# EXHIBIT 55



# Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy

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**OBJECTIVES:** Our first aim was to examine baseline differences in body dissatisfaction, depression, and anxiety symptoms by gender, age, and Tanner (ie, pubertal) stage. Our second aim was to test for changes in youth symptoms over the first year of receiving gender-affirming hormone therapy. Our third aim was to examine potential differences in change over time by demographic and treatment characteristics. Youth experiences of suicidal ideation, suicide attempt, and nonsuicidal self-injury (NSSI) are also reported.

METHODS: Participants (n = 148; ages 9–18 years; mean age 14.9 years) were receiving gender-affirming hormone therapy at a multidisciplinary program in Dallas, Texas (n = 25 puberty suppression only; n = 123 feminizing or masculinizing hormone therapy). Participants completed surveys assessing body dissatisfaction (Body Image Scale), depression (Quick Inventory of Depressive Symptoms), and anxiety (Screen for Child Anxiety Related Emotional Disorders) at initial presentation to the clinic and at follow-up. Clinicians completed the Quick Inventory of Depressive Symptoms and collected information on youth experiences of suicidal ideation, suicide attempt, and NSSI.

RESULTS: Affirmed males reported greater depression and anxiety at baseline, but these differences were small (P < .01). Youth reported large improvements in body dissatisfaction (P < .001), small to moderate improvements in self-report of depressive symptoms (P < .001), and small improvements in total anxiety symptoms (P < .01). No demographic or treatment-related characteristics were associated with change over time. Lifetime and follow-up rates were 81% and 39% for suicidal ideation, 16% and 4% for suicide attempt, and 52% and 18% for NSSI, respectively.

CONCLUSIONS: Results provide further evidence of the critical role of gender-affirming hormone therapy in reducing body dissatisfaction. Modest initial improvements in mental health were also evident.



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Dr Kuper oversaw data collection, conducted data analysis, and drafted the manuscript; Drs Stewart, Lau, and Lopez conceptualized and designed the study and provided feedback on manuscript drafts; Dr Preston assisted with drafting the manuscript; and all authors contributed to the development of study aims, approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.

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WHAT'S KNOWN ON THIS SUBJECT: Guidelines exist for providing genderaffirming hormone therapy (ie, puberty suppression and masculinizing or feminizing hormone therapy) to transgender youth; however, little research has been conducted on the impact of treatment on body dissetisfaction and mental health and factors that may influence this impact.

WHAT THIS STUDY ADDS: One year of receiving gender-affirming hormone therapy resulted in large reductions in youth body dissatisfaction and modest improvements in mental health. No demographic or treatment-related factors were associated with change over time.

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ARTICLE

Two influential longitudinal studies from the Netherlands have helped establish guidelines for providing gender-affirming hormone therapy (ie, puberty suppression and masculinizing or feminizing hormone therapy) to transgender youth with gender dysphoria.1,2 De Vries et al3 conducted a prospective study with 70 youth who received puberty suppression (ie, medication to stop the progression of puberty). After 2 years, internalizing, externalizing, and depressive symptoms improved along with global functioning, but there was no improvement in body dissatisfaction or anxiety symptoms. A subset of the same cohort (n = 55)was reassessed after masculinizing or feminizing hormone therapy and gender-affirming surgery (vaginoplasty or mastectomy and hysterectomy), at which point there was a sustained improvement in global functioning and most measures of mental health. Gender dysphoria and body dissatisfaction also improved, and self-reported quality of life was similar to the Dutch population.4 However, patients were not evaluated after masculinizing or feminizing hormone therapy alone.

In the only other longitudinal study of youth, participants seen in a gender clinic in the United Kingdom (n = 35) demonstrated improvement in clinician assessment of psychosocial functioning after 12 months of receiving puberty suppression.5 Only 1 cross-sectional study has included a subset of transgender youth (n = 82 of 202). In comparison with those who had not started treatment, individuals who received both puberty suppression and/or masculinizing or feminizing hormone therapy as well as surgery had more favorable body image but not those who received puberty suppression and/or masculinizing or feminizing hormone therapy only.6 Within this study, youth and adults as well as those receiving puberty suppression and/or masculinizing or

feminizing hormone therapy were combined.

The benefits of gender-affirming treatment are better described in adults. A recent review of 5 longitudinal and 2 cross-sectional studies found that receipt of masculinizing or feminizing hormone therapy alone was associated with improved depression in 5 of 7 studies, improved anxiety in 2 of 2 studies, and better quality of life in 3 of 3 studies.7 Two studies also found lower rates of body uneasiness in adults who received masculinizing or feminizing hormone therapy alone (ie, dissatisfaction with body parts and negative body-related experiences, such as avoidance and self-monitoring).8,9

Understanding the impact of genderaffirming hormone therapy on the mental health of transgender youth is critical given the health disparities documented in this population. Within samples of transgender youth presenting for gender-affirming hormone therapy, estimates of clinically significant depressive symptoms or diagnoses have averaged in the range of 30% to 60%, 10-13 and estimates of clinically significant anxiety symptoms or diagnoses have averaged in the range of 20% to 30%. 11,14-16 Lifetime history of suicidal ideation (average range 30%-50%), 10,11,16 suicide attempt (average range 15%-30%), 10,11,13 and nonsuicidal self-injury (NSSI) (average range 20%-40%)12,13,16 also appear common.

There is also some evidence that rates of mental health concerns may vary by gender, but no clear pattern has emerged. 11,14,15,17 Two studies have found higher levels of body dissatisfaction among affirmed females (ie, individuals assigned male at birth who identify as female) in comparison with affirmed males (ie, individuals assigned female at birth who identify as male). 6,18 Changes

associated with puberty, as reflected in age and/or Tanner stage (ie, stage of puberty), may exacerbate body dissatisfaction and mental health concerns. Fewer studies have examined differences by age; however, one study found greater symptoms of depression but not anxiety among older adolescents, <sup>16</sup> and one study found higher levels of body dissatisfaction. <sup>4</sup> None have specifically examined the impact of Tanner stage.

Our first aim in this study was to explore how transgender youth baseline body dissatisfaction, depression, and anxiety symptoms vary on the basis of their gender, age at initial assessment, and Tanner stage at first medical visit, Consistent with our earlier article examining differences in mental health functioning using the Child Behavior Checklist and Youth Self-Report, 14 we hypothesized that affirmed males will report greater symptoms of depression and anxiety. We also hypothesized that older age and greater Tanner stage will be associated with higher ratings of body dissatisfaction and more symptoms of depression and anxiety.

Our second aim was to examine how transgender youth body dissatisfaction, depression, and anxiety symptoms change over the first year of receiving genderaffirming hormone therapy. We anticipated improvements in each of these domains but did not have any a priori hypotheses regarding which domains would demonstrate the greatest improvements.

Our third aim was to explore how any changes over time vary by affirmed gender, Tanner stage, age, type of treatment, months on masculinizing or feminizing hormone therapy, mental health treatment received, and whether chest (ie, "top") surgery was also obtained (among those assigned female at birth). We hypothesized that older age, greater Tanner stage,

receipt of puberty suppression only, fewer months on masculinizing or feminizing hormone therapy, and lack of chest surgery will be associated with fewer changes over time. Lastly, for descriptive purposes, we report information on lifetime and follow-up rates of suicidal ideation, suicide attempts, NSSI, and mental health treatment.

### METHODS

### Participants and Procedure

Participants are youth who received gender-affirming hormone therapy with a multidisciplinary program in Dallas, Texas. Before initiating care, participants and their families participated in an initial assessment with the program's psychologist, psychiatrist, and/or clinical therapist after parents completed a phone intake survey and provided a referral letter from a licensed therapist or counselor documenting the presence of gender dysphoria (this letter is no longer required). Approximately 34% of families did not follow-up after the phone intake. Initial assessments occurred between August 2014 and March 2018, with most occurring in 2017 (41%) or 2016 (37%). At home before this visit, participants completed self-report measures of depression, anxiety, and body dissatisfaction. During the visit, clinicians also completed a report of depressive symptoms and collected information regarding lifetime and recent suicidal ideation, suicide attempts, and NSSI as well as current participation in therapy and support groups and use of psychiatric medication(s).

After the assessment, participants were discussed by the multidisciplinary team of providers from psychology, social work, pediatric endocrinology, pediatric and adolescent gynecology, and adolescent medicine. The Endocrine Society Clinical Practice Guidelines<sup>2</sup> guided the initiation of hormone

therapy. Chest surgery was not performed within the program, but participants were provided with referrals when requested.

Approximately 1 year after this initial assessment (range: 11–18 months), all patients were asked to participate in a yearly reassessment visit. Participants were readministered self-report measures, and clinicians again completed a report of depressive symptoms and documented information about suicidal ideation, suicide attempts, NSSI, and mental health treatment.

Survey and clinician data were entered into a research database for analysis along with demographic and treatment-related information (ie, Tanner stage at first medical visit, treatment start and end dates, and chest surgery date extracted from physicians' notes). All participants provided consent, or assent with parent consent, to allow this information to be used for research. The study was approved by the institutional review board at the University of Texas Southwestern Medical Center.

### Measures

Participants were asked to self-report their gender identity (all ages) and sexual orientation (age 12 and older). These responses were recorded verbatim by the clinician and entered into the research database. Gender identities were coded into the following categories: (1) male, boy, or man; (2) male spectrum (eg, "trans masculine" or "masculine nonbinary"); (3) female, girl, or woman; (4) female spectrum (eg, "mostly female, slightly nonbinary"); and (5) nonbinary (eg, "agender" or "part girl, part boy").

To assess body dissatisfaction, participants aged 12 years and older rated their degree of dissatisfaction with 29 areas of the body using the Body Image Scale (BIS).<sup>19</sup> Participants of all ages completed the

Screen for Child Anxiety Related Emotional Disorders (SCARED), which produces a total score as well as subscale scores for panic-related, social, separation-related, generalized, and school avoidance-related anxiety symptoms,20 as well as the Quick Inventory of Depressive Symptoms (QIDS)21 to measure symptoms of depression that reflect the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria for major depressive disorder.22 The QIDS produces a total score that can also be grouped into clinical categories: not elevated (0-5), mild (6-10), moderate (11-15), and severe (16-27). Clinicians also completed the clinician version of the QIDS. When the percentage of missing values for each total score and subscale score was ≤15%, missing values were imputed by using the mean of nonmissing values.

### Analyses

To examine baseline differences in depression (QIDS self and clinician), anxiety (SCARED), and body dissatisfaction (BIS), bivariate correlation coefficients were first examined by using Pearson's r for age, Spearman's  $\rho$  for Tanner stage, and point biserial for gender. Variables with significant correlations were then simultaneously entered into a linear regression for each outcome, and Cohen's  $f^2$  was calculated as a measure of effect size  $(0.1 = \text{small}, 0.25 = \text{moderate}, \text{and } 0.4 = \text{large}).^{23}$ 

To examine change over time, QIDS (self and clinician), SCARED, and BIS scores were first tested for normality by using the Kolmogorov-Smirnov test. Changes in normally distributed variables were examined by using paired t tests, and the Wilcoxon rank test was used when the Kolmogorov-Smirnov value was significant. Cohen's d was used as a measure of effect size (0.2 = small, 0.5 = moderate, and 0.8 = large). <sup>23</sup> Changes

in clinical groupings on the QIDS were also examined by using the Wilcoxon rank test. For both baseline and longitudinal analyses, we planned to first examine the SCARED total score then test for differences in subscale scores only if this change was significant.

To test for associations between change scores and demographic and treatment characteristics, change scores were calculated by subtracting baseline scores from follow-up scores for variables that exhibited a significant change over time. Bivariate correlation coefficients were then examined by using Pearson's r for age and months on feminizing or masculinizing hormone therapy, Spearman's p for Tanner stage and therapy frequency, and point biserial for gender, treatment type, psychiatric medication use, support group participation, and chest surgery receipt (for those assigned female at birth). We planned to include any variables with significant correlations in a linear regression. P < .01 was significant for all statistical tests to help account for the overall number of tests. Confidence intervals (CIs) are reported at the 95% level.

### RESULTS

Figure 1 presents a flow diagram of participants who were due for follow-up (≥18 months since initial assessment), participants with follow-up data, and the reasons why follow-up data were not available or excluded. The mean number of months between initial assessment and reassessments was 14.9 (SD 2.1). Table 1 presents demographic information on participants. At the initial assessment, patients ranged in age from 9 to 18 years (mean 15.4; SD 2.0). All but 1 participant met Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition criteria for gender dysphoria. This participant

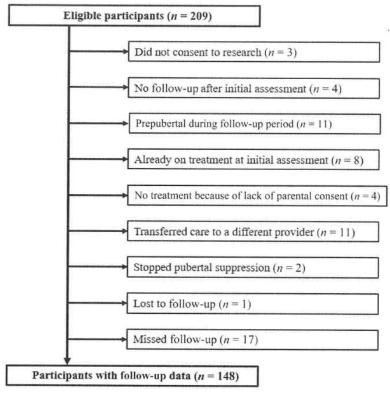


FIGURE 1 Flow diagram.

subsequently met criteria at a follow-up visit and was started on treatment. Participants who started puberty suppression only did so at a mean age of 13.7 years (range 9.8-14.9; SD 1.5), and participants started feminizing or masculinizing hormone therapy at a mean age of 16.2 years (range 13.2-18.6; SD 1.2). For participants who were on masculinizing or feminizing hormone therapy, the mean length of time receiving treatment before follow-up was 10.9 months (range 1-18; SD 3.3). During the follow-up period, 2 participants stopped puberty suppression without starting masculinizing or feminizing hormone therapy, and no participants stopped masculinizing or feminizing hormone therapy. Fifteen affirmed males obtained chest surgery at an average age of 17.1 years (range 15.2-18.7; SD 1.2) and at an average of

9.2 months from baseline (range 3.0-16.0; SD 3.3).

Table 2 presents means, SDs, and ranges for QIDS, SCARED, and BIS scores at initial assessment and follow-up for the full sample as well as by gender and treatment type. At baseline, affirmed males had greater clinician-reported depressive symptoms (CI -3.76 to -0.81), selfreported depressive symptoms (CI -4.46 to -0.79), total anxiety symptoms (CI -14.94 to -3.99), panic symptoms (CI -5.88 to -1.78), and school avoidance symptoms (CI -1.81, to -0.36) in comparison with affirmed females. However, Cohen's f <sup>2</sup> effect sizes were all in the small range (0.07, 0.06, 0.09, 0.10, and 0.07, respectively). No differences were found by age or Tanner stage.

Within the full sample, a significant decrease in body dissatisfaction (CI

TABLE 1 Participant Demographics

×	n (%)
Gender identity	
Male, boy, or guy	81 (55)
Male spectrum	9 (6)
Female, girl, or woman	52 (35)
Female spectrum	2 (1)
Something else <sup>a</sup>	3 (2)
Assigned sex	
Male	55 (37)
Female	94 (63)
Sexual orientation <sup>b</sup>	
Pansexual	25 (20)
Straight	24 (19)
Bisexual	15 (12)
Gay	12 (10)
Unsure	12 (10)
No label	11 (9)
Asexual	10 (8)
Something else	10 (8)
Lesbian	6 (5)
Race	
White	137 (95)
African American	3 (2)
Multiracial	3 (2)
American Indian	1 (1)
Ethnicity	
Hispanic	24 (17)
Non-Hispanic	120 (83)
Tanner stage	
The state of the s	3 (2)
II.	6 (4)
Ш	5 (4)
IV.	32 (23)
V	94 (67)
Treatment type <sup>c</sup>	7.204700
Puberty suppression only	25 (17)
Masculinizing or femininizing therapy only	93 (63)
Both treatments	30 (20)

<sup>&</sup>lt;sup>8</sup> Excluded from gender analyses.

14.74 to 21.90), self-reported depressive symptoms (CI 1.24 to 2.97), and total anxiety symptoms (CI 1.05 to 6.70) was observed during the follow-up period. Decreases in generalized, separation, and schoolrelated anxiety symptoms were significant at the P < .05 level but not the P < .01 level. No change in clinician report of depressive symptoms was found. Cohen's d effect sizes were large for change in BIS scores (1.04), small to moderate for change in QIDS self-report scores (0.44), and small for change in SCARED total scores (0.27). Table 3 reports the percentage of the sample

that fell into each clinical category on the QIDS at initial assessment and follow-up. A significant change was also found in self-reported depressive symptom categories (P < .001) but not clinician-reported categories. No correlations were found between change scores and demographic and treatment-related characteristics. Although change scores were generally higher for participants who received chest surgery, no correlations were significant.

Table 4 presents descriptive data on mental health treatment, and Table 5 presents data on suicidal ideation, suicide attempt, and NSSI. During the follow-up period, the distribution of therapy frequency was as follows: none (16%), less than every 3 months (15%), every 2 to 3 months (12%), monthly (22%), every other week (21%), and weekly (14%). Of those who experienced suicidal ideation during the follow-up period, 94% had a lifetime history. These figures were 67% for suicide attempt and 87% for NSSI.

### DISCUSSION

Youth reported large improvements in body dissatisfaction during the 1year follow-up period. The amount of improvement was not related to treatment type. These findings are consistent with a handful of studies that have documented improvements in body dissatisfaction within samples of adults receiving feminizing or masculinizing hormone therapy<sup>8,9</sup> but contrast with the 2 existing studies of youth. Within the longitudinal cohort from Amsterdam, puberty suppression alone was not associated with improvements in body dissatisfaction,3 and within a cross-sectional study with a mixed sample of youth and adults, puberty suppression and/or feminizing or masculinizing hormone therapy was not associated with more favorable body image.6 In contrast to the Amsterdam sample, youth in the current study were younger when starting puberty suppression (age: mean 12.5 and range 9.8-14.9 versus mean 13.7 and range 11.1-17.0).

Age, puberty stage, length of time receiving feminizing or masculinizing hormone therapy, and receipt of chest surgery were also not associated with amount of improvement. However, the sample size of participants receiving puberty suppression only and chest surgery were small, and variations in months on feminizing or masculinizing hormone therapy may not have been meaningful enough in the relatively short follow-up period.

b Age 12 and older.

Masculinizing or feminizing therapy only and both treatments were collapsed for analysis by treatment type.

TABLE 2 Body Dissatisfaction, Depression, and Anxiety Symptoms at Baseline and Follow-up

			Mean (SD)
	0-116		
96		69.9 (15.6)	51.7 (18.4)
66		71.1 (13.4)	52.9 (16.8)
30		67.5 (19.5)	49.0 (21.6)
10		64.1 (18.2)	53.8 (20.1)
86		70.7 (15.2)	51.4 (18.3)
	0-27		
118		9.4 (5.2)	7.3 (4.6)
76			7.5 (4.5)
40			6.6 (4.4)
13			7.0 (5.6)
			7.4 (4.5)
	0-27		(FAC) (* 1754)
125	9.50	5.8 (4.2)	5.9 (3.9)
			6.2 (4.1)
			5.4 (3.4)
1050			5.5 (4.8)
			6.0 (3.8)
100	0_82	0.3 (4.1)	0.0 (0.0)
100	0-02	30 / /18 3\	28.6 (16.1)
			29.8 (15.5)
			24.3 (15.4)
			29.3 (17.1)
80	0.00	52.6 (16.3)	28.4 (15.9)
104	0-26	0.0 (0.7)	7.4 (0.7)
			7.1 (6.3)
			7.9 (6.5)
(1000)		And the state of t	5.1 (4.9)
			7.2 (5.7)
82		8.1 (6.5)	7.1 (6.5)
1,5424.2	0–18	75 (50.775.5 (1994)	22/7/23/4/20/00/
			8.7 (5.1)
			9.0 (5.1)
			8.0 (5.1)
			8.2 (5.4)
82		10.0 (5.1)	8.8 (5.0)
	0-14		
			7.6 (4.3)
		8.5 (4.0)	7.8 (4.1)
2700		7.1 (3.9)	6.8 (4.4)
22		6.3 (3.6)	7.3 (4.7)
82		8.5 (4.1)	7.7 (4.2)
	0-16		
103		4.0 (3.4)	3.3 (2.7)
65		4.2 (3.4)	3.4 (2.6)
34		3.4 (3.3)	2.7 (2.3)
22		5.8 (4.0)	4.2 (3.1)
81		3.5 (3.0)	3.1 (2.5)
	0-8		
102	350050	2.6 (2.2)	2.0 (2.1)
65			2.0 (2.3)
\$27.70 h			1.9 (2.1)
			2.4 (2.4)
			2.0 (2.0)
	66 30 10 86 118 76 40 13 105 125 78 45 19 106 102 65 33 22 80 104 66 34 22 82 104 66 34 22 82 104 66 34 22 82 104 66 34 22 82 104 83 84 85 86 86 87 87 87 87 87 87 87 87 87 87	96 66 30 10 88 0-27 118 76 40 13 105 0-27 125 78 45 19 106 0-82 102 65 33 22 80 0-26 104 66 34 22 82 0-18 104 66 34 22 82 0-14 104 66 34 22 82 0-16 103 65 34 22 82 0-16 103 65 34 22 82 0-16 103 65 34 22 82 0-16	96 66 77.1. (13.4) 30 67.5 (19.5) 10 66.1 77.1. (13.4) 30 67.5 (19.5) 10 64.1 (18.2) 86 70.7 (15.2)  0-27  118 9.4 (5.2) 76 10.4 (5.0) 40 7.5 (4.9) 13 8.2 (6.1) 105 9.6 (5.0)  0-27  125 5.8 (4.2) 78 6.7 (4.4) 45 4.2 (3.2) 19 5.3 (4.9) 106 5.9 (4.1)  0-82  102 32.4 (16.3) 35.3 (26.4 (14.2) 31.8 (16.6) 32.6 (16.3)  0-26  104 8.2 (6.3) 80 32.6 (16.3)  0-26  104 9.7 (5.1) 66 9.3 (6.5) 34 5.7 (4.9) 22 8.7 (6.5) 82 0.18  104 9.7 (5.1) 66 10.4 (5.0) 65 4 8.6 (5.1) 65 3.4 8.6 (5.1) 65 3.4 8.6 (5.1) 66 3.5 (4.0) 5.7 (4.9) 6.7 (5.1) 6.8 10.4 (5.0) 6.8 6.5 (5.2) 6.3 (3.6) 6.3 (4.1) 6.5 (4.0) 6.5 (4.0) 6.5 (5.2) 6.5 (3.6) 6.5 (3.6) 6.5 (4.0) 6.5 (5.0) 6.5 (6.2

<sup>&</sup>lt;sup>8</sup> Absolute range.

 $<sup>^{\</sup>rm b}$  Significant change from initial assessment to follow-up (P < .001).

 $<sup>^{\</sup>circ}$  Significant difference in baseline scores by gender (P < .01).

 $<sup>^{\</sup>rm d}$  Significant change from initial assessment to follow-up (P < .01).

 $<sup>^{\</sup>circ}$  Significant difference in baseline scores by age (ho < .01).

TABLE 3 Depressive Symptoms (QIDS) Scoring Ranges

	Range	Self-Report <sup>a</sup>		Clinician Report	
		Baseline, N (%)	Follow-up, N (%)	Baseline, N (%)	Follow- up, N (%)
Not elevated	0-5	33 (25)	51 (40)	73 (53)	67 (49)
Mild	6-10	46 (35)	48 (37)	44 (32)	49 (36)
Moderate	11-15	29 (22)	22 (17)	15 (11)	16 (12)
Severe	16-27	24 (18)	8 (6)	5 (4)	4 (3)

 $<sup>^{\</sup>circ}$  Significant change from initial assessment to follow-up (P < .001).

Most participants (90%) were also in advanced stages of puberty (Tanner stage IV or V) when presenting for care. Limitations associated with collecting data within a busy clinical setting with multiple providers also resulted in missing data. Nonetheless, results suggest that youth receiving gender-affirming hormone therapy experience meaningful short-term improvements in body dissatisfaction, and no participants discontinued feminizing or masculinizing hormone therapy. These results provide additional support for the incorporation of these treatments into the standards of care for transgender youth experiencing gender dysphoria.1,2

Youth also reported modest improvements in mental health functioning during the follow-up period. These results are consistent with the existing longitudinal studies of youth.<sup>3–5</sup> Several factors may help explain why improvements were not greater than what was observed. Although physical changes associated with feminizing or masculinizing hormone therapy often start within the first 3 months, changes continue over the course of several years. Furthermore, environmental stressors associated with one's

transgender status may not improve after hormone therapy and could potentially worsen should they increase the youth's visibility as a transgender person. Research has consistently documented higher rates of bullying among transgender youth in comparison with nontransgender youth.<sup>24,25</sup> Within the current study, rates of school avoidance–related anxiety did not improve over the follow-up period.

The larger political context is also important to consider. Within Texas, where the current study was conducted, a well-publicized "bathroom bill" was introduced during the study period that prohibited transgender people from using a restroom that was different from the sex on their birth certificate, although the bill ultimately failed to pass.26 As a whole, the mental health functioning of youth from the present clinic as well as youth from a handful of other USand European-based clinics appears poorer than the mental health functioning of youth from the Amsterdam clinic, 11,14,17 Previous studies have attributed this difference to Amsterdam's social and political climate, which is known to be more supportive of the lesbian, gay, bisexual, and transgender population.17

Consistent with our study examining baseline differences in mental health functioning as measured by the Child Behavior Checklist and Youth Self-Report,14 affirmed males reported greater symptoms of depression and several forms of anxiety in comparison with affirmed females. However, the effect size of these differences was smaller within the current study in comparison with the former. Differences in measurement approach may help explain the mixed findings regarding gender differences in mental health functioning across youth clinics. 11,15,17 Although some research suggests that nonclinic samples of affirmed male youth report more experiences of bullying,24 affirmed females are thought to experience greater stigma regarding expression of femininity. Consistent with the current sample, the sex ratio of youth presenting to clinics also appears to be shifting from more affirmed females to more affirmed males presenting for care.27 Although causes of this shift are largely unknown, they may be associated with other shifts in clinical presentations (eg, mental health and psychosocial functioning).

### TABLE 4 Mental Health Treatment CONGLUSIO

At Initial	Follow-up	
Assessment, n (%)	Period, n (%)	
67 (47)	80 (61)	
144 (97)	114 (84)	
60 (43)	45 (35)	
	Assessment, n (%) 67 (47) 144 (97)	

Participation by parents and/or youth (eg. transgender family support organization; lesbian, gay, bisexual, and transgender youth center; or school-based Gay-Straight Alliance).

### CONCLUSIONS

The current study is the largest longitudinal study of youth receiving gender-affirming hormone therapy to date and documents important improvements in body dissatisfaction over the first year of treatment. Continued longitudinal study of this

TABLE 5 Suicidal Ideation, Suicide Attempt, and NSSI

	Lifetime, n (%)	1—3 mo Before Initial Assessment, an (%)	Follow-up Period, n (%)
Passive ideation	105 (81)	33 (25)	51 (38)
Suicide attempt	20 (15)	3 (2)	6 (5)
NSSI	68 (52)	13 (10)	23 (17)

a One month for passive ideation and 3 months for NSSI and suicide attempt(s).

population will increase the field's understanding of the benefits of gender-affirming hormone therapy and assist providers in better anticipating needs. Follow-up periods of several years or more will help document the full impact of the physical changes with feminizing or

masculinizing hormone therapy, and larger sample sizes will improve the ability to examine the specific impacts of treatment type and chest surgery. Greater consideration of intersectionality and sociocultural context will further strengthen these efforts.

### ACKNOWLEDGMENT

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### **ABBREVIATIONS**

BIS: Body Image Scale
CI: confidence interval
NSSI: nonsuicidal self-injury
QIDS: Quick Inventory of
Depressive Symptoms
SCARED: Screen for Child Anxiety
Related Emotional
Disorders

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**POTENTIAL CONFLICT OF INTEREST:** Dr Lopez has participated as a member of an advisory board for Endo International; the other authors have indicated they have no potential conflicts of interest to disclose.

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### Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy

Laura E. Kuper, Sunita Stewart, Stephanie Preston, May Lau and Ximena Lopez *Pediatrics* 2020;145;

DOI: 10.1542/peds.2019-3006 originally published online March 27, 2020;

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Body Dissatisfaction and Mental Health Outcomes of Youth on Gender-Affirming Hormone Therapy

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The online version of this article, along with updated information and services, is located on the World Wide Web at: http://pediatrics.aappublications.org/content/145/4/e20193006

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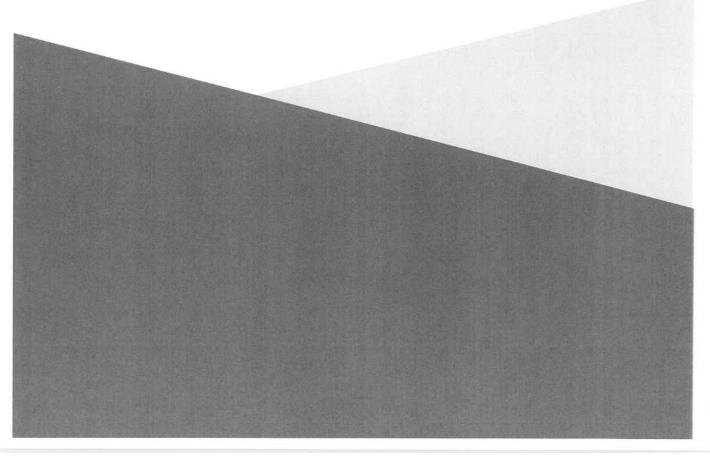
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# Care of children and adolescents with gender dysphoria

Summary





# Summary

The National Board of Health and Welfare (NBHW) has been commissioned by the Swedish government to update the national guidelines on care of children and adolescents with gender dysphoria, first published in 2015 [1]. Guidelines chapters are updated stepwise and this report contains revised guidance on psychosocial support and diagnostic assessment, and on puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment. This report thus replaces the corresponding chapters in the publication from 2015. Remaining chapters and the updated guidelines as a whole will be published later in 2022. In response to comments received during external review, two new chapters have been added, named New recommendations on hormonal treatment – their reasons and consequences and Non-binary gender identity – current knowledge and a need for clarification. Another difference compared to the guidelines from 2015 [1] is that the term "gender incongruence" is used alongside the term "gender dysphoria". For explanations of terms and abbreviations, see Appendix 2. For a description of the scientific evidence and clinical experience underlying the recommendations and the work process, see Appendices 3 and 4.

The guidelines apply to children and adolescents, i.e. people under 18 years of age. In the medical text sections, the term children (barn) refers to persons who have not yet entered puberty, while the term adolescents (ungdomar) refers to people whose puberty has started. In the text sections relating to juridical regulations, only the term children (barn) is used and denotes people younger than 18 years of age. Finally, the term "young people" (unga) is sometimes used in text sections addressing both children and adolescents.

# Introductory comment

The summary that follows and the introductory chapter describe that the updated recommendations for puberty suppression with GnRH-analogues and gender-affirming hormonal treatment have become more restrictive compared to 2015, and the reasons that they have changed. The new recommendations entail that a larger

proportion than before, among adolescents with gender incongruence referred for diagnostic assessment of gender dysphoria, will need to be offered other care than hormonal treatments. Questions on how to ensure that all young people suffering from gender dysphoria be taken seriously and confirmed in their gender identity, well received and offered adequate care are becoming increasingly relevant, and will need to be answered during the ongoing restructuring of certain care for gender dysphoria into three national specialised medical care services (NBHW decision in December 2020). The care for children, adolescents and adults with gender dysphoria in these three national specialised units aims to improve equality in care, coordination and dialogue, and may enhance the implementation of national guidelines.

# Recommendations and criteria for hormonal treatment

For adolescents with gender incongruence, the NBHW deems that the risks of puberty suppressing treatment with GnRH-analogues and gender-affirming hormonal treatment currently outweigh the possible benefits, and that the treatments should be offered only in exceptional cases. This judgement is based mainly on three factors: the continued lack of reliable scientific evidence concerning the efficacy and the safety of both treatments [2], the new knowledge that detransition occurs among young adults [3], and the uncertainty that follows from the yet unexplained increase in the number of care seekers, an increase particularly large among adolescents registered as females at birth [4].

A systematic review published in 2022 by the Swedish Agency for Health Technology Assessment and Assessment of Social Services [2] shows that the state of knowledge largely remains unchanged compared to 2015. High quality trials such as RCTs are still lacking and the evidence on treatment efficacy and safety is still insufficient and inconclusive for all reported outcomes. Further, it is not possible to determine how common it is for adolescents who undergo gender-affirming treatment to later change their perception of their gender identity or interrupt an ongoing treatment. An important difference compared to 2015 however, is that the occurrence of

detransition among young adults is now documented [3], meaning that the uncertain evidence that indicates a low prevalence of treatment interruptions or any aspects of regret is no longer unchallenged. Although the prevalence of detransition is still unknown, the knowledge that it occurs and that genderconfirming treatment thus may lead to a deteriorating of health and quality of life (i.e. harm), is important for the overall judgement and recommendation.

To minimize the risk that a young person with gender incongruence later will regret a gender-affirming treatment, the NBHW deems that the criteria for offering GnRH-analogue and gender-affirming hormones should link more closely to those used in the Dutch protocol, where the duration of gender incongruence over time is emphasized [5-7]. Accordingly, an early (childhood) onset of gender incongruence, persistence of gender incongruence until puberty and a marked psychological strain in response to pubertal development is among the recommended criteria. The publications that describe these criteria and the treatment outcomes when given in accordance [5, 6, 8] consitute the best available knowledge and should be used as guidance.

To ensure that new knowledge is gathered, the NBHW further deems that treatment with GnRH-analogues and sex hormones for young people should be provided within a research context, which does not necessarily imply the use of randomized controlled trials (RCTs). As in other healthcare areas where it is difficult to conduct RCTs while retaining sufficient internal validity, it is also important that other prospective study designs are considered for ethical review and that register studies are made possible. Until a research study is in place, the NBHW deems that treatment with GnRH-analogues and sex hormones may be given in exceptional cases, in accordance with the updated recommendations and criteria described in the guidelines. The complex multidisciplinary assessments will eventually be carried out in the three national units that are granted permission to provide highly specialized care services.

In accordance with the DSM-5, the recommendations in the guidelines from 2015 applied to young people with gender dysphoria in general, i.e. also young people with a non-binary gender identity. Another criterion within the Dutch protocol is that the child has had a binary ("cross-gender") gender identity since childhood [5, 6]. It has emerged during the review process, that the clinical experience and documentation of puberty-suppressing and hormonal treatment for young people with non-binary gender identity is lacking, and also that it is limited for adults. The NBHW still considers that gender dysphoria rather than gender identity should determine access to care and treatment. An urgent work thus remains, to clarify criteria under which adolescents with non-binary gender identity may be offered puberty-suppressing and gender-affirming hormonal treatment within a research framework.

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Art, nr 2022-3-7799

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### IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF ALABAMA NORTHERN DIVISION

REV. PAUL A. EKNES-TUCKER, et al.,

Plaintiffs,

and

UNITED STATES OF AMERICA,

Plaintiff-Intervenor,

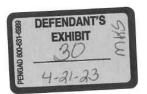
V.

KAY IVEY, in her official capacity as Governor of Alabama, et al.

Defendants.



Case No. 2:22-cv-184-LCB-SRW



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

- 1. Counsel for the United States have retained me as an expert in connection with the above-captioned litigation.
- 2. 2022 Alabama Senate Bill 184 (SB 184) singles out for anomalous treatment certain medical interventions when these interventions are used for the purpose of gender transition, which I will refer to as gender-affirming medical care, criminalizing healthcare professionals who provide minors gender-affirming medical care or who refer minors for such care.

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- 3. The legislative findings in SB 184 do not provide a sound medical or ethical basis for criminalizing the provision of gender-affirming medical care to minors with gender dysphoria nor could they because a sound medical or ethical basis for criminalizing such care does not exist.
- 4. I have actual knowledge of the matters stated in this declaration. In preparing this declaration, I reviewed the materials listed in the attached Bibliography (Exhibit A), as well as SB 184. I may rely on those documents as additional support for my opinions. I have also relied on my years of research and relevant experience, as set out in my curriculum vitae (Exhibit B), and on the materials listed therein. The materials I have relied upon in preparing this declaration are the same types of materials that experts in medicine and bioethics regularly rely upon when forming opinions on the subject. 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.

### BACKGROUND AND QUALIFICATIONS

5. I hold the following positions at Cincinnati Children's Hospital Medical Center: Director of the Ethics Center, Lee Ault Carter Chair of Pediatric Ethics, and Attending Physician in the Division of Hospital Medicine. I am also a

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Professor in the Departments of Pediatrics and Surgery at the University of Cincinnati College of Medicine.

- 6. In 2000, I received both my medical degree from Washington University School of Medicine in St. Louis, Missouri and my PhD in Religious Ethics from The University of Chicago Divinity School. I completed my Pediatrics residency at the University of Utah in 2003.
- 7. 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.
- 8. I have extensive experience as a practicing pediatrician. I have been in clinical practice since 2003 and approximately 30 percent of my current work is dedicated to caring for hospitalized patients.
- 9. I also have extensive experience as a bioethicist. Bioethicists examine the ethical issues that arise in medicine and the life sciences. 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 Hospital Medical Center since 2012. I consult on patients in the Transgender Health Clinic at Cincinnati Children's Hospital Medical Center whose

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care presents unique ethical issues 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 Hospital Medical Center team that cares for patients born with intersex traits, also known as differences or disorders of sex development (DSD). I am also the Chair of Cincinnati Children's Hospital Medical Center Fetal Care Center's Oversight Committee, which provides the Center with recommendations regarding innovation and research.

- 10. 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's Committee on Bioethics from 2005 to 2011. I served as a member of the ASBH's Clinical Ethics Consultation Affairs Committee from 2009 to 2014 and currently serve on its Healthcare Ethics Consultant Certification Commission.
- 11. I am the author of 38 peer-reviewed journal articles, 11 non-peer-reviewed journal articles, 6 book chapters, and 26 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

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author of 17 policy statements and technical reports, including 4 as lead author, by the AAP.

- 12. I am a member of the Executive Editorial Board and the Associate Editor for Ethics Rounds of *Pediatrics*. *Peditrics* is the AAP's flagship journal and Ethics Rounds is a type of article in which commentators analyze cases that raise ethical issues. I am an active peer reviewer for many medical journals, including the *American Journal of Bioethics* and the *Journal of Pediatrics*. I also review abstracts for meetings of professional organizations, including the Pediatric Academic Societies and ABSH. I was previously a member of the editorial boards of the *Journal of Clinical Ethics* and the *Journal of Medical Humanities*.
- 13. I have prepared declarations as an expert witness in the following cases involving the provision of gender-affirming medical care to adolescents with gender dysphoria: *Brant v. Rutledge*, Case No. 4:21CV450-JM (E.D. Ark.), *Doe v. Abbott*, No. D-1-GN-22-000977, 2022 WL 628912 (Tex. Dist. 353rd Judicial District, March 2, 2022), and *Walker v. Marshall*, No. 2:22-cv-167-ECM-SMD (M.D. Ala.). In *Doe v. Abbott*, I testified in court as an expert witness. I am being compensated at an hourly rate of \$250 per hour for preparation of expert declarations and reports, and \$400 per hour 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.

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### GENDER-AFFIRMING MEDICAL CARE IS CLINICAL CARE

- 14. The SB 184 legislative findings claim that the use of gonadotrophin releasing hormone (GnRH) agonists, colloquially known as puberty blockers, to treat gender dysphoria<sup>1</sup> are experimental and not approved by the U.S. Food and Drug Administration (FDA). These claims are inaccurate and irrelevant, respectively.
- 15. Clinical practice and research are distinguished by their goals and methods. The goal of clinical practice is to benefit individual patients, and its method is individualized decision-making. The goal of research is to contribute to generalizable knowledge, and its method uses formal protocols that describe the research study's objectives and procedures. See 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.
- 16. The clinical use of puberty blockers to treat gender dysphoria is not research or experimentation. The same is true for gender-affirming hormone treatment and mastectomies on transgender males (individuals assigned female at birth who identify as male) referred to at chest surgery. When administering these

<sup>&</sup>lt;sup>1</sup> Gender dysphoria 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." American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 5th ed. American Psychiatric Publishing; 2013.

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treatments, clinicians seek to benefit individual patients and adjust the treatment based on individual patients' responses.

- 17. To the extent the legislative findings use the term "experimental" to convey an absence of evidence for gender affirming medical care, that suggestion is baseless. Gender affirming medical care is supported by clinical studies, evidence comparable to many other treatments in pediatrics, as detailed below.
- 18. SB 184 not only criminalizes gender-affirming medical care as clinical care, but also criminalizes the provision of these interventions as research. Such research is necessary, as it is in every area of medicine, to continue to advance treatment.
- 19. The suggestion that because puberty blockers and gender-affirming hormone treatment are not approved by the FDA for the treatment of gender dysphoria they are therefore experimental or unsafe is misleading. Off-label use of FDA-approved medications is legal, common, and often evidence-based.
- 20. FDA approval is not required for all uses of a medication. Once the FDA has approved a medication for one indication,<sup>2</sup> thereby agreeing that it is safe

<sup>&</sup>lt;sup>2</sup> According to the FDA, an indication includes a number of factors: the particular disease or condition or the manifestion 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 Administation,

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(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. U.S. Food & Drug Administration. Understanding unapproved use of approved drugs "off label." February 5, 2018. Accessed March 23, 2022. <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>
The American Academy of Pediatrics (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 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."

21. The AAP Committee on Drugs further states "in no way does a lack of labeling signify that therapy is unsupported by clinical experience or data in children." Frattarelli DA, Galinkin JL, Green TP, et al. Off-label use of drugs in

U.S. Department of Health and Human Services. Inidcations 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 whould, for example, be prescribed off label if used to treat a different disease, like pneumonia, or a different age group, like children.

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children. *Pediatrics*. 2014;133(3):563-567. Among the reasons for this is that, even if there is substantial evidence of safety and efficacy for a new indication, a sponsor may not seek FDA approval for it because doing so is not economically beneficial. 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.

22. "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. See Nafcillin Injection, USP. February 2007. Accessed April 5, 2022. Available https://www.accessdata.fda.gov/drugsatfda docs/label/2008/050655s017lbl.pdf. A recent study of children's hospitals found that in 28.1% of encounters, at least one off-label drug was prescribed. 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. 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 gastrointestinal reflux. The rate of off-label use may be significantly higher in certain age groups, categories of drugs, and clinical settings.

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# THE SAFETY AND EFFICACY OF GENDER-AFFIRMING MEDICAL CARE IS SUPPORTED BY EVIDENCE

- 23. The SB 184 legislative findings also incorrectly characterize genderaffirming medical treatment as new, unproven, and poorly studied. Genderaffirming medical care is not new. Hormone treatment for gender dysphoria began
  soon after estrogen and testosterone became commercially available in the 1930's.
  Stryker S. *Transgender History*. 2<sup>nd</sup> ed. Seal Press; 2017. The use of puberty
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  1998;7(4):246-248. Prospective observational trials of puberty blockers began
  recruiting participants in 2000. de Vries AL, Steensma TD, Doreleijers TA, CohenKettenis PT. Puberty suppression in adolescents with gender identity disorder: A
  prospective follow-up study. *J Sex Med*. 2011;8(8):2276-2283
- 24. Gender-affirming medical care of adolescents with gender dysphoria is also neither poorly studied nor unproven. The major categories of studies used to evaluate innovative treatments are observational studies, which include cross-sectional and longitudinal studies, and randomized trials. In cross-sectional studies, investigators collect data at a single point in time. Cross-sectional design permits investigators to examine potential associations between factors, but it cannot prove

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one factor caused the other. In longitudinal studies, researchers follow individuals over time, making continuous or repeated measures. In a randomized trial, participants are randomly assigned to a treatment or a comparison group. Neither the investigators nor the participants know to which group the participant is assigned. The major benefit of a randomized trial is that it decreases the likelihood that any differences in the outcomes between the groups is the result of baseline differences between the groups rather than the result of the intervention. Guyatt G, Rennie D, Meade MO, et al., eds. *Users' Guide to the Medical Literature: A Manual for Evidence-Based Clinical Practice*. 3rd ed. McGraw Hill Education; 2015; Perry-Parrish C, Dodge R. Research and statistics: Validity hierarchy for study design and study type. *Pediatr Rev.* 2010;31(1):27-29.

25. While randomized controlled trials are described in 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. *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):666-673. For example, the Endocrine Society

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recommends that "clinicians prescribe and support the reduction of inactivity and also a minimum of 20 minutes of moderate to vigorous physical activity daily, with a goal of 60 minutes, all in the context of a calorie-controlled diet" to treat obesity. This recommendation is based on "low quality" evidence. 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.

- 26. It may, at times, be unethical to conduct randomized trials. For randomized trials to be ethical, clinical equipoise must exist; that is, there must be uncertainty about whether the efficacy of the intervention or the control is greater. It would be unethical to knowingly expose some trial participants to an inferior intervention. Trials must also be feasible. It would 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 generate generalizable knowledge due to an inadequate sample size. *See* Emanuel EJ, Wendler D, Grady C. What makes clinical research ethical? *JAMA*. 2000;283(20):2701-2711.
- 27. The use of puberty blockers to treat gender dysphoria is supported by prospective observational trials including: Delemarre-van de Waal HA, Cohen-

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Kettenis PT. Clinical management of gender identity disorder in adolescents: A protocol on psychological and pediatric endocrinology aspects. *Eur J Endocrinol*. 2006;155(suppl 1):S131–S137; 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; and 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.

- 28. Gender-affirming hormone therapy to treat gender dysphoria is also supported by prospective observational trails. These trials include 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.
- 29. There are also ongoing federally funded prospective observational trials of gender-affirming healthcare for adolescents with gender dysphoria in the U.S., trials that SB 184 would criminalize in Alabama. *See* National Institutes of Health RePORTER, The impact of early medical treatment in transgender youth. Accessed January

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https://reporter.nih.gov/search/lGJnh68uokiic97N2X00kA/project-

details 8965408; Olson-Kennedy J, Chan YM, Garofalo R, et al. Impact of early

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medical treatment for transgender youth: Protocol for the longitudinal, observational trans youth care study. *JMIR Res Protoc*. 2019;8(7):e14434.

- 30. Under the applicable ethical standards, randomized, placebo-controlled trials (trials that compare pharmacological treatment to no pharmacological treatment) in gender dysphoria 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 enough participants would enroll in randomized controlled trials for them to be informative. *See* 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.
- 31. Even if randomized, placebo-controlled trials of gender-affirming health care were ethical, 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 they were in the intervention or 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. Atkins D, Best

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- D, Briss PA, et al. Grading quality of evidence and strength of recommendations. *BMJ*. 2004;328(7454):1490.
- 32. In the field of pediatrics, parents and their children often must make decisions about medical care without the benefit of randomized trials. Clinical research focusing on children is less likely to use randomized trials than is clinical research for adults. Reasons for this disparity include the low prevalence of childhood disease or conditions, small market share for therapeutic agents in children, low level of National Institutes of Health funding, and difficulty enrolling children in research. *See* Martinez-Castaldi C, Silverstein M, Baucher H. Child versus adult research: The gap in high-quality study design. *Pediatrics*. 2008;122(1):52-57.
- 33. One directly relevant example of a widely accepted treatment based on prospective observational trials is the use of puberty blockers to treat central precocious puberty. Central precocious puberty is the premature initiation of puberty, before age 8 in people assigned female at birth and before age 9 in people assigned male, by the central nervous system. Its negative effects 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 and actual final height. These studies have additional limitations including

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small sample sizes. This "low quality" evidence is nonetheless sufficiently strong to support the use of GnRH agonists as the standard of care for treatment of central precocious puberty. *See* Mul D, Hughes IA. The use of GnRH agonists in precocious puberty. *Eur J Endocrinol*. 2008;159(Suppl 1):S3-8.

- 34. Professional medical organizations develop evidence-based clinical practice guidelines to provide clinicians with helpful, evidence-based recommendations and improve patient care and outcomes. Organizations develop guidelines using systematic processes to select and review scientific evidence. Guidelines typically rate the quality of the evidence and grade the strength of recommendations. 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.
- 35. 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 (GD)/gender-incongruent persons, which may include pubertal suppression, gender-affirming hormone therapy, and gender-affirming surgery. The guideline both rates the quality of the supporting evidence and grades the strength of its recommendations. It recommends both the

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use of puberty blockers and gender-affirming hormone therapy to treat gender dysphoria in adolescents based on the best available evidence. The guideline recommends delaying gender-affirming genital surgery that removes the testicles, ovaries, and/or uterus until adulthood. *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; *see also* World Professional Organization for Transgender Health. *Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People*, Version 7. World Professional Association for Transgender Health (WPATH); 2012.

- 36. Recommendations for pediatric care made by professional associations in guidelines are seldom based on well-designed and conducted randomized controlled trials due to their rarity and are frequently based on observational studies or, if such studies are unavailable, expert opinion. The medical use of the term "expert opinion" in this context differs from what I understand to be the use of this term in legal contexts. It refers to the consensus of experts in the field when studies are not available.
- 37. For example, none of the Endocrine Society's 84 recommendations in two of its other guidelines that focus on the pediatric population—guidelines on pediatric obesity and congenital adrenal hyperplasia—is based on "high quality"

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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. Table 1 (Exhibit C). See 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):4043-88; 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.

38. Guidelines issued by other professional associations concerning pediatric medical care are similar. For example, of the 130 recommendations in the American Heart Association's guideline for Pediatric Basic and Advanced Life Support, only 1 (1%) is based on "high-quality evidence from more than 1 [randomized clinical trial]" and 3 (3%) on "moderate-quality evidence from 1 or more [randomized clinical trials]." The remainder of the recommendations were based on lower quality evidence. 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. As reflected in medical professional associations' guidelines, medical treatment in pediatrics is infrequently

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based on "high" quality evidence and commonly based on lower quality evidence, including observational studies.

# PARENTS AND LEGAL GUARDIANS ARE CAPABLE OF PROVIDING INFORMED CONSENT FOR GENDER-AFFIRMING MEDICAL CARE

- 39. SB 184 also incorrectly asserts that minors and their parents are unable to comprehend and fully appreciate the risks and life implications of gender-affirming health care.
- 40. First and foremost, parents or legal guardians generally must provide informed consent for medical treatment for minors, including gender-affirming medical care. There is no evidence cited in support of the assertion that parents of adolescents with gender dysphoria are unable to comprehend and fully appreciate the implications of gender-affirming medical care. Parents or legal guardians are frequently asked to consent to medical treatments for minors with comparable risks, uncertainty, or levels of evidence. Limitations in adults' ability to predict what will contribute to satisfaction in the future, called affective forecasting, is not unique to decisions regarding gender-affirming medical care. And there are approaches healthcare providers use to improve affective forecasting. Wilson TD, Gilbert DT. Affective forecasting: Knowing what to want. *Curr Dir Psychol Sci.* 2005;14(3):131-134; Halpern J, Arnold RM. Affective forecasting: An unrecognized challenge in making serious health decisions. *J Gen Intern Med.* 2008;23(10):1708-1712.

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- 41. 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. Weithorn LA, Campbell SB. The competency of children and adolescents to make informed treatment decisions. Child Dev. 1982;53(6):1589-1598. There is evidence that most adolescents with gender dysphoria have sufficient medical decision-making capacity to make decisions regarding puberty blockers. 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. Similar to the aforementioned approaches to improve adult's affective forecasting, there are steps that healthcare providers take to promote adolescents' decision-making capacity. Katz AL, Webb SA, Committee on Bioethics. Informed consent in decision-making in pediatric practice. Pediatrics. 2016;138(2):e20161485.
- 42. The current standard of care for treating gender dysphoria in minors is consistent with general ethical principles instantiated in the practices of informed consent and shared decision-making. The Endocrine Society clinical practice guideline extensively discusses the potential benefits, risks, and alternatives to gender-affirming medical care, 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 informed consent for pubertal blockers and gender-affirming hormones include a discussion of the implications for fertility and options for fertility preservation. The Endocrine Society clinical guideline also advises delaying gender-affirming hormone treatment, which results in partly irreversible physical changes until an adolescent has has developed sufficient medical decision-making capacity. The guideline states clinicians should individualize decision-making for breast or chest surgery in transgender males and that chest surgery may be considered in individuals under 18 years old. *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.

## SB 184 SINGLES OUT GENDER-AFFIRMING MEDICAL CARE FOR ANOMALOUS TREATMENT

43. SB 184's legislative findings do not provide a sufficient basis for criminalizing and singling out for anamolous treatment the provision of gender-affirming healthcare to adolescents with gender dysphoria. For example, as previously mentioned, SB 184 permits the use of puberty blockers to treat central precocious puberty, but criminalizes the use of puberty blockers to treat gender dysphoria, even though using puberty blockers in connection with both conditions has comparable risks and is supported by comparable types of evidence.

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44. Additionally, while SB 184 would prohibit chest surgery on transgender males, minors are permitted to undergo many comparable surgeries, such as those for gynecomastia, pectus excavatum or carinatum, and breast reconstruction. Gynecomastia is the proliferation of ductal or glandular breast tissue, as opposed to adipose tissue or fat, in individuals whose sex assigned at birth is male. Pectus excavatum and carinatum are chest wall anomalies in which the sternum is depressed or protrudes, respectively. While surgeries to treat these conditions, as well as breast reduction and augmentation for individuals whose sex assigned at birth and gender identity are female, may at times be performed to lessen physical symptoms, such as pain or exercise intolerance, they are commonly performed to reduce psychosocial distress. Gynecomastia and breast augmentation surgery affirm patients' gender identity, that is, to respectively help someone assigned male at birth feel more typically masculine and someone assigned female at birth feel more typically feminine. Risks of these procedures include bleeding, infection, scarring and poor cosmetic outcome, loss of sensation, and impaired breast/chest feeding. Some surgeries have unique risks such as catastrophic perforations of the heart or lungs in some forms of pectus repair, or capsule formation around a breast implant causing hardening and pain. See Buziashvili D. Gopman JM, Weissler H, et al. An evidence-based approach to management of pectus excavatum and carinatum. Ann Plast Surg. 2019;82(3):352-358; Nordt CA,

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DiVasta AD. Gynecomastia in adolescents. *Curr Opin Pediatr*. 2008;20(4):375-382; Zuckerman D, Abraham A. Teenagers and cosmetic surgery: Focus on breast augmentation and liposuction. *J Adolesc Health*. 2008;43(4):318-324.

- 45. As these examples of chest surgeries in adolescents illustrate, surgeries for minors can require weighing short- and long-term effects, benefits, and risks in the face of uncertainty. Individual needs shape these evaluations and, therefore, the adolescents' participation is essential. There is nothing unique about chest surgery for gender dysphoria that justifies singling out this and other medical treatments for gender dysphoria for a criminal prohibition based on a concern for adolescents' inability to assent or parents or guardians' inability to consent. As with other medical decisions for adolescents, medical decisions regarding treatment for gender dysphoria should continue to be left to the discretion of transgender adolescents, their parents or guardians, and their healthcare providers.
- 46. Ironically, while SB 184 criminalizes gender-affirming medical care for youth with gender dysphoria in the name of protecting vulnerable children, the statute expressly allows doctors to perform irreversible surgeries on infants and children with intersex conditions or differences or disorders of sex development (DSD) at ages when they are unable to meaningfully participate in medical decision making. Such surgeries are highly controversial when performed at such an early age and can result in life-long complications and side effects. *See* Frader J, Alderson

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P, Asch A, et al. Health care professionals and intersex conditions, Arch Pediatr

Adolesc Med. 2004;158(5):426-428.

CONCLUSIONS

47. The Endocrine Society's recommendations for treating adolescents

with gender dysphoria with pubertal suppression, gender-affirming hormones, and

chest surgery are well within the range of other decisions that adolescents and their

parents or guardians in Alabama have the discretion to make. Based on my

research and experience as a pediatrician and bioethicist, there is no sound medical

or ethical basis to criminalize this care. Doing so puts clinicians in the untenable

position of having to either follow state law and knowingly harm their patients, or

face penalties including imprisonment and loss of their medical licenses.

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

that the foregoing is true and correct.

Executed: April 29, 2022

ARMAND H. MATHENY ANTOMMARIA, MD, PhD

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## **EXHIBIT A**

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## **EXHIBIT B**

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#### Curriculum Vitae

Last Updated: March 22, 2022

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1987-1989	MD	Washington University School of Medicine
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2000-2003	Resident	University of Utah (Pediatrics)
		Salt Lake City, UT
2005-2006	Certificate	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

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

## Part Time Positions

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

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2017	Expert Witness
	Robert J. Klickovich, MD, PLLC v. Tristate Arthritis & Rheumatology, PSC, et al.,
	Commonwealth of Kentucky, Boone Circuit Court, Division III, Civil Action No. 16-CI-
	01690
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, 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

## SCHOLASTIC AND PROFESSIONAL HONORS

2021	Hidden Gem Award, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
2019-2021	Presidential Citation, American Society for Bioethics and Humanities, Chicago, 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, 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
	TOWN E.S.

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## ADMINISTRATIVE EXPERIENCE

Administrativ	re Duties
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
2009	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

#### **Professional & Scientific Committees**

MD

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	Member, Literature Selection Technical Review Committee, National Library of
	Medicine, Bethesda, MD
2020	Member, Crisis Standards of Care Workgroup, The Health Collaborative, Cincinnati, OH
2019-Present	Member, Healthcare Ethics Consultant Certification Commission, Oak Park, IL
2019	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 and	d Monitoring Boards
2019-Present	Member, Data and Safety Monitoring Board, Sickle Cell Domestic Trials, National Heart,
	Lung, and Blood Institute, Bethesda, MD
2018-2019	Member, 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,

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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
2017	and Humanities Annual Meeting
2017 2017 P	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
Assets	
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 Examination,
	Healthcare Ethics Consultant Certification Commission
2018	Item Writer, Healthcare Ethics Consultant-Certified Examination, Healthcare Ethics
	Consultant Certification Commission

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## UNIVERSITY COMMUNITY ACTIVITIES

Cincinnati Children's Hospital Medical Center		
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	
2010-2019	Research Ethics Conference	
2017-Present	Member, Donor Selection Committee	
2017-11esent 2017-2020	Member, Employee Emergency Fund Review Committee	
2017-2020	Member, Root Cause Analysis Team	
2016-2017	Member, Planning Committee, Center for Clinical & Translational Science & Training	
2010 2017	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

Chiversity of Ctan Department of Lematrics	
2010-2011	Member, Planning Committee, 25th 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

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Primary Children's Medical Center

2012-2012Member, Shared Accountability Organization Steering Committee2009Member, H1N1 and Winter Surge Executive Planning Team2005-2010Member, Continuing Medical Education Committee2005-2010Member, Grand Rounds Planning Committee2003-2012Member, 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: Investigator

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: Investigator

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

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Interdisciplinary Research in Applied Ethics and Human Values, University Research Committee, University of Utah Role: Principal Investigator

#### TEACHING RESPONSIBILITIES/ASSIGNMENTS

Course and Cu	rriculum De	evelopment
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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 Biomedical Ethics, "Conscientious Objection in Healthcare" and "Ethical Issues in the Care of Transgender Adolescents," MEDS 4035 & MEDS 4036, University of Cincinnati College of Medicine, Taught 1 time per year, Taken by senior undergraduate students, Enrollment 52.

Foundations of Healthcare Ethics and Law, "Clinical Ethics," HESA 390, Xavier University.

2014-Present Physicians and Society, "Transfusion and the Jehovah's Witness Faith," "Obesity Management: Ethics, Policy, and Physician Implicit Bias," "Embryos and Ethics: The Ethics of Designer Babies," "Ethics and Genetic Testing," and "Ethics and Direct to Consumer Genetic Testing," 26950112 and 26950116, University of Cincinnati School of

Medicine, Taken by first and second year medical students, Enrollment 100.

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.

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**

2009

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**

Chair, Scholarship Oversight Committee, William Sveen, Pediatric Critical Care
Fellowship, Cincinnati Children's Hospital Medical Center, Cincinnati, OH
Member, Scholarship Oversight Committee, Anne Heueman, Genetic Counseling,
University of Cincinnati, Cincinnati, OH
Chair, Scholarship Oversight Committee, Bryana Rivers, Genetic Counseling, University of Cincinnati, Cincinnati, OH

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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, 16th 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

- Anne C Heuerman, Danielle Bessett, <u>Armand H. Matheny Antommaria</u>, Leandra. K. Tolusso, Nicki Smith, Alison H. Norris and Michelle L. McGowan (2021). "Experiences of reproductive genetic counselors with abortion regulations in Ohio." *Journal of Genetic Counseling*. Online ahead of print. PMID: 34755409.
- Armand H. Matheny Antommaria 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.
- 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." <u>Molecular Genetics and Metabolism</u>. 132: 59-75. PMID: 33419694.
- Armand H. Matheny Antommaria, 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.
- 5. <u>Armand H. Matheny Antommaria</u> (2020) "The Pediatric Hospital Medicine Core Competencies: 4.05 Ethics." *Journal of Hospital Medicine*. 15(S1): 120-121.
- 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.
- Armand H. Matheny Antommaria (2020) "Conflicting Duties and Reciprocal Obligations During a Pandemic." *Journal of Hospital Medicine*. 5:284-286. PMID: 32379030.
- 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.
- 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.
- 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.
- 11. <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.
- Armand H. Matheny Antommaria 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.
- Armand H. Matheny Antommaria (2017) "May Medical Centers Give Nonresident Patients Priority in Scheduling Outpatient Follow-Up Appointments?" *Journal of Clinical Ethics*. 28: 217-221. PMID: 28930708.
- 14. 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." <u>American Journal of Medical Genetics: Part A.</u> 173: 930-937. PMID: 28328120.
- 15. 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.
- 16. 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.
- 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

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- Difficult for Pediatric Centers in the United States." *Pediatric Transplant.* 20: 774-777. PMID: 27477950.
- 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.
- 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.
- 20. 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.
- Erin E. Bennett, Jill Sweney, Cecile Aguayo, Criag Myrick, <u>Armand H. Matheny Antommaria</u>, and Susan L. Bratton (2015) "Pediatric Organ Donation Potential at a Children's Hospital." <u>Pediatric Critical Care Medicine</u>. 16: 814-820. PMID: 26237656.
- 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.
- Armand H. Matheny Antommaria, Christopher A. Collura, Ryan M. Antiel, and John D. Lantos (2015) "Two Infants, Same Prognosis, Different Parental Preferences." *Pediatrics*, 135: 918-923. PMID: 25847802.
- Stefanie Benoit, <u>Armand H. Matheny Antommaria</u>, Norbert Weidner, and Angela Lorts (2015)
   "Difficult Decision: What should we do when a VAD supported child experiences a severe stroke?" Pediatric Transplantation 19: 139-43. PMID: 25557132.
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#### 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.
- Jill S Sweney, Brad Poss, Colin Grissom, Brent Wallace, and <u>Armand H Matheny Antommaria</u>, (2010) "Development of a Statewide Pediatric Pandemic Triage Plan in Utah." Pediatric Academic Societies Annual Meeting, Vancouver, Canada. E-PAS20103713.147.
- 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
- Armand H. Matheny Antommaria and Edward B. Clark (2007) "Resolving Conflict through Bioethics Mediation." 3<sup>rd</sup> International Conference on Ethics Consultation and Clinical Ethics, Toronto, Canada.
- 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.
- 2017, Invited Speaker, Spina Bifida Fetoscopic Repair Study Group and Consortium, "Ethics of Innovation and Research in Fetal Surgery," Cincinnati, Ohio, October 26.
- 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.
- 2019, Panelist, National Society of Genetic Counselors Prenatal Special Interest Group, "Fetal Intervention Ethics," Webinar, September 12.
- 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.
- 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.
- 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.
- 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.
- 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.
- 2014, Invited Speaker, 6th 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.
- 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.
- 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.
- 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.
- 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.
- 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
- 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.
- 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.
- 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.
- 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.
- 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, 17th Annual Regional Perinatal Summit, Cincinnati, Ohio, October 12.
- 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.
- 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.

- 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.
- 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 21st Century, University
  of Cincinnati Center for Clinical & Translational Science & Training, "Empirical vs. Normative
  Ethics: A Comparison of Methods," Cincinnati, Ohio, February 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, 15th 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.
- 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.
- 2002, Speaker, 16th Annual Biologic Basis of Pediatric Practice Symposium, "Stem Cells: Religious Perspectives," Deer Valley, Utah, September 14.

## **Meeting Presentations**

#### International

 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. Casse 2 222-6x400189441.CBS-SFRW/ IDmin.meentt 782-123 | Filted 0.05/202/222 | France 552 off 558

#### National

- 2021, Panelist, Pediatric Endocrine Society Annual Meeting, Difference of Sex Development Special Interest Group, Virtual Conference, April 29.
- 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.
- 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.
- 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.
- 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.
- 2019, Moderator, Pediatric Academic Societies Annual Meeting, Clinical Bioethics, Baltimore, Maryland, April 28.
- 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.
- 2018, Speaker, American Society for Bioethics and Humanities Annual Meeting, "Should Vaccination Be a Prerequisite for Sold Organ Transplantation?" Anaheim, California, October 18.
- 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.
- 2018, Alan Schroeder, <u>Armand H. Matheny Antommaria</u>, Hannah Bassett, Kevin Chi, Shawn Ralston, Rebecca Blankenburg. <u>Workshop Speaker</u>, Pediatric Hospital Medicine Annual Meeting, "When You Don't Agree with the Plan: Balancing Diplomacy, Value, and Moral Distress," Atlanta, Georgia, July 20.
- 11. 2018, Alan Schroeder, Hannah Bassett, Rebecca Blankenburg, Kevin Chi, Shawn Ralston, <u>Armand H. Matheny Antommaria</u>. *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.
- 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.
- Lindsey Douglas, <u>Armand H. Matheny Antommaria</u>, and Derek Williams. 2017, <u>Workshop Leader</u>, PHM[Pediatric Hospital Medicine]2017, "IRB Approved! Tips and Tricks to Smooth Sailing through the Institutional Review Board (IRB) Process," Nashville, Tennessee, July 21.
- 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.
- 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.
- 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.
- Armand H. Matheny Antommaria, Valerie Gutmann Koch, Susie A. Han, Carrie S. Zoubul. 2012, Moderator, American Society for Bioethics and Humanities Annual Meeting, "Representing the

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- Underrepresented in Allocating Scarce Resources in a Public Health Emergency: Ethical and Legal Considerations," Washington, DC, October 21.
- 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.
- 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.
- Armand H. Matheny Antommaria 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.
- 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.
- 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.
- 23. 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.
- 24. 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.
- 25. 2007, Speaker, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Consultation and Alternative Dispute Resolution: Opportunities for Collaboration," Washington, DC, October 21.
- 2007, Speaker, American Society of Bioethics and Humanities Annual Meeting, "DNAR Orders in Schools: Collaborations Beyond the Hospital," Washington, DC, October 18.
- Armand H. Matheny Antommaria 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.
- 2006, Speaker, American Society of Bioethics and Humanities Annual Meeting, "Bioethics Mediation: A Critique," Denver, Colorado, October 28.
- 29. 2005, Panelist, American Society of Bioethics and Humanities Annual Meeting, "How I See This Case: 'He Is Not His Brain," Washington, DC, October 20.
- 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
- 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.
- 32. 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**

- 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.
- 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.

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#### **Grand Round Presentations**

- 2019, David Green Lectureship, "Establishing Goals of Care and Ethically Limiting Treatment," Primary Children's Hospital, Salt Lake City, Utah, December 5.
- 2018, "The Ethics of Medical Intervention for Transgender Youth," El Rio Health, Tucson, Arizona, September 29.
- 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.
- 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.
- 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.
- 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.
- 2014, Respiratory Therapy, "Do-Not-Resuscitate (DNR) Orders," Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, July 15.
- 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.
- 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.
- 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.
- 2012, "Mandate or Moratorium?: Persisting Ethical Controversies in Donation after Circulatory Death," Cedars-Sinai Medical Center, Los Angeles, California, May 16.
- 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.
- 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.
- 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.
- 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**

- 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.

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- 2016, Speaker, Conversations in Bioethics: The Intersection of Biology, Technology, and Faith, Mt. Washington Presbyterian Church, "Genetic Testing," Cincinnati, Ohio, October 12.
- 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.

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## EXHIBIT C

#### **EXHIBIT C**

TABLE 1: 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 Practice Statement <sup>3</sup>	6 (21)	2 (7)	9 (17)
Either Low or Very Low	19 (68)	24 (80)	25 (46)
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.

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<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.