detransition among a cohort discharged by a UK national adult gender identity clinic: Retrospective case-note review. *BJPsych Open.* 2021;7(6):e184.

result in harm to the majority of patients who benefit. Support and services should nonetheless be provided to individuals who experience regret.

55. The potential for regret is also not unique to gender-affirming medical care. Ironically, at the same time that Oklahoma prohibits gender-affirming medical care for minors, the statute expressly allows doctors to perform irreversible genital surgeries on infants and children with DSDs at ages when they are unable to meaningfully participate in medical decision-making. The evidence base for these surgeries is poor and they are highly controversial when performed at such an early age. <sup>70</sup> Parents of children who have undergone feminizing genitoplasty and hypospadias repair have experienced regret over their decisions. <sup>71</sup> For example, Rachel S. Fisher and colleagues found that 38% of caregivers of infants with congenital adrenal hyperplasia reported some level of regret about their child's genital surgery. <sup>72</sup>

# THE INCREASED PREVALENCE OF GENDER-AFFIRMING CARE DOES NOT SUPPORT A BAN

56. The increased number of transgender individuals and those receiving medical treatment does not justify a ban. The causes of these changes are likely to be multifactorial including increased social acceptance of transgender individuals and availability of gender-affirming medical care. <sup>73</sup> Changes in demographics are not unique to gender dysphoria and have

<sup>&</sup>lt;sup>70</sup> Jesus LE. Feminizing genioplasties: Where are we now? *J Pediatr Urol*. 2018;14(5):407-415; Frader J, Alderson P, Asch A, et al. Health care professionals and intersex conditions. *Arch Pediatr Adolesc Med*. 2004;158(5):426-428.

<sup>&</sup>lt;sup>71</sup> Fisher RS, Espeleta HC, Baskin LS, et al. Decisional regret about surgical and non-surgical issues after genitoplasty among caregivers of female infants with CAH. *J Pediatr Urol*. 2022;18(1):27-33; Vavilov S, Smith G, Starkey M, Pockney P, Deshpande AV. Parental decision regret in childhood hypospadias surgery: A systematic review. *J Paediatr Child Health*. 2020;56(10):1514-1520.

<sup>&</sup>lt;sup>72</sup> Fisher RS, Espeleta HC, Baskin LS, et al. Decisional regret about surgical and non-surgical issues after genitoplasty among caregivers of female infants with CAH. *J Pediatr Urol*. 2022;18(1):27-33.

<sup>&</sup>lt;sup>73</sup> Wiepjes CM, Nota NM, de Blok CJM, et al. The Amsterdam Cohort of Gender Dysphoria

been seen in other conditions such as autism spectrum disorder and childhood-onset type 1 diabetes.<sup>74</sup> These changes are a justification for further research on gender-affirming medical care rather than prohibiting these treatments and thereby preventing further research on them.

#### TREATMENT PROTOCOLS IN EUROPE DO NOT SUPPORT A BAN

57. Some have pointed to the actions of European health authorities as support for banning gender-affirming medical care.<sup>75</sup> It is difficult to evaluate the actions of the Swedish and Finnish health authorities because all of the relevant material is not available in official English translations. While some of these authorities have conducted systematic reviews of the evidence, none have developed a formal clinical practice guideline. While both systematic reviews and clinical practice guidelines ideally grade the quality of the evidence, only clinical practice

Study (1972-2015): Trends in prevalence, treatment, and regrets. *J Sex Med.* 2018;15(4):582-590.

<sup>&</sup>lt;sup>74</sup> Christensen DL, Maenner MJ, Bilder D, et al. Prevalence and characteristics of autism spectrum disorder among children aged 4 years - Early Autism and Developmental Disabilities Monitoring Network, seven sites, United States, 2010, 2012, and 2014. *MMWR Surveill Summ*. 2019;68(2):1-19; The DIAMOND Project Group. Incidence and trends of childhood type 1 diabetes worldwide 1990-1999. *Diabet Med*. 2006;23(8):857-866.

<sup>&</sup>lt;sup>75</sup> The relevant documents include the following: Socialstyrelsen. God vård av barn och ungdomar med könsdysfori. March 2021. Accessed November 23, 2022. Available at <a href="https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2015-4-6.pdf;">https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2015-4-6.pdf;</a> Socialstyrelsen. Stöd, utredning och

hormonbehandling vid könsinkongruens hos barn och ungdomar. February 2022. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf; Socialstyrelsen: The National Board of Health and Welfare. Care of children and adolescents with gender dysphoria: Summary. Accessed November 23, 2022. Available at https://www.socialstyrelsen.se/globalassets/sharepointdokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf; Palveluvalikoima. Medical treatment methods for dysphoria associated with variations in gender identity in minors – recommendations. June 2020. Accessed November 23. 2022. Available 16. https://palveluvalikoima.fi/documents/1237350/22895008/Summary minors en+(1).pdf/fa2054c 5-8c35-8492-59d6-b3de1c00de49/Summary minors en+(1).pdf?t=1631773838474; The Cass Review. Independent review of gender identity services for children and young people: Interim report. February 2022. Accessed November 23, 2022. Available at https://cass.independentreview.uk/publications/interim-report/.

guidelines make recommendations and grade their strength. Of the documents by European health authorities that do make treatment recommendations, none rate the quality of the evidence and the strength of the recommendations.

58. Critically, none of the European health authorities has prohibited gender-affirming medical care as does Oklahoma. The authorities instead emphasize the importance of multidisciplinary evaluation and treatment, including psychological care, and the need for additional research. Even though Sweden has called for the provision of gender-affirming medical care within the research context, the Swedish National Board of Health and Welfare states that doing so "does not necessarily imply the use of randomized controlled trials," acknowledging that other study designs are appropriate to evaluate gender-affirming medical care. The European documents do not support the claims that gender-affirming medical care should be banned let alone criminalized.

# THE MEDICAL CARE BAN UNDERMINES THE INTEGRITY OF THE MEDICAL PROFESSION

- 59. The ban violates the integrity of the medical profession and coerces medical professionals to violate their integrity and ethical duties. The medical profession has processes by which it evaluates treatments and determines whether they are safe and effective. The ban intervenes in these processes replacing medical professionals' judgement with the judgment of the legislature.
- 60. Healthcare providers have an ethical obligation to promote their patients' well-being and to protect them from harm. When providers believe that the potential benefits of gender-

<sup>&</sup>lt;sup>76</sup> Socialstyrelsen. Stöd, utredning och hormonbehandling vid könsinkongruens hos barn och ungdomar. February 2022. Accessed November 23, 2022. Available at <a href="https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf">https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-2-7774.pdf</a>.

affirming medical care outweigh the potential risks for a particular patient, prohibiting them from providing this treatment forces them to violate their ethical obligations to their patients or risk losing their licenses, being convicted of a crime, and incurring financial penalties. While the ability to gradually decrease and discontinue puberty blockers and gender-affirming hormones within 6 months of the ban's effective date may mitigate some of the medical risks of abruptly discontinuing these medications, it does not obviate the fundamental medical and ethical shortcomings of the ban.

#### AN EMERGENCY DOES NOT EXIST

61. The ban erroneously contends that an emergency exists. As noted above, the current paradigm of gender-affirming medical care for adolescents was introduced to the medical literature 25 years ago. Studies demonstrating the safety and efficacy of gender-affirming medical care for adolescents were published in 2011 and 2014 and the Endocrine Society's current clinical practice guideline on the topic was published in 2017. Arkansas House Bill 1570, which similarly bans gender affirming medical care and which is currently enjoined, was introduced on February 25, 2021. No fundamental changes have occurred in the past 2 or more years that would constitute an emergency.

#### **CONCLUSION**

62. Treating adolescents with gender dysphoria with gender-affirming medical care under clinical practice guidelines, like the Endocrine Society's, is evidence-based; its potential benefits outweigh its potential risks for many patients; and these risks are well within the range of

<sup>&</sup>lt;sup>77</sup> Arkansas State Legislature. HB 1570 – To Crease the Arkansas Save Adolescents form Experimentation (SAFE) Act. Accessed April 28, 2023. Available at https://www.arkleg.state.ar.us/Bills/Detail?id=HB1570&ddBienniumSession=2021%2F2021R.

other medical decisions that adolescents and their parents or guardians have the discretion to make

in consultation with their healthcare professionals.

63. Based on my research and experience as a pediatrician and bioethicist, there is no

sound medical or ethical basis to prohibit healthcare professionals from providing gender-

affirming medical care to minors. Doing so puts clinicians in the untenable position of having to

harm their patients, and violate their integrity and ethical obligations due to the threat of

administrative, criminal, and civil penalties.

I declare under penalty of perjury under the laws of the United States of America that the foregoing

is true and correct.

Executed on April 30, 2023

Ormandth Mackeny Contaminaria

ARMAND H. MATHENY ANTOMMARIA, MD, PhD

#### **EXHIBIT A**

Curriculum Vitae

Last Updated: April 28, 2023

#### **PERSONAL DATA**

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# **EDUCATION**

1983-1987	<b>BSEE</b>	Valparaiso University, with High Distinction
		Valparaiso, IN
1983-1987	BS	Valparaiso University (Chemistry), with High Distinction
		Valparaiso, IN
1987-1989	MD	Washington University School of Medicine
1998-2000		Saint Louis, MO
1989-2000	PhD	The University of Chicago Divinity School (Religious Ethics)
		Chicago, IL
2000-2003	Resident	University of Utah (Pediatrics)
		Salt Lake City, UT
2005-2006	Certificate	e Conflict Resolution Certificate Program, University of Utah
		Salt Lake City, UT

#### **BOARD CERTIFICATION**

- 2019 Pediatric Hospital Medicine, American Board of Pediatrics
- 2019 Healthcare Ethics Consultant-Certified, Healthcare Ethics Consultation Certification Commission
- 2004 General Pediatrics, American Board of Pediatrics

# **PROFESSIONAL LICENSES**

2012-Present	Doctor of Medicine, Ohio
2006-2010	Alternative Dispute Resolution Provider—Mediator, Utah
2001-2014	Physician and Surgeon, Utah
2001-2014	Physician and Surgeon Controlled Substance, Utah

# **PROFESSIONAL EXPERIENCE**

# **Full Time Positions**

2019-Present Professor

Cincinnati Children's Hospital Medical Center, Cincinnati, OH

Department of Surgery

2019-Present Professor of Clinical-Affiliated University of Cincinnati, Cincinnati, OH Department of Surgery 2017-Present Professor Cincinnati Children's Hospital Medical Center, Cincinnati, OH Division of Pediatric Hospital Medicine 2017-Present Professor of Clinical-Affiliated University of Cincinnati, Cincinnati, OH Department of Pediatrics Associate Professor of Clinical-Affiliated 2016-2017 University of Cincinnati, Cincinnati, OH Department of Pediatrics Associate Professor 2012-2017 Cincinnati Children's Hospital Medical Center, Cincinnati, OH Division of Pediatric Hospital Medicine 2012-Present Lee Ault Carter Chair in Pediatric Ethics Cincinnati Children's Hospital Medical Center Associate Professor-Affiliated 2012-2016 University of Cincinnati, Cincinnati, OH Department of Pediatrics Associate Professor of Pediatrics (with Tenure) 2010-2012 University of Utah School of Medicine, Salt Lake City, UT Divisions of Inpatient Medicine and Medical Ethics Adjunct Associate Professor of Medicine 2010-2012 University of Utah School of Medicine, Salt Lake City, UT Division of Medical Ethics and Humanities Assistant Professor of Pediatrics (Tenure Track) 2004-2010 University of Utah School of Medicine, Salt Lake City, UT Divisions of Inpatient Medicine and Medical Ethics Adjunct Assistant Professor of Medicine 2004-2010 University of Utah School of Medicine, Salt Lake City, UT Division of Medical Ethics and Humanities *Instructor of Pediatrics* (Clinical Track) 2003-2004 University of Utah School of Medicine, Salt Lake City, UT Divisions of Inpatient Medicine and Medical Ethics Adjunct Instructor of Medicine 2003-2004 University of Utah School of Medicine, Salt Lake City, UT Division of Medical Ethics

#### **Part Time Positions**

2022-Present Expert Witness, Reports and Deposition
 Dekker, et al., v. Marstiller, et al., United States District Court for the Northern
 District of Florida, Case No. 4:22-cv-oo325-RH-MAF
 2022- Present Expert Witness, Report, Deposition, and Testimony
 Brianna Boe, et al., and United States v. Marshall, et al., United States District
 Court Middle District of Alabama Northern Division, Case No. 22-cv-184-LCB-

CWB.

2022-Present Expert Witness, Report and Testimony

Jane Doe, et al., v. Greg Abbott, et al., District Court of Travis County, Texas

353<sup>rd</sup> Judicial District, Case No. D-1-GN-22-000977

2021-2022 Expert Witness, Reports, Deposition, and Testimony

Dylan Brandt, et al., v. Leslie Rutledge, et al., United States District Court,

Eastern District of Arkansas, Case No.: 5:21-CV-00450-JM-1

2021 Consultant

Proctor & Gamble, Cincinnati, OH

2019 Consultant

Sanofi Genzyme, Cambridge, MA

2018-Present Consultant

Center for Conflict Resolution in Healthcare, Memphis, TN

2017-2020 *Consultant* 

Amicus Therapeutics, Cranbury, NJ

2017 Consultant

Sarepta Therapeutics, Cambridge, MA

2014 Consultant

Genzyme, A Sanofi Company, Cambridge, MA

# **Editorial Experience**

**Editorial Board** 

2020-Present Pediatrics, Associate Editor for Ethics Rounds and Member of the Executive

**Editorial Board** 

2015-2020 Journal of Clinical Ethics

2009-2020 Journal of Medical Humanities

**Guest Academic Editor** 

2017 PLOS|ONE

Ad Hoc Reviewer: Academic Medicine, Academic Pediatrics, AJOB Primary Research, American Journal of Bioethics, American Journal of Law & Medicine, American Journal of Medical Genetics, American Journal of Transplantation, BMC Medical Ethics, BMJ Open, Canadian Journal of Bioethics, CHEST, Clinical Transplantation, European Journal of Human Genetics, European Journal of Pediatrics, Frontiers in Genetics, Hospital Medicine, International Journal of Health Policy and Management, International Journal of Nursing Studies, Journal of Adolescent and Young Adult Oncology, Journal of Clinical Ethics, Journal of Empirical Research on Human Research Ethics, Journal of General Internal Medicine, Journal of Healthcare Leadership, Journal of Hospital Medicine, Journal of the Kennedy Institute of Ethics, Journal of Law, Medicine & Ethics, Journal of Medical Ethics, Journal of Medical Humanities, Journal of Medicine and Life, Journal of Palliative Care, Journal of Pediatrics, Journal of Pediatric Surgery, Mayo Clinic Proceedings, Medicine, Healthcare and Philosophy, Molecular Diagnosis & Therapy, New England Journal of Medicine, Patient Preference and Adherence, Pediatrics, Pediatrics in Review, Personalized Medicine, PLOS ONE, Risk Management and Healthcare Policy, Saudi Medical Journal, SSM - Qualitative Research in Health, and Theoretical Medicine and Bioethics

<b>SCHOLASTI</b>	C AND	PRO!	<u>FESS</u>	I(	<b>NAL</b>	<b>HONORS</b>
2021	YY. 11	~	,	•	~· ·	

2021	Hidden Gem Award, Cincinnati Children's Hospital Medical Center, Cincinnati,
2021	OH
2019-2022	Presidential Citation, American Society for Bioethics and Humanities, Chicago,
2017 2022	IL
2016	Laura Mirkinson, MD, FAAP Lecturer, Section on Hospital Medicine, American Academy of Pediatrics, Elk Grove Village, IL
2016, 2018	Certificate of Excellence, American Society for Bioethics and Humanities,
2010, 2016	Glenview, IL
2013, 2016	Senior Resident Division Teaching Award, Cincinnati Children's Hospital
	Medical Center, Cincinnati, OH
2012	Role Model, Quality Review Committee, Primary Children's Medical Center, Salt
	Lake City, UT
2011	Member, Society for Pediatric Research, The Woodlands, TX
2011	Presidential Citation, American Society for Bioethics and Humanities, Glenview,
	IL
2009	Role Model, Quality Review Committee, Primary Children's Medical Center, Salt
	Lake City, UT
2008	Nominee, Physician of the Year, Primary Children's Medical Center, Salt Lake
	City, UT
2005-2006	Fellow, Medical Scholars Program, University of Utah School of Medicine, Salt
	Lake City, UT
1995-1997	Doctoral Scholar, Crossroads, A Program of Evangelicals for Social Action,
	Philadelphia PA
1989-1992	Fellow, The Pew Program in Medicine, Arts, and the Social Sciences, University
	of Chicago, Chicago, IL

# **ADMINISTRATIVE EXPERIENCE**

#### **Administrative Duties**

2009

2023-Present	Chair, Literature Selection Technical Review Committee, National Library of
	Medicine, Bethesda, MD
2019-Present	Chair, Oversight Committee, Cincinnati Fetal Center, Cincinnati, OH

2014-Present *Chair*, Ethics Committee, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

2012-Present *Director*, Ethics Center, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

2012-Present *Chair*, Ethics Consultation Subcommittee, Cincinnati Children's Hospital Medical Center, Cincinnati, OH

2010 *Co-Chair*, Ethics Subcommittee, Work Group for Emergency Mass Critical Care in Pediatrics, Centers for Disease Control and Prevention, Atlanta, GA

*Chair*, Ethics Working Group, H1N1 and Winter Surge, Primary Children's Medical Center, Salt Lake City, UT

2005-2012 *Chair*, Ethics Committee, Primary Children's Medical Center, Salt Lake City, UT 2005-2012 *Chair*, Ethics Consultation Subcommittee, Primary Children's Medical Center,

Salt Lake City, UT

2003-4 *Chair*, Clinical Pertinence Committee, Primary Children's Medical Center, Salt Lake City, UT

Professional & Scientific Committees				
Committees 2021	Member, EMCO Capacity Collaboration, Ohio Hospital Association, Columbus, OH			
2020-2021	Member, Allocation of Scarce Resources Work Group, Ohio Hospital Association, Columbus, OH			
2020-Present	<i>Member</i> , Literature Selection Technical Review Committee, National Library of Medicine, Bethesda, MD			
2020	<i>Member</i> , Crisis Standards of Care Workgroup, The Health Collaborative, Cincinnati, OH			
2019-Present 2019	Member, Healthcare Ethics Consultant Certification Commission, Oak Park, IL Member, Expert Panel, Pediatric Oncology End-of-Life Care Quality Markers, Institute for Cancer Outcomes & Survivorship, University of Alabama at Birmingham, Birmingham, AL			
2018	Member, Resource Planning and Allocation Team Implementation Task Force, Ohio Department of Health, Columbus, OH			
2012-Present	Member, Gaucher Initiative Medical Expert Committee, Project HOPE, Millwood, VA			
2009-2014	Member, Clinical Ethics Consultation Affairs Committee, American Society for Bioethics and Humanities, Glenview, IL			
2005-2011	Member, Committee on Bioethics, American Academy of Pediatrics, Oak Park, IL			
Data Safety a	nd Monitoring Boards			
2019-Present	Member, Data and Safety Monitoring Board, Sickle Cell Domestic Trials, National Heart, Lung, and Blood Institute, Bethesda, MD			
2018-2019	<i>Member</i> , Standing Safety Committee for P-188-NF (Carmeseal-MD <sup>TM</sup> ) in Duchenne Muscular Dystrophy, Phrixus Pharmaceuticals, Inc., Ann Arbor, MI			
2017-Present	Member, Observational Study Monitoring Board, Sickle Cell Disease Observational Monitoring Board, National Heart, Lung, and Blood Institute, Bethesda, MD			
2016-2018	Member, Observational Study Monitoring Board, Long Term Effects of Hydroxyurea in Children with Sickle Cell Anemia, National Heart, Lung, and Blood Institute, Bethesda, MD			
Reviewer				
2020-Present	Abstract Reviewer, American Society for Bioethics and Humanities Annual Meeting			
2020	Grant Reviewer, The Croatian Science Foundation, Hvatska zaklada za znanost (HRZZ)			
2018	Book Proposal Reviewer, Elsevier			
2018-2019	Category Leader, Religion, Culture, and Social Sciences, American Society for Bioethics and Humanities Annual Meeting			

2017	Timekeeper, American Society for Bioethics and Humanities Annual Meeting
2017-Present	Abstract Reviewer, Pediatric Academic Societies Annual Meeting
2016-2021	Workshop Reviewer, Pediatric Academic Societies Annual Meeting
2016	Grant Reviewer, Innovation Research Incentives Scheme, The Netherlands
	Organisation for Health Research and Development
2016-2017	Abstract Reviewer, American Society for Bioethics and Humanities Annual
	Meeting
2014, 2016	External Peer Reviewer, PSI Foundation, Toronto, Ontario, Canada
2014	Member, Scientific Committee, International Conference on Clinical Ethics and
	Consultation
2013	Abstract Reviewer, American Society for Bioethics and Humanities Annual
	Meeting
2013	Reviewer, Open Research Area Plus, Agence Nationale de la Research, Deutsche
	Forschungsgemeinschaft, Economic and Social Research Council, National
	Science Foundation, and Organization for Scientific Research
2011-2012	Abstract Reviewer, Pediatric Academic Societies Annual Meeting
2011-2013	Workshop Reviewer, Pediatric Academic Societies Annual Meeting
2011-2014	Abstract Reviewer, Pediatric Hospital Medicine Annual Meeting
2011-2012	Religious Studies Subcommittee Leader, Program Committee, American Society
	for Bioethics and Humanities Annual Meeting
2010	Abstract Reviewer, American Society for Bioethics and Humanities Annual
	Meeting
Other	
2021	Timekeeper, American Society for Bioethics and Humanities Annual Meeting
2021	Mentor, Early Career Advisor Professional Development Track, American
	Society for Bioethics and Humanities.
2021	Mentor, Early Career Advisor Paper or Project Track, American Society for
	Bioethics and Humanities.
2109	Mentor, Early Career Advising Program, American Society for Bioethics and
	Humanities
2018	Passing Point Determination, Healthcare Ethics Consultant-Certified
	Examination, Healthcare Ethics Consultant Certification Commission
2018	Member, Examination Committee, Healthcare Ethics Consultant-Certified
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2018	Item Writer, Healthcare Ethics Consultant-Certified Examination, Healthcare
	Ethics Consultant Certification Commission

# **UNIVERSITY COMMUNITY ACTIVITIES**

# Cincinnati Children's Hospital Medical Center

Cincinnati C	march 5 Hospital Medical Center
2023-Present	Member, Biospecimen Access Committee, Discover Together Biobank
2020-Present	Member, Faculty Diversity and Inclusion Steering Committee
2020-Present	Member, Medical Management of COVID-19 Committee
2020-2021	Member, Caregiver Refusal Team
2020-2021	Member, COVID-19 Vaccine Allocation Committee
2020	Member, Personal Protective Equipment Subcommittee of the COVID-19
	Steering, Committee

2018-2019	Member, Planning Committee, Center for Clinical & Translational Science &				
	Training Research Ethics Conference				
2017-Present	Member, Donor Selection Committee				
2017-2020	Member, Employee Emergency Fund Review Committee				
2017	Member, Root Cause Analysis Team				
2016-2017	Member, Planning Committee, Center for Clinical & Translational Science &				
	Training Research Ethics Conference				
2015-2019	Member, Destination Excellence Medical Advisory Committee				
2015-Present	Member, Disorders of Sexual Development Case Review Committee				
2015-2019	Member, Destination Excellence Case Review Committee				
2014-2018	Member, Genomics Review Group, Institutional Review Board				
2014-2017	Member, Center for Pediatric Genomics Leadership Committee				
2013-2017	Member, Genetic Testing Subcommittee, Health Network				
2013-2016	Member, Schwartz Center Rounds Planning Committee				
2013-2014	Member, Genomics Ad Hoc Subcommittee, Board of Directors				
2012-Present	Member, Cincinnati Fetal Center Oversight Committee				
2012-Present	Member, Ethics Committee				
2012-Present	Member, G-23				
2012-2016	Member, Integrated Solid Organ Transplant Steering Committee				

# **University of Utah**

2009-2012 *Member*, Consolidated Hearing Committee

# **University of Utah School of Medicine**

2010-2012	Member, Medical Ethics, Humanities, and Cultural Competence Thread
	Committee
2008-2010	Member, Fourth Year Curriculum Committee

# **University of Utah Department of Pediatrics**

2010-2011	<i>Member</i> , Planning Committee, 25 <sup>th</sup> Annual Biological Basis of Children's Health
	Conference, "Sex, Gender, and Sexuality"
2009-2012	Member, Medical Executive Committee
2005-2012	Member, Retention, Promotion, and Tenure Committee
2004-2012	Interviewer, Residency Program
2003-2012	Member, Education Committee

# **Intermountain Healthcare**

2009-2012	Member, System-Wide Bioethics Resource Service
2009-2012	Member, Pediatric Guidance Council

# **Primary Children's Medical Center**

2012-2012	Member, Shared Accountability Organization Steering Committee
2009	Member, H1N1 and Winter Surge Executive Planning Team
2005-2010	Member, Continuing Medical Education Committee
2005-2010	Member, Grand Rounds Planning Committee
2003-2012	Member, Ethics Committee

## ACTIVE MEMBERSHIPS IN PROFESSIONAL SOCIETIES

2012-Present Association of Bioethics Program Directors

2011-Present Society for Pediatric Research 2000-Present American Academy of Pediatrics

1999-Present American Society of Bioethics and Humanities

# **FUNDING**

## **Past Grants**

2015-2019 "Better Outcomes for Children: Promoting Excellence in Healthcare Genomics to

Inform Policy." Percent Effort: 9%

National Human Genome Research Institute

Grant Number: 1U01 HG008666-01

Role: <u>Investigator</u>

2015-2016 "Ethics of Informed Consent for Youth in Foster Care"

Direct Costs: \$10,000

Ethics Grant, Center for Clinical and Translational Science and Training

University of Cincinnati Academic Health Center

Role: Co-Investigator

2014-2015 "Extreme Personal Exposure Biomarker Levels: Engaging Community Physicians

and Ethicists for Guidance" Direct Costs: \$11,640

Center for Environmental Genetics

University of Cincinnati College of Medicine

Role: Investigator

2014-2015 "Child, Adolescent, and Parent Opinions on Disclosure Policies for Incidental

Findings in Clinical Whole Exome Sequencing"

Direct Costs: \$4,434

Ethics Grant, Center for Clinical and Translational Science and Training,

University of Cincinnati Academic Health Center

Role: Principal Investigator

2013-2014 "Better Outcomes for Children: GWAS & PheWAS in eMERGEII

Percent Effort: 5%

National Human Genome Research Institute Grant Number: 3U01HG006828-0251

Role: <u>Investigator</u>

2004-2005 "Potential Patients' Knowledge, Attitudes, and Beliefs Regarding Participating in

Medical Education: Can They be Interpreted in Terms of Presumed Consent?"

Direct Costs: \$8,000

Interdisciplinary Research in Applied Ethics and Human Values, University

Research Committee, University of Utah Role: <u>Principal Investigator</u>

# TEACHING RESPONSIBILITIES/ASSIGNMENTS

# **Course and Curriculum Development**

2003-2012 Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100

## **Course Lectures**

2018, 2021	Introduction to Biotechnology, "Ethics and Biotechnology" and "Clinical Ethics," BIOL 3027, University of Cincinnati, Taught 1 time per year, Taken by undergraduate students, Enrollment 25.
2018-Present	•
2016	Foundations of Healthcare Ethics and Law, "Clinical Ethics," HESA 390, Xavier University.
2014-Present	•
2014-Present	Ethical Issues in Health Care, "Ethical Issues in Managing Drug Shortages: The Macro, Meso, and Micro Levels," HESA 583, College of Social Sciences, Health, and Education Health Services Administration, Xavier University, Taken by health services administration students, Enrollment 25.
2009	Physical Diagnosis II, Internal Medicine 7160, University of Utah School of Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100
2003-2012	Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine, Taught 1 time per year, Taken by fourth year medical students, Enrollment 100

# **Small Group Teaching**

2018-Present	Ethics in Research, GNTD 7003-001, University of Cincinnati School of
	Medicine, Taught 1 time per year, Taken by fellows, MS, and PhD students,
	Enrollment 110.
2007	Physical Diagnosis I, Internal Medicine 7150, University of Utah School of
	Medicine, Taught 1 time per year, Taken by medical students, Enrollment 100
2003-2012	Medical Ethics, Internal Medicine 7560, University of Utah School of Medicine,
	Taught 1 time per year, Taken by fourth medical students, Enrollment 100
2003	Pediatric Organ System, Pediatrics 7020, University of Utah School of Medicine,
	Taught 1 time per year, Taken by medical students, Enrollment 100

## **Graduate Student Committees**

2018-2022	Chair, Scholarship Oversight Committee, William Sveen, Pediatric Critical Care
	Fellowship, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2018-2020	Member, Scholarship Oversight Committee, Anne Heueman, Genetic Counseling,
	University of Cincinnati, Cincinnati, OH
2017-2019	Chair, Scholarship Oversight Committee, Bryana Rivers, Genetic Counseling,
	University of Cincinnati, Cincinnati, OH
2013-2015	Mentor, Sophia Hufnagel, Combined Pediatrics/Genetics Residency, Cincinnati
	Children's Hospital Medical Center, Cincinnati, OH
2013-2015	Co-Chair, Scholarship Oversight Committee, Andrea Murad, Genetic Counseling,
	University of Cincinnati, Cincinnati, OH
2013-2014	Member, Scholarship Oversight Committee, Grace Tran, Genetic Counseling,
	University of Cincinnati, Cincinnati, OH
2011-2012	Chair, Scholarship Oversight Committee, Kevin E. Nelson, MD, PhD, Pediatric
	Inpatient Medicine Fellowship, University of Utah, Salt Lake City, UT

## **Continuing Education Lectures**

- 2008 Choosing Healthplans All Together (CHAT) Exercise Facilitator, 18<sup>th</sup> Annual Intermountain Medical Ethics Conference, "Setting Priorities for Healthcare in Utah: What Choices are We Ready to Make?," Salt Lake City, Utah, October 3.
- 2007 *Speaker*, Infant Medical Surgical Unit, Primary Children's Medical Center, "Withholding and Withdrawing Artificial Nutrition and Hydration: Can It Be Consistent With Care?," Salt Lake City, Utah, September 6.
- 2007 Faculty Scholar-in Residence, Summer Seminar, "The Role of Religion in Bioethics," Utah Valley State College, Orem, Utah, May 1.
- 2006 *Workshop Leader*, Faculty Education Retreat, "Publications and Publishing in Medical Education," University of Utah School of Medicine, Salt Lake City, Utah, September 15.
- 2006 Breakout Session, 16<sup>th</sup> Annual Intermountain Medical Ethics Conference, "Donation after Cardiac Death: Evolution of a Policy," Salt Lake City, Utah, March 28.

## **Other Educational Activities**

- 2008 *Instructor*, Contemporary Ethical Issues in Medicine and Medical Research, Osher Lifelong Learning Institute, University of Utah, "Religion and Bioethics: Religiously Based Demands for and Refusals of Treatment," Salt Lake City, Utah, February 7.
- 2007 *Speaker*, Biology Seminar, Utah Valley State College, "Is He Dead?: Criteria of the Determination of Death and Their Implications for Withdrawing Treatment and Recovering Organs for Transplant," Orem, Utah, September 21.

# PEER-REVIEWED JOURNAL ARTICLES

- 1. William N. Sveen, <u>Armand H. Matheny Antommaria</u>, Stephen Gilene, and Erika L. Stalets. (Forthcoming) "Adverse Events During Apnea Testing for the Determination of Death by Neurologic Criteria: A Single Center, Retrospective Pediatric Cohort." *Pediatric Critical Care Medicine*.
- 2. Erica K. Salter, Jay R. Malone, Amanda Berg, Annie Friedrich, Alexandra Hucker, Hillary King, and <u>Armand H. Matheny Antommaria.</u> (Online ahead of print) "Triage Policies at U.S. Hospitals with Pediatric Intensive Care Units." *AJOB Empirical Bioethics*. PMID: 36576201.

- 3. <u>Armand H. Matheny Antommaria</u>, Elizabeth Lanphier, Anne Housholder, and Michelle McGowan. (2023). "A mixed methods analysis of requests for religious exemptions to a COVID-19 vaccine requirement." *AJOB Empirical Bioethics*. 14: 15-22. PMID: 36161802.
- 4. Anne C Heuerman, Danielle Bessett, <u>Armand H. Matheny Antommaria</u>, Leandra. K. Tolusso, Nicki Smith, Alison H. Norris and Michelle L. McGowan (2022). "Experiences of reproductive genetic counselors with abortion regulations in Ohio." *Journal of Genetic Counseling*. 31: 641-652. PMID: 34755409.
- 5. <u>Armand H. Matheny Antommaria</u> and Ndidi I. Unaka. (2021) "Counterpoint: Prioritizing Health Care Workers for Scarce Critical Care Resources is Impractical and Unjust. *Journal of Hospital Medicine*. 16: 182-3. PMID 33617445.
- 6. Gregory A. Grabowski, <u>Armand H. Matheny Antommaria</u>, Edwin H. Kolodny, and Pramod K. Mistry. (2021) "Gaucher Disease: Basic and Translational Science Needs for More Complete Therapy and Management." *Molecular Genetics and Metabolism*. 132: 59-75. PMID: 33419694.
- 7. <u>Armand H. Matheny Antommaria</u>, Laura Monhollen, and Joshua K. Schaffzin. (2021) "An Ethical Analysis of Hospital Visitor Restrictions and Masking Requirements During the COVID-19." *Journal of Clinical Ethics*. 32(1): 35-44. PMID 33416516.
- 8. <u>Armand H. Matheny Antommaria</u> (2020) "The Pediatric Hospital Medicine Core Competencies: 4.05 Ethics." *Journal of Hospital Medicine*. 15(S1): 120-121.
- 9. Armand H. Matheny Antommaria, Tyler S. Gibb, Amy L. McGuire, Paul Root Wolpe, Matthew K. Wynia, Megan K. Applewhite, Arthur Caplan, Douglas S. Diekema, D. Micah Hester, Lisa Soleymani Lehmann, Renee McLeod-Sordjan, Tamar Schiff, Holly K. Tabor, Sarah E. Wieten, and Jason T. Eberl for a Task Force of the Association of Bioethics Program Directors (2020) "Ventilator Triage Policies During the COVID-19 Pandemic at U.S. Hospitals Associated With Members of the Association of Bioethics Program Directors." Annals of Internal Medicine. 173(3): 188-194. PMID: 32330224.
- 10. <u>Armand H. Matheny Antommaria</u> (2020) "Conflicting Duties and Reciprocal Obligations During a Pandemic." *Journal of Hospital Medicine*. 5:284-286. PMID: 32379030.
- 11. Mary V. Greiner, Sarah J. Beal, and <u>Armand H. Matheny Antommaria</u> (2020) "Perspectives on Informed Consent Practices for Minimal-Risk Research Involving Foster Youth." *Pediatrics*. 45:e20192845. PMID: 32156772.
- 12. Jennifer deSante-Bertkau, Michelle McGowan, and <u>Armand H. Matheny Antommaria</u> (2018) "Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations." *Journal of Clinical Ethics*. 29:291-304. PMID: 30605439.
- 13. Andrew J. Redmann, Melissa Schopper, <u>Armand H. Matheny Antommaria</u>, Judith Ragsdale, Alessandro de Alarcon, Michael J. Jutter, Catherine K. Hart, and Charles M. Myer. (2018) "To Transfuse or Not to Transfuse? Jehovah's Witnesses and PostOperative Hemorrhage in Pediatric Otolaryngology." *International Journal of Pediatric Otorhinolaryngology*. 115:188-192. PMID: 30368384.
- 14. <u>Armand H. Matheny Antommaria</u>, Kyle B. Brothers, John A. Myers, Yana B Feygin, Sharon A. Aufox, Murray H. Brilliant, Pat Conway, Stephanie M. Fullerton, Nanibaa' A. Garrison, Carol R. Horowitz, Gail P. Jarvik, Rongling Li, Evette J. Ludman, Catherine A. McCarty, Jennifer B. McCormick, Nathaniel D. Mercaldo, Melanie F. Myers, Saskia C. Sanderson, Martha J. Shrubsole, Jonathan S. Schildcrout, Janet L. Williams, Maureen E. Smith, Ellen Wright Clayton, Ingrid A. Holm. (2018) "Parents' Attitudes toward Consent and Data

- Sharing in Biobanks: A Multi-Site Experimental Survey." *AJOB Empirical Research*. 21:1-15. PMID: 30240342.
- 15. <u>Armand H. Matheny Antommaria</u> and Cynthia A. Prows. (2018) "Content Analysis of Requests for Religious Exemptions from a Mandatory Influenza Vaccination Program for Healthcare Personnel" *Journal of Medical Ethics*. 44: 389-391. PMID: 29463693.
- 16. <u>Armand H. Matheny Antommaria</u> (2017) "May Medical Centers Give Nonresident Patients Priority in Scheduling Outpatient Follow-Up Appointments?" *Journal of Clinical Ethics*. 28: 217-221. PMID: 28930708.
- 17. Andrea M. Murad, Melanie F. Myers, Susan D. Thompson, Rachel Fisher, and <u>Armand H. Matheny Antommaria</u> (2017) "A Qualitative Study of Adolescents' Understanding of Biobanks and Their Attitudes Toward Participation, Re-contact, and Data Sharing." *American Journal of Medical Genetics: Part A.* 173: 930-937. PMID: 28328120.
- 18. Saskia Sanderson, Kyle Borthers, Nathaniel Mercaldo, Ellen Wright Clayton, <u>Armand Antommaria</u>, Sharon Aufox, Murray Brillant, Diego Campos, David Carrell, John Connolly, Pat Conway, Stephanie Fullerton, Nanibaa Garrison, Carol Horowitz, Gail Jarvik, David Kaufman, Terrie Kitchner, Rongling Li, Evette Ludman, Cahterine McCarty, Jennifer McCormick, Valerie McManus, Melanie Myers, Aaron Scrol, Janet Williams, Martha Shrubsole, Jonathan Schildcrout, Maureen Smith, and Ingrid Holm (2017) "Public Attitudes Towards Consent and Data Sharing in Biobank Research: A Large Multisite Experimental Survey in the US." *The American Journal of Human Genetics*. 100: 414-427. PMID: 28190457.
- 19. Maureen E. Smith, Saskia C Sanderson, Kyle B Brothers, Melanie F Myers, Jennifer McCormick, Sharon A Aufox, Martha J Shrubsole, Nanibaa' A Garrison, Nathaniel D Mercaldo, Jonathan S Schildcrout, Ellen Wright Clayton, <u>Armand H. Matheny Antommaria</u>, Melissa Basford, Murray Brilliant, John J Connolly, Stephanie M Fullerton, Carol R Horowitz, Gail P Jarvik, Dave Kaufman, Terrie Kitchner, Rongling Li, Evette J Ludman, Catherine McCarty, Valerie McManus, Sarah C Stallings, Janet L Williams, and Ingrid A Holm (2016) "Conducting a Large, Multi-Site Survey about Patients' Views on Broad Consent: Challenges and Solutions." *BMC Medical Research Methodology*. 16: 162. PMID: 27881091.
- 20. Angela Lorts, Thomas D. Ryan, <u>Armand H. Matheny Antommaria</u>, Michael Lake, and John Bucuvalas (2016) "Obtaining Consensus Regarding International Transplantation Continues to be Difficult for Pediatric Centers in the United States." *Pediatric Transplant*. 20: 774-777. PMID: 27477950.
- 21. Sophia B. Hufnagel, Lisa J. Martin, Amy Cassedy, Robert J. Hopkin, and <u>Armand H. Matheny Antommaria</u> (2016) "Adolescents' Preferences Regarding Disclosure of Incidental Findings in Genomic Sequencing That Are Not Medically Actionable in Childhood." *American Journal of Medical Genetics Part A.* 170: 2083-2088. PMID: 27149544.
- 22. Nanibaa' A. Garrison, Nila A. Sathe, <u>Armand H. Matheny Antommaria</u>, Ingrid A. Holm, Saskia Sanderson, Maureen E. Smith, Melissa McPheeters, and Ellen Wright Clayton (2016) "A Systematic Literature Review of Individuals' Perspectives on Broad Consent and Data Sharing in the United States." *Genetics in Medicine*. 18: 663-71. PMID: 26583683.
- 23. Kyle B. Brothers, Ingrid A. Holm Janet E. Childerhose, <u>Armand H. Matheny Antommaria</u>, Barbara A. Bernhardt, Ellen Wright Clayton, Bruce D. Gelb, Steven Joffe, John A. Lynch, Jennifer B. McCormick, Laurence B. McCullough, D. William Parsons, Agnes S. Sundaresan, Wendy A. Wolf, Joon-Ho Yu, and Benjamin S. Wilfond (2016) "When

- Genomic Research Participants Grow Up: Contact and Consent at the Age of Majority." *The Journal of Pediatrics* 168: 226-31. PMID: 26477867.
- 24. Erin E. Bennett, Jill Sweney, Cecile Aguayo, Criag Myrick, <u>Armand H. Matheny</u> <u>Antommaria</u>, and Susan L. Bratton (2015) "Pediatric Organ Donation Potential at a Children's Hospital." *Pediatric Critical Care Medicine*. 16: 814-820. PMID: 26237656.
- 25. Anita J. Tarzian, Lucia D. Wocial, and the ASBH Clinical Ethics Consultation Affairs Committee (2015) "A Code of Ethics for Health Care Ethics Consultants: Journey to the Present and Implications for the Field." *American Journal of Bioethics*. 15: 38-51. PMID: 25970392.
- 26. <u>Armand H. Matheny Antommaria</u>, Christopher A. Collura, Ryan M. Antiel, and John D. Lantos (2015) "Two Infants, Same Prognosis, Different Parental Preferences." *Pediatrics*, 135: 918-923. PMID: 25847802.
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#### Letters

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- 5. <u>Armand H. Matheny Antommaria</u> and Joel Frader (2009) "Policies of Children's Hospitals on Donation After Cardiac Death—Reply." *Journal of the American Medical Association*, 302: 845.

#### **Case Reports**

<u>Armand H. Matheny Antommaria</u> (2002) "Case 4.9: Inappropriate Access to a Celebrity's Medical Records." In *Ethics and Information Technology: A Case-Based Approach to a Health Care System in Transition*, James G. Anderson and Kenneth W. Goodman, 79-80. New York: Springer-Verlag.

#### **Book Reviews**

- 1. <u>Armand H. Matheny Antommaria</u> (2023) Review of *Disability's Challenge to Theology:* Genes, Eugenics, and the Metaphysics of Modern Medicine by Devan Stahl. Hastings Center Report 53(2): 44-45.
- 2. <u>Armand H. Matheny Antommaria</u> (2021) Review of *When Harry Became Sally: Responding to the Transgender Moment*, by Ryan T. Anderson. *Journal of Medical Humanities* 42: 195-9. PMID 31808021.
- 3. <u>Armand H. Matheny Antommaria</u> (2012) Review of *The Ethics of Organ Transplantation*, by Steven J. Jensen, ed., *Journal of the American Medical Association* 308: 1482-3.
- 4. <u>Armand H Matheny Antommaria</u> (2012) Review of *The Soul of Medicine: Spiritual Perspectives and Clinical Practice*, by John R. Peteet and Michael N. D'Ambra, ed., *Journal of the American Medical Association* 308: 87.
- 5. <u>Armand H. Matheny Antommaria</u> (2009) Review of *Conflicts of Conscience in Health Care: An Institutional Compromise*, by Holly Fernandez Lynch. *American Journal of Bioethics* 9: 63-4.
- 6. <u>Armand H. Matheny Antommaria</u> (2008) Review of *A Practical Guide to Clinical Ethics Consulting: Expertise, Ethos, and Power*, by Christopher Meyers. *American Journal of Bioethics* 8: 72-3.
- 7. <u>Armand H. Matheny Antommaria</u> (2004) Review of *Children, Ethics, and Modern Medicine*, by Richard B. Miller. *American Journal of Bioethics* 4: 127-8.
- 8. <u>Armand H. Matheny Antommaria</u> (2002) Review of *Ward Ethics: Dilemmas for Medical Students and Doctors in Training*, by Thomasine Kushner and David Thomasma, ed. *American Journal of Bioethics* 2: 70-1. PMID: 22494193.
- 9. <u>Armand H. Matheny Antommaria</u> (1999) Review of *Human Cloning: Religious Responses*, by Ronald Cole-Turner, ed. *Prism* 6 (March/April): 21.
- 10. <u>Armand H. Matheny Antommaria</u> (1999) Review of *Christian Theology and Medical Ethics:* Four Contemporary Approaches, by James B. Tubbs, Jr. *Journal of Religion* 79 (April): 333-5.
- 11. <u>Armand H. Matheny Antommaria</u> (1997) Review of *Body, Soul, and Bioethics*, by Gilbert C. Meilaender. *Prism* 4 (May/June): 28.

# **Newspaper Articles**

- 1. W. Bradley Poss and <u>Armand H. Matheny Antommaria</u> (2010) "Mass casualty planning must incorporate needs of children." *AAP News* 31 (July): 38.
- 2. Robert Murray and <u>Armand H. Matheny Antommaria</u> (2010) "Pediatricians should work with school nurses to develop action plans for children with DNAR orders." *AAP News* 31 (May): 30..
- 3. <u>Armand H. Matheny Antommaria</u> (2009) "Addressing physicians' conscientious objections in health care." *AAP News* 30 (December): 32.

# **UNPUBLISHED POSTER PRESENTATIONS**

- 1. <u>Armand H. Matheny Antommaria.</u> (2018) "Ethical Issues in the Care of International Patients: A Case Study." International Conference on Clinical Ethics and Consultation, Oxford, United Kingdom.
- 1. Jill S Sweney, Brad Poss, Colin Grissom, Brent Wallace, and <u>Armand H Matheny</u> <u>Antommaria</u>, (2010) "Development of a Statewide Pediatric Pandemic Triage Plan in Utah." Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20103713.147.

- 2. Christopher G. Maloney, <u>Armand H. Matheny Antommaria</u>, James F. Bale, Thomas Greene, Jian Ying, Gena Fletcher, and Rajendu Srivastava (2010) "Why Do Pediatric Interns Violate the 30 Hour Work Rule?" Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20101500.596
- 3. <u>Armand H. Matheny Antommaria</u> and Edward B. Clark (2007) "Resolving Conflict through Bioethics Mediation." 3<sup>rd</sup> International Conference on Ethics Consultation and Clinical Ethics, Toronto, Canada.
- 4. Elizabeth Tyson, Tracy Hill, <u>Armand Antommaria</u>, Gena Fletcher, and Flory Nkoy (2007) "Physician Practice Patterns Regarding Nasogastric Feeding Supplementation and Intravenous Fluids in Bronchiolitis Patients." Pediatrics Academic Societies Annual Meeting, Toronto, Canada. E-PAS2007:61300.

### **ORAL PRESENTATIONS**

## **Keynote/Plenary Lectures**

### International

- 1. 2021, *Panelist*, Partnership for Quality Medical Donations, Charitable Access Programming for Rare Diseases, "Ethical Issues," Webinar, April 6.
- 2. 2017, *Invited Speaker*, Spina Bifida Fetoscopic Repair Study Group and Consortium, "Ethics of Innovation and Research in Fetal Surgery," Cincinnati, Ohio, October 26.
- 3. 2014, *Invited Speaker*, CIC 2013 CCI: Canadian Immunization Conference, "Condition-of-Service Influenza Prevention in Health Care Settings," Ottawa, Canada, December 2.
- 4. 2014, *Invited Speaker*, National Conference of the Chinese Pediatric Society, "A Brief Introduction to Pediatric Research and Clinical Ethics," Chongqing, China, September 12.

## National

- 1. 2020, *Panelist*, Children's Mercy Bioethics Center, "Ethical Issues in the COVID Pandemic at Children's Hospitals," Webinar, March 2.
- 2. 2019, *Invited Speaker*, North American Fetal Therapy Network (NAFTnet), "Ethics of Innovation," Chicago, Illinois, October 12.
- 3. 2019, *Panelist*, National Society of Genetic Counselors Prenatal Special Interest Group, "Fetal Intervention Ethics," Webinar, September 12.
- 4. 2017, *Invited Participant*, American College of Epidemiology Annual Meeting, Preconference Workshop, "Extreme Personal Exposure Biomarker Levels: Guidance for Study Investigators," New Orleans, Louisiana, September 24.
- 5. 2016, *Invited Speaker*, American Academy of Pediatrics National Conference & Exhibition, Joint Program: Section on Hospital Medicine and Section on Bioethics, "Resource Allocation: Do We Spend Money to Save One Patient with Ebola or Over a 1,000?" San Francisco, California, October 23.
- 6. 2016, *Invited Speaker*, 26<sup>th</sup> Annual Specialist Education in Extracorporeal Membrane Oxygenation (SEECHMO) Conference, "Ethical Issues in ECMO: The Bridge to Nowhere," Cincinnati, Ohio, June 5.
- 7. 2015, *Invited Speaker*, Extracorporeal Life Support Organization (ELSO) 26<sup>th</sup> Annual Conference, "ECMO-Supported Donation after Circulatory Death: An Ethical Analysis," Atlanta, Georgia, September 20.

- 8. 2014, *Invited Speaker*, Pediatric Evidence-Based Practice 2014 Conference: Evidence Implementation for Changing Models of Pediatric Health Care, "Ethical Issues in Evidence-Based Practice," Cincinnati, Ohio, September 19.
- 9. 2014, *Invited Speaker*, 6<sup>th</sup> Annual David Kline Symposium on Public Philosophy: Exploring the Synergy Between Pediatric Bioethics and Child Rights, "Does Predictive Genetic Testing for Adult Onset Conditions that Are Not Medically Actionable in Childhood Violate Children's Rights?" Jacksonville, Florida, March 6.
- 10. 2010, *Invited Speaker*, Quest for Research Excellence: The Intersection of Standards, Culture and Ethics in Childhood Obesity, "Research Integrity and Religious Issues in Childhood Obesity Research," Denver, Colorado, April 21.
- 11. 2010, *Invited Speaker*, Symposium on the Future of Rights of Conscience in Health Care: Legal and Ethical Perspectives, J. Reuben Clark Law School at Brigham Young University and the Ave Maria School of Law, "Conscientious Objection in Clinical Practice: Disclosure, Consent, Referral, and Emergency Treatment," Provo, Utah, February 26.
- 12. 2009, *Invited Speaker*, Pediatric Organ Donation Summit, "Research Findings Regarding Variations in Pediatric Hospital Donation after Cardiac Death Policies," Chicago, Illinois, August 18.
- 13. 2008, *Meet-the-Experts*, American Academy of Pediatrics National Conference & Exhibition, "Physician Refusal to Provide Treatment: What are the ethical issues?" Boston, Massachusetts, October 11.
- 14. 2008, *Invited Conference Faulty*, Conscience and Clinical Practice: Medical Ethics in the Face of Moral Controversy, The MacLean Center for Clinical Medical Ethics at the University of Chicago, "Defending Positions or Identifying Interests: The Uses of Ethical Argumentation in the Debate over Conscience in Clinical Practice," Chicago, IL, March 18.
- 15. 2007, *Symposium Speaker*, Alternative Dispute Resolution Strategies in End-of-Life Decisions, The Ohio State University Mortiz College of Law, "The Representation of Children in Disputes at the End-of-Life," Columbus, Ohio, January 18.
- 16. 2005, *Keynote Speaker*, Decisions and Families, *Journal of Law and Family Studies* and The University of Utah S.J. Quinney College of Law, "Jehovah's Witnesses, Roman Catholicism, and Calvinism: Religion and State Intervention in Parental, Medical Decision-Making," Salt Lake City, Utah, September 23.

#### Regional/Local

- 2021, Panelist, Pediatric Residency Noon Conference, University of Tennessee Health Science Center, "Bioethics Rounds—Ethical Issues in the Care of Transgender Adolescents," Memphis, Tennessee, September 21.
- 2. 2020, *Keynote Speaker*, 53<sup>rd</sup> Annual Clinical Advances in Pediatrics, "Referral to a Fetal Care Center: How You Can Help Patients' Mothers Address the Ethical Issues," Kansas City, Kansas, September 16.
- 3. 2019, *Speaker*, Patient and Family Support Services, Primary Children's Hospital, "Ethical Issues in the Care of Trans Adolescents," Salt Lake City, Utah, December 5.
- 4. 2019, *Speaker*, Evening Ethics, Program in Medical Ethics and Humanities, University of Utah School of Medicine, "Patients, Parents, and Professionals: Ethical Issues in the Treatment of Trans Adolescents," Salt Lake City, Utah, December 4.
- 5. 2019, *Speaker*, Pediatric Hospital Medicine Board Review Course, "Ethics, Legal Issues, and Human Rights including Ethics in Research," Cincinnati, Ohio, September 8.

- 6. 2019, *Speaker*, Advances in Fetology, "Evolving Attitudes Toward the Treatment of Children with Trisomies," Cincinnati, Ohio, September 6.
- 7. 2019, *Speaker*, Half-Day Ethics Training: Ethics Consultation & Ethics Committees, "Navigating the Rapids of Clinical Ethics Consultation: Intake, Recommendations, and Documentation," Salt Lake City, Utah, June 1.
- 8. 2019, *Speaker*, Scientific and Ethical Underpinnings of Gene Transfer/Therapy in Vulnerable Populations: Considerations Supporting Novel Treatments, BioNJ, "What Next? An Ethical analysis of Prioritizing Conditions and Populations for Developing Novel Therapies," Cranbury, New Jersey, March 7.
- 9. 2018, *Panelist*, Periviability, 17<sup>th</sup> Annual Regional Perinatal Summit, Cincinnati, Ohio, October 12.
- 10. 2018, *Speaker*, Regional Advance Practice Registered Nurse (APRN) Conference, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati, Ohio, April 26.
- 11. 2018, *Speaker*, Southern Ohio/Northern Kentucky Sigma Theta Tau International Annual Conference, "Between Hope and Hype: Ethical Issues in Precision Medicine," Sharonville, Ohio, March 2.
- 12. 2017, *Speaker*, Advances in Fetology 2017, "Ethics of Innovation and Research: Special Considerations in Fetal Therapy Centers," Cincinnati, Ohio, October 27.
- 13. 2016, *Speaker*, End-of-Life Pediatric Palliative Care Regional Conference, "Ethical/Legal Issues in Pediatric Palliative Care," Cincinnati, Ohio, September 15.
- 14. 2016, *Speaker*, 26<sup>th</sup> Annual Bioethics Network of Ohio (BENO) Conference, "When Does Parental Refusal of Medical Treatment for Religious Reasons Constitute Neglect?" Dublin, Ohio, May 29.
- 15. 2014, *Speaker*, Cincinnati Comprehensive Sickle Cell Center Symposium: Research Ethics of Hydroxyurea Therapy for Sickle Cell Disease During Pregnancy and Lactation, "Ethical Issues in Research with Pregnant and Lactating Women," Cincinnati, Ohio, October 30.
- 16. 2014, *Speaker*, Advances in Fetology 2014, "The 'Miracle Baby' and Other Cases for Discussion," Cincinnati, Ohio, September 26.
- 17. 2014, *Speaker*, Advances in Fetology 2014, "Can you tell me ...?': Achieving Informed Consent Given the Prevalence of Low Health Literacy," Cincinnati, Ohio, September 26.
- 18. 2014, *Panelist*, Center for Clinical & Translational Science & Training, Secrets of the Dead: The Ethics of Sharing their Data, Cincinnati, Ohio, August 28.
- 19. 2014, *Speaker*, Office for Human Research Protections Research Community Forum: Clinical Research ... and All That Regulatory Jazz, "Research Results and Incidental Findings: Do Investigators Have a Duty to Return Results to Participants," Cincinnati, Ohio, May 21.
- 20. 2013, *Opening Presentation*, Empirical Bioethics: Emerging Trends for the 21<sup>st</sup> Century, University of Cincinnati Center for Clinical & Translational Science & Training, "Empirical vs. Normative Ethics: A Comparison of Methods," Cincinnati, Ohio, February 21.
- 21. 2012, *Videoconference*, New York State Task Force on Life and the Law, "Pediatric Critical Care Triage," New York, New York, March 1.
- 22. 2011, *Presenter*, Fall Faculty Development Workshop, College of Social Work, University of Utah, "Teaching Ethics to Students in the Professions, "Salt Lake City, Utah, November 14.

- 23. 2011, *Speaker*, 15<sup>th</sup> Annual Conference, Utah Chapter of the National Association of Pediatric Nurse Practitioners, "Ethical Issues in Pediatric Practice," Salt Lake City, Utah, September 22.
- 24. 2011, *Speaker*, Code Silver! Active Shooter in the Hospital, Utah Hospitals & Health Systems Association, Salt Lake City, Utah, March 21.
- 25. 2009, *Speaker*, Medical Staff Leadership Conference, Intermountain Healthcare, "The Ethics of Leadership," Park City, Utah, October 30.
- 26. 2008, *Speaker*, The Art and Medicine of Caring: Supporting Hope for Children and Families, Primary Children's Medical Center, "Medically Provided Hydration and Nutrition: Ethical Considerations," Salt Lake City, Utah, February 25.
- 27. 2005, *Speaker*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners) Chapter Pharmacology and Pediatric Conference, "Immunization Update," Salt Lake City, Utah, August 18.
- 28. 2005, *Keynote Speaker*, 17th Annual Conference, Utah Society for Social Work Leadership in Health Care, "Brain Death: Accommodation and Consultation," Salt Lake City, March 18.
- 29. 2004, *Continuing Education Presentation*, Utah NAPNAP (National Association of Pediatric Nurse Practitioners), "Febrile Seizures," Salt Lake City, Utah, April 22.
- 30. 2004, *Speaker*, Advocacy Workshop for Primary Care Providers, "Ethics of Advocacy," Park City, Utah, April 3.
- 31. 2002, *Speaker*, 16<sup>th</sup> Annual Biologic Basis of Pediatric Practice Symposium, "Stem Cells: Religious Perspectives," Deer Valley, Utah, September 14.

# **Meeting Presentations**

#### International

1. 2018, *Speaker*, International Conference on Clinical Ethics and Consultation, "A Systematic Review of Typologies Used to Characterize Clinical Ethics Consultations," Oxford, United Kingdom, June 21.

#### National

- 1. 2023, Kelsey S. Ryan, Rakhi Gupta Bassuray, Leela Sarathy, Sharon Ostfeld, <u>Armand H. Matheny Antommaria</u>, Erin Rholl, Steven R. Leuthner, and Christy L. Cummings. *Workshop Presenter*, Pediatric Academic Societies Annual Meeting, "How Can Newborn Toxicology Testing be Equitable?" Washington, DC, April 30.
- 2. 2022, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "A Mixed Methods Analysis of Requests for Religious Exemptions to a COVID-19 Vaccine Requirement." Portland, Oregon, October 27.
- 3. 2022, *Panelist*, American Society for Bioethics and Humanities Annual Meeting, Pediatric Ethics Affinity Group, "When Ethical Healthcare Is Prohibited By Law, How Do We Respond?" Portland, Oregon, October 27.
- 4. 2022, *Speaker*, APPD/PAS Fellow Core Curriculum Workshop, Pediatric Academic Societies Annual Meeting, "From Idea to Implementation: Navigating the Ethical Landscape of Pediatric Clinical Research," Denver, Colorado, April 22.
- 5. 2021, *Panelist*, Pediatric Endocrine Society Annual Meeting, Difference of Sex Development Special Interest Group, Virtual Conference, April 29.
- 6. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Is This Child Dead? Controversies Regarding the Neurological Criteria for Death," Virtual Conference, October 17.

- 7. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Contemporary Ethical Controversy in Fetal Therapy: Innovation, Research, Access, and Justice," Virtual Conference, October 15.
- 8. 2020, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "K-12 Schools and Mandatory Public Health Programs During the COVID-19 Pandemic," Virtual Conference, October 15.
- 9. 2019, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Issues in Translating Gene Transfer Studies Involving Children with Neurodegenerative Disorders," Pittsburgh, Pennsylvania, October 26.
- 10. 2019, *Moderator*, Pediatric Academic Societies Annual Meeting, Clinical Bioethics, Baltimore, Maryland, April 28.
- 11. 2018, *Presenter*, American Society for Bioethics and Humanities Annual Meeting, "Looking to the Past, Understanding the Present, and Imaging the Future of Bioethics and Medical Humanities' Engagement with Transgender Health," Anaheim, California, October 19.
- 12. 2018, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Should Vaccination Be a Prerequisite for Sold Organ Transplantation?" Anaheim, California, October 18.
- 13. 2018, Lindsey Douglas, <u>Armand H. Matheny Antommaria</u>, Derek Williams. *Workshop Presenter*, Pediatric Hospital Medicine Annual Meeting, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB)." Atlanta, Georgia, July 20.
- 14. 2018, Alan Schroeder, <u>Armand H. Matheny Antommaria</u>, Hannah Bassett, Kevin Chi, Shawn Ralston, Rebecca Blankenburg. *Workshop Speaker*, Pediatric Hospital Medicine Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Atlanta, Georgia, July 20.
- 15. 2018, Alan Schroeder, Hannah Bassett, Rebecca Blankenburg, Kevin Chi, Shawn Ralston, Armand H. Matheny Antommaria. *Workshop Speaker*, Pediatric Academic Societies Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Toronto, Ontario, Canada, May 7.
- 16. 2017, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Tensions in Informed Consent for Gender Affirming Hormone Therapy and Fertility Preservation in Transgender Adolescents," Kansas City, Missouri, October 19.
- 17. Lindsey Douglas, <u>Armand H. Matheny Antommaria</u>, and Derek Williams. 2017, *Workshop Leader*, PHM[Pediatric Hospital Medicine]2017, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB) Process," Nashville, Tennessee, July 21.
- 18. 2016, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Ethical Challenges in the Care of International Patients: Organization, Justice, and Cultural Considerations," Washington, DC, October 9.
- 19. 2015, *Coauthor*, The American Society of Human Genetics Annual Meeting, "Adolescents' Opinions on Disclosure of Non-Actionable Secondary Findings in Whole Exome Sequencing," Baltimore, Maryland, October 9.
- 20. 2012, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "A Public Health Ethics Analysis of the Mandatory Immunization of Healthcare Personnel: Minimizing Burdens and Increasing Fairness," Washington, DC, October 21.
- 21. <u>Armand H. Matheny Antommaria</u>, Valerie Gutmann Koch, Susie A. Han, Carrie S. Zoubul. 2012, *Moderator*, American Society for Bioethics and Humanities Annual Meeting,

- "Representing the Underrepresented in Allocating Scarce Resources in a Public Health Emergency: Ethical and Legal Considerations," Washington, DC, October 21.
- 22. 2012, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of International Variation in Donation after Circulatory Death Policies and Rates," Boston, Massachusetts, April 30. Publication 3150.4.
- 23. 2011, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "The Intersection of Policy, Medicine, and Ethics during a Public Health Disaster: Special Considerations for Children and Families," Minneapolis, Minnesota, October 13.
- 24. <u>Armand H. Matheny Antommaria</u> and Joel Frader. 2010, *Workshop Leader*, Pediatric Academic Societies Annual Meeting, "Conscientious Objection in Health Care: Respecting Conscience and Providing Access," Vancouver, British Columbia, Canada. May 1. Session 1710.
- 25. 2009, Workshop Leader, American Society for Bioethics and Humanities Annual Meeting, "Advanced Clinical Ethics Consultation Skills Workshop: Process and Interpersonal Skills," Washington, DC, October 15.
- 26. 2009, *Platform Presentation*, Pediatric Academic Societies Annual Meeting, "Qualitative Analysis of Donation after Cardiac Death Policies at Children's Hospitals," Baltimore, Maryland, May 2. Publication 2120.6.
- 27. 2008, *Speaker*, American Society for Bioethics and Humanities Annual Meeting, "Qualitative Analysis of Donation After Cardiac Death (DCD) Policies at Children's Hospitals," Cleveland, Ohio, October 26.
- 28. 2007, *Participant*, Hamline University School of Law Biennial Symposium on Advanced Issues in Dispute Resolution, "An Intentional Conversation About Conflict Resolution in Health Care," Saint Paul, Minnesota, November 8-10.
- 29. 2007, Speaker, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Consultation and Alternative Dispute Resolution: Opportunities for Collaboration," Washington, DC, October 21.
- 30. 2007, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "DNAR Orders in Schools: Collaborations Beyond the Hospital," Washington, DC, October 18.
- 31. <u>Armand H. Matheny Antommaria</u> and Jeannie DePaulis. 2007, *Speaker*, National Association of Children's Hospitals and Related Institutions Annual Meeting, "Using Mediation to Address Conflict and Form Stronger Therapeutic Alliances," San Antonio, Texas, October 9.
- 32. 2006, *Speaker*, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Mediation: A Critique," Denver, Colorado, October 28.
- 33. 2005, *Panelist*, American Society of Bioethics and Humanities Annual Meeting, "How I See This Case: 'He Is Not His Brain," Washington, DC, October 20.
- 34. 2005, *Paper Presentation*, Pediatric Ethics: Setting an Agenda for the Future, The Cleveland Clinic, "'He Is Not His Brain:' Accommodating Objections to 'Brain Death," Cleveland, Ohio, September 9.
- 35. 2004, *Speaker*, American Society for Bioethics and Humanities Spring Meeting, "Verification and Balance: Reporting Within the Constraints of Patient Confidentiality," San Antonio, Texas, March 13.
- 36. 2002, *Panelist*, American Society for Bioethics and Humanities Annual Meeting, "'Who Should Survive?:' Mental Retardation and the History of Bioethics," Baltimore, Maryland, October 24.

## **Invited/Visiting Professor Presentations**

- 1. 2013, Visiting Professor, "How to Listen, Speak and Think Ethically: A Multidisciplinary Approach," Norton Suburban Hospital and Kosair Children's Hospital, Louisville, Kentucky, May 22.
- 2. 2010, Visiting Professor, Program in Bioethics and Humanities and Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Ethics Facilitation," University of Iowa Carver College of Medicine, Iowa City, Iowa, September 10.

## **Grand Round Presentations**

- 1. 2019, David Green Lectureship, "Establishing Goals of Care and Ethically Limiting Treatment," Primary Children's Hospital, Salt Lake City, Utah, December 5.
- 2. 2018, "The Ethics of Medical Intervention for Transgender Youth," El Rio Health, Tucson, Arizona, September 29.
- 3. 2018, Pediatrics, "Patient Selection, Justice, and Cultural Difference: Ethical Issues in the Care of International Patients," Cleveland Clinic, Cleveland, Ohio, April 10.
- 4. 2018, Bioethics, "Reversibility, Fertility, and Conflict: Ethical Issues in the Care of Transgender and Gender Nonconforming Children and Adolescents," Cleveland Clinic, Cleveland, Ohio, April 9.
- 5. 2017, Heart Institute, "Have you ever thought about what you would want—if god forbid—you became sicker?': Talking with adult patients about advance directives," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 16.
- 6. 2017, Pediatrics, "Respectful, Effective Treatment of Jehovah's Witnesses," with Judith R. Ragsdale, PhD, MDiv and David Morales, MD, Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, March 14.
- 7. 2017, Pediatrics, "Ethical Dilemmas about Discharging Patients When There Are Disagreements Concerning Safety," Seattle Children's Hospital, Seattle, Washington, January 19.
- 8. 2015, Pediatrics, "Nonbeneficial' Treatment: What must providers offer and what can they withhold?," Greenville Health System, Greenville, South Carolina, May 10.
- 9. 2014, Advance Practice Providers, "Common Ethical Issues," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, August 13.
- 10. 2014, Respiratory Therapy, "Do-Not-Resuscitate (DNR) Orders," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, July 15.
- 11. 2013, Heart Institute, "No Not Months. Twenty-Two *Years*-Old: Transiting Patients to an Adult Model of Care." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 21.
- 12. 2013, Division of Neonatology, "This Premature Infant Has a *BRCA1* Mutation!?: Ethical Issues in Clinical Whole Exome Sequencing for Neonatologists." Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, October 11.
- 13. 2013, Department of Pediatrics, "Adults are Not Large Children: Ethical Issues in Caring for Adults in Children's Hospitals," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, February 26.
- 14. 2012, "Mandate or Moratorium?: Persisting Ethical Controversies in Donation after Circulatory Death," Cedars-Sinai Medical Center, Los Angeles, California, May 16.

- 15. 2011, Division of Pediatric Neurology Friday Lecture Series, "Inducing or Treating 'Seizures' with Placebos: Is It Ever Ethical?," University of Utah, Salt Lake City, Utah, October 7.
- 16. 2011, Department of Surgery, "DNR Orders in the OR and other Ethical Issues in Pediatric Surgery: Case Discussions," Primary Children's Medical Center, Salt Lake City, Utah, October 3.
- 17. 2009, Department of Pediatrics, "What to Do When Parents Want Everything Done: 'Futility' and Bioethical Mediation," Primary Children's Medical Center, Salt Lake City, Utah, September 17.
- 18. 2008, Division of Pulmonology and Critical Care, "Futility: May Clinicians Ever Unilaterally Withhold or Withdraw Medical Treatment?" Utah Valley Regional Medical Center, Provo, Utah, April 17.
- 19. 2007, Division of Otolaryngology-Head and Neck Surgery, "Advance Directives, Durable Powers of Attorney for Healthcare, and Do Not Attempt Resuscitation Orders: Oh My!," University of Utah School of Medicine, Salt Lake City, Utah, June 20.

#### **Outreach Presentations**

- 1. 2019, *Panelist*, Cincinnati Edition, WVXU, "The Ethics of Human Gene Editing," Cincinnati, Ohio, June 13.
- 2. 2019, *Speaker*, Adult Forum, Indian Hill Church, "Medical Ethics," Indian Hill, Ohio, March 24.
- 3. 2016, *Speaker*, Conversations in Bioethics: The Intersection of Biology, Technology, and Faith, Mt. Washington Presbyterian Church, "Genetic Testing," Cincinnati, Ohio, October 12.
- 4. 2008, *Speaker*, Science in Society, Co-sponsored by KCPW and the City Library, "Death—Choices," Salt Lake City, Utah, November 20.
- 5. 2003, *Panelist*, Utah Symposium in Science and Literature, "The Goodness Switch: What Happens to Ethics if Behavior is All in Our Brains?" Salt Lake City, Utah, October 10.
- 6. 2002, *Respondent*, H. Tristram Englehardt, Jr. "The Culture Wars in Bioethics," Salt Lake Community College, Salt Lake City, Utah, March 29.

## **Podcasts**

- 1. 2021, "Ethics of COVID Vaccines in Kids," PHM from Pittsburgh, August 12.
- 2. 2020, COVID Quandaries: Episode 1, "Is Getting Sick Just Part of the Job?" Hard Call, October 6.

#### **EXHIBIT B**

TABLE 1: Level (Quality) of Evidence and Class (Strength) of Recommendation<sup>1</sup> and in 2020 American Heart Association Guideline for Pediatric Basic and Advanced Life Support

	Class 1	Class 2a	Class 2b	Class 3	Class 3	Total
	(Strong)	(Moderate)	(Weak)	No Benefit	Harm	
	Benefit >>>	Benefit >>	Benefit >=	(Moderate)	(Strong)	
	Risk	Risk	Risk	Benefit =	Risk >	
				Risk	Benefit	
Level A	1 (0.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.8%)
Level B-R	1 (0.8%)	2 (1.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (2.3%)
(Randomized)						
Level B-NR	5 (3.8%)	9 (6.9%)	3 (2.3%)	0 (0.0%)	2 (1.5%)	19 (14.6%)
(Nonrandomized)						
Level C-LD	24 (18.5%)	22 (16.9%)	21 (16.2%)	1(0.8%)	2 (1.5%)	70 (53.8%)
(Limited Data)						
Level C-EO	22 (16.9%)	9 (6.9%)	6 (4.6%)_	0 (0.0%)	0 (0.0%)	37 (28.5%)
(Expert Opinion)						
Total	53 (40.8%)	42 (32.3%)	30 (23.1%)	1 (0.8%)	4 (3.1%)	130 (100%)

1. Level (Quality) of Evidence

### Level A

- High-quality evidence from more than 1 [Randomized Controlled Trial (]RCT[)]
- Meta-analyses of high-quality RCTs
- One or more RCTS corroborated by high-quality registry studies

## Level B-R (Randomized)

- Moderate-quality evidence from 1 or more RCTS
- Meta-analyses of moderate-quality RCTs

## Level B-NR (Nonrandomized)

- Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

## Level C-LD (Limited Data)

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Psychological or mechanistic studies in human subjects

## Level C-EO (Expert Opinion)

• Consensus of expert opinion based on clinical experience

Topjian AA, Raymond TT, Atkins D, et al. Part 4: Pediatric basic and advanced life support: 2020 American Heart Association guidelines for cardiopulmonary resuscitation and emergency cardiovascular care. Circulation. 2020;142(16 suppl 2):S469-S523.

#### **EXHIBIT C**

TABLE 2: Strength of Recommendation and Quality of Evidence in Recommendations Made by the Endocrine Society

Strength of the Recommendation/ Quality of the Evidence <sup>1</sup>	Endocrine Treatment of Gender-Dysphoric/Gender- Incongruent Persons	Pediatric Obesity- Assessment, Treatment, and Prevention	Congenital Adrenal Hyperplasia Due to Steroid 21-Hydroxylase Deficiency
Strong High	$0(0)^2$	0 (0)	0 (0)
Strong Moderate	3 (11)	4 (13)	18 (33)
Strong Low	5 (18)	6 (20)	13 (25)
Strong Very Low	2 (7)	1 (3)	1 (2)
Weak High	0 (0)	0 (0)	0 (0)
Weak Moderate	0 (0)	0 (0)	2 (4)
Weak Low	9 (32)	5 (17)	4 (7)
Weak Very Low	3 (11)	12 (40)	7 (13)
Ungraded Good	6 (21)	2 (7)	9 (17)
Practice			
Statement <sup>3</sup>			
Either Low or	19 (68)	24 (80)	25 (46)
Very Low			
Total	28	30	54

<sup>&</sup>lt;sup>1</sup> Quality of the Evidence

High: "Consistent evidence from well-performed RCTs [Randomized Controlled Trials] or exceptionally strong evidence from unbiased observational studies"

Moderate: "Evidence from RCTs with important limitations (inconsistent results, methodological flaws, indirect or imprecise evidence), or unusually strong evidence from unbiased observational studies"

Low: "Evidence for at least one critical outcomes from observational studies, from RCTs with serious flaws, or indirect evidence"

Very Low: "Evidence for at least one of the critical outcomes from unsystematic clinical observations or very indirect evidence"

See Swiglo BA, Murad MH, Schunemann HJ, et al. A case for clarity, consistency, and helpfulness: State-of-the-art clinical practice guidelines in endocrinology using the grading of recommendations, assessment, development, and evaluation system. *J Clin Endocrinol Metab*. 2008;93(3):666-73.

<sup>&</sup>lt;sup>2</sup> n (%)

<sup>3</sup>Ungraded Good Practice Statement: "Direct evidence for these statements was either unavailable or not systematically appraised and considered out of the scope of this guideline. The intention of these statements is to draw attention to these principles." See Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

#### Guidelines:

Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine treatment of gender-dysphoric/gender-incongruent persons: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(11):3869-3903.

Styne DM, Arslanian SA, Connor EL, et al. Pediatric obesity-assessment, treatment, and prevention: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2017;102(3):709-757.

Speiser PW, Arlt W, Auchus RJ, et al. Congenital adrenal hyperplasia due to steroid 21-hydroxylase deficiency: An Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2018;103(11):4043-4088.