THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v.

JASON WEIDA, et al.,

Defendants.

Case No. 4:22-cv-00325-RH-MAF

PLAINTIFFS' OPPOSITION TO DEFENDANTS' OMNIBUS MOTION IN LIMINE

Plaintiffs AUGUST DEKKER; BRIT ROTHSTEIN; SUSAN DOE, a minor, by and through her parents JANE and JOHN DOE; and K.F., a minor, by and through his parent and next friend JADE LADUE (collectively, "Plaintiffs"), submit this opposition to the Defendant's, Secretary Weida and the Florida Agency for Healthcare Administration (collectively, "Defendants" or "AHCA"), Omnibus Motion *in Limine* [Dkt. 124] (the "Motion").

For the for the reasons outlined below, Plaintiffs respectfully request the Motion be denied.

INTRODUCTION

Defendants' Motion, in a sweeping fashion, seeks to "(1) exclude from trial all mention of World Professional Association for Transgender Health ("WPATH"), the Endocrine Society ("ES"), and Plaintiffs' preferred medical organizations, and the organizations' standards of care, guidelines, and policy positions on treatments for gender dysphoria; (2) exclude the testimony of Plaintiffs' expert Dr. Edmiston because Plaintiffs prevented him from answering deposition questions related to his rebuttal expert report; and (3) exclude Plaintiffs' experts' opinions that are based on the based on the organizations' standards of care, guidelines, and policy positions on treatments for gender dysphoria." Mot., at 1. Apart from being a vague and unduly prejudiced request against Plaintiffs, it is improper and unenforceable.

The primary issue before this Court is "whether, based on current medical knowledge, the state's determination that these treatments are experimental is reasonable." ECF 64 at 4. "Current medical evidence" includes the current and widely accepted standards of care, clinical guidelines, and policy statements issued by professional medical associations regarding the treatment of gender dysphoria. It is therefore evidence that should be considered at trial and upon which experts may rely. Just because Defendants did not consider this evidence in promulgating the Challenged Exclusion or do not like that it contradicts their GAPMS Report

does not establish good grounds for this Court to exclude. To the contrary, under Florida law, "[t]o determine whether [a] health service is consistent with generally accepted medical standards, the Agency ***shall consider*** … ***Evidence-based clinical practice guidelines***." Fla. Admin. Code 59G-1.035(4)(a).

Defendants base their motion on their purported inability to obtain information relating to the inner workings of the Third-Party Medical Organizations. Not only are such inner workings irrelevant, however, but it is also false that Defendants were precluded from obtaining relevant and lawfully discoverable information from these third parties. For one, Defendants received documentary evidence from each of these Third-Party Medical Organizations in response to their subpoenas seeking the production of documents. For another, Defendants' inability to obtain *some* of this information resulted from other courts' actions that either limited or stopped the discovery that Defendants sought from these non-parties because it was either overly burdensome or based on First Amendment concerns raised by the Third-Party Medical Organizations.

The fact that Defendants were precluded *by lawful court orders* from obtaining irrelevant information or information to which it had no right to obtain is not a sufficient reason for the exclusion of the current and widely accepted standards of care, clinical guidelines, and policy statements issued by professional medical associations regarding the treatment of gender dysphoria. Parties to

litigation are precluded from obtaining certain discovery all the time because it is too broad, unnecessary, too burdensome, or, as alleged by the Third-Party Medical Organizations, infringes of others' First Amendment rights. *See*, *e.g.*, ECF 105 (Order on the Motion to Quash the Grossman Subpoena, which limited the discovery Plaintiffs could obtain from one AHCA's consultants and the inner workings of groups with which AHCA's consultants work); ECF 118 (Order Allowing Mr. Weida's Deposition, but setting limits on such deposition).[1] The fact that Defendants were unable to obtain *some* of the discovery they wanted through arguably harassing fishing expeditions into the inner workings of third-party organizations they actively and ideologically oppose is not a reason to preclude Plaintiffs from presenting their case. This is particularly so when information Defendants seek to preclude is information that they, by operation of law, *must* consider in determining whether a health service is experimental or

[1] The lack of seriousness of Defendants' Motion is demonstrated by the fact that Defendants themselves have continually resisted discovery into their own inner workings and the inner workings of those with whom they worked with, including their consultants, the Executive Office of the Governor, and Florida Department of Health. At one point or another, Defendants have raised the apex doctrine, attorney-client privilege, work product doctrine, and common defense privileges to obstruct Plaintiffs' ability to discover the full truth of the machinations that lead to the Challenged Exclusion. Should that preclude any discussion of the GAPMS Memo or testimony from AHCA? That would be absurd, as is Defendants' request that this Court "exclude from trial all mention of [World Professional Association for Transgender Health ("WPATH")], [Endocrine Society ("ES")], and Plaintiffs' preferred medical organizations, and the organizations' standards of care, guidelines, and policy positions on treatments for gender dysphoria." ECF 64 at 4.

investigational, and is widely relied upon by experts in the relevant fields of medicine.

Simply put, Defendants' Omnibus Motion *in Limine* has no merit and in fact is illustrative of their failure to undergo a lawful and reasonable process before arriving at their desired result: the unlawful and discriminatory Challenged Exclusion. Defendants' Motion should be denied, in full.

ARGUMENT

I. The Internal Workings of WPATH, the Endocrine Society, and other Third-Party Medical Organizations are Irrelevant to this Case.

In the first instance, AHCA seeks to exclude "all mention of [WPATH], [Endocrine Society] and Plaintiffs' preferred medical organizations, and the organizations' standards of care guidelines, and policy position on treatment for gender dysphoria." Mot., 1. AHCA claims that the evidence should be excluded because they were prevented from obtaining certain information from these third parties and therefore this Court should make the severe decision to exclude "any mention" of the organizations. But Defendants were not prevented from obtaining any relevant, let alone essential, information.

The Court has identified the "controlling" issue in this case as being "whether, based on current medical knowledge, the state's determination that these treatments are experimental is reasonable." Dkt. 64, 4. This is a question that will

be answered by the parties' experts.[2] Moreover, each of the guidelines already provides, on its face, a description of its methodology and cites the studies on which it relies. Inquiry beyond the four corners of the guidelines into the internal deliberations of the Third-Party Medical Organizations are of no concern to resolving the issue of whether these services are experimental or investigational and AHCA's efforts to tie the two issues together should be dismissed out of hand.

A. Defendants Have Not Demonstrated The Information They Requested From Third-Party Medical Organizations Is Relevant or Necessary for this Case.

Defendants served nearly limitless third-party subpoenas for documents and depositions of over twenty Third Party Medical Organizations, all of whom are non-parties to this litigation. Mot., 7-8. The subpoenas sought information about how the organizations established and developed their standards of care, guidelines, and policy positions. *Id.* They also sought substantial proprietary internal information about the standards of care, guidelines and policy statements—including communications evidencing who created them, supported them, opposed them, and why. Mot., 10. The Third-Party Medical Organizations moved to quash the subpoenas, arguing that the information sought by Defendants

[2] As discussed throughout, state Medicaid regulations require Defendants to consider, in determining whether a particular medical service is experimental, "evidence-based clinical practice guidelines," but this inquiry merely asks what clinical guidelines exist and does not require investigation into how they were developed. Fla. Admin. Code R. 59G-1.035(4)(a).

was (1) irrelevant, (2) unduly burdensome, and (3) infringed on their free speech and associational rights under the First Amendment. *E.g., In re Subpoenas Served on Am. Acad. Of Pediatrics*, 1:23-mc-00004-CJN (D.D.C. 2023) (herein "D.C. Dkt.") D.C. Dkt. 27. The U.S. District Court for the District of Columbia substantially narrow the scope of the requests but still allowed Defendants to go fishing (D.C. Dkt. 18) a decision which the Third-Party Medical Organizations appealed, moving for a stay that the U.S. Court of Appeals for D.C. Circuit granted.

As a threshold issue, Defendants have not demonstrated that the information they seek is relevant, let alone essential, to their defense of Plaintiffs' claims or that it has any grounds to conduct an overly broad fishing expedition that would violate Third-Party Medical Organizations' constitutional rights. To justify their intrusive and improper requests into the decision-making function of the Third-Party Medical Organizations, AHCA cites to Plaintiffs' experts testimony that they routinely treat patients in accordance with these guidelines. Mot., at 6. Defendants also reference the cross-examination of Dr. Laidlaw at the hearing on Plaintiffs' Motion for Preliminary Injunction to suggest that because some position statements were used to discredit Dr. Laidlaw's qualifications and properly represent him as an outlier in the field of medicine, the information bears on the issues presented. Mot., 6-7. AHCA is wrong.

The question is not whether the standards of care, guidelines, and policy positions on treatments for gender dysphoria are relevant, but whether the inner workings of the Third-Party Medical Organizations' inner workings are relevant. And even if they were, Defendants' inability to obtain *all* of the information they desired, as opposed to *some* of the information which they did obtain, is if no consequence.

The WPATH Standards of Care and the Endocrine Society's Clinical Practice Guidelines are evidence-based recommendations, which cite to and rely upon a deluge of scientific studies and literature. *See* ECF 144-21 (WPATH's Standards of Care, Version 8); ECF 120-20 (Endocrine Society's Clinical Practice Guidelines). They exist. And no amount of wishing otherwise by Defendants will erase that undeniable fact.

To the extent that AHCA decided to wholly ignore the clinical guidelines for the treatment of gender dysphoria during the GAPMS process notwithstanding that the mandate the consider them during the GAPMS process, their witnesses and experts can so testify. To the extent that Defendants take issue with the science supporting the standards of care and clinical guidelines, they can cross-examine Plaintiffs' expert witnesses or present their own affirmative testimony about the scientific literature. These perspectives do not put at issue the internal deliberations, procedures, or communications about the standards of care,

guidelines, and policy statements. *See In re Schaefer*, 331 F.R.D. 603, 612 (W.D. Pa. 2019) (quashing subpoena seeking the deposition of the lead author of a publicly available report on transgender persons in the military, because the respondent had access to the report and "the same studies and data that [the petitioner] did in formulating her opinions and conclusions in the [] Report[,]" which "foreclose[d] any argument that the [respondent] ha[d] a 'substantial need" (or anything close to it) for [the petitioner's] testimony"); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 249 F.R.D. 8, 12–13 (D. Mass. 2008) (finding that a non-party publisher of medical journal was entitled to protective order to avoid disclosing peer review comments and communications with authors of articles; although materials sought were relevant to litigation, the probative value of documents was limited, since peer reviewers' and authors' confidential comments were not at issue in the case).

This analysis, nor the inevitable outcome of Defendants' improper motion here, does not change because AHCA "asserts that WPATH and ES don't speak for the medical community, and that other organizations, like the [American Academy of Pediatrics], might not actually speak for its membership on gender-affirming care." Mot., 16. It is incontrovertible that within any organization there are members who do not agree with the organization's position on any given issue. *E.g.*, ECF 81-4 (Email from then-AHCA employee Jeffrey English stating with

regards to the GAPMS Report, "All I can say about that report, as I have read it, is that it does not present an honest and accurate assessment of the current evidence and practice guidelines as I understand them to be in the existing literature."). It is undeniable that these organizations have adopted clinical guidelines or position statements that *represent the organization's position*. How an organization arrives at its position does not negate the fact that it is the organization's position. Moreover, Defendants cannot cite and have provided no example of any *major medical organization* that adopts guidelines or position statements by having its *entire* membership vote on it.

Here, Plaintiffs' experts have and will testify that these standards of care, clinical practice guidelines, and policy statements reflect the wide acceptance of professionals who, unlike all of Defendants' experts save one, treat transgender patients and the clinical practice guidelines make recommendations consistent with the scientific literature. Plaintiffs' experts will also explain, based on the scientific evidence, why the standards and guidelines are sound and why they rely on them. Of course, Defendants can ask and have asked the expert witnesses about the scientific evidence and how the clinical guidelines are supported by it.

WPATH, the Endocrine Society, and the other Third-Party Medical Organizations are simply not witnesses in this case. The fact that qualified health professionals in the field rely on their standards of care, clinical guidelines, and policy statements does not transform these entities into witnesses, nor does it transform their internal communications into relevant or admissible evidence . Nor would it be proper or relevant how these organizations establish their standards, guidelines, and policies. By analogy, it would be no more proper for a party to seek to depose the American Institute of Certified Public Accountants (AICPA) in an accounting dispute or the American Institute of Architects (AIA) in a construction related dispute. What *is* relevant is the testimony of the parties' expert witnesses and how they arrived at their opinions. Thus, to the extent Defendants question Plaintiffs' experts' qualifications, reliability, or helpfulness (which they do not), , Defendants are free to cross-examine Plaintiffs' experts.

Despite the irrelevant nature of the information Defendants sought, they claim the lawful court orders limiting or staying their intrusive subpoenas justify the exclusion of *any mention* of more than a dozen well-recognized and respected medical associations while at the same time allowing Defendants and their expert witnesses to question and attempt to undermine their:

> American Academy of Pediatrics, American Academy of Child & Adolescent Psychiatry, American Academy of Family Physicians, American Academy of Nursing, American College of Obstetricians and Gynecologists, American College of Physicians, American

> Medical Association, American Pediatric Society, American Psychiatric Association, Association of American Medical Colleges, National Association of Pediatric Nurse Practitioners, North Central Florida Council of Child & Adolescent Psychiatry, Societies for Pediatric Urology, Society for Adolescent Health and Medicine, Society for Pediatric Research, and Society of Pediatric Nurses.

Mot., 7; *Id.* at 8 n. 1.

But again, it is AHCA's own regulations which require Defendants to consider "evidence-based clinical practice guidelines" and makes reference to the views of "the relevant medical community or practitioner specialty associations." Fla. Admin. Code 59G-1.035(4)(a), (b). The regulation at issue makes no mention of the *inner workings* of these organizations, nor does require such an inquiry to determine if a health service is experimental or investigational. Indeed, AHCA cites no example where such an inquiry was performed or sought as part of the GAPMS process. It thus boggles the mind that Defendants seek to exclude any mention of "the relevant medical community or practitioner specialty associations" and the views and "evidence-based clinical practice guidelines" of these organizations, when ***AHCA's own regulations require a different result.***

In support of its unmoored and incredible request, AHCA cites to two cases (*Kosilek* and *Gibson*) for the proposition that a small minority of courts did not follow WPATH's recommendations. But not only is this disingenuous, but, at most, it goes to weight. It is not a reason to exclude any mention of the Third-Party Medical Organizations or their clinical guidelines and position statements.

Defendants disingenuously leave out that most federal courts consider the clinical practice guidelines and the positions statements adopted by the Third-Party Medical Organizations, including WPATH and the Endocrine Society, to be widely accepted and represent the consensus within the medical community. These include, among others:

- The Fourth Circuit, *see Williams v. Kincaid*, 45 F.4th 759, 768 n.3 (4th Cir. 2022); *Kadel v. N. Carolina State Health Plan for Tchrs. & State Emps.*, 12 F.4th 422, 427 (4th Cir. 2021), as amended (Dec. 2, 2021), *cert. denied*, 142 S. Ct. 861 (2022); *Grimm v. Gloucester Cnty. Sch. Bd.*, 972 F.3d 586, 595 (4th Cir. 2020), as amended (Aug. 28, 2020); *De'lonta v. Johnson*, 708 F.3d 520, 522-23 (4th Cir. 2013);
- The Seventh Circuit, *see Fields v. Smith*, 653 F.3d 550, 553 (7th Cir. 2011); *see also Fields v. Smith*, 712 F.Supp.2d 830, 843 (E.D. Wis. 2010), supplemented (July 9, 2010), *aff'd*, 653 F.3d 550;
- The Eighth Circuit, *see Brandt by & through Brandt v. Rutledge*, 47 F.4th 661, 671 (8th Cir. 2022);
- The Ninth Circuit, *see Edmo v. Corizon, Inc.*, 935 F.3d 757, 769, 771 (9th Cir. 2019);
- The U.S. District Court for the Middle District of Alabama, *see Eknes-Tucker v. Marshall*, 603 F.Supp.3d 1131, 1139 (M.D. Ala. 2022);

- The U.S. District Court for the Eastern District of Arkansas, *see Brandt v. Rutledge*, 551 F.Supp.3d 882, 890 (E.D. Ark. 2021), *aff'd*, 47 F.4th 661;
- The U.S. District Court for the Middle District of North Carolina, *see Kadel v. Folwell*, No. 1:19CV272, 2022 WL 3226731, at *32 (M.D.N.C. Aug. 10, 2022); and
- The U.S. District Court for the Western District of Wisconsin, *see Campbell v. Kallas*, No. 16-CV-261-JDP, 2020 WL 7230235, at *4 (W.D. Wis. Dec. 8, 2020); and *Flack v. Wisconsin Dep't of Health Servs.*, 395 F.Supp.3d 1001, 1018 (W.D. Wis. 2019).

In sum, Defendants' unprecedent request should be denied because the wide-ranging information pertaining to the Third-Party Medical Organizations' inner workings that Defendants sought and which they were only *partially* unable to obtain is irrelevant to this case. However, the information that they seek to exclude, which is undeniable, ***must be considered under AHCA's own regulations***. Finally, to the extent the information Defendants sought to obtain from third parties and were unable to obtain is relevant (and it is not), such information or lack thereof goes to the weight of the evidence and testimony Defendants seek to exclude, not to its admissibility.

B. The Requested Information Does Not Bear on the GAPMS Factors.

As noted above, to determine if a service meets Florida's Generally Accepted Professional Medical Standards (GAPMS), AHCA is required to consider several factors, including the existence of "evidence-based clinical practice guidelines" and the views of "the relevant medical community or practitioner specialty associations." Fla. Admin. Code 59G-1.035(4)(a), (b). Defendants cannot cite to, because no such requirement exists, that AHCA look at the internal communications and processes in determining how a particular guideline was established. Thus, previous GAPMS reports do not even comment on the organization that developed the guidelines, much less delve into the inner workings of those organizations or their processes for developing the guidelines. *See, e.g.*, Exhibit "A" (Def-000286954), Exhibit "B" (Def_000286961), Exhibit "C" (Def_000286947), Exhibit "D" (Def_000286931). Similarly, AHCA is required to rely on the "[r]ecommendations or assessments by clinical experts on the subject or field." Fla. Admin. Code 59G-1.035(4)(f). The discovery AHCA sought from the Third-Party Medical Organizations has no bearing on the medical necessity of these treatments or their scientific merits.

Defendants' position is particularly disingenuous because each of these organizations (i.e., WPATH and the Endocrine Society) cite to every study and piece of evidence on which they rely, and outlines the methodology used to

develop their recommendations. *See* ECF 144-21 (WPATH's *Standards of Care for the Health of Transgender and Gender Diverse People*, Version 8); 120-20 (Endocrine Society's *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline*).

Looking into the internal processes of the creation of the guidelines is not a factor for AHCA to consider in arriving at its decision because it is irrelevant to making a scientific determination. Rather, it has available the same data and information utilized by these organizations; if Defendants' experts review and analyze those same studies and have different opinions, they are free to bring that to this Court's attention. But they are not free, and indeed are well outside of the proper bounds of third-party discovery or the GAMPS process requirements to seek the inner workings of established professional medical associations in an effort to intimidate or silence them to serve Defendants' aims in this litigation.

Notably, there is *no evidence* AHCA reviewed or otherwise requested this information from WPATH, the Endocrine Society, or any of the organizations during the GAPMS process. If it was not relevant then, why is it relevant now? AHCA made its (erroneous) decision that gender-affirming medical care is "experimental" and purportedly has the evidence to support it.

Defendants are entitled to demonstrate the basis for promulgating the Challenged Exclusion and attempt to convince this Court that it was based on legitimate analysis. Defendants, however, are not entitled to exclude otherwise relevant evidence and testimony that undoubtedly goes to the heart of what AHCA is required to consider by claiming they were prevented from probing into the inner workings of non-party medical organizations, which AHCA's regulations do not require and they have never done.

That Plaintiffs rely on the internationally recognized WPATH's Standards of Care and the Endocrine Society's Clinical Practice Guidelines does not open the door to explore and turn over every rock of the inner workings and decision-making processes of these organizations. Nor is a lack of insight into the inner workings decision-making processes of these organizations a basis to not consider their widely recognized recommendations, positions, and statements, which AHCA's own regulations require. Indeed, these organizations are not parties to this case and Defendants have never sought to make them so.

C. Plaintiffs have not withheld any evidence.

While it is, according to court order, not the non-parties' obligation to provide Defendants with the irrelevant information sought, it is undoubtedly not Plaintiffs' obligation to provide it either. The Third-Party Medical Organizations, which are not under Plaintiffs' agency or control, properly objected to the requests

propounded on them by Defendants. Plaintiffs do not speak for the Third-Party Medical Organizations nor could they have provided the information Defendants sought. In any event, Defendants never served Plaintiffs with discovery requests seeking this information.

Defendants' contention that it has been "thwarted … by Plaintiffs from obtaining this discovery" (Mot., 4.) is entirely without merit. It was the U.S. District Court for the District of Columbia and the U.S. Court of Appeals for the D.C. Circuit, at the request of the Third-Party Medical Organizations, who limited or barred Defendants from *partially* obtaining the information they sought.

Defendants now toss a Hail Mary by arguing that Plaintiffs stopped them from obtaining the information by objecting to their improper questioning of an expert witness to discuss information he was not at liberty to discuss. But notably, as further explained below, Defendants cannot and do not point to any substantive questions which Dr. Edmiston refused to answer.

The only example they point to is that Dr. Edmiston responded "Yeah, that would – that would – discussing that would be in violation of the confidentiality agreement," when he was asked "did you contribute in authoring any other chapters in WPATH?" Mot., at 16. But a single question to a single expert, without any follow up, is not a basis to "exclude from trial all mention of World Professional Association for Transgender Health ("WPATH"), the Endocrine

Society ("ES"), and Plaintiffs' preferred medical organizations, and the organizations' standards of care, guidelines, and policy positions on treatments for gender dysphoria," or to "exclude Plaintiffs' experts' opinions that are based on the based on the organizations' standards of care, guidelines, and policy positions on treatments for gender dysphoria." Mot., at 1. Not only is it irrelevant, but, as explained below, Dr. Edmiston had previously testified that "[m]any different people were involved in" SOC8 and that "the document was written collaboratively." Mot., at 15.

II. There Is No Basis to Exclude Dr. Edmiston as He Did Not Rely on WPATH's Standards of Care or Endocrine Society's Guidelines in Rendering His Opinions and Did Not Withhold Any Relevant Information.

In reading AHCA's Motion, the reader is left with the impression that Dr. Edmiston was prevented from answering questions relevant to his opinions. But a close examination of the facts reveals something strikingly different. AHCA's arguments are misguided for two reasons. *First,* Dr. Edmiston's opinions are not based on the WPATH Standards of Care or on the Endocrine Society's Clinical Practice Guidelines, to say nothing of the policy position statements of other medical professional organizations. *Second,* the questioning of Dr. Edmiston was a thinly veiled attempt to circumvent the D.C. Circuit's stay. Dr. Edmiston responded to all but *a single question* in his deposition, because that question

(which was outside the scope of his testimony and opinions) was in direct violation of the stay order.

A. Dr. Edmiston Rebuttal Opinions Do Not Rely on WPATH's Standards of Care or the Endocrine Society's Guidelines.

Dr. Edmiston is a neuroscientist and is proffered by Plaintiffs as a limited rebuttal witness to opinions raised by Defendants designated expert Professor Scott. Even a cursory review of Professor Scott's report shows her testimony is wholly unrelated to WPATH, the Endocrine Society, and any of the other Third-Party Medical Organizations to which Defendants' Motion relates. *See generally* Exhibit "E" (Scott Report).[3] Professor Scott's report includes *no mention* of WPATH or of the Endocrine Society either. The same holds true for Dr. Edmiston. Dr. Edmiston's opinions and testimony are primarily based on his own research and academic experience and the peer-reviewed literature relating to neuropsychological assessment and brain development. Throughout his opinions, he makes mention of the SOC8 *only once* (and completely unrelated to either the information upon which the instant motion is based, i.e., inner workings of

[3] Plaintiffs moved to exclude the expert report, opinions, and testimony of Professor Scott in its entirety. *See* ECF 119. As outlined in the motion, Professor Scott is not a qualified expert on gender dysphoria or its treatment, and her opinions and testimony are neither relevant nor reliable under Federal Rule of Evidence 702 and the standards set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), and its progeny. A copy of Professor Scott's Expert Report is attached as Exhibit "E" ("Scott Report").

WPATH and other Third-Party Medical Organizations), (*see* Exhibit "F" (Edmiston Report), at ¶ 20), and makes no mention of the Endocrine Society's Guidelines or position statements from Medical Organizations.[4] This makes sense as his testimony limited to rebutting Professor Scott's opinions outlined in her report (which makes no mention of the organizations). Accordingly, and naturally, the lack of WPATH and Endocrine Society related discovery could not and did not affect Defendants' ability to conduct a proper deposition of Dr. Edmiston.

In fact, Dr. Edmiston confirmed as much at deposition. However, AHCA grossly mischaracterizes Dr. Edmiston's deposition testimony. A review of the deposition transcript makes clear that Dr. Edmiston did not rely on the WPATH's Standards of Care or Endocrine Society's Clinical Practice Guidelines to form the opinions contained in his exert report.[5]

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[4] A copy of Corrected Expert Rebuttal Report of E. Kale Edmiston, Ph.D. is attached as Exhibit "F" ("Edmiston Report"); a copy of his deposition transcript is attached as Exhibit "G" ("Edmiston Dep."). Citation to Edmiston's Report will be referenced as "Edmiston Report" followed by the page number. Citation to his deposition will be referenced as "Edmiston Dep." followed by the page(s) and line(s).

[5] Other than mentioning his experience as a contributing author of WPATH SOC 8 and emphasizing its recommendation of an "individualized approach to joint decision-making regarding healthcare[,]" Dr. Edmiston does not rely on WPATH's Standards of Care or any of the Third-Party Medical Organizations' positions. As noted above, a review of Dr. Edmiston's report reveals only a singular passing mention of the SOC8 (Exhibit "F" (Edmiston Report), at ¶ 20) and the bibliography attached to his report does not cite WPATH's Standards of Care or the Endocrine Society's Guidelines.

> **Q: Did you rely on the WPATH Standards of Care 8 in making conclusions in your expert report?**
>
> A. I relied on my expertise on the topic. …
>
> **Q. Is it your opinion that WPATH sets professional standards of care for treatments for gender dysphoria? …**
>
> A. They are one organization. There are other medical organizations that also have standards of care. …
>
> **Q. Did you review any Endocrine Society documents in making this expert report?**
>
> A. No.

See Exhibit "G" (Edmiston Dep.), at 16:21-17:14. If the deposition was not "illuminating," it is due to the lack of appropriate and relevant questioning, not to Dr. Edmiston's answers. Indeed, AHCA's counsel deposed Dr. Edmiston for less than two hours. Further, in response to the following exchange **"**Q: Did you rely on the WPATH Standards of Care 8 in making conclusions in your expert report? A. I relied on my expertise on the topic. …" (Exhibit "G" (Edmiston Dep.), at 16:21-16:24), there was not a single follow up question as to what specific expertise that referenced or what—if anything it had to do with WPATH.

It seems likely that Defendants did not ask the question because the answer is was an obvious "nothing." In reviewing the bibliography of Dr. Edmiston's report for the sources he relies upon for his specific opinions, there is no mention of WPATH's Standards of Care or the Endocrine Society's Guidelines. And the

only mention within Dr. Edmiston's opinions of WPATH's Standards is a single passing sentence that is completely unrelated to the questions he was asked at his deposition and unrelated to the information of which Defendants complain in their motion.

Indeed, the sought-after discovery is wholly irrelevant and unrelated to Dr. Edmiston's opinions and testimony. Thus, Dr. Edmiston's co-authorship of a WPATH Standards of Care Version 8, Chapter 5, the Assessment of Adults, (Edmiston Dep., at 32:2-32:9), is immaterial to his rebuttal opinions presented in this case.[6] Instead of Defendant's line of questioning focusing on the content of Dr. Edmiston's expert report, as discussed below, Defendant opted to spend their time questioning him on issues of the internal processes of WPATH and Endocrine Society in a clear attempt to circumvent the D.C. Circuit's stay order prohibiting AHCA from seeking *further* discovery into the inner working of the Third-Party Medical Organizations.

[6] The Assessment chapter discusses how to diagnose gender dysphoria in adults and has nothing to do with the opinions Dr. Edmiston's proffers in this case, where Dr. Scott's and his testimony related to the effects of brain development in *adolescents*. Nevertheless, AHCA deposed Dr. Edmiston extensively on this Chapter and he answered every single one of those question. *See* Edmiston Dep., at 22:13-45:2.

There simply is no basis to exclude Dr. Edmiston's opinions in their entirety or even in part.

B. Defendants Improperly Attempted to Circumvent the Stay Order By Its Questioning of Dr. Edmiston.

The D.C. Circuit stayed the D.C. district court's order allowing *further* limited discovery into the Third-Party Medical Organizations' inner workings. No. 23-7025 (D.C. Cir. Mar. 8, 2023). Despite this, AHCA attempted to circumvent the stay order by asking Dr. Edmiston about topics unrelated to his expert report or expert opinions, and that they were prohibited from further seeking discovery on by the stay. That is, AHCA asked Dr. Edmiston about the specific internal processes to the drafting process of the WPATH Standards of Care, Version 8. There is nothing improper about this Court ensuring Defendants comply with a duly issued and binding order from a court with jurisdiction over the matter.

Defendants' strategic attempt to circumvent the stay order through the deposition of Dr. Edmiston should not be permitted. Plaintiffs' counsel was acting within the rules when they objected to questioning, to the extent that the answers would violate the stay granted by the D.C. Circuit or violate a confidentiality agreement entered into by Dr. Edmiston, and in any event, but for one question, Dr. Edmiston *answered every question asked of him*.

During a deposition, "[a] person may instruct a deponent not to answer only when necessary to preserve a privilege, to enforce a limitation ordered by the court, or to present a motion under Rule 30(d)(3)." *See* FED. R. CIV. P. 30(c)(2). As a matter of "comity and respect for the effect of preexisting judicial orders," *Donovan v. Lewnowski*, 221 F.R.D. 587, 588 (S.D. Fla. 2004), there is no dispute that the existing order continues to have full force and effect on the parties subject to it, including Defendants. Defendants' attempt to circumvent the lawful stay order through the deposition of Dr. Edmiston goes directly against principles of comity and courtesy. To the extent that Defendants want to obtain the information it seeks, that request should be addressed to the D.C. Circuit, which issued the stay.[7] In their motion, Defendants acknowledge that they were "*again* prevented from probing into how WPATH creates its standards of care." Mot., at 22. Defendants *admit* they intentionally sought a line of questioning that was specifically limited by the D.C. Circuit's Order staying the third-party subpoena. No matter how frustrating to their purposes outside the scope of this dispute,

[7] As an aside and to highlight the principles of comity and respect for the effect of preexisting judicial orders, courts also respect protective orders entered by other courts. *See*, e.g., *Santiago v. Honeywell Int'l, Inc*., 16-CIV-25359, 2017 WL 3610599, at *2 (S.D. Fla. Apr. 6, 2017) (discussing that courts faced with deciding discovery motions that involve requests to modify or terminate a protective order previously issued by another court, frequently feel constrained by principles of comity and courtesy, and citing cases in support).

Defendants simply cannot circumvent the stay order by using Plaintiffs' expert Dr. Edmiston as a vehicle for that prohibited discovery, particularly when the information does not relate to Dr. Edmiston's proffered expert opinions.

Despite any objections premised on protection by the stay order and the existence of a confidentiality agreement, Dr. Edmiston answered every question related to WPATH and the Endocrine Society but for *one*:

> **Q**: … And, again, you authored this document, or at least this chapter in the Standards of care 8?
>
> **Plaintiffs' Counsel:**
>
> **A**: I –
>
> **Plaintiffs' Counsel**: Objection to form; scope and the other restrictions that we 've talked about before relating to your confidentiality agreement and the stay order in place.
>
> **A**: Yes, I was a co-author of SOC8.
>
> **Q**: And this chapter?
>
> **A**: Yes.
>
> **Q**: Any other chapters, Doctor?
>
> **Plaintiffs' Counsel**: Objection. Form; scope; and same objections relating to the confidentiality agreement and the violation of -- and any – and not to violate the stay in place.
>
> **A**: I would, again, refer you to the WPATH website which outlines the process by which this document was drafted. It was written via consensus and was drafted collaboratively.
>
> **Q**: Okay. So I don't think you answered my question. Did you- -again noting the objections, did you contribute in authoring any other chapters in WPATH?

> **Plaintiffs' Counsel**: I'm going to object to form; scope. Again, do not violate your confidentiality agreement or the stay that's in place.
>
> **A**: Yeah, that would – that would – discussing that would be in violation of the confidentiality agreement.
>
> **Q**: All right. I'll move on.

See Edmiston Dep., at 23:1-45:2. While Dr. Edmiston cited his confidentiality agreement, this is also precisely the information prohibited by the existing stay order, i.e., the internal workings of WPATH and how the consensus driven, collaborative guidelines were established.[8]

The exchanges in the transcript clearly evidence the fact that Dr. Edmiston answers all but *one* question related to WPATH. Defendants' position that the answers elicited by the line of questioning were "hardly illuminating" is not a valid reason to exclude Dr. Edmiston's testimony, in part or in total, particularly when none of the questions relate to Dr. Edmiston's opinions in this matter. Plaintiffs' counsel did not instruct Dr. Edmiston not to answer any questions and did not prevent Defendants' counsel from asking follow-up questions. Indeed, after not answering only one question—based on the confidentiality agreement—AHCA's counsel immediately stopped pursuing the line of questioning under his own volition and moved on to a different subject.

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[8] Defendants argue Plaintiffs' Counsel should have sought a protective order. But there is already such as order in place from the D.C. Circuit. As a result, no additional protective order was necessary.

Defendants also conveniently omit important portions of the deposition transcript which highlight Plaintiffs' counsel's deference in allowing Defendant to question Dr. Edmiston about WPATH. Specifically, when asked if it was "plaintiffs' position that [Defendant's counsel] cannot ask any WPATH-specific questions to [Dr. Edmiston], (Exhibit "G" (Edmiston Dep.), at 19:10-19:12), Plaintiff's counsel made it abundantly clear that they were "not suggesting that [Defendant's counsel] can't ask WPATH questions." Exhibit "G" (Edmiston Dep.), at 19:13-19:24. Moreover, Plaintiffs' counsel did not make any "blanket prohibition or objection," but instead, objected on a "question by question" basis with the goal being not to "reveal confidential information or information that would otherwise be barred by the current stay and order." Exhibit "G" (Edmiston Dep.), at 20:18-21:10. Again, Dr. Edmiston answered every question but *one*.

More importantly, Defendants make no showing as to why any of this undermines Dr. Edmiston's qualifications, or the helpfulness and reliability of his testimony, which are the factors to be considered under *Daubert*. *See United States v. Frazier*, 387 F.3d 1244, 1260 (11th Cir. 2004).

III. There is No Prejudice to AHCA Not Obtaining Records Resulting from Their Overbroad and Irrelevant Requests.

Denying the Motion will not unfairly prejudice Defendants. Defendants cannot claim unfair prejudice when any prejudice faced is a direct result of their inaction in obtaining the requested information either during the GAPMS process

or because a court found the third-party discovery to be unjustified as unduly burdensome or unconstitutional. If Defendants now want to "'test the conclusions in the [WPATH's Standard of Care], it can, of course, retain its own experts to utilize their own knowledge, skill, experience, training, or education to analyze the data and sources that [WPATH] did, and then affirm or critique the Report." *In re Schaefer*, 331 F.R.D. 603, 613 (W.D. Pa. 2019) (citation omitted). Accordingly, there is no prejudice, and the Motion should be denied.

IV. There is No Basis to Exclude Any Expert Testimony on "*Daubert* concerns."

AHCA also seems to suggest that Plaintiffs' experts should wholesale be excluded because of "*Daubert* concerns" because they did not get the information they requested before now. Mot., at 22-23. But that is not the standard for the exclusion of an expert witness or their testimony. Nor has AHCA put forth any evidence from which this Court should exclude any of the expert witnesses on such grounds.

In determining the admissibility of expert testimony under Federal Rule of Evidence 702, district courts consider whether "(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in Daubert; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to

understand the evidence or to determine a fact in issue." *Frazier*, 387 F.3d at 1260 (cleaned up).

Defendants do not challenge the qualifications of any of Plaintiffs' experts nor do they challenge the helpfulness of their testimony. At most, Defendants indirectly challenge the reliability of Plaintiffs' experts' opinions and testimony by making the unremarkable point that information that Courts can rely on to test an expert's theory include "consider[ing] whether the scientific community agrees with the theory or technique" and "published sources" that are "generally accepted by the medical community in defining the applicable standard of care." *United States v. Azmat*, 805 F.3 1018, 1042 (11th Cir. 2015); Mot., at 23. Bizarrely, Defendants go on to say that *this* is what they requested from these organizations. *Id.* ("Of course, that's the information that the State has sought and doesn't have."). Not so.

For one, whether a particular medical organization agrees with an expert's theory is a binary question: yes or no. The problem for Defendants is that every major medical organization agrees with Plaintiffs' experts on this issue, and they would like to erase that reality from existence for their convenience. For another, Defendants have had unfettered access to the published sources at issue, whether those are the WPATH Standards of Care, the Endocrine Society's Clinical Practice Guidelines, or the positions statements of other medical organizations, or the

underlying studies cited within each of those documents. The information Defendants sought and which they do not have is therefore unrelated and not part of any inquiry under Federal Rules of Evidence or *Daubert* pertaining to the admissibility of expert testimony. .

The question at hand is simple and straightforward. Plaintiffs' experts have relied, in part, on WPATH's Standards of Care, the Endocrine Society's Clinical Practice Guidelines, and the positions and views of other medical organizations to formulate their opinions. They are entitled to do so because they are relying on or referencing "materials other experts in the particular field would reasonably rely on … in forming an opinion on the subject." Fed. R. Evid. 703. That is what the Rules of Evidence envision, permit, and endorse as the basis for an expert's opinion. Defendants do not grapple with this, at all. Nowhere in their motion do Defendants reference, let alone allude to Rule 703.

In fact, Defendants themselves has previously relied on these clinical practice guidelines. A 2016 GAPMS determination by Defendants concluding that they could not "categorically exclude" coverage of puberty-delaying medications to treat an adolescent's gender dysphoria explicitly cited and relied upon the Endocrine Society's Clinical Practice Guidelines and a consensus statement by the American Academy of Pediatrics regarding the use of puberty-delaying medications. *See* ECF 81-5 at 6; *see also* Exhibit "H" (Def_000366785)

(considering the Endocrine Society's guidelines in developing internal criteria for the coverage of puberty suppressing medications).

What is more, one of the Defendants' own purported experts, Dr. Levine, adheres to the WPATH Standards of Care in his own practice. *See Kadel*, 2022 WL 3226731, at *15 ("In his own practice, Levine adheres to the WPATH Standards of Care and personally provides letters of authorization for medical and surgical treatments for his gender dysphoric patients after advising them on the risks associated with those treatments.").[9] Defendants cannot ask to exclude any mention of WPATH's standards of care, the Endocrine Society's Clinical Practice Guidelines, and policy position statements of the Third-Party Medical Organizations while simultaneously relying on them themselves and relying on purported experts who adhere to and observe those same materials and concepts.

It also simply cannot be that an expert witness relying on or otherwise referencing materials "other experts in the particular field would reasonably rely on … in forming an opinion on the subject," necessitates unfettered and limitless access to every aspect of an organization's operations in order for the expert to

[9] Plaintiffs also moved to exclude the expert report, opinions, and testimony of Dr. Levine because his opinions are either unhelpful or unreliable under Federal Rule of Evidence 702 and the standards set forth in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993), and its progeny. *See* ECF 141.

formulate and provide a reliable opinion. Nothing in the Federal Rules of Evidence nor *Daubert* dictate such a result.

Given the number of experts and attendant reports offered by Defendants, the Court will hear substantial opinions and analyses on the core question in this case. There is no prejudice to Defendants in Plaintiffs and their experts referencing medical organizations and the organizations' standards of care, guidelines, and policy positions on treatments for gender dysphoria. On the other hand, there is substantial prejudice to Plaintiffs in not being able to mention or refer to the "evidence-based clinical practice guidelines" and views of "the relevant medical community or practitioner specialty associations" that AHCA's own regulations require be considered. Fla. Admin. Code 59G-1.035(4)(a), (b).

What is more, Defendants can question (and have questioned) Plaintiffs' experts on the mountain of scientific studies cited by each of these documents and that support the provision of gender-affirming medical care. And while a district court can consider whether the scientific community agrees with a theory or technique (Mot. at 23), Defendants cannot cite a single example where this has justified a free-wheeling and boundless inquiry into a third party's decision-making for arriving at that conclusion, particularly, when the third party is not a party to the litigation nor serves as an expert in the case. This is routine. Experts routinely rely on peer-reviewed studies and publications (like the WPATH

Standards of Care and Endocrine Society Guidelines are). That a party is unable to obtain non-public proprietary information underlying said peer-reviewed publication is not a basis to exclude the expert's opinion. And again, Defendants have not pointed to a single example where this has occurred.

In any event, and importantly, the Plaintiffs' expert witnesses do not rely on the WPATH and the Endocrine Society guidelines in a vacuum. Not only are these guidelines reasonably that are reasonably relied upon by other experts in the field that are providing this care to people with gender dysphoria, but Plaintiffs' experts cite to and rely to their extensive clinical and research experience, as well as a plethora scientific studies.

That AHCA was unable to fully look under the hood of WPATH's Standards of Care, the Endocrine Society's Clinical Practice Guidelines, and the position statements of other medical organizations is not a reason to exclude qualified, relevant, and reliable testimony.

V. The Court Should Not Exclude Expert Testimony Under Rule 403.

Exclusion under Rule 403 is only appropriate if the probative value of otherwise admissible expert testimony is ***substantially outweighed*** by its potential to confuse or mislead the jury, or if the testimony is cumulative or needlessly time consuming. *Hendrix v. Evenflo Co.*, 255 F.R.D. 568, 579 (N.D. Fla. 2009), *aff'd sub nom. Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183 (11th Cir. 2010). But

"Rule 403 has a limited role, if any, in a bench trial." *Cmty. Ass'n for Restoration of the Env't, Inc. v. Cow Palace, LLC*, 80 F.Supp.3d 1180, 1216 (E.D. Wash. 2015); *see also E.E.O.C. v. Farmer Bros. Co.*, 31 F.3d 891, 898 (9th Cir.1994) (citing *Gulf States Utils. Co. v. Ecodyne Corp.*, 635 F.2d 517, 519 (5th Cir.1981)); *Brister v. Universal Sodexho*, No. CIV.A. 05-4034, 2006 WL 5156736, at *1 (E.D. La. Sept. 12, 2006) ("Because this will be a bench trial, the dangers listed in Rule 403 are significantly reduced and do not substantially outweigh Mr. Barbe's potential value as a witness.").

CONCLUSION

For the foregoing reasons, the Court should deny Defendants' Omnibus Motion in *Limine* in its entirety.

Respectfully submitted this 21 day of April, 2023.

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of April, 2023, a true copy of the foregoing has been filed with the Court utilizing its CM/ECF system, which will transmit a notice of electronic filing to counsel of record for all parties in this matter registered with the Court for this purpose.

/s/ Shani Rivaux
Attorney for Plaintiffs

CERTIFICATE OF WORD COUNT

As required by Local Rule 7.1(F), I certify that this Opposition contains 7,776 words.

/s/ Shani Rivaux
Attorney for Plaintiffs

RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

SPECIALLY MODIFIED LOW-PROTEIN FOODS GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS (GAPMS) DETERMINATION REPORT WITH RECOMMENDATION

Date: July 5, 2017

To: Beth Kidder, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Specially Modified Low-Protein Foods**

PURPOSE

In order for the use of specially modified low-protein foods (SMLPF) to be covered under the Florida Medicaid program, it must meet the medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code. (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in 59G-1.010, F.A.C., the use of SMLPFs must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether SMLPFs are consistent with generally accepted professional medical standards and are not experimental or investigational.

If it is determined that SMLPFs are consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in 59G-1.035, F.A.C. based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high-level review of relevant disease processes.
- An overview of the health service information.
- Clearance from the government regulatory body (e.g. U.S. Food and Drug Administration).

product categorized as a medical food can be an enteral formula vital to treating a disease, while another is an ordinary food item designed without an ingredient that can be harmful for patients with certain diagnoses or conditions. Understanding the purpose for each medical food requires in-depth investigation beyond the label.

Formulas

Formulas are nutritional drinks designed to provide nutrients for patients who are unable to obtain them from their diet. Depending on the disease, formulas can contain specific proteins and vitamins specially processed to sustain a patient's nutrition while not exacerbating the disease. For example, formulas for PKU patients contain amino acids absent of phenylalanine and serve as a primary source of protein (Van Calcar et al, 2012).

Specially Modified Low-Protein Foods

Used as an adjunct to manage PKU, SMLPFs resemble conventional items such as hamburgers, bread, cheese, and hot dogs but contain ingredients free of phenylalanine. Based on wheat starch recipes, these products' intent is not to provide core nutrients but rather to promote more normal appearing diets and give satiety to patients.

Unlike formulas, SMLPFs are not necessary to treat PKU. They do not provide proteins free of phenylalanine and cannot act as substitutes for formulas. Instead, these foods help to increase dietary variety and normalize the appearance of a low protein diet (Vockley et al, 2013).

Due to the rarity of PKU, patients wishing to acquire these foods must do so directly from the manufacturers as they are not commercially available in local grocery stores. This makes the products more difficult to access due to higher costs and shipping (Camp et al, 2012). The products may cost two to eight times as much as similar (unmodified) products in grocery stores. Additionally, given that some of these items are soft (bread) or frozen (microwaveable entrees), shipping costs can be more expensive (Camp et al 2012).

Intended for use in addition to formula, these products range from basic staples such as low-protein flour to frozen microwaveable dishes. Product examples and their ingredients are listed below (Cambrooke, 2017):

- Baking Mix, 2 lb. bag, $15.49. Ingredients: wheat starch, sugar, canola oil, fully hydrogenated cottonseed oil, and xanthan gum
- Blueberry Scones, 16 oz. package, $12.99. Ingredients: wheat starch, non-dairy creamer, blueberries, tapioca starch, butter, sugar, powdered sugar, xanthan gum, canola oil, fully hydrogenated cottonseed oil, baking powder, cinnamon, and malic acid
- American Cheese Singles, 32 slice package, $12.99. Ingredients: water, food starch, partially hydrogenated soybean oil, modified food starch, milk protein concentrate, salt, natural flavor, sodium phosphate, stabilizers (xanthan, locust bean, guar gums), sorbic acid, lactic acid, and artificial color

Government Regulatory Body Approval

The FDA does not subject medical foods to the same regulatory process as drugs. However, they must meet and follow certain guidelines and are exempt from the nutrient content labeling rule mandated by the Nutrition Labeling and Education Act of 1990. The FDA requires all medical foods to adhere to the following criteria:

- Be specially formulated and processed products
- Be intended for the dietary management of a patient that is unable to digest nutrients
- Provide nutrition specifically for the unique needs caused by a disease or condition
- Be used under a medical professional's supervision

Obtaining medical food does not require a prescription because the FDA does not regulate them as drugs.

LITERATURE REVIEW

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to SMLPFs. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Dietary Management of PKU

The medical community agrees that the best treatment for PKU is through dietary management and that controlling phenylalanine levels with a combination of formula and low protein foods is the ideal method (Camp et al, 2012). However, available scholarship does not indicate a medical necessity for SMLPFs as opposed to fruits, vegetables, and sugars, as patients are still required to obtain essential nutrients from formulas (Vockley et al, 2014).

To treat PKU, the primary method of controlling dietary intake presents problems such as adherence, malnutrition, and effects on quality of life (Ho et al, 2014). Research notes that 60-80% of patients begin failing to maintain their diets by adolescence and those that do still show impaired cognitive function. Much of the reason why patients struggle with adherence is due to the palatability of a PKU diet. They must avoid all foods high in protein and can only eat starches, fruits, and vegetables in limited quantities. In addition, the phenylalanine-free amino acid formulas have large quantity servings and poor flavor (Santos et al, 2006).

Adding glycomacropeptide (GMP) to PKU patients' diets has improved nutrition and quality of life. Based on a natural by-product of cheese production, GMP has a high protein concentration and contains little phenylalanine. Replacing synthetic amino acids with GMP in formulas results in more satiety, better nutrition, and higher compliance with PKU diets (Strisciuglio et al, 2014). Although GMP is present in formulas, it is not an ingredient in SMLPFs.

Van Calcar et al (2012) provided an analysis evaluating how alternatives were needed for amino acid-based formulas to help patients stay compliant with a PKU diet. They emphasized that persistent hunger was one of the main challenges with PKU diets and that GMP could serve as a better alternative. The analysis noted that GMP provided improved satiety and better taste over amino acid formulas.

MacLeod et al (2010) conducted a study with 11 PKU patients completed over an eight-day period. During the first four days, participants consumed a diet using a synthetic amino acid formula as their primary source of protein. In the last four days, the researchers switched the formula to food containing GMP. Participants gave daily blood samples throughout the study. The conclusions noted that the participants had lower levels of the hunger hormone, ghrelin,

when they consumed a GMP-based diet. This indicated higher rates of satiety because increased ghrelin levels occur when the body is hungry.

When determining the best method for improving satiety while providing essential proteins, research indicates that using foods and formulas with GMP offers an ideal strategy. Van Calcar et al (2012) states "protein is the most satiating nutrient." Low-protein foods based on starches do not have amino acids or GMP and cannot provide basic nutrition (Vockley et al, 2014).

Current Research on PKU Treatments

New research focuses on reinforcing the PKU diet by making it more palatable and satisfying. This includes introducing formulas based on glycomacropeptide but also exploring large neutral amino acids (LNAA). In 2016, Concolino et al conducted a study that evaluated LNAA efficacy and concluded that this method is effective in lowering blood phenylalanine levels. They based this on the findings from 12 participants who also reported that the LNAA based foods tasted better than their traditional formulas. Concolino et al also noted that this method provided an effective means of delivery for other essential vitamins and nutrients. Although LNAAs appear promising, more studies with larger groups are needed to determine their full potential. If LNAAs become a mainstay in treating PKU, they will function as part of the dietary management strategy (Ney et al, 2014).

Another option gaining support is through pharmaceuticals. In 2007, the FDA approved Kuvan (sapropterin dihydrochloride), which can enhance tolerance of phenylalanine in PKU patients. Muntau et al published the results of a trial in 2017 showing that the drug raised acceptable levels but that it should be taken in conjunction with a traditional PKU diet. To reach these conclusions, the researchers placed 27 participants on Kuvan for a 26-week regimen and compared phenylalanine tolerance with a control group that only used the diet. Despite findings like these and those of similar trials, Kuvan cannot become the new mainstay of PKU treatment. The drug's efficacy varies depending on the severity of each patient's condition and is not recommended for cases that are difficult to manage (Ho et al, 2014).

Advancing research for PKU treatment is highly challenging due to the rarity of the disease. The small number of patients and their geographic dispersion do not allow for adequate sample sizes when conducting studies. Because of this, demonstrating effectiveness is difficult and slows progress in comparison to common diseases (Agency for Healthcare Research and Quality, 2012).

Research on Specially Modified Low-Protein Foods

Current research on treating PKU continues to focus on managing the condition through diet with formula as the primary means of obtaining vital nutrients. However, these studies do not examine the efficacy of SMLPFs. Without research and trials, questions remain as to whether these products promote dietary adherence, can be consumed in quantities adequate to achieve satiety, and are necessary to provide complete nutrition in addition to formula.

Evidence-Based Clinical Practice Guidelines

The American College of Medical Genetics and Genomics (ACMG) released a guideline for the management of PKU in 2014. It stated that "dietary therapy with restriction of phenylalanine intake remains the mainstay" of PKU therapy and that without medical foods the disease "will result in inadequate protein to support normal growth and health." However, the ACMG

differentiates between medical foods that are formulas containing glycomacropeptide or amino acids from those that are SMLPFs. In regards to formulas, it asserts that they are the main factor in a PKU diet and are needed to "meet established dietary requirements." The ACMG also considers SMLPFs to be necessary because they "mimic higher protein foods" and increase variety. The guidelines further state that formulas and SMLPFs "should be regarded as medications." Aside from these statements, the ACMG issues no further opinion or guidelines on the use of SMLPFs.

COVERAGE POLICY

This section provides a summary of coverage and policy information from Medicaid, Medicare, and private insurers.

Medicare

Medicare does not cover SMLPFs. The Centers for Medicare and Medicaid Services (CMS) have not issued a national coverage determination and none of its contracted insurers have issued a local coverage determination (CMS, 2017).

Medicaid

Florida Medicaid covers PKU formulas such as Glytactin for patients under 21. These products consist of glycomacropeptide and/or other phenylalanine-free ingredients that provide essential protein and nutrients while improving satiety.

Connecticut offers coverage for SMLPFs only with prior authorization (Connecticut Husky Health, 2015).

Georgia's coverage policy for SMLPFs must have prior authorization and are only available to enrollees age 21 and under (Georgia Department of Community Health, 2017).

Idaho covers SMLPFs but requires prior authorization (Idaho Department of Health and Welfare, 2017).

Indiana covers SMLPFs and reimburses $5.33 per unit (Indiana Medicaid, 2016).

Iowa covers SMLPFs only with prior authorization and for those products that have a National Drug Classification number (Iowa Department of Human Services, 2014).

Maine does not offer coverage for SMLPFs (Maine Department of Health and Human Services, 2017)

Minnesota's Health Care Program covers SMLPFs for up to $525 per month (Minnesota Department of Human Services, 2017).

Kentucky covers SMLPFs, requiring prior authorization and certificate of medical necessity (Kentucky Department of Public Health, 2016).

Nevada covers SMLPFs only with prior authorization and for a six-month period. Patients must acquire their SMLPFs through a pharmacy or durable medical equipment provider (Nevada Department of Health and Human Services, 2015).

New Jersey covers SMLPFs when prescribed by a practitioner (New Jersey Department of Human Services, 2015).

West Virginia does not cover SMLPFs (West Virginia Department of Health and Human Resources, 2016).

Wyoming and Texas cover SMLPFs only with prior authorization and will not reimburse for foods traditionally classified as low in nutritional value such as cakes, cookies, and onion rings (Wyoming Department of Health, 2016 and Texas Department of Health and Human Services, 2016).

Other Insurers

Aetna does not cover specially modified low-protein foods except when state law mandates it.

United Healthcare lists low-protein foods among its coverage exclusions for oral and enteral nutrition and does not cover it unless state law requires it.

Blue Cross Blue Shield (BCBS) of Rhode Island and BCBS of Massachusetts cover low-protein foods when ordered by a physician.

Florida Blue (BCBS) does not cover low-protein foods.

Oregon statutorily requires private insurers to cover low-protein foods using code S9435 (Huntington et al, 2009).

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report does not recommend specially modified low-protein foods as a health service that is consistent with generally accepted professional medical standards. Such foods are not demonstrated to be an effective treatment option for PKU.

Rationale

The medical profession notes that SMLPFs can assist in the management of PKU by increasing dietary variety and satiety. However, it does not indicate that these foods are necessary for sustaining the health and nutrition of patients. SMLPFs do not provide essential nutrients and can only be used to supplement formula. Using them to treat PKU alone would result in complications and developmental issues for patients. The clinical practice guidelines also do not indicate necessity, noting that SMLPFs help create the appearance of a normal diet.

While research has demonstrated the vitality of formulas for managing PKU, it does not do the same for SMLPFs. The available literature does not cite any studies to support necessity, causing the statement supporting their use to appear as opinion rather than fact. In order for SMLPFs to share the same medically necessary status of formula, research needs to show that PKU patients cannot manage the disease without it. Stating that such food provides "dietary variety" is insufficient to consider it as medication.

Considering the lack of essential nutrition and the limited research supporting its efficacy, specially modified low-protein foods are not consistent with the generally accepted professional medical standards pursuant to Rule 59G-1.035, F.A.C.

✓ **Concur** ____ **Do not Concur**

Comments:

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Deputy Secretary for Medicaid (or designee)

7/6/17
date

RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

SCLERAL CONTACT LENS
COVERAGE DETERMINATION REPORT WITH RECOMMENDATION

Date: November 14, 2017

To: Beth Kidder, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Scleral Contact Lenses**

PURPOSE

The purpose of this report is to determine whether scleral contact lenses should be covered under the Florida Medicaid program under CPT code V2531.

REPORT WITH RECOMMENDATION

This report represents a summary of information and reliable evidence considered when making the coverage recommendation. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- Background on the coverage request
- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals
- A review of existing coverage policies for similar health services under the Florida Medicaid program
- A summary of coverage policy from other state Medicaid and commercial insurers
- A fiscal analysis

BACKGROUND

The Agency for Health Care Administration received a request for coverage of scleral contact lenses. This product was determined to be a generally accepted professional medical standard (GAPMS), not requiring a complete GAPMS review. Scleral contact lenses were evaluated for a coverage determination.

Scleral contact lenses are a type of rigid gas permeable lens that rest completely on the sclera and do not touch the cornea. They are composed of three portions: the scleral (haptic) portion that rests on the sclera; the vault, which is responsible for corneal and limbal clearance of the lens; and the optical portion of the lens. When properly fitted, the lenses are stable and do not move on the eye. The diameter of the lenses is 15 mm or larger. Mini-scleral contact lenses

have diameters between 15 mm – 18 mm, and true scleral contact lenses have diameters greater than 18 mm. The lenses are filled with either unpreserved saline or normal saline fluid before being inserted in the eye (Rathi, Mandathara, Taneja, Dumpati, & Sangwan, 2015). This fluid reservoir masks corneal surface irregularities, thereby improving visual acuity for patients with corneal surface irregularities. The fluid reservoir also serves as a liquid bandage, which can be used to treat ocular surface disorders (Schornack & Patel, 2010).

Sclera and Cornea

The sclera is the white, outer coating of the eye and is made of tough, fibrous tissue that extends from the cornea to the optic nerve at the back of the eye. The cornea is the clear, dome-shaped, outermost layer of the eye. It serves as a barrier to protect the eye from germs, dust, and other harmful matter (Medline Plus, 2017). The cornea also helps the eye focus and accounts for two-thirds of the eye's refractive power (Katzman & Jeng, 2014). Many types of disease processes and irregularities can affect the cornea.

Diseases and Irregularities of the Cornea

Corneal damage is a leading cause of blindness worldwide, with causes including injuries to the outermost layer of the cornea, damage or scars from other eye surgeries, infections, hereditary corneal defects, and inflammation from chronic dry eye (Research to Prevent Blindness, 2017). Corneal diseases and irregularities are also prevalent, occurring in young and old populations alike. In their 2009 report, Shepard, Razavi, Stason, Jacobs, Suaya, Cohen, et al. found that corneal disease ranked fifth among major eye diseases among Medicare recipients in terms of frequency and physical and economic burden. Keratoconus is the most common degenerative disease affecting the cornea and the most common corneal dystrophy in the United States. Keratoconus is a progressive thinning of the cornea that causes the middle of the cornea to thin, bulge outward, and form a rounded cone shape. The abnormal curvature can result in double or blurred vision, nearsightedness, astigmatism, and increased sensitivity to light. Most prevalent among teenagers and adults in their 20's, keratoconus affects one in 2000 Americans (National Eye Institute, 2016).

Ocular surface diseases include severe dry eye syndromes of various etiologies (Alipour, Kheirkhah, & Behrouz, 2012); corneal ectasia disorders such as keratoconus and pellucid marginal degeneration (Rathi, Mandathara, Vaddavalli, Srikanth, & Sangwan, 2012); and persistent epithelial defects (Katzman & Jeng, 2014). These diseases can result in poor visual acuity, ocular discomfort, and decreased quality of life. In addition to ocular surface disease, corneal irregularities also lead to poor visual acuity despite conservative treatment with eyeglasses or conventional soft or rigid gas permeable contact lenses. Irregularities can result from disease processes, can occur after various types corneal surgeries, or can be due to corneal trauma (Romero-Jiménez & Flores-Rodriguez, 2012; Steele & Davidson, 2007; Ye, Sun, & Weissman, 2006).

Mild forms or early stages of corneal diseases can be treated with topical and systemic medications, bandage soft contact lenses, and various other types of contact lenses (such as soft, rigid gas permeable, Rose K, piggy back, or hybrid), depending on the particular disease. Advanced ocular surface diseases and corneal irregularities are quite challenging to treat because of distortions to the corneal shape. Conventional treatments become less and less tolerated and effective as these diseases progress (Shepard et al., 2009; Stason, et al., 2009).

Treatment

Conventional Lenses

There are two common types of contact lenses: soft and standard rigid gas permeable. Soft contact lenses are small in diameter and conform to the shape of the cornea. Certain conditions of the eye may cause the cornea to become warped or severely damaged (e.g., keratoconus, corneal surgery, trauma) and cannot be managed with soft contact lenses due to the fit of the lens on the eye.

Standard rigid gas permeable lenses float on a layer of tears on top of the cornea; because they are rigid, they do not conform to the shape of the cornea like soft contact lenses. The tears accumulated under a standard rigid gas permeable lens fill in the damaged areas, providing greatly improved visual acuity. While results with standard rigid gas permeable lenses may be satisfactory, there are cases in which standard rigid gas permeable lenses are still unable to provide acceptable vision or a comfortable fit. For example, as keratoconus advances and the cornea becomes more irregular in shape, the ocular surface could be damaged if an optimal fit cannot be achieved (Rathi et al., 2013).

Scleral Contact Lenses

If soft contact lenses or standard rigid gas permeable contact lenses are not therapeutically successful, cannot be tolerated, or are otherwise contraindicated, scleral contact lenses may then be evaluated for use. The large diameter of scleral contact lenses (15.5-23 mm) allows them to be supported entirely by the sclera and completely vault the cornea, which creates a fluid-filled space (Rosenthal & Croteau, 2005). The large diameter of these lenses also improves centration, comfort, and corneal health (Romero-Jimenez & Flores-Rodriguez, 2012). Steele and Davidson (2007) reported that scleral contact lenses completely neutralize an irregular corneal surface, making the fitting of such eyes much easier. Scleral contact lenses can also be used to improve vision in patients who have corneal transplants (Schornack & Patel, 2010).

Surgical Interventions

Keratectomies (excising damaged parts of the cornea) and keratoplasty procedures (corneal transplants) are performed on deformed, damaged, and scarred corneas (Blackmore, 2010; Baran, Bradley, Alipour, Rosenthal, Le, & Jacobs, 2012). Surgical options, including repeat keratoplasty, may be delayed or avoided if scleral contact lenses can be effectively utilized (Schornack & Patel, 2010). Furthermore, Rathi et al. (2015) reported the use of scleral contact lenses can reduce the rate of keratoplasty for patients with keratoconus, which in turn reduces the cost, effort, and other issues related to maintaining corneal grafts.

Various surgical interventions, such as punctal occlusion and amniotic membrane transplantation, have been proposed for managing severe dry eye disease refractory to other treatment methods. The use of scleral contact lenses has been shown to be safe and effective in managing dry eye symptoms, which may result in regression of the disease and negate the need for surgical intervention (Alipour et al., 2012). The use of scleral contact lenses for persistent epithelial defects, if successful, can lead to a decreased need for surgical options, such as anterior stromal puncture, diamond burr debridement, and phototherapeutic keratectomy (Blackmore 2010).

Government Regulatory Body Approval

The Food and Drug Administration (FDA), under Subchapter H, Part 886 – Ophthalmic Devices, Subpart D – Prosthetic Devices, identifies a scleral shell as a device "made of glass or plastic that is intended to be inserted for short time periods over the cornea and proximal-cornea sclera for cosmetic or reconstructive purposes. An artificial eye is usually painted on the device. The device is not intended to be implanted."

The device is exempt from the Premarket Notification requirements as a Class II device under special controls.

The Boston Scleral Lens received approval via the premarket approval process on November 30, 1987. The FDA approved the Boston Scleral Lens for managing corneal disorders on March 1, 1994 (Hayes, 2006). The FDA has since approved two additional scleral contact lenses. On February 9, 2016, BostonSight IC Scleral Lens, sold by Boston Foundation for Sight, was approved. On April 27, 2016, the EYEPRINTPRO Scleral GP Lenses, sold by Advanced Vision Technologies, were approved (FDA, 2017).

LITERATURE REVIEW

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to scleral contact lenses. This section also briefly cites the positions from the relevant medical societies and summarizes the key articles referenced in support of their positions.

Clinical Indications

Pullum (1999) identified the clinical indications for scleral contact lenses as irregular corneal topography, high refractive errors, iris encapsulation, therapeutic or protective applications, and "other" applications (e.g., working in dusty environments, intolerance to corneal or hydrogel lens wear).

In their research, Rosenthal and Croteau (2005) studied two primary clinical indications for scleral contact lenses: management of severe ocular disease and improvement of optical function. Scleral contact lenses serve as a liquid bandage in the management of various types of severe ocular diseases (e.g., persistent epithelial defects, severe dry eye disease, chronic graft-versus-host disease). The lenses provide a fluid-filled reservoir that bathes the cornea, provides an adequate supply of oxygen, and protects the cornea from friction/shearing from the eyelid, which occurs during blinking. In addition to restoring or maintaining the integrity of the corneal surface, the use of these lenses to manage severe ocular disease has been shown to reduce ocular pain and photophobia and improve visual acuity. Scleral contact lenses can also be utilized to deliver prophylactic and therapeutic topical medications to the cornea (Rosenthal, Cotter, & Baum, 2000).

Clinical Outcomes

To describe the therapeutic benefits of scleral contact lenses in the management of ocular surface diseases, Romero-Rangel et al. (2000) reviewed the medical charts of 49 patients (76 eyes) with a diagnosed ocular surface disease, ages 3 to 87 years. Their diagnosed diseases included Stevens-Johnson syndrome, ocular cicatricial pemphigoid, toxic epidermal necrolysis, several types of keratitis, a congenital deficiency, Sjogren syndrome, and inflammatory corneal

degeneration. In 25 of 76 eyes, other types of contact lenses had been tried unsuccessfully. Visual acuity improved in 40 eyes (53%). Defects were healed in eight of 15 eyes with a corneal epithelial defect at time of lens insertion. Of the eyes with a history of recurrent or persistent epithelial defects, 48% did not experience a recurrence of epithelial defects after lens fitting. Thirty-seven of 49 patients (75%) reported a marked decrease in photophobia. Forty-five of the 49 patients (92%) reported improvement in their quality of life due to a reduction of photophobia and ocular discomfort. Forty-seven of 49 patients (72 of 76 eyes) were able to maintain or improve their visual acuity. The authors concluded gas permeable scleral contact lenses provide an additional effective strategy in the surface management and visual rehabilitation of patients with severe ocular disease.

Rosenthal et al. (2000) conducted a retrospective study of treatment outcomes in 13 patients (14 eyes), ages 16 to 74 years, with persistent epithelial defects fitted with scleral contact lenses. Re-epithelization of the cornea requires a combination of oxygenation, moisture, and protection of the epithelium. The design of scleral contact lenses allows them to avoid suction through a fluid-filled tear interchange. This creates a unique environment for the corneal epithelium, consisting of an adequate oxygen supply, a constant aqueous interface, and the absence of friction, negating the need for surgery. The authors concluded scleral contact lenses were effective in promoting healing in the eyes of eight patients that failed to heal after other therapeutic measures were tried. Healing time varied from 36 hours to 36 days. The lenses used in the study also served as a vehicle for delivering prophylactic and therapeutic topical ocular medications (an antibiotic and a steroid) to the cornea.

Rosenthal and Croteau (2005) conducted a retrospective study involving the record review of 538 patients (875 eyes) fitted for gas permeable scleral contact lenses for whom rigid gas permeable lenses either were not tolerated or were contraindicated in all eyes. Of note, patient age was not indicated. They studied the impact of scleral contact lenses on optical function (501 eyes) and management of severe ocular surface disease (374 eyes). Of the eyes fitted primarily to improve visual functioning, most had corneal ectasia (including keratoconus), abnormal astigmatism after penetrating keratoplasty, or other failed surgical interventions, and eyeglasses were inadequate in correcting their vision. In many of those cases, the scleral contact lenses were effective in providing excellent vision correction. Of the eyes fitted to manage various ocular surface diseases, the scleral contact lenses were used as a corneal bandage. The use of the lenses significantly mitigated ocular pain and disabling photophobia, helped heal persistent epithelial defects and prevent recurrence, and improved vision. This study identified scleral contact lenses as an important palliative and therapeutic tool, especially in regards to relief of pain and photophobia in patients with primary severe dry eye. Scleral contact lenses were also a superior alternative to tarsorrhaphy in managing exposure keratitis. The study did note extended scleral contact lens wear and dry eye disease were risk factors for developing bacterial keratitis, especially when epithelial defects were present. However, this complication did not occur when the fluid reservoir was inoculated with moxifloxacin. Overall, scleral contact lenses were reported to be an important tool for managing many corneal disorders that have not responded to other treatment measures.

E-S. Visser, R. Visser, van Lier, and Otten (2007) published two studies using the same population data, drawn from the authors' practices. One study pertained to the clinical features of modern scleral lenses and the second study examined patient satisfaction. Their study recruited 178 patients (284 eyes), ages 18 to 80 years. Among these patients, 106 were wearing scleral contact lenses in both eyes and 72 were wearing scleral contact lenses in only one eye. These patients were fitted with scleral contact lenses due to failure with other lens types. Among the 284 eyes, 87 eyes were uncorrected with contact lenses prior to their fitting

for scleral contact lenses; 142 eyes were using a standard rigid gas permeable lens; and 55 eyes were using other types of lenses (such as eyeglasses and corneal, piggyback, and soft lenses). The patients were divided into six main groups based on their diagnoses: keratoconus (143 eyes), post-penetrating keratoplasty (56 eyes), primary or secondary irregular astigmatism (36 eyes), keratitis sicca (15 eyes), corneal dystrophy (10 eyes), and "multiple diagnoses" (24 eyes). The authors found significant increases in visual acuity with scleral contact lenses in comparison to best-corrected visual acuity without scleral contact lenses. The highest median increase was seen in eyes with keratoconus. With regards to patient satisfaction, 78.9% of patients reported increased ocular comfort, 78.2% reported improved visual quality, and 87.7% reported overall satisfaction with their scleral contact lenses.

Scleral contact lenses have been shown to provide significant improvements in visual acuity and visual functioning for patients with corneal ectasia, irregular astigmatism, and ocular surface disease for whom other correction methods failed (Baran et al., 2012). In 59 patients (118 eyes) with corneal ectasia, ages 18 to 89 years, 93% were able to achieve visual acuity of 20/40 or better even though 53 of those patients had failed attempts with other correction methods.

Advantages and Disadvantages

Scleral contact lenses can effectively treat a variety of ocular surface diseases and corneal aberrations where other lens types have been unsuccessful. Their large diameter makes them easier to fit over irregular corneas and they provide good centration on the eye. They can also be used to deliver topical medications to the cornea. Noted advantages of scleral contact lenses include improvements in corneal health, improvements in visual acuity and visual functioning, decreases in ocular pain and photophobia, decreased need for surgical interventions, and improvements in quality of life. Developments in lens materials and designs, the use of new technology for making the lenses, and improvements in lens-fitting techniques have resulted in wider acceptance for using scleral contact lenses. Scleral contact lenses are relatively easy to fit. The number of fitting sessions required to successfully fit these lenses is comparable to fitting other rigid gas permeable lenses, and the initial fitting is often times successful. In many instances, standard design lenses can provide an acceptable fit (Schornack, Baratz, Patel, & Maguire, 2008), which reduces cost in comparison to customized lenses.

Shepard et al. (2009) conducted an economic appraisal of the Boston Ocular Surface Prosthesis (a particular brand of scleral contact lenses). They compared the costs of dispensing (manufacturing and professional services) to the benefits of improvements in visual acuity and visual functioning, which, in combination with other information, was converted to quality adjusted life years. The authors determined that the lenses were a cost-effective technology in terms of improving quality adjusted life years. The cost-effectiveness ratio was similar in patients with ectasia/astigmatism and ocular surface disease.

Regarding disadvantages, some studies have shown a risk of keratitis (infection) with the use of scleral contact lenses. Rosenthal et al. (2000) found the risk of bacterial keratitis was high in patients who wore the lenses for an extended period of time, especially if an epithelial defect was present. Rosenthal and Croteau (2005) indicated that dry eye and extended contact lens wear were risk factors for developing bacterial keratitis, but the risk was mitigated when the fluid reservoir was inoculated with moxifloxacin. The risk of keratitis has been shown to be rare in patients with keratoconus. The risk of infection can be reduced by following standard hygiene protocols for scleral contact lenses. Additional contraindications for use of scleral contact lenses include corneal edema, acute hydrops, and post filtration surgery; however, scleral

contact lenses may be resumed after the hydrops heals (Rathi et al., 2013). Corneal vascularization due to hypoxia is a known complication in all forms of contact lens wear, though the cause of hypoxia varies with different lens types. Because of the design of scleral contact lenses, they can be utilized in patients who develop corneal vascularization associated with wearing other types of contact lenses. The design of scleral contact lenses also provides an oxygenated environment for the cornea. The handling and care regimen can be a challenge for some individuals, as there are different insertion and removal techniques utilizing miniature plungers, frequent changing of saline bottles, and the use of multiple solution types for cleaning and disinfecting. However, Vreugdenhil, Geerards, and Vervaet (1998) found that even patients with low visual acuity did not have difficulty handling the lenses. The cost of the specialized equipment to manufacture these lenses is high, which increases manufacturing costs. As noted above, not all patients require custom-made lenses, which should lower overall costs.

Limitations

Studies pertaining to the clinical aspects of scleral contact lenses tend to be retrospective and uncontrolled with small sample sizes and a lack of long-term follow up. Some studies were supported by the Boston Foundation for Sight (the company that manufactures the scleral contact lens evaluated in numerous studies) and/or Bausch & Lomb, or were conducted by authors who are salaried employees of the Boston Foundation for Sight. The articles noted neither Bausch & Lomb nor the authors of the studies had personal financial interest in the scleral contact lens.

Evidence-Based Clinical Practice Guidelines

The American Academy of Ophthalmology (2014) published a retrospective study of patients, ages 6 to 92 years, who utilized scleral contact lenses for a wide range of ocular problems, including undifferentiated dry eye syndrome, neurotrophic keratopathy, exposure keratopathy, chronic graft-versus-host disease, limbal stem cell deficiency, post-refractive surgery dry eye, and Sjogren's syndrome. The findings from this report indicated:

- Commercially available scleral lenses can be successfully used in the management of moderate to severe ocular surface disease
- The scleral lens fitting process can be completed efficiently for most eyes by using diagnostic trial lenses
- In addition to protecting the ocular surface, scleral lenses improve visual acuity in patients whose surface disease has compromised vision
- Therapeutic goals (improved comfort, ocular surface protection, or resolution of keratopathy) were achieved in 113 of 115 patients

COVERAGE POLICY

Medicare

According to the National Coverage Determination (Section 80.1), payment may be made under Section 1861(s)(2) of the Social Security Act for some FDA-approved contact lenses in certain situations. Specifically:

> Some hydrophilic contact lenses are used as moist corneal bandages for the treatment of acute or chronic corneal pathology and for other therapeutic reasons.

The National Coverage Determination (Section 80.4) also states payment may be made under the prosthetic device benefit for hydrophilic contact lenses when prescribed for an aphakic patient.

Additionally, the National Coverage Determination (Section 80.5), pertaining to scleral shells, indicates payment may be made under Section 1861(s)(8) of the Social Security Act under certain circumstances. Specifically:

> Scleral shell (or shield) is a catchall term for different types of hard scleral contact lenses. A scleral shell fits over the entire exposed surface of the eye as opposed to a corneal contact lens, which covers only the central non-white area encompassing the pupil and iris. Where an eye has been rendered sightless and shrunken by inflammatory disease, a scleral shell may, among other things, obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue. In such a case, the device serves essentially as an artificial eye. In this situation, payment may be made for a scleral shell under §1861(s)(8) of the Act.

Scleral shells are occasionally used in combination with artificial tears in the treatment of "dry eye" of diverse etiology. Tears ordinarily dry at a rapid rate, and are continually replaced by the lacrimal gland. When the lacrimal gland fails, the half-life of artificial tears may be greatly prolonged by the use of the scleral contact lens as a protective barrier against the drying action of the atmosphere. Thus, the difficult and sometimes hazardous process of frequent installation of artificial tears may be avoided. The lens acts in this instance to substitute, in part, for the functioning of the diseased lacrimal gland and would be covered as a prosthetic device in the rare case when it is used in the treatment of "dry eye."

Procedure code V2531 was added to Florida's Medicare contractor, First Coast, Part A Medicare fee-for-service Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) fee schedule for dates of service on or after January 1, 2015. The code is considered a DME, prosthetic device, and the maximum reimbursement rate is $522.08 (First Coast Service Options, Inc., 2017).

Florida Medicaid

Florida Medicaid currently covers 33 different procedure/treatment options for management and treatment of ocular issues, including keratectomies, corneal transplant/keratoplasty, implantation of intrastromal corneal ring segments, removal of eye lesions, correction of astigmatism, closure of eyelid by suture, conjunctivoplasty procedures, and contact lens fitting and contact lens prescriptions for the treatment of ocular surface disease.

State Medicaid Programs

Thirty Medicaid programs include coverage for scleral contact lenses on their fee schedules, as outlined in the following table:

State	Fee Schedule
Arizona	$417.07
Colorado	$330.88
Delaware	$421.66
District of Columbia	$405.47
Idaho	$150.00
Illinois	Unspecified
Indiana	$506.52
Iowa	Manual
Kansas	Unspecified
Maine	$201.17
Massachusetts	Individual Consideration
Michigan	Manual
Minnesota	$211.03
Mississippi	$53.45
Missouri	$78.28

State	Fee Schedule
Nebraska (V2530 only)	Individual Consideration
New Hampshire	$309.14
New Jersey	By Report
New Mexico	$177.30
Oklahoma	Manual
Oregon	$160.84
Rhode Island	$239.57
South Dakota	$479.80
Texas	$236.58
Vermont	Unspecified
Virginia	Individual Consideration
West Virginia	$406.67
Wisconsin	Manual
Wyoming	By Report

Missouri, Vermont, and Wyoming Medicaid programs cover scleral contact lenses for recipients 0-20 years of age. Medical necessity documentation and invoice of cost are required. Minnesota manually covers scleral contact lenses without prior authorization for bandage lenses and patients with diagnoses of aphakia, keratoconus, or aniseikonia; all other diagnoses or conditions require authorization for lens services and supplies. Texas covers scleral contact lenses for any age as long as there is no other option to correct visual defect; however, replacement lenses are only covered for recipients 0-20 years of age. Illinois covers scleral contact lenses with prior authorization.

Commercial Insurers

Aetna (2016) considers scleral contact lenses medically necessary for any one of the following indications:

- For the treatment of severe dry eyes (keratoconjunctivitis sicca), such as from Sjogren's syndrome, chronic graft-versus-host disease, radiation, surgery, Meibomian gland deficiency
- Corneal disorders associated with systemic autoimmune diseases
- Congenital etiologies

Replacement lenses are considered medically necessary under medical plans if required because of a change in the member's physical condition (not including refractive changes).

Blue Cross and Blue Shield of Florida (2017) indicates scleral contact lenses meet the definition of medical necessity for patients who have not responded to topical medications or standard spectacle or contact lens fitting for the following conditions:

- Corneal ectatic disorders (e.g., keratoconus, keratoglobus, pellucid marginal degeneration, Terrien's marginal degeneration, Fuchs' superficial marginal keratitis, postsurgical ectasia)
- Corneal scarring and/or vascularization
- Irregular corneal astigmatism (e.g., after keratoplasty or other corneal surgery)
- Ocular surface disease (e.g., severe dry eye, persistent epithelial defects, neurotrophic keratopathy, exposure keratopathy, graft-versus-host disease, sequelae of Stevens

Johnson syndrome, mucus membrane pemphigoid, post ocular surface tumor excision, post-glaucoma filtering surgery) with pain and/or decreased visual acuity

Blue Cross/Blue Shield of Mississippi (no date) considers scleral contact lenses medically necessary when a patient has not responded to topical medications or standard spectacle or contact lens fitting for the following conditions:

- Corneal ectatic disorders (e.g., keratoconus, pellucid marginal degeneration)
- Corneal scarring and/or vascularization
- Irregular corneal astigmatism (e.g., after keratoplasty or other corneal surgery)
- Ocular surface disease (e.g., severe dry eye, graft-versus-host disease, sequelae of Stevens Johnson syndrome)

Blue Cross/Blue Shield of Texas (2016) considers scleral contact lenses medically necessary when the eye has been rendered sightless, shrunken or deformed, or when people are not candidates for corneal transplant. Premature babies or children who did not develop properly or completely may be candidates for medical necessity.

Fallon Health (2016) covers scleral contact lenses for certain medically necessary diagnoses. Prior authorization is required, as defined below:

Corneal contact lenses:

- Post-cataract surgery with insertion of intraocular lenses
- Treatment of aphakia (absent natural lens)
- Treatment of keratoconus (irregular protrusion of cornea)
- As moist bandages for treatment of acute or chronic corneal pathology

Scleral contact lenses:

- To treat eyes rendered sightless and shrunken by inflammatory disease. A scleral shell may obviate the need for surgical enucleation and prosthetic implant and act to support the surrounding orbital tissue.

Fiscal Analysis

During Fiscal Year 2015/2016 (FY15/16), there were 44,463 unique recipients with an associated diagnosed eye disease (see Attachment 1 for a list of diagnosed eye diseases and total number of recipients per disease). When recipients with more than one associated diagnosed eye disease are included, the number of recipients increases to 46,202. The age of diagnosed recipients ranged from 0 – 109 years.

For the purpose of this fiscal analysis, 33 procedure codes (see Attachment 2) currently covered by Florida Medicaid related to the management and treatment of multiple ocular issues were utilized (Agency for Health Care Administration, 2017). The Bureau of Medicaid Data Analytics provided information for fee-for-service claims and managed care encounter data. It should be noted the managed care encounters are low projections because the amount paid listed on the encounter was $0. During FY15/16, the total cost of claims for all analyzed treatment codes under fee-for-service transactions was $255,544.05. The total cost of claims for the same treatment codes under managed care encounters was $1,397,067.28. Combined, these costs totaled $1,652,611.33.

Removal of eye lesions (including keratectomy with grafts) was the costliest treatment during FY15/16, at a combined cost of $698,654.44. Corneal transplant procedures (keratoplasty) were performed at a combined cost of $292,928.01. Ocular surface reconstruction/amniotic membrane transplantations were performed at a combined cost of $231,237.84.

If covered, the Bureau of Medicaid Program Finance recommends that scleral contact lenses be reimbursed at $279.39. These lenses should last approximately 1-3 years.

According to Dalton and Sorbara (2011), 12-26% of patients with keratoconus need surgical intervention, and penetrating keratoplasty is the most commonly performed surgery. Baran et al. (2012) indicate penetrating keratoplasty corrects opacity but often results in post-operative astigmatism or anisometropia, which still requires correction with contact lenses. Contact lens fitting after keratoplasty is difficult. Schornack and Patel (2010) also report that despite a high initial success rate of penetrating keratoplasty, many patients still require rigid contact lenses to achieve their best vision. Additionally, complications such as graft rejection and graft failure occur in approximately 20% and 10% of eyes, respectively, and ectasia can recur in 6-11% of eyes receiving a penetrating keratoplasty for keratoconus. This frequently results in repeat keratoplasty procedures. Consequently, costs associated with treating corneal disorders increase.

During FY15/16, the total combined cost of penetrating keratoplasty (CPT code 65730) for Florida Medicaid was $133,413.88. If 12% of those individuals (using the low end of estimates provided by Dalton and Sorbara, 2012) had been prescribed scleral contact lenses, the cost of lenses would have been $4,392.01. By comparison, the cost of 12% of surgeries was $16,009.67. The use of scleral contact lenses instead of surgery for just 12% of cases would have resulted in a savings of $11,617.26. As mentioned previously, penetrating keratoplasty is not always successful in restoring vision and lenses are still needed. However, the use of scleral contact lenses prior to considering penetrating keratoplasty could result in some patients not requiring surgery, which would reduce the overall cost of treatment over the recipient's lifetime. Research indicates the use of scleral contact lenses can delay or avoid initial or repeat keratoplasty, which in turn reduces the cost, effort, and other issues related to maintaining corneal grafts (Schornack & Patel, 2010; Rathi et al., 2015). Savings would further increase with the use of scleral contact lenses in place of other corneal surgical procedures, such as keratectomy and ocular surface reconstruction. Also of note, scleral contact lens use may not be required throughout a recipient's life, thereby reducing costs associated with replacement lenses. Schornack, Pyle, and Patel (2014) conducted a retrospective study regarding scleral contact lens use in the management of ocular surface disease. Among 83 patients who had 12 or more months of follow-up after scleral contact lens therapy, 9 patients discontinued using the lenses because they found adequate relief with less aggressive intervention. For four patients, their conditions resolved and the lenses were no longer needed.

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report recommends scleral contact lenses as a health service that has been demonstrated to be an effective treatment option for certain advanced diseases of the cornea whereby no other types of contact lenses have been successful. If scleral contact lenses become a covered service under the Florida Medicaid program, it is recommended that they be prior authorized. Supporting medical documentation must include the recipient's diagnosis, the symptoms associated with the condition, the prescription for each eye, and documentation of all prior treatments attempted.

Rationale

✓ **Concur** ____ **Do not Concur**

Comments:

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_____
Deputy Secretary for Medicaid (or designee)

11/17/17
Date

Attachment 1

Recipient Count per Diagnosis

Diagnosis Category	Unique Recipient Count	Percentage
Dry Eye Syndrome	32,131	69.5%
Keratoconjunctivitis	4,417	9.6%
Irregular Astigmatism	4,241	9.2%
Ulcer	2,043	4.4%
Keratoconus	1,286	2.8%
Aphakia	1,216	2.6%
Bullous Keratopathy	427	0.9%
Recurrent Cornea Erosion	324	0.7%
Corneal Ectasia	88	0.2%
Keratopathy (Bullous aphakic)	29	0.1%

Attachment 2

Procedure Codes Reimbursed by Florida Medicaid

Excision
65400 – Excision of Lesion, cornea (keratectomy, lamellar, partial), except pterygium
65420 – Excision or transposition of pterygium, without graft
65426 – with graft

Removal or Destruction
65450 – Destruction of lesion of cornea by cryotherapy, photocoagulation, or thermocauterization

Keratoplasty
65710 – Keratoplasty (corneal transplant); anterior lamellar
65730 – penetrating (except in aphakia or pseudoaphakia)
65750 – penetrating (in aphakia)
65755 – penetrating (in pseduoaphakia)
65756 – endothelial

Other Corneal Procedures of the Anterior Segment
65770 – Keratoprosthesis
65772 – Corneal relaxing incision for correction of surgically induced astigmatism
65775 – Corneal wedge resection for correction of surgically induced astigmatism
65778 – Placement of amniotic membrane on the ocular surface; without sutures
65779 – single layer, sutured
65780 – Ocular surface reconstruction; amniotic membrane transplantation, multiple layers
65782 – limbal conjunctival autograft (includes obtaining graft)
65785 – Implantation of intrastromal corneal ring segments
66999 – Unlisted procedure, anterior segment of eye

Posterior Sclera, Repair
67250 – Scleral reinforcement, without graft
67255 – with graft

Tarsorrhaphy
67875 – Temporary closure of eyelids by suture

Conjunctivoplasty
68320 – Conjunctivoplasty; with conjunctival graft or extensive rearrangement
68325 – with buccal mucous membrane graft (includes obtaining graft)
68326 – Conjunctivoplasty, reconstruction cul-de-sac; with conjunctival graft or extensive rearrangement
68328 – with buccal mucous membrane graft (includes obtaining graft)
68330 – Repair of symblepharon; conjunctivoplasty, without graft
68335 – with free graft conjunctiva or buccal mucous membrane (includes obtaining graft)

Special Ophthalmological Services
92025 – Computerized corneal topography, unilateral or bilateral, with interpretation and report
92071 – Fitting of contact lens for treatment of ocular surface disease

Contact Lenses
V2511 – Contact lens, gas permeable, toric (maximum fee for bilateral fitting = $280; each replacement lens = $59)
V2513 – Contact lens, gas permeable, extended wear (maximum fee for bilateral fitting = $278; each replacement lens = $58.50)
V2521 – Contact lens, hydrophilic, toric (maximum fee for bilateral fitting = $284; each replacement lens = $60)
V2523 – Contact lens, hydrophilic, gas permeable (maximum fee for bilateral fitting = $266; each replacement lens = $55.50)

RICK SCOTT
GOVERNOR

JUSTIN M. SENIOR
SECRETARY

FRACTIONAL EXHALED NITRIC OXIDE MEASUREMENT GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS (GAPMS) DETERMINATION REPORT WITH RECOMMENDATION

Date: June 13, 2017

To: Beth Kidder, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Fractional Exhaled Nitric Oxide Measurement Device**

PURPOSE

In order for the use of Fractional Exhaled Nitric Oxide (FeNO) measurement to be covered under the Florida Medicaid program, it must meet the medical necessity criteria as defined in Rule 59G-1.010, Florida Administrative Code. (F.A.C.), and be funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in 59G-1.010, F.A.C., the use of FeNO must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not be experimental or investigational.

In accordance with the determination process established in rule 59G-1.035, F.A.C., the Deputy Secretary for Medicaid will make the final determination as to whether FeNO is consistent with generally accepted professional medical standards and not experimental or investigational.

If it is determined that FeNO is consistent with generally accepted professional medical standards, this report will be supplemented with an addendum which analyzes additional factors to determine whether this health service should be covered under the Florida Medicaid program.

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in 59G-1.035, F.A.C. based on the collection of information from credible sources of reliable evidence-based information. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- A high-level review of relevant disease processes.
- An overview of the health service information.
- Clearance from the government regulatory body (e.g. U.S. Food and Drug Administration).
- Evidence based clinical practice guidelines.

- A review of the literature considered by the relevant medical community or practitioner specialty associations from credible scientific evidence-based literature published in peer reviewed journals and consensus of coverage policy from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

Asthma

Asthma is a chronic lung disease that affects 25 million people, including 7 million children, in the United States. The disease causes the inflammation and narrowing of the airways (bronchial tubes) that carry air into and out of the lungs. People diagnosed with asthma have inflamed airways which are swollen and sensitive. In most cases, inhalation of certain substances causes the muscles to contract around the airways, narrowing them and limiting airflow into the lungs. This can result in an asthma exacerbation marked by wheezing, shortness of breath, and coughing. (National Heart, Lung, and Blood Institute, 2012)

Diagnosing asthma requires evaluating a patient's history, physical examination, and tests such as pulmonary function tests (spirometry). Due to the numerous factors that can cause asthma or asthma symptoms, no standard procedure exists to make a diagnosis. Practitioners base their diagnoses on the likelihood of asthma and treat symptoms accordingly. (National Heart, Lung, and Blood Institute, 2012)

Diagnostic Testing

Spirometry measures lung function and is used in the diagnosis and management of respiratory conditions such as asthma, pulmonary fibrosis, and chronic obstructive pulmonary disease (COPD). (Global Initiative for Chronic Obstructive Lung Disease, 2007)

When administering spirometry, the practitioner has the patient take a deep breath and exhale as hard as possible into an apparatus that measures how much air moves in and out of the lungs. The results consist of two measurement types, forced vital capacity (FVC) and forced expiratory volume (FEV1), and are compared to a predicted result based on age, sex, height, and ethnicity. If the patient's FVC and FEV1 are lower than the predicted result, the test indicates an obstructive airway disease. (Global Initiative for Chronic Obstructive Lung Disease, 2007)

Practitioners also use bronchodilator reversibility testing to determine whether a fixed airway is narrowing. This consists of a comparison and contrast of two spirometry tests, one where the patient performs the test normally and a second conducted 15-20 minutes later following bronchodilator administration. If the second test's results show improved lung function, it indicates that the airway obstruction is reversible and supports a diagnosis of asthma. (Global Initiative for Chronic Obstructive Lung Disease, 2007)

Treatment

Asthma does not have a cure, and the treatment goal is to keep the disease well controlled. To attain this, practitioners instruct patients to avoid factors that trigger exacerbations such as allergens and treat other conditions that provoke asthma symptoms. For patients having difficulty controlling the disease, practitioners prescribe inhaled corticosteroids (ICS). These are the preferred medications to reduce inflammation and achieve long-term control. Other

treatments such as nebulizers (a device that delivers a medication as a fine mist to the lungs) and monthly Omalizumab (anti-inflammatory) injections are used when ICSs are inadequate. (National Heart, Lung, and Blood Institute, 2012)

Fractional Nitric Oxide Measurement (FeNO)

Nitric oxide (NO), a pollutant produced by the lungs, is a highly reactive molecule/free radical that is detectable in exhaled breath. Its oxidant properties and role in lung function cause it to play a key role in the pathophysiology of pulmonary diseases such as asthma.

Patients with asthma diagnoses tend to have elevated levels of NO in their exhaled breath as a result of allergic airway inflammation (Shaw et al, 2007). Research studies have been conducted to determine if measuring the FeNO levels in a patient's breath can assist with the diagnosis of asthma and if adjustments in medication are needed to attain optimal control.

Aerocrine – NIOX Product Line

Aerocrine manufactures FeNO monitoring devices (NIOX) for research and clinical applications. Only trained healthcare professionals may operate the device as directed by the user manual. The latest portable system on the market is the NIOX VERO (Aerocrine, 2014).

To use the device, a patient empties their lungs, takes a deep breath through the patient filter to test capacity, and slowly exhales for 10 seconds. The device measures the NO concentration of the last 3 seconds of the 10 second exhalation and displays the result in approximately 1.5 minutes. According to the manufacturer, the device can last 5.5 years or 15,000 measurements. (Aerocrine, 2014)

Government Regulatory Body Approval

According to Title 21 CFR 862.3080, a breath nitric oxide test system is identified as a "device intended to measure fractional nitric oxide in human breath. Measurement of changes in fractional nitric oxide concentration in expired breath aids in evaluating an asthma patient's response to anti-inflammatory therapy, as an adjunct to established clinical and laboratory assessments of asthma." (U.S. Food and Drug Administration, 2003)

In 2014, the U.S. Food and Drug Administration (FDA) determined that NIOX VERO is approved for use as a prescription device. The FDA further stated that NIOX VERO cannot be used with infants or children under seven years old. (U.S. Food and Drug Administration, 2014)

LITERATURE REVIEW

This analysis summarizes information obtained from scientific literature published in credible peer-reviewed journals related to FeNO measurement. This section also briefly cites the positions from the relevant medical societies, and summarizes the key articles referenced in support of their positions.

Asthma Exacerbation Reduction and Monitoring

Powell et al (2011) conducted a research trial that assigned 220 non-smoking, pregnant women with asthma into two groups, one to monitor FeNO levels in regards to treatment (111 participants) and the other to continue management without monitoring (109 participants).

During the trial, the participants having their FeNO levels monitored had lower exacerbation rates than those who did not with a mean rate of 0.29 exacerbations per pregnancy in comparison to 0.69. As a result of evaluating their FeNO levels, the participants in the monitoring group received different treatment regimens consisting of higher doses of inhaled corticosteroids (ICS) and long-acting beta-agonists.

Petsky et al (2014) tracked the asthma management of 63 children separated into two groups, 31 receiving FeNO monitoring and 32 continuing management without monitoring. Of the participants who completed the trial (eight did not complete the trial), 6 of the 27 children receiving FeNO monitoring reported having an exacerbation as opposed to 15 of the 28 children in the other group. Petsky et al acknowledged that the FeNO monitoring group used higher doses of ICS and that the strategy is not likely to improve asthma control and a second-larger study is needed.

Shaw et al (2007) conducted a trial with 118 asthma patients divided into two groups, one that used FeNO monitoring to determine ICS treatment (58 participants) and the other to continue management without monitoring (60 participants). The results showed that a treatment strategy using FeNO measurements did not translate into a large reduction of ICS usage or exacerbations over a 12-month period in comparison to current asthma guidelines.

In both the Powell et al and Petsky et al trials, the FeNO monitoring groups experienced fewer significant exacerbation but also took higher doses of medication. The Shaw et al trial noted an 11% increase in ICS used by the FeNO monitoring group but indicated that the group had a smaller daily dose. When determining the methodology, the trials used different cutoffs of FeNO measurements to determine whether or not to increase ICS with a range of 26 ppb (Shaw et al) to 35 ppb (parts per billion) (Petsky et al).

Asthma Diagnosis

Pedrosa et al (2010) conducted a trial with 114 adult patients reporting asthma symptoms but did not have a diagnosis. All of the participants had normal spirometry (pulmonary function test) and negative bronchodilator tests. Prior to undergoing a methacholine challenge test (evaluates the narrowing and tightening of airways), the participants had FeNO measurements taken. The results showed that 35 of the 114 received diagnoses of asthma and that those diagnosed had higher FeNO levels with a cutoff value of 40 ppb.

Schneider et al (2013) conducted a prospective diagnostic study with 393 participants who had reported asthma symptoms. The participants provided FeNO measurements and morning sputum samples. The study resulted in 154 asthma and 5 COPD (chronic obstructive pulmonary disease) diagnoses and concluded that FeNO measurement functioned best as a diagnostic tool when inflammatory patterns are considered. However, Schneider et al noted that FeNO measurements had a low predictive value when the pre-test probability for asthma was also low.

Other studies such as Ciprandi et al (2010), Buslau et al (2014), Woo et al (2012), and Jerzynska et al (2014) showed varying cutoff levels for FeNO measurements when diagnosing asthma with a range of 18.05 ppb (Buslau et al) to 40 ppb (Pedrosa et al). These variances do not allow for a fixed cutoff, making the diagnosis of asthma difficult based on FeNO measurements.

Evidence-Based Clinical Practice Guidelines

The American Thoracic Society (ATS) released a clinical practice guideline (2011) for the interpretation of FeNO levels. It concluded that conventional tests such as spirometry provide limited information regarding airway inflammation and that FeNO measurements can aid in detecting eosinophilic inflammation (allergy driven) and determine ICS responsiveness. The ATS also recommended FeNO measurement cutoffs of >50 ppb in adults and >35 ppb in children to indicate eosinophilic inflammation that is likely to respond to ICS. However, the ATS indicated that FeNO measurements alone cannot serve as a basis for diagnosis or treatment plan and that they need to be applied within the clinical context. The ATS also stated that FeNO values may apply best when compared to a personal baseline as opposed to a normal range and recommended further trials using multiple clinical settings. In 2012, the American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) released a joint statement supporting the ATS's clinical practice guideline.

The National Institute for Health and Care Excellence (NICE), which is based in the United Kingdom, released recommendations (2014) for the use of FeNO measurements in the diagnosis and management of asthma. NICE concluded that FeNO testing is useful as a diagnostic tool for patients who have an intermediate probability of having asthma and must be done in combination with other tests. NICE further determined that FeNO measurements function as a "rule in" test and that a negative or low reading does not rule out asthma. For management, NICE recommended that FeNO testing can serve as support for patients continuing to show symptoms despite ICS use. However, it is not optimal for lowering ICS medication in patients who have well-controlled asthma.

COVERAGE POLICY

Medicare

Medicare does not have a National Coverage Determination (NCD) for FeNO measurement. This does not preclude individual states from making a Local Coverage Determination (LCD) and adding the Current Procedural Terminology (CPT) code 95012 to their fee schedules. Florida's Medicare contractor, First Coast Service Options, covers FeNO testing under CPT code 95012.

Medicaid

Thirty-seven Medicaid programs cover FeNO testing under CPT code 95012. Keystone First's (Pennsylvania's Managed Medicaid Plan) clinical policy (2014) states that FeNO testing is covered only to establish an eosinophilic asthma diagnosis when testing and physical examinations are inconclusive. All other uses for FeNO measurements are not medically necessary.

Other Insurers

Cigna stated in its 2015 coverage policy that it does not cover FeNO measurement for any indication due to insufficient evidence of beneficial health outcomes. The company deemed the test as investigational.

Blue Cross Blue Shield (BCBS) of North Carolina reported in its 2016 corporate medical policy that it considers FeNO measurement to be investigational and does not cover the service.

Regence, the BCBS company for Oregon and Utah, completed a literature review of FeNO measurements in 2016 and concluded that the test was investigational and not eligible for coverage.

WellCare in a position statement (2014) stated that it does not cover FeNO measurement due to its investigational status. However, WellCare does cover the test for Georgia Medicaid which does consider it medically necessary.

Aerocrine reported that United Healthcare and Health Care Service Corporation (HCSC) cover FeNO testing in two press releases from 2012 and 2014 respectively.

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report does not recommend Fractional Exhaled Nitric Oxide (FeNO) Measurement as a health service that is consistent with generally accepted professional medical standards.

Rationale

The medical profession agrees that measuring FeNO levels can aid in the diagnosis and treatment of asthma. However, the profession differs on how to use those levels appropriately and what thresholds should be established. More conclusive research and trials are necessary to understand the potential benefits of this test. Furthermore, trials already conducted do not make a case for the necessity of FeNO. To control asthma, practitioners prescribe inhaled corticosteroids and can measure the dosage depending on severity. Patients who report exacerbations can have their medications adjusted without having to take an additional test. Regardless of whether FeNO levels are known, physicians can follow the standard treatment and diagnostic testing for asthma while attaining the same results.

Given the need for further research to establish more definite clinical guidelines, FeNO measurements have not been determined to be a generally accepted professional medical standard consistent with Rule 59G-1.035(2), F.A.C. When assessing patient benefit, research and trials indicated that improved results can be attained without measuring FeNO levels and that the test serves as an adjunct to established methods for evaluating asthma.

EPSDT Considerations

The American Thoracic Society's guidelines indicate that measuring FeNO levels can aid in the diagnosis of asthma when other tests prove inconclusive and that it can assist in determining appropriate ICS doses. Florida Medicaid pays for children's services when they protect life and prevent significant disability or harm in accordance with the state's medical necessity definition.

Though, it is not recommended that further analysis be conducted to add FeNO as a covered Medicaid service, consistent with EPSDT requirements, the Agency and its health plans can evaluate individualized requests through its special services processes (as described in Rule 59G-5.020, F.A.C.) to determine if the service is medically necessary and to ensure that this treatment approach presents as the child's best alternative given the pending circumstances.

Concur **____Do not Concur**

Comments:

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_____ 7/3/17

Deputy Secretary for Medicaid (or designee) *date*

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

BREAST PUMP
GAPMS DETERMINATION REPORT WITH RECOMMENDATION

Date: May 18, 2015

To: Justin Senior, Deputy Secretary for Medicaid

From: Bureau of Medicaid Policy

Subject: **Breast Pump Coverage**

PURPOSE

In order for a breast pump to be covered under the Florida Medicaid program, it must meet medical necessity criteria as defined in 59G-1.010(166),[A1] Florida Administrative Code. (F.A.C.), and funded through the General Appropriations Act of Chapter 216, Florida Statutes (F.S.).

Pursuant to the criteria set forth in 59G-1.010(166)(a)(3), F.A.C., breast pumps must be consistent with generally accepted professional medical standards (GAPMS) as determined by the Medicaid program, and not experimental or investigational.

In accordance with the determination process established in 59G-1.035,[A2] F.A.C., this GAPMS Determination Report with Recommendation is submitted for review to the Deputy Secretary for Medicaid.

The Deputy Secretary for Medicaid will make the final determination as to whether breast pumps are consistent with generally accepted professional medical standards and not experimental or investigational.

RECOMMENDATION

This report recommends breast pumps as a health service that is consistent with generally accepted professional medical standards. It is further recommended that the following devices be covered:

1. A rent-to-purchase electric breast pump may be considered medically necessary when a nursing mother is experiencing prolonged separation from her infant because of work, school, or a medical reason.

2. Electric hospital grade breast pump rental may be considered medically necessary when a newborn recipient has one of the following conditions:
   - Prematurity (less than 37 weeks gestation),
   - Neurologic disorder,
   - Genetic abnormalities (e.g., Down Syndrome),

- Anatomic and mechanical malformation (e.g., cleft lip and palate),
- Congenital malformations requiring surgery (e.g., respiratory, cardiac, gastrointestinal, central nervous system)

An electric hospital grade breast pump rental may also be considered medically necessary when the nursing mother has been diagnosed with and is receiving treatment for mastitis or related infection of the breast.

Coverage of an electric hospital grade breast pump rental would be limited to no more than a three month period. Exceptions can be made on a case by case basis, based upon medical necessity.

REPORT WITH RECOMMENDATION

This report with recommendation is presented as the summary assessment considering the factors identified in 59G-1.035 F.A.C., based on the collection of information from sources of reliable evidence. The intent is to provide a brief analysis with justification in support of the final recommendation.

The analysis described in this report includes:

- Background information and pertinent current Medicaid policies
- An overview of the health service
- Information submitted by the requestor
- Confirmation of clearance from the government regulatory body
- Evidence based clinical practice guidelines
- Coverage policies from commercial and other state Medicaid insurers.

HEALTH SERVICE SUMMARY

Breast Pumps – Device Summary

There are three basic types of breast pumps:

- Manual pumps
- Battery-powered pumps
- Electric pumps

These pumps may be offered with single or double pumping actions. Table 1 provides information on different types and descriptions of breast pumps that are available.

Pumping Type	How it works	Types of Breast Pumps
Single	Extracts milk from one breast at a time.	Most manual breast pumps are single pumps. Most battery-powered pumps are single pumps.
Double	Can be used to extract milk from both breasts at the same time.	Some electric pumps are double pumps.

Table 1

GOVERNMENT REGULATORY BODY APPROVAL

Medical devices (including breast pumps) are regulated by the United States Food and Drug Administration (FDA). Breast pumps are often used by breastfeeding women to extract ("express") their breast milk. Breast pumps can also be used to maintain or increase a woman's milk supply, relieve engorged breasts and plugged milk ducts, or pull out flat or inverted nipples so a nursing baby can latch-on to its mother's breast more easily. Many women find it convenient, or even necessary, to use a breast pump to express and store their breast milk once they have returned to work, are traveling, or are otherwise separated from their baby. A breast pump can be used as a supplement to breastfeeding and some pumps are designed to mimic the suckling of a nursing baby. A number of breast pumps have been reviewed and approved by the FDA (U.S. Food and Drug Administration, 2015).[A3]

CLINICAL OUTCOMES

The benefits of breastfeeding are widely acknowledged, and as such, breastfeeding is the infant feeding method recommended by numerous organizations, including the Association of Women's Health, Obstetric and Neonatal Nurses[A4]; the World Health Organization[A5]; the Dietitians of Canada and Breastfeeding Committee for Canada[A6]; the American Dietetic Association[A7]; and the American Academy of Pediatrics (AAP).[A8]

The American Academy of Family Physicians[A9] and most all of the organizations listed above recommends that all babies, with rare exceptions, be breastfed and/or receive expressed human milk exclusively for the first six months of life.

The AAP[A8] reports that breastfeeding is associated with reductions in middle ear infections, gastrointestinal infections, sudden infant death syndrome, and adolescent and adult obesity rates. Therefore, the AAP also recommends exclusive breastfeeding for the first 6 months after birth, and then continued breastfeeding for one year or longer, as other foods are introduced. These benefits are further supported by literature published by the Institute of Child Health and Human Development.

The Institute of Child Health and Human Development (ICHHD)[A10] also proposes certain benefits of breastfeeding for the nursing mother, including:

- Less blood loss following childbirth and improved healing
- Improved postpartum weight loss
- Lower likelihood of experiencing postpartum depression, which is seen more often in new mothers who do not breastfeed
- Less chance of developing certain health conditions, such as rheumatoid arthritis, cardiovascular disease, and certain cancers (for example, breast cancer)
- Physical and emotional benefits of breastfeeding directly from a mother's breast due to skin-to-skin contact with her infant

EVIDENCE-BASED CLINICAL PRACTICE GUIDELINES

Both the ICHHD and in an issue paper regarding Medicaid coverage of lactation services, the Department of Health and Human Services, Centers for Medicare & Medicaid Services, provides that improving the health of the population and reducing preventable causes of poor health, such as obesity, is a priority; and current research indicates that breastfeeding or using

expressed milk for the first 6 to 12 months of life is highly beneficial for both the mother and infant in reducing these and other preventable health conditions. [A11]

On January 20, 2011, the United States Surgeon General released "The Surgeon General's Call to Action to Support Breastfeeding." This report indicates that there is a 32% higher risk of childhood obesity and a 64% higher risk of type 2 diabetes for children who are not breastfed. This report also provides recommended actions to remove some of the obstacles faced by women who want to breastfeed their babies; pointing out the health and economic benefits of breastfeeding, and offering opportunities for women to be supported in the workplace for breastfeeding including access to high-grade electric breast pumps. [A12]

In July, 2014, the National Center for Chronic Disease Prevention and Health Promotion's Division of Nutrition, Physical Activity, and Obesity, which is a division of the Centers for Disease Control and Prevention, published a Breastfeeding Report Card. Florida is within approximately two percentage points of national averages for the number of babies being breastfed with three quarters of all babies born being breastfed at some point, and around half still being breastfed at six months (Table 2). [A13]

Centers for Disease Control and Prevention National Immunization Survey (July 2014)					
Breastfeeding Rates	Ever Breastfed (%)	Breastfeeding at 6 months (%)	Breastfeeding at 12 months (%)	Exclusive breastfeeding at 3 months (%)	Exclusive breastfeeding at 6 months (%)
U.S. National	79.2	49.4	26.7	40.7	18.8
Florida	77.0	48.7	26.9	38.9	18.3

Table 2

An effective electric breast pump is an important tool for the management of breastfeeding challenges such as providing human milk to sick or premature infants. A breast pump is also, in Western culture, critical for breastfeeding mothers who return to work. Obtaining an effective electric breast pump can be difficult for uninsured or impoverished women because of the expense, complicated insurance reimbursements, and scarcity of providers that supply breast pumps to the inner-city community (Chamberlain, McMahon, Philipp, and Merewood, 2006).[A14]

Mothers who work outside the home initiate breastfeeding at the same rate as mothers who stay at home. However, the breastfeeding continuance rate declines sharply in mothers who return to work. While the work environment may be less than ideal for the breastfeeding mother, obstacles can be overcome. Electric piston pumps may be the most suitable type for mothers who work outside the home for more than 20 hours per week; however, when a mother is highly motivated, any pump type can be successful in any situation (Biagioli, 2003). [A15]

COVERAGE POLICY [A16]

Affordable Care Act

The Affordable Care Act (2010) requires most health insurance plans to cover the cost of a breast pump as part of women's preventative health services. These rules apply to health insurance marketplace plans and all other private health insurance plans, except for grandfathered plans. State Medicaid programs are not required by the Affordable Care Act to provide lactation services including breast pumps. [A11]

Florida Women, Infants, and Children (WIC)
Florida's Special Supplemental Nutrition Program covers breast pumps under certain circumstances. However, funding for breast pumps statewide is limited. Of the available pumps, local WIC offices use a priority system to determine who will receive a breast pump, as the resource is limited.

Medicare
Medicare does not cover breast pumps or breast pump supplies.

Aetna
Aetna covers the rental of breast pumps under its DME benefit when either of the following criteria is met:

- The newborn is detained in the hospital after the mother is discharged
- The infant is diagnosed with a congenital disorder that interferes with feeding

Florida Blue (Commercial Insurer Blue Cross/Blue Shield)
Florida Blue covers the following:

- One electrical or manual breast pump per member, per delivery (hospital grade electric breast pumps are excluded except when medically necessary during an inpatient hospital stay)

Minnesota Medicaid
Minnesota Medicaid covers breast pumps when ordered by the treating provider for any nursing mother experiencing separation from her infant because of work, school, illness or any other medical reason.

New York Medicaid
New York Medicaid covers hospital or professional grade breast pump under the following circumstances impacting the newborn:

- Prematurity (including multiple gestation),
- Neurologic disorders,
- Genetic abnormalities (e.g., Down's Syndrome),
- Anatomic and mechanical malformations (e.g., cleft lip and palate),
- Congenital malformations requiring surgery (e.g., respiratory, cardiac, gastrointestinal, CNS),
- Prolonged infant hospitalization.

Oregon Medicaid
Oregon Medicaid covers breast pumps taking into consideration the medical appropriateness for the infant and/or mother.

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FISCAL

Reimbursement rates for electric and hospital grade breast pumps are variable, based on research and review of other states coverage polices (Table 3).

Table 1: Other States' Medicaid Rates

	Electric Pump	Electric Hospital-Grade Pump[1]
Alaska	$1.27	$91.50
Connecticut	$118.75	
Idaho	$394.34	
Illinois	$119.74	
Maryland	$87.90	$56.21
Michigan	$134.32	$61.82
Minnesota	$256.14	$51.31
New Mexico	$49.25	
New York	$173.47	$38.61
Oregon	$80.92	
Texas	$152.88	$39.15
Washington	$65.60	$80.52
Average Mean[2]	**$124.00**	**$58.07**

Table 3

In conducting the fiscal analysis for coverage breast pumps under Florida Medicaid, we utilized the average reimbursement rates, as reflected above for each device.

Electric Breast Pump Purchase
In 2013, Florida Medicaid reimbursed for 111,619 births. In Florida, while 77% of newborns born in 2013 were reported to have ever been breastfed, only about 49% are still being breastfed at six months of age (Table 2). This signals that while a large percentage (the majority) of women in Florida have attempted to breastfeed their newborn/infant, only about half continue to do so for as long as recommended. Therefore, assuming 50% of these newborns were breastfed and there was a need to utilize an electric breast pump, the total cost for Florida Medicaid is expected to be $6,920,378.

Hospital Grade Breast Pumps Rentals
During state fiscal year 2013-2014, there were approximately 60,000 infants diagnosed with prematurity (less than 37 weeks gestation), a neurologic disorder, genetic abnormalities (e.g., Down Syndrome), an anatomic and/or mechanical malformation (e.g., cleft lip and palate), and congenital malformations requiring surgery (e.g., respiratory, cardiac, gastrointestinal, central nervous system).

[1] Per month rental rate
[2] Removed outlier rates

Assuming 50% of these newborns' mothers desired to breastfeed, but due to the child's condition required a hospital grade breast pump, the total cost for Florida Medicaid is expected to be $5,226,300 (based on a maximum rental period of three months). The estimated annual fiscal impact of covering both electric and hospital grade breast pumps is $12,146,678. The cost of this may be partially offset in the short-term by reductions in middle ear and gastrointestinal infections and in the long-term by reduced rates of obesity with its associated chronic disease costs (e.g. diabetes).

GENERALLY ACCEPTED PROFESSIONAL MEDICAL STANDARDS RECOMMENDATION

This report recommends breast pumps as a health service that is consistent with generally accepted professional medical standards. It is further recommended that the following devices be covered:

1. A rent-to-purchase electric breast pump may be considered medically necessary when a nursing mother is experiencing prolonged separation from her infant because of work, school, or a medical reason.

2. Electric hospital grade breast pump rental may be considered medically necessary when a newborn recipient has one of the following conditions:
   - Prematurity (less than 37 weeks gestation),
   - Neurologic disorder,
   - Genetic abnormalities (e.g., Down Syndrome),
   - Anatomic and mechanical malformation (e.g., cleft lip and palate),
   - Congenital malformations requiring surgery (e.g., respiratory, cardiac, gastrointestinal, central nervous system).

   An electric hospital grade breast pump rental may also be considered medically necessary when the nursing mother has been diagnosed with and is receiving treatment for mastitis or related infection of the breast.

   Coverage of an electric hospital grade breast pump rental would be limited to no more than a three month period. Exceptions can be made on a case by case basis, based upon medical necessity.

✓ **Concur** ____ **Do Not Concur**

Comments:

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_____ 5/28/15

Signature **Date**

Deputy Secretary for Medicaid (or designee)

Attachments

A1. 59G-1.010(166), F.A.C., "Medically Necessary"
A2. 59G-1.035, F.A.C., "Determining Generally Accepted Professional Medical Standards"
A3. FDA. 501(k) Devices: Megna Breast Pumps K142479. U.S. Food and Drug Administration. February 2015.
FDA. 501(k) Devices. Ardo Carum and Calypso Powered Breast Pumps K141742 . U.S. Food and Drug Administration. October 2014
FDA. 501(k) Devices. Expresse and Premier Powered Breast Pumps K973501. U.S. Food and Drug Administration. December 1997
A4. Association of Women's Health, Obstetric and Neonatal Nurses. AWHONN Position Statement: Breastfeeding. *Journal of Obstetric, Gynecologic, & Neonatal Nursing.* 2015. 44(1);145-150.
A5. World Health Organization. Media Centre: Infant and young child feeding Fact Sheet N342. February 2014. http://www.who.int/mediacentre/factsheets/fs342/en/
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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION

AUGUST DEKKER, et al.,

Plaintiffs,

v. Case No. 4:22-cv-00325-RH-MAF

JASON WEIDA, et al.,

Defendants.
_____/

EXPERT REPORT OF SOPHIE SCOTT, PH.D.

Pursuant to 28 U.S.C. 1746, I declare:

1. I have been retained by counsel for Defendants as an expert witness in connection with the above-captioned litigation. I have actual knowledge of the matters stated in this report. My professional background, experience, and publications are detailed in my curriculum vitae. A true and accurate copy of my curriculum vitae, which includes a list of my publications, is attached as Exhibit A to this report.

2. I have testified as an expert witness in the following cases, at trial or in deposition in the last four years: Bell v Mrs A vs Tavistock and Portman Trust, Case No: CO/60/2020, December 2020.

3. I am being compensated at an hourly rate for actual time devoted, at the rate of $400 per hour including report drafting, testimony, and consultation. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I provide.

4. The opinions expressed in this report are based on my training and experience as a neuroscientist, my reading and my assessment of the relevant neuroscientific literature on brain development, and the potential effects of gonadotropin-releasing hormone (GnRH) agonists (the most common form of what are often called puberty blockers) on the developing brain.

5. If called to testify in this matter, I would testify truthfully and based on my expert opinion. The opinions and conclusions I express herein are based on a reasonable degree of scientific certainty.

Introduction

6. I am the Director of University College London's (UCL's) Institute of Cognitive Neuroscience. I have published over 130 peer reviewed scientific papers, including papers in Nature, Science, and the Proceedings of the Academy of Natural Sciences. I am a fellow of the Academy of Medical Sciences, and of the British Academy. Since my PhD was awarded in 1994, I have been working in cognitive neuroscience, a scientific field that examines the relationships between human behaviour to the human brain, and how these can be affected by age, disease and individual differences. *See* Attached Curriculum Vitae.

7. As a neuroscientist I am very familiar with the existence of variations of sexual preference, and the existence of variations in gender identity. I think that the anecdotal evidence we have suggests that transition may, for some younger people, be an effective treatment for gender dysphoria, and that the medical approaches taken to achieve this may therefore be appropriate. Thus is it entirely possible that the use of puberty blockers is appropriate in some exceptional cases of gender dysphoria in prepubescent and adolescent individuals. My concern is that we do not yet have enough evidence about the best ways to identify the individuals for whom they are appropriate: we have not identified any biological markers or other characteristics to identify individuals for whom GnRH antagonists might provide effective; we do not have any reliable studies that show which young gender dysphoric individuals will remain gender dysphoric after adolescence; and we thus do not yet know who might benefit from

this highly medicalised and largely non-reversible treatment. I am also very concerned that the implications of the effects of puberty blockers on the developing brain and body are not well understood. In both of these areas much more research is needed.

8. All cultures recognise the onset of adolescence as the start of the entry into the adult world: it is a journey into that world, and a journey that takes place over several years. In 2005 the US supreme court, influenced partly by this emerging neuroscience research, increased the minimum age for capital punishment to be the same as that for voting and serving on juries. Around the world, many such limitations on the responsibility for teenagers for their own actions are in place – alongside laws which mean that teenagers could not engaging in risky behaviours that could place them or others at risk or having to live with long terms consequences (e.g. ages for driving, drinking alcohol, age of consent, getting a tattoo). Much of this reflects a lay understanding of what neuroscience is now confirming – there is variation from child to child, but teenage brains on the whole are structurally and functionally different from adult brains, and this affects both their engaging with risky behaviour, and their understanding of the implications of risky behaviour.

9. The human brain is formed of approximately 89 billion brain cells, or neurones, most of which are grown during gestation (Bayer et al. 1993; Rakic 1995). Following birth, there is a further period of extended brain development. Directly after birth, the brain grows rapidly, quadrupling in size

between birth and age 6, when it is roughly 90% the size of an adult brain. However the pattern of growth is underpinned by some complex changes that are occurring. These are:

- Synaptic pruning
- Myelination of different brain networks
- Differential growth of specific functional and anatomical areas.

10. Before I go into this in detail it's important to note that brain cells, or neurones, are formed of a cell body, with a long projection (an axon) and branch-like shorter projections (dendrites) from the cell body or from the far end of the axon. The axons can be thought of as ways the neurone can connect to more distant neurones, while the dendrites connect to nearby neurones. These connections are called synapses. Changes in the brain – associated with learning and development - occur largely through the connections between neurones, which can be through the strengthening of existing connections, or through the development of new dendritic connections. The axons are coated in a slim fatty sheath, called myelin: this enables the electrical discharges that enable transfer of information in the brain to be propagated rapidly along the length of the axon. Myelination is a process that increases the speed and efficiently of neural function. Neurones are highly organised in the brain, with the cell bodies forming structure layers on the surface of the brain (the cortex), as well as in sub cortical nuclei of cell bodies: the axons form tracts of connections between cortical areas, to and from sub cortical areas, and between the two hemispheres of the brain.

These tracts look white, due to the fatty myelin sheaths: this leads to the name 'white matter' for these tracts or connective networks. In contrast, the unmyelinated neuronal cell bodies look grey, hence the term 'grey matter'.

11. At birth and in early infancy, many dendritic connections exist and are created between neurones: this is known as *synaptic exuberance*. In the early years of life these are rapidly pruned, at first quickly, then more slowly. During adolescence a more adult profile of synaptic connections starts to appear: this appears most slowly in prefrontal fields compared to sensory and is still not established fully at age 18yrs (Huttenlocher and Dabholkar, 1997). The relationship between synaptic exuberance and pruning and their implications for the developing brain and experience are still being explored, but in terms of brain connectivity, the adult pattern is not yet established at 18: development continues into the early 20s.

12. Myelination in the human brain begins in visual brain areas a couple of months before birth and continues in other sensory brain areas over the first year. This process continues in other cortical and subcortical systems into the middle of the third decade. This has been expressly linked to the development of cognitive skills in children and adolescents, as myelination greatly improves the speed of condition of neurones, and hence their efficiency. Myelination proceeds in a roughly caudal to rostral direction in the brain, which means form back to front. This means that it is frontal and prefrontal fields that are those continuing to be myelinated into the mid 20s: this has been confirmed by more recent studies

looking at fractional anisotopy in the brain (Lebel et al., 2008). At 18yrs old, the connections to the frontal lobes are not myelinated like a mature adult brain, and this is likely to affect frontal lobe functions.

13. Throughout childhood, the brain grows and changes: this involves a non-linear pattern of change in the proportion of white and grey matter, which may partly involve changes in myelination (see above) and also the loss of cells through cell death (Sowell et al. 2004). A recent study looking at this pattern into adolescence found that "First, we found evidence for continued development of both intracranial volume (ICV) and whole brain volume (WBV) through adolescence, albeit following distinct trajectories. Second, our results indicate that CGMV is at its highest in childhood, decreasing steadily through the second decade with deceleration in the third decade, while CWMV increases until mid-to-late adolescence before decelerating" (Mills et al, 2016). This indicates that considerable changes are still happening in the structure of the adolescent brain. In terms of specific brain areas, while the cortex continues to thin through adolescence, the decreases are most marked in the parietal lobes and least marked (or growth is seen) in temporal and prefrontal fields (Tamnes et al, 2017).

Implications

14. The pattern of maturation of the brain in adolescence suggests a particular issue with frontal lobe functions – the frontal and temporal lobes are showing a different pattern of change (in terms of movement towards adult profiles) compared to more caudal fields, and the frontal lobes are the last to be

fully myelinated. The frontal lobes are associated with complex cognitive control processes, so called 'meta-cognitive processes' that enable us to plan our behaviour, control our responses, to be able to adapt our behaviour to different contexts and requirements, and to anticipate the implications and consequences of behaviour. The absence of mature frontal lobe connectivity and functions has been linked to increased impulsivity and risk-taking in adolescence, and to their greater susceptibility to peer opinions and behaviour (Blakemore and Robbins, Nature Neuroscience, 2012). Functional imaging studies – addressing how brains function under different task requirement – have shown that while adults recruit frontal lobe networks during decision making tasks, teenagers are more likely to recruit 'limbic networks" i.e. sub cortical networks linked more to emotional processing and reward processing: the implication is that the differential integrity of frontal lobe connectivity leads to teenagers making different, more risky decisions than adults, and relying on different brain networks to do so. This is backed up by behavioural studies showing that when decision making is 'hot' (i.e. more emotional), under 18yr olds make less rational decisions than when the responses are being made in a colder, less emotional context.

15. Puberty blockers (specifically, gonadotrophin-releasing hormone agonists) work by preventing the release of gonadotrophin-releasing hormone from the hypothalamus. Gonadotrophin releasing hormones have many effects, including stimulating the gonads (testes and ovaries) to produce testosterone and oestrogen. In childhood, the level of Gonadotrophin releasing hormones is very

low, but an increase in this prompts the onset of puberty, with the release of testosterone and oestrogen; these in turn have masculinising or feminising effects on the bodies and the brain. As puberty is associated with very marked changes in the structure of the brain (as outlined above) the use of puberty blockers may have serious consequences for the development of the human brain. We know from studies on sheep (Nuruddin et al, 2013) that treatment around the onset of puberty with gonadotrophin-releasing hormone agonists is associated with significant differences in the size of the amygdala (found to be larger in treated animals) and this was linked to some differences in emotional reactions. The male treated sheep showed greater approach responses and more risk taking behaviours, while the treated female sheep showed higher levels of anxiety and greater avoidance behaviour (Wojniusz et al, 2011). A behavioural study of natal girls who were treated for precocious (early) puberty with Gonadotrophin releasing hormone agonists (Wojniusz 2016) found that they also showed significant greater emotional reactivity on one of the tests used, relative to the control group. The treated girls also showed significantly lower heart rates than the untreated control group. In a commentary on this article (Hayes, 2017) it was pointed out that there were also notably lower scores on IQ measures and sub scales in the group of girls who were treated with Gonadotrophin releasing hormone agonists. He points out that “their reassuring statement in the abstract that girls undergoing GnRHa treatment for CPP and controls “showed very similar scores with regard to cognitive performance” and their conclusion that

"GnRHa treated girls do not differ in their cognitive functioning ... from the same age peers" (Wojniusz et al., 2016) may be overly optimistic. These statements minimize the fairly substantial difference found in IQ scores" (Hayes, 2017). Hayes also points to an older study that found a significant drop in IQ associated with taking triptorelin acetate to treat precocious puberty (Mul et al, 2001). Note that in all of these cases, in humans and other mammals, we cannot say if the results are due to direct effects of the Gonadotrophin releasing hormones on the brain, heart and behaviour, or if they are secondary to this (e.g. due to the altered levels of testosterone or oestrogen, or changes in the heart rate itself). All the papers I can find suggest that we need much more data on the long-term brain effects of Gonadotrophin releasing hormones when administered around puberty, the effects this can have on behaviour, and the extent to which any of this is altered if the treatment with Gonadotrophin releasing hormones is stopped.

16. I am very concerned that the current treatment regime is exposing young people to significant risk of harm. The greater susceptibility to peer pressure in those under 18 may make them especially vulnerable to risk taking, and this may well be enhanced by social media, where actions can be encouraged without any responsibility for outcomes. We need more research to be able to determine the potential for puberty blockers to be effective in alleviating some aspects of gender dysphoria, and to be able to differentiate those who might be helped by this treatment from those who will not. Furthermore, given the risks of puberty blocking treatment, and the fact that these will have irreversible, lifelong

effects, it is very possible for an adolescent to be unable to fully grasp the implications of puberty-blocking treatment, even if the risks are well explained. All the evidence we have suggests that the complex, emotionally charged decisions required to engage with this treatment are not yet acquired as a skill at this age, both in terms of brain maturation and in terms of behaviour.

I declare, pursuant to 28 USC § 1746, under penalty of perjury that the foregoing is true and correct. Executed on February 16th, 2023.

/s/ Sophie Scott
Sophie Scott, Ph.D.

Exhibit "A"

PROF SOPHIE KERTTU SCOTT CBE, FMEDSCI, FBA

Date of Birth: 16-11-1966
Address: Institute of Cognitive Neuroscience, UCL, 17 Queen Square, London, WC1N 3AR
email: sophie.scott@ucl.ac.uk

CURRENT POSITION

2019 – Director, Institute of Cognitive Neuroscience, University College London

EDUCATION/QUALIFICATIONS

1994 University College London, PhD in Cognitive Science
1990 Polytechnic of Central London, BSc (Hons) 2:1, Psychology

PROFESSIONAL HISTORY

1993-1998 MRC Applied Psychology Unit, Cambridge, Senior Scientific Officer
1998-2001 Research Fellow, Institute of Cognitive Neuroscience, UCL.
2001-2005 Wellcome Career Development Fellow, Dept. Psychology, UCL
2004 - Group Leader, Speech Communication Lab
2006- Professor of Cognitive Neuroscience, UCL
2005-2016 Wellcome Trust Senior Fellow, Institute of Cognitive Neuroscience
2013-2019Deputy Director, Institute of Cognitive Neuroscience, UCL
2019 – Director, Institute of Cognitive Neuroscience, University College London
I took maternity leave between June 2006-June 2007.

PRIZES AND RECOGNITION

2022 Awarded an Honorary degree by the University of Westminster
2021 awarded the Michael Faraday prize by the Royal Society
2020 appointed Commander of the Most Excellent Order of the British Empire for services to Neuroscience
2019 Royal Literature Society "Reading Matters" prize, for "The Neuromantics", my podcast with poet and writer Dr Will Eaves
2017 presented the Royal Institution Christmas Lectures
2017 Royal Society Summer Science Exhibition, "What's in a Voice?"
2016 elected as a Fellow of the British Academy
2016-2018 UCL TEDx License holder

2015 spoke at the annual TED conference, Vancouver (talk has been viewed over 4.4 million times on TED.com).
2015 gave Prize Lecture at the Physiology Society meeting, Cardiff.
2014 included in Who's Who
2013 won UCL Provosts' Award for Public Engagement (grade 8 and above category).
2012 Royal Society Summer Science Exhibition, "LOL: Science and Art of Laughter"
2012 Elected as Fellow of the Academy of Medical Sciences
2003 Royal Society Summer Science Exhibition, "Science of Speaking"

SUPERVISION OF GRADUATE STUDENTS

Since 2002, 14 PhD students supervised at UCL, and 35 MSc students at UCL, 2 at City University and one at the University of Reading

EDITORIAL WORK

2015 – associate editor for *The Psychologist* (British Psychological Society monthly journal).
2009 – 2014 Editorial Board of *Cognitive Neuroscience*
2010 – 2013 Section Editor, Language, *Neuropsychologia*
2008 – 2015 Associate Editor of *Brain and Language*
2004 –2009 Associate Editor of the *Quarterly Journal of Experimental Psychology*

MANAGEMENT AND FACILITATION

2020 - PALS Director for EDI
2015 – member, PALS Academic Careers and Diversity Committee
2015-2019– chair of ICN Public Activities Committee
2014 – 2019 deputizing for Prof Neil Burgess (ICN Director) at Faculty of Brain Sciences' Faculty Executive Committee meetings
2004 – representing the Speech Communication Group at the ICN Group Leader's committee

JUDGING AND COMMITTEES

2022 - member of ILCB advisory board
2019- Chair of Board of Trustees, Told By An Idiot theatre company (https://www.toldbyanidiot.org/about/)
2017- 2022 member of the Royal Society Dorothy Hodgkin Fellowship Committee
2015- associate Editor of the Psychologist and Digest Policy Advisory Committee, British Psychological Society

2015 Judge, Comment Awards
2015, 2018 Judge, Philip Leverhulme Prize
2014 Judge, Wellcome science writing prize
2013- Trustee, Jericho House theatre company (registered charity number 1131984)

EXTERNAL EXAMINING

2009-2012 External Examiner, BSc Psychology, University of Sussex
2009-2013 External Examiner, MSc Cognitive Neuroscience, University of York
2015-2019 External Examiner, BSc Psychology, University of Reading

TEACHING

2011-2014 Course convener, "Theories and Paradigms in Cognitive Neuroscience" UCL MSc in Cognitive Neuroscience.
2015- Module Convener, "Science Communication for Cognitive Neuroscientists" UCL MSc/MRes in Cognitive Neuroscience.
2023- Module Convener, "Power, Inclusion, Exclusion and Working with local communities".

GRANTS

Wellcome Trust Hub award development funding, for 'Talking Funny', £13000 over 18 months
Wellcome Trust Public engagement award, for "What's in a Voice" exhibit at the Royal Society Summer Science Exhibition, £20,000 over 12 months.
Wellcome Trust People Award for public engagement activities: for LOL event at the Royal Society, awarded 2012, amount £19,000 over 12 months.
Wellcome Trust Senior Fellowship, awarded April 2010 "Neurobiology of speech communication - cognition, plasticity, and social interactions" total amount awarded £1,184, 506, over 60 months.
Wellcome Trust Senior Fellowship, awarded May 2004 'the Neurobiology of Speech Perception – Cognitive and Clinical Links'. Total amount awarded £800,270, over 60 months.
Wellcome Trust RCDF grant, from April 2001-April 2005, 'the Neurobiology of speech perception'. Total amount awarded £358,376, over 48 months.
Marie Curie Incoming Scientist Fellowship, awarded November 2004, sponsoring Narly Golestani, £100,914 over 24 months.
ESRC grant awarded for new post doctoral researchers, sponsoring Charlotte Jacquemot, awarded May 2004, £30,919 awarded over 12 months.
ESRC grant awarded for new post doctoral researchers, sponsoring Patti Adank, awarded May 2005, £31,591 awarded over 12 months

ESRC +3 studentship award, awarded May 2004 (supervising Carolyn McGettigan)
British Academy meetings award, for the John Morton Festschrift, £2000
Experimental Psychology Society research seminar award, for the John Morton Festschrift, £3000
British Association for the Advancement of Science award for Key events in National Science and Engineering Week, 2008, £1000

ACADEMIC SUPERVISION

2001 -2004 Supervised Charvy Narain, the research assistant on my Wellcome RCDF award. Charvy was awarded a PhD in 2003 and took a job as an editor at Nature Neuroscience: she is now a Scientific Outreach Manager at the University of Oxford.
2002 -2006 supervised Disa Sauter, a research student in the Dept. Psychology at UCL. Disa passed her PhD viva without corrections in December 2006, and currently holds her a lecturer position at the University of Amsterdam..
2004 -2005 Supervised Dr. Charlotte Jacquemot, a post-doctoral fellow. Charlotte has been awarded a permanent CNRS position in France, which she began in 2006
2004 - 2012 supervised Carolyn McGettigan, a research student in the Dept of Human Communication Sciences. Carolyn passed her PhD viva without corrections in March 2008, was employed as a post-doctoral fellow on my Wellcome SRF grant until 2012 when she left to take up a lectureship at RHUL. She is now a Professor at UCL.
2005 -2006 supervised Dr. Patti Adank, a post-doctoral fellow. Patti is now a Professor at UCL.
2005 -2008 Supervised Dr Frank Eisner as a post-doctoral fellow on my Wellcome SRF award. Since January 2009, Frank held post-doc position at the Max-Planck-Institute for Psycholinguistics in Nijmegen, and is now a researcher at the Centre for Cognition of the Donders Institute for Brain, Cognition and Behaviour.
2005 -2007 Supervised Dr. Jonas Obleser as a post-doctoral fellow on my Wellcome SRF award. Since April 2007, Jonas has held a Junior Staff Scientist position at the Max Planck Institute for Human Cognitive and Brain Sciences, Leipzig, Germany, where ran his own research group: he is now a Professor at the Department of Psychology, University of Lübeck.
2005-2007 supervised Dr. Narly Golestani, a post-doctoral fellow, who now heads the Brain and Language Lab at the Cognitive Science Hub of the

University of Vienna, Austria, and at the Department of Psychology at the University of Geneva, Switzerland.2008 -2009 – supervised Nicholas Abreu, who has a Fulbright Scholarship to work in the UK for a year. Nicholas started medical school at Harvard in September 2009.
2009 - 2013 Dr Zarinah Agnew appointed as a post-doctoral fellow on my Wellcome SRF grant. Zarinah now works at UCSF as a post-doc in John Houde's lab.
2010 -2015 supervised Pradheep Shanmugalingam as an ESRC funded PhD student. Pradheep is now training in simultaneous translation.
2012 - 2015 supervising Kyle Jasmin as a PhD student on the UCL/NIH program (NIH supervisor Alex Martin). Kyle joined my lab as a post-doctoral fellow and then was awarded a a Leverhulme research fellowship at Birkbeck: he is now a lecturer at Royal Holloway UL.
2012 -2013 Nadine Lavan joined my lab as an RA for 12 months. Nadine left to take up a PhD place at RHUL: she now holds a Wellcome Fellowship at QMUL.
2013 - Supervising Sophie Meekings as an ESRC funded PhD student. Sophie was awarded a BA fellowship at Newcastle University, and was awarded a Dorothy Hodgkin fellowship in 2021, held at University of York.
2013 - Supervising Sinead Chen as a PhD student funded by a grant from the Taiwanese Government. Sinead now works for a policy think tank in Taiwan.
2013 -2015 Samuel Evans joined my lab as a post-doc on my Wellcome SRF grant. Now a lecturer at the University of Westminster
2013 – 2014 Dana Boebinger joined my lab as an RA. Dana left in August 2014 to start a PhD at Harvard, she is now a post do at the University of Rochester.
2015 – 2016 César Lima joined my lab as a senior post-doctoral fellow on my Wellcome SRF grant. César Lima is Assistant Professor of Psychology at Iscte - University Institute of Lisbon since 2017.
2017- Qing Cai joined my lab as a PhD student with funding from the Chinese government from 2018.
2017- Alexis Deighton McIntyre joined my lab as a PhD student with a UCL Graduate School studentship. In October 2021 she joined the MRC CBU as a postdoctoral researcher.
2018-Addison Billings joined my lab as a PhD student
2019 - Efe Caswell Niven joined my lab as a PhD student

SCIENTIFIC PUBLICATIONS-*REFEREED ARTICLES*

1. Scott, SK, Jasmin, K (2022) Rostro-caudal networks for sound processing in the primate brain, Frontiers in Neuroscience, 16, 1076374, 10.3389/fnins.2022.1076374
2. Scott, SK, Cai, CQ, Billing, A (2022) Robert Provine: the critical human importance of laughter, connections and contagion. Philosophical Transactions of the Royal Society B-Biological Sciences, 377(1863) 20210178 10.1098/rstb.2021.0178
3. Scott, SK (2022) Why public engagement is important for neuroscientists. Nature Reviews Neuroscience, 23(8):453-4.
4. MacIntyre, AD, Scott, SK (2022) Listeners are sensitive to the speech breathing time series: Evidence from a gap detection task. Cognition, 225, 105171 10.1016/j.cognition.2022.105171
5. Conde, T, Correia, AI, Roberto, MS, Scott, SK, Lima, CF, Pinheiro, AP (2022) The time course of emotional authenticity detection in nonverbal vocalizations, Cortex, 151:116-132.
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7. Billing, ADN, Scott, SK (2022) Possible limitations of perceptual studies for informing production networks-The case of laughter. Cortex, 148: : 218-221.
8. MacIntyre, AD, Cai, CQ, Scott, SK (2022) Pushing the envelope: Evaluating speech rhythm with different envelope extraction techniques, Journal of the Acoustical Society of America. 151(3):2002:2026.
9. Alderson-Day B, Moffatt, J, Lima, CF, Krishnan, S, Fernyhough, C, Scott, SK, Denton, S, Leong, IYT, Oncel, AD, Wu, YL, Gurbuz, Z, Evans, S (2022) Susceptibility to auditory hallucinations is associated with spontaneous but not directed modulation of top-down expectations for speech. Neuroscience of Consciousness, 2022(1) https://doi.org/10.1093/nc/niac002
10. Kamiloglu, RG, Tanaka, A, Scott, SK, Sauter, DA (2022) Perception of group membership from spontaneous and volitional laughter. Philosophical Transactions of the Royal Society B-Biological Sciences, 377: 20200404.
11. Pinheiro, AP, Anikin, A, Conde, T, Sarzedas, J, Chen, S, Scott, SK, Lima, CF (2021) Emotional authenticity modulates affective and social trait inferences from voices. Philosophical Transactions of the Royal Society B-Biological Sciences 376: 20200402.
12. Billing ADN, Cooper RJ, Scott SK (2021) Pre-SMA activation and the perception of contagiousness and authenticity in laughter sounds, Cortex, 143: 57-68.
13. Scott SK (2021) The neural control of volitional vocal production-from speech to identity, from social meaning to song. Philos Trans R Soc Lond B Biol Sci, 377(1841):20200395.

14. Lavan N, Scott SK, McGettigan C (2017) Impaired generalization of speaker identity in the perception of familiar and unfamiliar voices. J Exp Psychol Gen., 145(12):1604-1614
15. Cosme G, Rosa PJ, Lima CF, Tavares V, Scott S, Chen S, Wilcockson TDW, Crawford TJ, Prata D (2021). Pupil dilation reflects the authenticity of received nonverbal vocalizations. Scientific Reports. 11:3733.
16. Meekings S, Scott SK. (in press) Error in the Superior Temporal Gyrus? A Systematic Review and Activation Likelihood Estimation Meta-Analysis of Speech Production Studies. Journal of Cognitive Neuroscience.
17. Cai Q, Chen S, White SJ, Scott SK (2019). Modulation of humor ratings of bad jokes by other people's laughter. Current Biology. 29(14):R677-R678
18. Scott SK (2019) From speech and talkers to the social world: The neural processing of human spoken language. *Science*. Oct 4;366(6461):58-62.
19. Jasmin K, Lima CF, Scott SK (2019) Understanding rostral-caudal auditory cortex contributions to auditory perception. Nature Reviews Neuroscience, 20(7):425-434
20. Lima CF, Anikin A, Monteiro AC, Scott SK, Castro SL (2018) Automaticity in the recognition of nonverbal emotional vocalizations. Emotion. 2018 May 24. doi: 10.1037/emo0000429.
21. Neves L, Cordeiro C, Scott SK, Castro SL, Lima CF (2018) High emotional contagion and empathy are associated with enhanced detection of emotional authenticity in laughter, Q J Exp Psychol (Hove). Nov;71(11):2355-2363.
22. Krishnan S, Lima CF, Evans S, Chen S, Guldner S, Yeff H, Manly T, Scott SK (2018) Beatboxers and Guitarists Engage Sensorimotor Regions Selectively When Listening to the Instruments They can Play. Cereb Cortex. 2018 Nov 1;28(11):4063-4079.
23. Smith AV, Proops L, Grounds K, Wathan J, Scott SK, McComb K. (2018) Domestic horses (Equus caballus) discriminate between negative and positive human nonverbal vocalisations. Sci Rep. 2018 Aug 29;8(1):13052.
24. Lavan N, Burton AM, Scott SK, McGettigan C. (2018) Flexible voices: Identity perception from variable vocal signals. Psychon Bull Rev. 2018 Jun 25. doi: 10.3758/s13423-018-1497-7.
25. Agnew ZK, Banissy MJ, McGettigan C, Walsh V, Scott SK (2018) Investigating the Neural Basis of Theta Burst Stimulation to Premotor Cortex on Emotional Vocalization Perception: A Combined TMS-fMRI Study. FRONTIERS IN HUMAN NEUROSCIENCE Volume: 12 Article Number: 150 Published: MAY 15 2018
26. Agnew ZK, McGettigan C, Banks B, Scott SK (2018) Group and individual variability in speech production networks during delayed auditory feedback.

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
Tallahassee Division

AUGUST DEKKER, et al., *Plaintiffs*, v. JASON WEIDA, et al., *Defendants*.	Case No. 4:22-cv-00325-RH-MAF

CORRECTED EXPERT REBUTTAL REPORT OF E. KALE EDMISTON, PH.D.

I, E. Kale Edmiston, Ph.D., hereby declare and state as follows:

1. I am over the age of eighteen and submit this expert rebuttal report based on my expert opinion.

2. I have been retained by counsel for plaintiffs as an expert in connection with the above referenced litigation. The opinions expressed herein are my own and do not express the views or opinions of my employer.

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

Background and Qualifications

4. I am an Associate Professor of Psychiatry at the University of Massachusetts Chan Medical School. Prior to this appointment, I was an Assistant

Professor of Psychiatry at the University of Pittsburgh from 2019 to 2022. I have more than 15 years of experience conducting psychiatric neuroimaging research, with a focus on adolescence and young adulthood, mood and anxiety disorders, and impulsivity and emotional regulation. My methodological expertise lies in neuropsychological assessment, multimodal neuroimaging, psychophysiological measures such as heart rate variability, and measures of neuroendocrine function across adolescent development.

5. I completed a bachelor's degree from Hampshire College in 2007, where I studied cognitive science. I received postbaccalaureate training in psychiatric neuroimaging at the Yale School of Medicine. I earned a PhD in neuroscience from Vanderbilt University in 2015, as well as a graduate certificate in medical humanities, with a focus on bioethics and medical decision-making. I then completed post-doctoral training at China Medical University and the University of Pittsburgh.

6. In 2014, I co-founded the Trans Buddy Program at Vanderbilt University Medical Center, a peer navigator and support program for transgender people seeking healthcare. As a part of this program, my work primarily focused on supporting transgender adolescents experiencing mental health crisis. At this time, I also served as the Co-Director for the Vanderbilt University Program for LGBTI

Health. I later replicated the Trans Buddy Program at the University of Pittsburgh Department of Adolescent Medicine.

7. From 2018-2022, I served as a chapter author for the Assessment chapter of the World Professional Association for Transgender Health's *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8*.

8. I have authored over 100 peer-reviewed manuscripts, book chapters, and conference proceedings in psychiatric neuroscience and transgender health.

9. Further information about my professional background and experience is outlined in my curriculum vitae, a true and accurate copy of which is attached as **Exhibit A** to this report.

Prior Testimony

10. I have not testified as an expert at trial or by deposition within the last four years.

Compensation

11. I am being compensated for my time at a rate of $175/hour. My compensation is in no way contingent on the conclusions reached as a part of my testimony or on the outcome of this case.

Basis for Opinions

12. In preparing this report, I have reviewed: the Complaint in this case; Florida Administrative Code 59G-1.050(7) (the "Challenged Exclusion"); the document titled "Florida Medicaid: Generally Accepted Professional Medical Standards Determination on the Treatment of Gender Dysphoria," published by the Florida Agency for Health Care Administration in June 2022, and its attachments; the expert reports of Drs. Armand Antommaria, Dan Karasic, Johanna Olson-Kennedy, Loren Schechter, and Dr. Daniel Shumer, submitted by plaintiffs; and the expert reports Drs. Michael Biggs, G. Kevin Donovan, Paul Hruz, Kristopher Kaliebe Michael Laidlaw, Patrick Lappert, Stephen Levine, Sophie Scott, and Joseph Zanga, submitted by defendants.

13. My opinions are based on my years of research and academic experience, as well as my professional knowledge, as set out in my curriculum vitae (**Exhibit A**) and the materials listed therein; my knowledge of the peer-reviewed literature relating to neuropsychological assessment and brain development; my knowledge of the clinical practice guidelines for the treatment of gender dysphoria, including my work as a contributing author of WPATH SOC 8; and my review of any of the materials cited herein.

14. I have also reviewed the materials listed in the bibliography attached as **Exhibit B**. I may rely on those documents as additional support for my opinions.

15. The materials I have relied upon in preparing this report are the same types of materials that experts in my field of study 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.

Adolescent Brain Development

16. Dr. Scott's report stating that adolescents are more likely to engage in risky behaviors relative to adults fails to include the specific context in which this is true. That is, the literature indicates that there are *highly specific circumstances* in which adolescents are more likely to engage in risky or impulsive behavior. Indeed, Dr. Scott lists some of these circumstances in her testimony: driving, drinking alcohol, getting a tattoo. However, none of these examples are relevant to the issue at hand: protracted medical decision-making made in the context of adult guidance and consultation with a medical professional.

17. Dr. Scott fails to cite the large body of evidence indicating that adolescents are capable of deliberative decision making in the presence of adults (i.e., healthcare providers and caregivers) and when decision making occurs over a protracted period. This is the exact context in question: decisions about accessing gender-affirming medical care, such as gonadotropin releasing hormone agonists

(GnRHa) and hormone treatment, are made jointly among the adolescent patient, their caregiver(s), and medical professionals. These decisions are also made over time; data show that the typical time between an adolescent realizing they are transgender and coming out to an adult is three years (Bauer et al., 2022). Furthermore, once an adolescent discloses their identity to a supportive adult, they will then have to schedule a healthcare appointment and undergo assessment prior to accessing treatment. This process typically takes months and for some, even years.

18. Dr. Scott misrepresents the literature on adolescent decision making by generalizing findings made in "hot" contexts to those made in "cold" contexts. Indeed, the Blakemore and Robbins review from 2012 that she cites explicitly states that the literature concludes that adolescents demonstrate adult-typical decision-making abilities in cold contexts. It is not that adolescence is associated with a failure to engage cognitive control networks, but rather, that cognitive control networks are engaged with greater variability during this time than during adulthood. Decision-making is a multifactorial process that includes valuation of both risk and reward. While adolescents are more likely to overvalue reward and underestimate risk when peers are present or when decisions must be made quickly, they demonstrate deliberative and appropriate consideration of reward and risk valuation in the absence of peers, in the presence of adults, and when decisions are made over time.

This important difference in the contextual nature of decision-making in adolescence is an established finding that has been replicated across multiple studies (Chein et al., 2011; O'Brien et al., 2011; Simons-Morton et al., 2011; Smith et al., 2014; Weigard et al., 2014; Hartley & Somerville, 2015; Guassi Moreira & Telzer, 2018). Indeed, deliberative decision making in contexts without pressure to decide quickly has been repeatedly shown in adolescents (Byrnes, 2002; Figner et al., 2009; Wolff & Crockett, 2011; Icenogle & Cauffman, 2021).

19. Dr. Scott also states that "at 18yrs old, the connections to the frontal lobes are not myelinated[1] like a mature adult brain, and this is likely to affect frontal lobe functions." This is an oversimplification of an extremely complex literature. A study of over 10,000 participants has shown quite the opposite: that by the age of 18, adult-level cognition is established (Tervo-Clemmens et al., 2022), while other studies have shown mature integration of functional networks by late adolescence (Marek et al., 2015) and fractional anisotropy of prefrontal white matter (Lebel & Beaulieu, 2011, fractional anisotropy is an indirect measure of myelination). Even though, on average, there are developmental differences in prefrontal myelination,

[1] Myelin is a protein sheath that covers the axons of neurons. The axons comprise white matter in the brain, and bundles of these fibers transmit signals from region to region in the brain. When an axon is myelinated, the signal can travel faster down the axon.

there is not strong evidence that these differences are associated with an inability to make deliberative decisions with the support of caregivers and expert clinical guidance.

20. Furthermore, there is a great deal of variation in the timing of development between different prefrontal white matter tracts, as well as a great deal of variation between individuals. Indeed, in Lebel & Beaulieu's longitudinal study of over 100 individuals from childhood to young adulthood, many individuals showed decreases or no changes in fractional anisotropy (FA) during adolescence, and these differences also varied by prefrontal white matter tract (2011). This literature represents differences in group averages and should not be used to predict the behavior or development of an individual adolescent; we cannot draw conclusions about all 18-year-olds from these studies. This is why the WPATH SOC 8 recommends an individualized approach to joint decision-making regarding healthcare.

There is Little Evidence to Support Defendants' Designated Experts' Speculation about Negative Effects of GnRHas on Cognition

21. Dr. Scott cites a 2016 study by Wojniusz and colleagues as evidence of the negative effects of GnRHas on emotional reactivity in a sample of girls with central precocious puberty. This is puzzling because the authors of this paper explicitly state the opposite interpretation: "Overall, our findings do not provide firm

conclusions with regard to differences in emotional processing between the GnRHa treated CPP girls and age-matched controls." (pp13).

22. Perhaps Dr. Scott has misinterpreted the nature of the emotional flanker task. This task asks participants to determine if two simultaneously presented houses are the same or different. The houses are presented at the center of a screen, and emotional or neutral face distractors flank them. The outcome of interest is the reaction time for the determination of whether the houses are the same or different. The idea here is that people with poor emotional regulation will be more distracted during the emotional face condition and therefore take longer to respond. This interpretation can only be made when reaction times are increased in both the emotional face conditions. In this study, the CPP girls showed longer reaction time than controls during the emotional face condition only when the houses were different, but not when the houses were the same. Thus, the findings do not indicate an issue with emotional regulation. More likely, the results are incidental and due to statistical issues regarding false discovery rate correction, an argument that the authors of the paper themselves make.

23. The authors do find reduced heart rate and elevated heart rate variability (HRV) during the emotional task. HRV is distinct from heart rate and is a measure of cardiac vagal tone. HRV is a proxy for parasympathetic system or "rest and

digest" function. Thus, elevated HRV is associated with increased regulatory capacity and is a marker of health. Thus, these findings are a sign of *optimal* emotional regulation. Indeed, the authors state, "…the lower HR and higher HRV could suggest that treated CPP girls have better emotion regulation capacity and higher adaptability to changing contexts than controls" (pp13).

24. Dr. Scott then points out that, in a separate commentary on the article, Dr. Hayes states that there were "notably" lower scores on IQ measures in the CPP group relative to controls. However, Dr. Hayes's comment, and Dr. Scott's reliance on it, is not supported by the findings of the study. Specifically, none of the differences in IQ were statistically significant, and the mean IQ scores for both groups were within the normal range. Furthermore, the mean difference between groups in this study is within the realm of variation that may occur from repeated administration of the WISC-III, i.e., although scores for an individual tend to remain relatively stable over time, there is fluctuation that occurs even within an individual and small differences in IQ (Watkins & Smith, 2013), as reported in this study, are not only not statistically significant, they are not clinically significant. Dr. Scott has, again, offered a misrepresentation of the literature.

25. Dr. Levine cites a single case study as evidence for an effect of GnRHa treatment on IQ. Case studies are the lowest quality of evidence. Case studies can

provide important evidence for future areas of study or to provide an illustrative example of a common clinical phenomenon, but they should not be used to make general conclusions or policy positions. Putting aside the low quality of evidence typical of case studies in general, this case study does not even provide sufficient support for Dr. Levine's opinion as it describes a transgender girl who, prior to initiation of treatment, already had below average IQ. While Dr. Levine highlights the lack of change in fractional anisotropy values over the course of the study in this case, this could be due to developmental delays that are independent of treatment and are instead related to her low IQ. Therefore, the findings of this case study are simply not generalizable to the broader population.

26. Dr. Michael Biggs, a sociologist, also offers speculation regarding cognitive effects of GnRHa treatment as well, describing it as "…stopping normal sexual and cognitive development…" This statement regarding cognitive development appears to be pure speculation as he offers no citation regarding evidence for deleterious effects of GnRHa treatment on cognition. In reviewing the literature, including through specific searches, I have been unable to find compelling evidence of this. I was able to identify two studies that showed no effect of GnRHa treatment on executive function (Soleman et al., 2016; Staphorsius et al., 2015). The

lack of evidence for these effects is itself compelling, given that these medications have been used in adolescents with central precocious puberty for decades.

Evidence for Effects of GnRHa treatment on the Brain

27. Both Dr. Levine and Dr. Laidlaw state that the effects of GnRHa treatment on the brain are both "unknown" and "likely negative." They do not cite any original research that supports this conclusion and thus it is unclear to me how they concluded that the effects are likely negative in the absence of evidence. Dr. Laidlaw even goes so far as to speculate on the individual brain maturation of three specific transgender individuals. Both Levine and Laidlaw admit that there is no evidence from the neuroimaging literature on negative effects of these treatments on brain development, but even if there was, any neuroimaging study that compares group averages would not support an inference about the brains of individual people. There is a great deal of variation between and within individuals in many commonly used neuroimaging measures. For this reason, neuroimaging methods commonly used in research, such as fMRI, cannot be used diagnostically for individual people in the absence of organic brain disease (Schleim & Roise, 2019).

28. Dr. Hruz also speculates in his testimony that there are negative effects of GnRHa treatment on the brain: "A possible effect of blocking normally timed puberty is alteration of normal adolescent brain maturation". Dr. Hruz then cites a

2013 review paper that describes typical adolescent brain maturation but does not mention or describe any effects of blocking or delaying puberty on the brain (Arain et al., 2013). Dr. Hruz therefore has not cited any support for his conclusion, and I have not identified any studies relating to the evidence of negative longitudinal effects on brain development related to GnRHa treatment in central precocious puberty or in transgender adolescents, even after targeted searches for it.

29. There is not a large literature on the effects of GnRHa treatment on the brain in humans, but this does not render such care experimental. GnRHa treatments have been in used for decades, including for the treatment of gender dysphoria. That said, there are a few cross-sectional studies on this issue, and it is significant that none of the experts (nor the GAPMS memo) cited this literature in their testimonies. In a study that compared transgender adolescent boys and girls taking GnRH agonists to cisgender boys and girls, there were differences in brain function in some brain regions that would indicate congruence with gender identity and other differences that would indicate congruence with sex assigned at birth. However, there were no between-group differences in network function on the basis of GnRHa treatment. Furthermore, the authors searched for relationships between duration of GnRHa treatment in the transgender adolescents and brain function and *were unable to find any effects.* In a diffusion tensor imaging study of fractional anisotropy

values, an index of white matter myelination, *again there was no significant association between fractional anisotropy values and GnRHa treatment* (van Heesewijk et al., 2022). Similarly, in an fMRI study comparing cisgender boys and girls to transgender boys and girls, there were no significant differences in brain activity between transgender and cisgender adolescents during a verbal fluency task, and no deficits in verbal ability in transgender youth (Soleman et al., 2013). In a study of transgender individuals receiving GnRHa treatment and cisgender people, there were differences in brain activity between groups, but these differences were not associated with hormone levels, leading the authors to conclude that these differences are associated with group differences that predate GnRHa treatment (Soleman et al., 2016). In summary, to my knowledge, there have been three studies of brain structure and function of transgender adolescents receiving GnRHa treatment, and none of them have found any significant effects of treatment on the brain.

30. A recent primate study provides evidence for some regional neuroprotective effects of GnRHa treatment, although the results are complex (Godfrey et al., 2023). In this study, the authors compared dominant and subordinate adolescent rhesus monkeys. These monkeys form social hierarchies much like human adolescents, and subordinate monkeys are subjected to aggression from the

more dominant monkeys. Both dominant and subordinate monkeys were randomly assigned to a GnRHa treatment or control group and then followed longitudinally. In the primates exposed to chronic social subordination stress, GnRHa treatment rescued the negative effect of stress on regional brain volume over time. These differences were seen in brain regions such as the amygdala that are well-established in the pathophysiology of depression and anxiety. There were also effects of GnRHa treatment in general; treatment in both social groups was associated with smaller hippocampal volume than control animals. Regarding the prefrontal cortex, a critical region during adolescent development, GnRHa treatment was associated with greater prefrontal grey matter volume prepubertally but this difference decreased by adolescence. There was an effect of GnRHa treatment early in puberty on prefrontal white matter volume; however, this difference was no longer present by the end of the study. Importantly, there are species-specific differences in prefrontal volume changes across puberty; the generalizability of the prefrontal findings to humans should be made with caution. Finally, the authors also assessed social behavior in both submissive and dominant primates over time and were able to determine that, at prepuberty, submissive primates were more socially isolated, but that GnRHa-treated subordinate animals had normalized social behavior (reduced time spent alone) and normalized cortisol response to threat (cortisol is a stress hormone

associated with the hypothalamic pituitary adrenal axis). The authors conclude that "…delayed puberty and estrogen suppression may be protective against the impact of social stress" (pp12). This study provides strong evidence that GnRHa treatment normalizes brain structure, physiological stress reactivity, and social behavior in adolescent primates subjected to social subordination, an ecologically valid non-human primate model of the psychosocial environment for transgender youth.

31. There is a small body of literature on the effects of gender affirming hormone care on the brain in transgender adolescents. In a study comparing transgender boys receiving testosterone therapy and those who were not, testosterone treatment was associated with reductions in mood and anxiety symptoms, as well as reductions in body image dissatisfaction. Gender affirming hormone care was associated with an increase of functional coupling between the amygdala and prefrontal cortex while research participants viewed threatening emotional faces, likely indicating improved emotional regulation of the amygdala in the boys who were treated with testosterone. Indeed, in the boys who were treated with testosterone, greater coupling between these two regions was associated with lower anxiety symptom severity (Grannis et al., 2021). Another study of transgender boys receiving testosterone found that testosterone caused a shift in amygdala

activation, such that it became more typical of cisgender boys than cisgender girls (Beking et al., 2020).

32. 17. Both Dr. Scott and Dr. Biggs cite studies from the animal literature regarding the "side effects" of GnRHa treatment on the brain and behavior. However, they misinterpret or misrepresent the meaning of the term "side effect" in this context. Pharmacological agents have effects. The determination of what is a side effect and what is a desired effect is contextual. For example, Scott cites a 2021 rodent study of GnRHa treatment as an example of the "side effects" associated with GnRHa treatment (Anacker, et al., 2021). If one were to read the abstract of the study and not the full text, it may lead some to come to such a conclusion. However, what the study shows is that, prior to GnRHa treatment, there are sex differences in rodent behavior. Following GnRHa treatment, those sex differences are no longer present. This is the expected and desired outcome of GnRHa treatment, not a side effect. For example, female mice show greater locomotion behavior than male mice. Following GnRHa treatment, male mice show greater locomotion behavior than untreated male mice. Similarly, in a test of social interaction, GnRHa-treated males showed differences in the time spent with male versus female mice relative to untreated male mice, but not relative to untreated female mice. In both force-swim tests and a test of feeding behavior, female GnRHa-treated mice differed from control female mice,

but not from male mice. This is a consistent pattern across behavioral assays performed in the study, and this pattern was present in biological assays as well. GnRHa-treated male mice showed greater corticosterone stress response to novelty than control male mice but did not differ from female mice. GnRHa treatment increased neural activity in the hippocampus of female mice, but this activity increase did not differ from male mice. This is not a compelling study of the side effects of GnRHa treatment, but rather, a study that shows us exactly what we would expect: that blocking sex hormones decreases sex differences, the intended outcome for transgender youth.

33. Dr. Scott and Dr. Biggs cite a series of studies of GnRHa effects on sheep from a specific laboratory. One study from this group did show sex-specific changes in feeding behavior and HRV following GnRHa treatment. While Dr. Biggs opts to highlight changes in behavior in the female sheep that could be interpreted as an increase in anxiety-like behavior, he fails to mention that GnRHa treatment was associated with *improvements* in these behaviors in the treated male sheep (Wojniusz et al., 2011). They also fail to mention that other studies from this group show no effects of GnRHa treatment on cognition (Nuruddin et al., 2013; Wojniusz et al., 2013), and, like the Anacker study, brain differences are best explained by an expected reduction of sex differences following treatment (Nuruddin et al., 2013).

This issue of inappropriate reference group is a common problem in the GnRHa animal literature and its extrapolation to transgender youth (Edmiston & Juster, 2022). While the literature regarding the effects of GnRHa treatment on sheep behavior from this research group is complex, it by no means offers compelling evidence of negative effects of GnRHa treatment. Furthermore, Dr. Biggs highlights a negative effect from one study- an increase in anxiety-like behavior in female sheep only. However, we know from studies of transgender youth and young adults that anxiety and depression symptoms decrease with treatment (de Vries et al., 2014; Dhejne et al., 2016; Aldridge et al., 2021; Chen et al., 2023). This is more compelling evidence than a single animal study, as sheep do not have the complex psychosocial identities that humans do.

Evidence for Negative Consequences of Depression and Anxiety on the Developing Brain

34. The brain is more plastic during adolescence than during adulthood. This means that adolescents are particularly vulnerable and at increased risk for the onset of mood and anxiety disorders, and, if untreated, that the onset of mood and anxiety symptoms can permanently alter the developmental trajectory of the brain into adulthood (Holder & Blaustein, 2014). Termed the "kindling effect", the concept here is that, as the efficiency of neural circuits is reinforced over time (i.e., "neurons that fire together wire together"), each depressive episode or

environmental stressor increases the risk for later depressive episodes. This effect may be amplified during adolescence because of the greater plasticity of the brain.

35. There are well-documented disparities in mental health outcomes in transgender youth that are caused by minority stress (for review, see White Hughto et al., 2015). This includes evidence that transgender people who live in areas with more accepting political climates show reduced biological stress markers and fewer mental health symptoms than transgender people who live in less accepting areas (DuBois & Juster, 2022). Others have shown an association between decreased social support and biological markers of stress in transgender adolescents (McQuillan et al., 2021). Given that transgender adolescents report high chronic stress and high rates of depression, anxiety, and suicidality, transgender adolescents are particularly vulnerable to the effects of stress on brain development, stress system regulation, and long-term mental health outcomes (DuBois et al., 2021; Potter et al., 2021; Randall et al., 2022).

36. In Dr. Levine's testimony, he quotes the Hippocratic Oath, "Above All Do No Harm". He makes this argument on the assumption that GnRHa treatment must necessarily cause harm because it is an intervention. This assumes that the psychosocial environment and biology of transgender youth is like that of cisgender youth. There is a great deal of evidence that this is not the case. Instead, in my

opinion not offering an intervention to transgender individuals that require treatment actually does harm.

37. In this case, puberty blockers have demonstrated efficacy in reducing symptoms of depression in transgender adolescents (de Vries et al., 2011), and therefore may in fact be neuroprotective to the cumulative effects of stress caused by gender dysphoria.

Conclusion

38. There is little to support the Defendants' designated experts' speculation about the negative effects of GnRHa treatment on the brain. In contrast, there is a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents. Furthermore, it is well-known that transgender adolescents face higher rates of psychosocial stress than their cisgender peers, and there is clear evidence for the negative effects of psychosocial stress and poor mental health on brain development. While the effects of GnRHa treatment on the brain are an important area for future research, this does not render such care experimental. To the contrary, this is treatment that has existed for decades and arguments that a purported lack of evidence is equivalent to known harm are spurious, particularly when there is a large literature indicating benefits of treatment and harm of withholding treatment.

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

Executed this 22 day of March 2023.

E. Kale Edmiston, Ph.D.

Exhibit A

Curriculum Vitae

E. Kale Edmiston, PhD

Associate Professor
Department of Psychiatry
University of Massachusetts Chan Medical School
kale.edmiston@umassmed.edu

ACADEMIC APPOINTMENTS

Associate Professor of Psychiatry University of Massachusetts Chan Medical School	2022-present Worcester, MA
Assistant Professor of Psychiatry University of Pittsburgh School of Medicine	2019-2022 Pittsburgh, PA
Postdoctoral Scholar University of Pittsburgh Medical Center PI: Mary L. Phillips, MD, MD (CANTAB)	2016-2019 Pittsburgh, PA
Postdoctoral Fellow China Medical University PI: Fei Wang, MD, PhD	2016 Shenyang, China
Research Assistant Yale University School of Medicine PI: Hilary P. Blumberg, MD	2007-2010 New Haven, CT

EDUCATION

PhD, Neuroscience Vanderbilt University	2010-2015 Nashville, TN
Graduate Certificate Medicine, Health and Society Vanderbilt University	2015 Nashville, TN
BA, Cognitive Science Hampshire College	2005-2007 Amherst, MA

RESEARCH

CITATION METRICS (03/23):

Citations: 2087 H-Index: 25 i10 Index: 34

RESEARCH INTERESTS:

social and affective neuroscience, visual processing, anxiety disorders, multimodal MRI, neuromodulation

AWARDED GRANTS:

American Foundation for Suicide Prevention Award 2022

Title: *Real-time study of psychotherapy, suicide risk, and resilience in transgender and non-binary adults*
PI: Sarah Victor
Co-I: **E. Kale Edmiston**
Award amount: $90,000.00

K01 MH117290 Mentored Scientist Career Development Award 2019-2024
Title: *Feed forward visual system function in high trait anxiety*
PI: **E. Kale Edmiston**
Award amount: $868,978.00

Brain and Behavior Research Foundation Early Career Award 2019-2021
Title: *Neuromodulation of visual cortex BOLD in high trait anxiety*
PI: **E. Kale Edmiston**
Award amount: $69,401.00

The Opportunity Fund 2019
Title: *Trans Buddy PGH: Peer healthcare support program*
PI: Gerald Montano
Co-I: **E. Kale Edmiston**
Award amount: $15,000

Center for Interventional Psychiatry 2018
Title: *Neuromodulation of visual cortex and threat sensitivity in high anxiety*
PI: **E. Kale Edmiston**
Award amount: $9,900.00

Campaign for Southern Equality 2017
Title: *The Trans Buddy Program: Mental health advocacy for trans communities*
PI: **E. Kale Edmiston**
Award amount: $1,000.00

University of Pittsburgh Office of Diversity and Inclusion Mini-Grant 2017
Title: *Developing health promotion materials for the transgender community*
PI: **E. Kale Edmiston**
Award amount: $1,000.00

Trans Justice Funding Project 2017
Title: *The Trans Buddy Program: Peer advocacy solutions for mental health care access*
PI: **E. Kale Edmiston**
Award amount: $2,500.00

The Pollination Project 2016
Title: *The Trans Buddy Program: An innovative solution to transgender mental health disparity*
PI: **E. Kale Edmiston**
Award Amount: $1,500.00

Culture, Brain, and Development Grant 2006

Title: *Brain sex differences in mood disorders*
PI: **E. Kale Edmiston**
Award amount: $3,000.00

PEER-REVIEWED PUBLICATIONS (https://orcid.org/0000-0002-3548-6026):
2023:
48. Hoelscher EC, Victor SE, **Edmiston EK**. Gender minority resilience and suicidal ideation: a longitudinal and daily examination of transgender and non-binary adults. Behavior Therapist. (In Press).
47. Schroth-Erickson L, Levin R, Mak K, **Edmiston EK**. A review of the neurobiobehavioral literature of transgender identity. J Gay and Lesbian Mental Health. (In Press).
2022:
46. Coleman E, Radix AE, Bouman WP…**Edmiston EK**…Arcelus J. Standards of care for the health of transgender and gender diverse people, version 8. International Journal of Transgender Health. 2022; 23:1-258.
45. Juster RP, **Edmiston EK**. Refining research and representation of sexual and gender diversity in neuroscience. Biological Psychiatry: CNNI. 2022; 7(21):1251-7.
44. Colic L, Clark A, Sankar A, Rathi D, Goldman D, Kim JA, Villa LM, **Edmiston EK**, Lippard ETC, Mazure CM, Blumberg HP. Gender-related associations among childhood maltreatment on brain circuitry and clinical features of bipolar disorder. European Neuropsychopharmacology. 2022; 63:35-46.
43. **Edmiston EK**, Fournier JC, Chase HW, Aslam H, Lockovich J, Graur S, Bebko G, Bertocci M, Rozovsky R, Mak K, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortical activity during reward expectancy predicts mania risk up to one year post scan. J Affective Disorders. 2022; 319:325-8.
2021:
42. Bertocci MA, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman B, Greenberg T, Phillips ML. Reward circuitry-targeted cathodal transcranial direct current stimulation impacts reward circuitry and affect in bipolar disorder. Molecular Psychiatry. 2021; 26(8):4137-45.
2020:
41. Feng R, Womer FY, **Edmiston EK**, Chen Y, Wang Y, Chang M, Yin Z, Wei Y, Duan J, Ren S, Li C, Liu Z, Jiang X, Wei S, Li S, Zhang X, Nuo X, Tang Y, Wang F. Antipsychotic effects on cortical morphology in schizophrenia and bipolar disorders. Frontiers Neuroscience. 2020; 14:579139.
40. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S, Wang F. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2020; 10:923.
39. Wang Y, Wei Y, **Edmiston EK**, Womer FY, Zhang X, Duan J, Zhu Y, Zhang R, Zhang Y, Jiang X, Wei S, Liu Z, Zhang Y, Tang Y, Wang F. Altered structural connectivity and cytokines levels in schizophrenia and genetically high-risk individuals: associations with disease state and vulnerability. Schizophrenia Research. 2020; 223:158-165.
38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships

among impulsive sensation-seeking, reward circuitry activity, and risk for psychopathology: an fMRI replication and extension study. Biological Psychiatry: CNNI. 2020; 5(7):660-68.

37. Sha Z, Versace A, **Edmiston EK**, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler R, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Quirk G, Haber S, Phillips ML. Functional disruption in prefrontal-striatal network in obsessive compulsive disorder. Psychiatry Research: Neuroimaging. 2020; 300:111081.

36. **Edmiston EK,** Song Y, Chang M, Yin Z, Zhou Q, Zhou Y, Jiang X, Wei S, Xu K, Tang Y, Wang F. Hippocampal functional connectivity in patients with schizophrenia and unaffected family members. Frontiers in Psychiatry. 2020; 11:278.

35. Wei S, Womer F, **Edmiston EK**, Zhang R, Jiang X, Wu F, Kong L, Zhou Y, Tang Y. Structural alterations associated with suicide attempts in major depressive disorder and bipolar disorder: a diffusion tensor imaging study. Progress in Neuropsychopharmacology & Biological Psychiatry. 2020; 98.

34. Beach L, Eckstrand K, Ehrenfeld J, **Edmiston EK**, Ding J. A model for improving transgender healthcare quality. The Joint Commission Journal on Quality and Patient Safety. 2020; 46:37-43.

2019:

33. Sha Z*, **Edmiston EK***, Versace A, Fournier JC, Graur S, Greenberg T, Lima Santos JP, Chase HW, Stiffler RS, Bonar L, Hudak R, Yendiki A, Greenberg BD, Rasmussen S, Liu H, Buckner R, Quick G, Haber S, Phillips ML. Multimodal disruption of cerbello-thalamo-motor circuit in obsessive compulsive disorder. Biological Psychiatry: CNNI. 2019; 5(4):438-47. *co-first authors

32. Wang L, Zhao Y, **Edmiston EK**, Womer FY, Zhang R, Zhao P, Jiang X, Wu F, Kong L, Zhou Y, Tang Y, Wei S. Structural and functional abnormalities of amygdala and prefrontal cortex in major depressive disorder with suicide attempts. Frontiers Psychiatry. 2019; 10:923.

30. Chang M, **Edmiston EK**, Womer F, Zhou Q, Shengnan W, Jiang X, Zhou Y, Ye Y, Huang H, Zui X, Xu K, Tang Y, Wang F. Spontaneous low-frequency fluctuations in the neural system for emotional perception in major psychiatric disorders: amplitude similarities and differences across frequency bands. Journal of Psychiatry and Neuroscience. 2019; 44:132-41.

29. Xia M, Womer FY, Chang M, Zhu Y, **Edmiston EK**, Jiang X, Wei S, Duan J, Xu K, Tang Y, He Y, Wang F. Shared and distinct functional architecture of brain networks across psychiatric disorders. Schizophr Bulletin. 2019; 47:450-63.

2018:

28. Li J, **Edmiston EK**, Tang Y, Fan G, Xu K, Wang F, Xu J. Shared facial emotion processing in medication-naive major depressive disorder and healthy individuals: detection by sICA. BMC Psychiatry, 2018; 18:96.

27. Chang M, Womer FY, **Edmiston EK**, Bai C, Zhou Q, Jiang X, Wei S, Wei Y, Ye Y, Huang H, He Y, Xu K, Tang Y, Wang F. Neurobiological commonalities among three major psychiatric diagnostic categories: a structural MRI study. Schizophrenia Bulletin. 2018; 44:65-74.

2017:

26. Wang N, **Edmiston EK**, Luo X, Yang H, Chang M, Wang F, Fan G. Comparing amplitude of low-frequency fluctuations in multiple system atrophy and idiopathic Parkinson's disease. Psychiatry Research Neuroimaging, 2017; 269:73-81.

25. Jiang X, **Edmiston EK**, Zhou Q, Xu K, Zhou Y, Wu F, Kong L, Wei S, Zhou Y, Chang M, Geng H, Wang D, Wang Y, Cui W, Tang Y, Wang F. Alteration of a cortico-striatal-limbic neural system in major depressive disorder and bipolar disorder. Journal of Affective Disorders, 2017; 221:297-303.

24. Corbett BA, Blain S, **Edmiston EK**. The role of context in psychosocial stress among adolescents with Autism Spectrum Disorder: piloting a semi-structured, video game-based paradigm. Journal of Intellectual & Developmental Disability. 2017; 43:20-8.

23. **Edmiston EK**, Muscatello RA, Corbett BA. Altered pre-ejection period response to social evaluative threat in adolescents with autism spectrum disorder. Research in Autism Spectrum Disorders. 2017; 36:57-65.

2016:

22. **Edmiston EK**, Donald CA, Sattler AR, Peebles JK, Ehrenfeld JM, Eckstrand KL. Opportunities and gaps in transgender primary healthcare: a systematic review. Transgender Health. 2016; 1(1):216-30.

21. **Edmiston EK**, Jones RM, Corbett BA. Physiological response to social evaluative threat in adolescents with autism spectrum disorder. Journal of Autism Developmental Disorders. 2016; 46(9):2992-3005.

20. **Edmiston EK**, Blain S, Corbett BA. Salivary cortisol and behavioral response to social evaluative threat in adolescents with autism spectrum disorder. Autism Research. 2016; Epub ahead of print.

2015:

19. Tang Y, Chen K, Zhou Y, Wang Y, Driesen N, **Edmiston EK**, Chen X, Jiang X, Kong L, Zhou Q, Li H, Wu F, Xu K, Wang Z, Tang Y, Wang F. Neural activity changes in unaffected children of patients with schizophrenia: a resting-state fMRI study. Schizophrenia Research. 2015; 168(1-2):360-5.

18. **Edmiston EK**, Merkle K, Corbett BA. Neural and cortisol responses during play with human and computer partners in children with autism. Social Cognitive Affective Neuroscience. 2015; 10(8):1074-83.

2014:

17. Corbett BA, Newsom C, Key AP, Qualls L, **Edmiston EK**. Examining the relationship between face processing and social interaction behavior in children with and without autism spectrum disorder. J Neurodevelopmental Disorders, 2014; 6(1):35.

16. Li J*, **Edmiston EK**,* Chen B, Tang Y, Ouyang X, Jiang Y, Fan G, Ren L, Liu J, Zhou Y, Jiang W, Liu Z, Xu K, Wang F. A comparative diffusion tensor imaging study of corpus callosum subregion integrity in bipolar disorder and schizophrenia. Psychiatry Res. 2014; 221(1):58-62.*co-first authors

2013:

15. **Edmiston EK***, McHugo M*, Dukic MS, Smith SD, Abou-Khalil B, Zald DH. Enhanced visual cortical activation for emotional stimuli is preserved in patients with unilateral amygdala resection. J Neuroscience, 2013; 33(27):11023-11031. *co-first authors

14. Liu H, **Edmiston EK**, Fan G, Ku X, Zhao B, Shang X, Wang F. Altered resting-state functional connectivity of the dentate nucleus in Parkinson's disease. Psychiatry Research: Neuroimaging. 2013; 211(1):64-71.

13. **Edmiston EK**, Blackford JU. Childhood maltreatment and response to novel face stimuli presented during functional magnetic resonance imaging in adults. Psychiatry Research: Neuroimaging. 2013; 212(1):36-42.

2012:

12. Fengrong O, Kai L, Qian G, Dan L, Jinghai L, Liwen H, Xian W, **Edmiston EK**; Yang L. An urban neo-poverty population-based quality of life and related social characteristics investigation from northeast china. PLoS One. 2012; 7(6):e38861.

11. Chepenik LG, Wang F, Spencer L, Spann MN, Kalmar JH, Womer F, **Edmiston EK**, Pittman B, Blumberg HP. Structure-function associations in hippocampus in bipolar disorder. Biological Psychiatry. 2012; 90(1):18-22.

2011:

10. Wang F, Kalmar JH, Womer FY, **Edmiston EK**, Chepenik LG, Chen R, Spencer L, Blumberg HP. Olfactocentric paralimbic cortex morphology in adolescents with bipolar disorder. Brain. 2011; 134(7):2005-12.

9. **Edmiston E**, Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. Archives of Pediatric and Adolescent Med. 2011; 165(12):1069-77.

8. **Edmiston E**, Wang F, Kalmar JH, Womer FY, Chepenik LG, Pittman B, Gueorguieva R, Hur E, Spencer L, Staib LH, Constable RT, Fulbright RK, Papademetris X, Blumberg HP. Lateral ventricle volume and psychotic features in adolescents and adults with bipolar disorder. Psychiatry Research. 2011; 194(3):400-2.

2009:

7. Womer FY, Wang F, Chepenik LG, Kalmar JH, Spencer L, **Edmiston E**, Constable RT, Papademetris X, Blumberg HP. Sexually dimorphic features of vermis morphology in bipolar disorder. Bipolar Disord 2009; 11(7):753-8.

6. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Papademetris X, Staib, LH. Improving the reliability of shape comparison by perturbation. IEEE Biomedical Imaging 2009; 1:686-9.

5. Jiang Y, **Edmiston E**, Wang F, Blumberg HP, Staib LH and Papademetris X. Shape comparison using perturbing shape registration. IEEE Computer Vision Pattern Recognition 2009;683-90.

4. Wang F, Kalmar JH, He Y, Jackowski M, Chepenik LG, **Edmiston E**, Tie K, Gong G, Shah MP, Jones M, Uderman J, Constable RT, Blumberg HP. Functional and structural connectivity between the perigenual anterior cingulate and amygdala in bipolar disorder. Biological Psychiatry 2009; 66(5):516-21.

3. Kalmar JH, Wang F, Spencer L, **Edmiston E**, Lacadie CM, Martin A, Constable RT, Duncan JS, Staib LH, Papademetris X, Blumberg HP. Preliminary evidence for progressive prefrontal abnormalities in adolescents and young adults with bipolar disorder. J Int Neuropsychol Soc. 2009; 15(3):476-81.

2008:

2. Blumberg HP, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Duman RS, Gelernter J. Influence of vascular endothelial growth factor variation on human hippocampus morphology. Biological Psychiatry 2008; 64(10):901-3.

1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Bhagwagar Z, Spencer L, Pittman B, Jackowski M, Papademetris X, Constable RT, Blumberg HP. Abnormal corpus callosum

integrity in bipolar disorder: A diffusion tensor imaging study. Biological Psychiatry 2008; 64(8):730-3.

MANUSCRIPTS (IN PROGRESS):

Ravindranath O, Perica MI, Parr AC, Pjha A, McKeon SD, Montano G, Ullendorf N, Luna B, **Edmiston EK**. Adolescent neurocognitive development and decision-making regarding gender affirming care. (Submitted).

Soehner AM, **Edmiston EK**, Wallace M, Chase HW, Lockovich J, Aslam H, Stiffler R, Graur S, Skeba A, Bebko G, Benjamin OE, Wang Y, Phillips ML. Neurobehavioral reward and sleep-circadian phenotypes predict present and next-year mania/hypomania risk. (Submitted).

Sequiera S, Tervo-Clemmens B, Carmel T, **Edmiston EK.** Towards a biopsychosocial model for neurodevelopment in transgender and gender diverse adolescents: understanding risk and resilience for mood disorders. (Submitted).

POSTERS, ABSTRACTS, AND CONFERENCE PROCEEDINGS:

53. Victor SE, **Edmiston EK**. Ecological momentary assessment of gender-relevant versus other interpersonal stressors predicting self-injurious thoughts and behaviors among transgender and non-binary adults. *Association for Behavioral and Cognitive Therapy Annual Convention. Submitted.*

52. **Edmiston EK**, Fournier JC, Chase HW, Phillips ML. Ventral visual stream functional coupling during implicit emotional face perception is associated with internalizing symptoms: a double dissociation by face valence at baseline and six months post-scan. *American College of Neuropsychopharmacology.* 2023.

51. Victor SE, Hoelscher E, Sandel D, Trieu T, **Edmiston EK.** Interpersonal and intrapersonal gender minority stressors as contribution to suicidal ideation among transgender and non-binary adults. *Suicide Research Symposium.* 2022.

50. Aslam MA, Mak K, **Edmiston EK.** Piloting transcranial direct current stimulation to reduce threat sensitivity in high trait anxiety. *University of Pittsburgh Department of Psychology Undergraduate Directed Experiences in Research Poster Day*. 2022.

49. **Edmiston EK** & Strakowski S. Understanding diagnosis and assessment disparities in transgender populations. *Society of Biological Psychiatry Annual Meeting.* 2022. Discussant, Lunchtime “Fireside Chat” Series.

48. Bertocci M, Afriyie-Agyemang Y, Rosovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Network interference during emotion regulation in distressed adults consistently predicts depression symptoms. *Society of Biological Psychiatry Annual Meeting.* 2022.

47. Afriyie-Agyemang Y, Bertocci M, Rozovsky R, Aslam H, Graur S, **Edmiston EK**, Chase HW, Bebko G, Stiffler R, Phillips ML. Overcompensation of the central executive network during working memory may be a neural marker for youth at risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.

46. Schumer MC, Bertocci MA, Bebko G, Stiffler RS, Lockovich JC, Aslam HA, Graur S, **Edmiston EK**, Chase HW, Johnson SL, Phillips ML. Trait urgency mediates associations between neural emotion-processing markers of emotion-triggered impulsivity and mania in young adults at-risk for bipolar disorder. *Society of Biological Psychiatry Annual Meeting*. 2022.

45. Young J, Roepke T, Anacker C, Ehrensaft D, **Edmiston EK**, Guthman EM, Eshel N, Marrocco J. Challenges and opportunities for translational research and clinical strategies within the LGBTQIA2S+ community. *American College of Neuropsychopharmacology Annual Meeting.* 2021. Discussant, Study Group.

44. Phillips ML, Bertocci M, Chase HW, Graur S, Stiffler R, **Edmiston EK**, Coffman BA. Targeted non-invasive neuromodulation impacts reward expectancy-related reward circuitry activity and affect in bipolar disorder and healthy adults. *Society of Biological Psychiatry Annual Meeting.* 2021.

43. **Edmiston EK,** Fournier JC, Rozovsky R, Chase HW, Bertocci MA, Aslam HA, Lockovich J, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Left ventrolateral prefrontal cortex structure and reward-expectancy related activity predict manic symptom changes one year later. *American College of Neuropsychopharmacology Annual Meeting.* 2021.

42. **Edmiston EK**, Phillips ML, Mak K, Chase HW, Fournier JC. Visual cortex coupling and childhood maltreatment: associations with major depression and a compensatory mechanism. *Society of Biological Psychiatry Annual Meeting.* 2021.

41. Marrocco J, **Edmiston EK**, Anacker C, Bangasser D. The study of sex differences and gender bias, and trans inclusive research practices. *American College of Neuropsychopharmacology Annual Meeting.* 2020. Panelist, Networking Session.

40. Chase HW, Fournier JC, Bertocci MA, **Edmiston EK**, Lockovich JC, Aslam H, Stiffler RS, Graur S, Bebko G, Phillips ML. Decision-making variability in mood disorders: new insights for a replication attempt. *Society of Biological Psychiatry Annual Meeting.* 2020 (Submitted, meeting canceled due to COVID-19).

39. **Edmiston EK,** Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. A double dissociation between anxiety and depression symptom improvement and fusiform coupling and positive and negative emotional face processing. *Society of Biological Psychiatry Annual Meeting.* 2020 (Submitted, meeting canceled due to COVID-19).

38. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam HA, Lockovich JC, Graur S, Bebko G, Forbes EE, Stiffler R, Phillips ML. Assessing relationships among impulsive sensation-seeking, reward circuitry activity, and predisposition to bipolar disorder: an fMRI replication and extension study. *American College of Neuropsychopharmacology Annual Meeting. 2019.*

37. Paglisotti T, Montano G, Simpson A, **Edmiston EK**. Preliminary implementation of Trans Buddy PGH: establishing trust among transgender patients and healthcare providers. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day.* 2019.

36. **Edmiston EK**, Fournier JC, Chase HW, Bertocci MA, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Phillips ML. Left ventrolateral prefrontal cortical BOLD signal during reward expectancy and impulsive sensation seeking: a replication study. *University of Pittsburgh Medical Center Department of Psychiatry 19th Annual Research Day. 2019.*

35. Chase HW, **Edmiston EK**, Bertocci M, Fournier JC, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Forbes EE, Phillips ML. Similar neural representation of appetitive and loss avoidance prediction errors across distressed and healthy individuals. *Society of Biological Psychiatry Annual Meeting.* 2019.

34. **Edmiston EK**, Simpson A. Progress report: Quality improvement programming for transgender mental health. Symposium. *TransPride PGH Professional Conference.* 2018.

33. Schroth-Erickson L, Levin R, **Edmiston EK**. Talking to your patients about the biological basis of transgender identity. *Philadelphia Trans Wellness Conference Professional Track. 2018*.

32. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Fusiform gyrus-salience network coupling during emotion processing predicts anxiety and depression symptom change. *University of Pittsburgh Medical Center Department of Psychiatry 18th Annual Research Day*. 2018.

31. **Edmiston EK**, Fournier J, Greenberg T, Chase HW, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Salience network BOLD response to emotional faces predicts anxiety and depression symptom outcomes. *Society of Biological Psychiatry Annual Meeting.* 2018.

30. Chase HW, Qiu H, Kerestes R, Shah N, Alkhar H, **Edmiston EK**, Soehner A, Greenberg T, Aslam H, Stiffler R, Lockovich J, Graur S, Bebko G, Pan L, Eickhoff SB, Phillips ML. Implication of the visual cortex in resting state fMRI studies of mood and anxiety disorders may relate to the propensity for within-scanner sleep. *Society of Biological Psychiatry Annual Meeting.* 2018.

29. Ding J, Ehrenfeld J, Raynor L, **Edmiston EK**, Eckstrand K, Beach L. A proposed systems level quality improvement model for transgender healthcare delivery. *The National Transgender Health Summit*. 2017.

28. **Edmiston EK.** Setting the agenda for transgender neuroimaging: a critical review and future directions. Symposium. *The National Transgender Health Summit.* 2017.

27. **Edmiston EK,** Fournier J, Greenberg T, Bertocci M, Stiffler R, Aslam H, Lockovich J, Phillips ML. Trait anxiety predicts visual system response to emotional faces. *Developmental Affective Neuroscience Symposium*. 2017.

26. **Edmiston EK.** The Trans Buddy Program: an innovative intervention for increasing health care utilization. Symposium. *TransPride PGH Professional Conference.* 2017.

25. Buchanan K, Richmond M, Sattler AR, **Edmiston EK**. Red state solutions for transgender health care access: provision in low resource areas. Symposium. *Philadelphia Transgender Health Conference.* 2017.

24. **Edmiston EK,** Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Predicting quality of life in distressed youth: Cortico-thalamic BOLD signal and reward processing. *University of Pittsburgh Medical Center Department of Psychiatry 17th Annual Research Day*. 2017.

23. **Edmiston EK**, Chase H, Stiffler R, Lockovich J, Aslam H, Graur S, Bebko G, Phillips ML. Cortico-thalamic BOLD signal during reward processing predicts quality of life at follow up in distressed young adults. *Society of Biological Psychiatry Annual Meeting.* 2017.

22. Eckstrand KL, Mitchell L, **Edmiston EK.** The Trans Buddy Program: Transgender Leadership and peer advocacy for reducing health disparities. *University of Pittsburgh Health Sciences Health Disparity Poster Competition.* 2017.

21. **Edmiston EK.** Reframing the search for transgender neuroimaging biomarkers. *New Materialisms Annual Meeting* Warsaw, Poland. 2016.

20. Corbett BA, Muscatello R, **Edmiston EK**, Muse I. Examining the Diurnal Profile of Children and Adolescents with Autism Spectrum Disorder (ASD) and Typical Development between 8 to 17 years of age. *International Society for Psychoneuroendocrinology.* 2016.

19. Corbett BA, Muse I, **Edmiston EK**, Muscatello R. Diurnal and Stress Hormonal Profiles of Testosterone and Cortisol in Adolescents with Autism Spectrum Disorder (ASD) and Typical Development (TD). *International Society for Psychoneuroendocrinology.* 2016.

18. **Edmiston EK**. Psychophysiological characterization of adolescents with Autism Spectrum Disorder. Presentation, *Chinese Psychiatric Association Annual Meeting.* 2016.

17. **Edmiston EK**, Jones RM, Blain S, Corbett BA. Neuroendocrine and physiological responsivity during social stress in adolescents with and without autism spectrum disorder. *Vanderbilt Kennedy Center Science Day.* 2015.

16. **Edmiston EK**, Valencia B, Corbett BA. Autonomic nervous system function in response to social judgment in adolescents with and without autism spectrum disorder. *International Meeting for Autism Research.* 2015.

15. Corbett BA, Newsom C, Key S, Qualls L, **Edmiston EK**. A randomized wait-list control trial of a peer-mediated, theatre-based intervention to improve social ability in children with autism spectrum disorder. *International Meeting for Autism Research.* 2015.

14. Singer B, Eckstrand K, Ehrenfeld J, **Edmiston EK**. Transgender health and advocacy in academic medicine: an empowerment model. Workshop; *Gay and Lesbian Medical Association Annual Meeting.* 2014.

13. **Edmiston EK**, Corbett BA. Behavioral and endocrine alterations in adolescents with autism spectrum disorder. Selected presentation; *Vanderbilt Kennedy Center Science Day*. 2014.

12. **Edmiston EK.** Effects of a neurobiological explanation of sexual orientation on student attitudes towards lesbian, gay and transgender people. *Society for Neuroscience.* 2013.

11. Corbett BA, **Edmiston EK**, Zald DH. Neural and physiological responses during play with human and computer partners in children with autism. *Society for Neuroscience.* 2013.

10. **Edmiston EK,** McHugo M, Dukic MS, Eggers E, Zald DH. Visuocortical BOLD response to emotional stimuli in the absence of a functional amygdala. *Society for Neuroscience.* 2012.

9. **Edmiston EK.** Pelvic and chest exams in transgender men. Workshop; *Philadelphia Trans Health.* 2011.

8. **Edmiston EK**, Blackford JU. Childhood maltreatment affects face processing. *Biology of Prosocial Behavior.* 2011.

7. **Edmiston E,** Wang F, Mazure CM, Sinha R, Mayes LC, Blumberg HP. Cortico-striatal limbic gray matter morphology in adolescents reporting exposure to childhood maltreatment. *Vanderbilt Kennedy Center Science Day.* 2011.

6. Wang F, **Edmiston E**, Hur E, Kalmar JH, Womer FY, Chepenik LG, Blumberg HP. An Altered Developmental Trajectory of Frontotemporal Connectivity in Bipolar Disorder. *Biological Psychiatry* 2010; 67 (Supplement 9): 107.

5. Wang F, Chepenik LG, Shah MP, Kalmar JH**, Edmiston E**, Spencer L, Duman R, Gelernter J, Blumberg HP. Genes Regulating Neurotrophic Factors that Influence the Corticolimbic Connectivity in Mood Disorders: Treatment Implications. *Biological Psychiatry* 2009; 65 (Supplement 1): 174.

4. Kalmar JH, Wang F, Chepenik LG, Shah MP, McDonough A, **Edmiston E**, Blumberg HP. Amygdala functioning during emotional processing in adolescents with bipolar disorder or ADHD. *Biological Psychiatry* 2008; 63 (Supplement 1): 184.

3. Womer F, Wang F, Chepenik LG, Kalmar JH, **Edmiston E**, Spencer L, Constable RT, Papademetris X, Blumberg HP. Structural abnormalities of the cerebellar vermis in bipolar disorder. *Biological Psychiatry* 2008; 63 (Supplement 1): 141.

2. Wang F, Kalmar JK, Womer F, He Y, Chepenik L, **Edmiston E**, Blumberg HP. Abnormal morphological correlations within a cortico-limbic neural system in adolescents with bipolar disorder. *American Academy of Childhood and Adolescent Psychiatry.*

1. Wang F, Kalmar JH, **Edmiston E**, Chepenik LG, Tie K, Spencer L, Jackowski M, Papademetris X, Constable RT & Blumberg HP. Abnormal callosal integrity in bipolar disorder determined from diffusion tensor imaging. *Biological Psychiatry* 2008; 63 (Supplement 1): 43.

BOOK CHAPTERS:

Edmiston EK, Bertocci M, Phillips ML. Neuroimaging and Circuit Mechanisms of Bipolar Disorder. In *Neurobiology of Mental Illness*. 6th Ed. Eds: Eric Nestler & Alexander Charney. Oxford University Press. (In Press).

Tomson A & **Edmiston EK**. Understanding the basis of gender identity development: biological and psychosocial models. In *Trans Bodies, Trans Selves*. 2nd Ed. Ed: Sand Chang. Oxford University Press. 2022.

Edmiston EK. Community-led peer advocacy for transgender health care access in the southeastern United States: The Trans Buddy Program. In *Healthcare in Motion: Mobility forms in health service delivery and accessibility.* Berghahn Books. 2017.

Robles RJ & **Edmiston EK**. Community Responses to Trauma. In *Trauma, Resilience, and Health Promotion for LGBT Patients.* Springer Press. 2017.

Edmiston EK & Mitchell L. Trans Buddy: Innovation Profile. In *The Remedy: Queer and Trans Voices on Health and Health Care.** Arsenal Press. 2016. *Lambda Literary Award Winner, Non-Fiction Anthology

Eckstrand KL, **Edmiston EK**, Potter J. Obstetric and Gynecologic Care to LGBT Individuals. In *Lesbian, Gay, Bisexual, Transgender, and Intersex Healthcare: A Clinical Guide to Preventative, Primary, and Specialist Care*. Springer Press. 2015.

ADDITIONAL SCHOLARSHIP:

Edmiston EK. Letter to the Editor: The legacy of transgender surgery access is complex. *Annals of Plastic Surgery.* 2019.

Edmiston EK. Invited Commentary: Transgender health research must serve transgender people. *BJOG.* 2018.

Edmiston EK. Feminist bioethics and intersex medical interventions: A review of *Making Sense of Intersex*. *Catalyst: Feminism, Theory, Technoscience*. 2016; 2(1).

Jann JT, **Edmiston EK**, Ehrenfeld J. Letter to the Editor: Important considerations for addressing LGBT health care competency. *American J of Public Health* 2015; e1.

HONORS, AWARDS, AND FELLOWSHIPS:

American College of Neuropsychopharmacology Travel Award	2021
Society of Biological Psychiatry Early Career Investigator Travel Award	2019
NYC tDCS Fellowship City University of New York, New York, NY	2018
Trainee, T32 MH018951 Child and Adolescent Mental Health Research University of PIttsburgh, Pittsburgh, PA	2018-2019
Research Day Department of Psychiatry Outstanding Poster Award	2018
PLOS One Travel Award	2017
Fellow, Winter School in the Neuroscience of Consciousness Canadian Institute For Advanced Research	2017
Trainee, T32 MH16804 Transformative Discovery in Psychiatry	2016-2018

University of Pittsburgh, Pittsburgh, PA

WPATH Outstanding Student Award 2015
International honor for contributions to transgender health research

The Trans 100 2015
National honor for excellence in the transgender community

Point Foundation Scholar 2014-2015
One of 20 selected nationally for program that funds education of LGBT students

Vanderbilt Brain Institute Student Leadership and Service Award 2014

Graduate Student Travel Grant, Vanderbilt University 2013

Fellow, Summer Program in Neuroscience Ethics and Success 2013
Marine Biology Laboratory, Woods Hole, MA

Clinical Neuroscience Scholar for Translational Research 2012-2015
Dan Marino Foundation

Neurobiology of Social Behavior Travel Award 2011
Emory University, Atlanta, GA

President's Scholarship 2003-2005
Case Western Reserve University, Cleveland, OH

TEACHING AND MENTORSHIP

SELECTED TALKS:

Invited Speaker: *Neuroscience in Service of Our Community:* 2023
How Research Rooted in Empathy and Humility Makes Us Better Scientists
Neuroscience Diversity Seminar
University of Maryland School of Medicine

Invited Speaker: *Visual Cortex Distinguishes Anxiety and Depression* 2023
Fournier Group Lab Meeting
The Ohio State Medical School

Presenter: *Assessing Visual Perception in Depression and Anxiety* 2023
Department of Psychiatry Faculty Meeting
UMass Chan Medical School

Invited Speaker: *Neuroimaging Studies of Transgender People* 2022
The Friedman Brain Institute and oSTEM
The Icahn School of Medicine at Mount Sinai

Invited Speaker: *Impulsivity and Reward-related Activity:* 2022
A Stable Marker for Bipolar Disorder risk
STEP Seminar
Truman State University

Invited Speaker: *Assessing Relationships Among impulsivity, Reward Circuitry, and Risk for Psychopathology* Magnetic Resonance Research Center Forum Yale School of Medicine	2019
Presenter: *Fusiform Gyrus Alterations During Emotion Processing: Predicting the Future in Anxiety Disorders* Center for the Neural Basis of Cognition Seminar University of Pittsburgh and Carnegie Mellon University	2018
Panelist: *Setting the Research Agenda in Transgender Health* 27th Annual Issues in Medical Ethics Conference The Icahn School of Medicine at Mount Sinai	2017
Panelist: *Neuroimaging in Child and Adolescent Mental Disorders* Chinese Society of Psychiatry 14th Annual Meeting	2016
The Trans Buddy Program: An Innovative Model for Healthcare Access Medicine Health and Society Colloquium Series Vanderbilt University	2015
Panel Organizer: *Intra-community Stigma in LGBT Populations* 615Thrive Conference Tennessee Department of Health	2015
Transgender Health: Provider Considerations Department of Hearing and Speech Sciences Grand Rounds Vanderbilt University	2014
Sexual and Reproductive Health in LGBT Populations Sarah Fogel, PhD Department of Nurse Midwifery Vanderbilt University School of Nursing	2014, 2015
Panelist: *(Im)Possible Politics: Intersectional Trans Organizing* Ben Singer, PhD; Dean Spade, JD; Lisa Guenther PhD Department of Women and Gender Studies Vanderbilt University	2014
Plenary Speaker: *Creating Change for LGBTI Health* Gay and Lesbian Medical Association Annual Meeting	2013
Invited Speaker: *Threat Detection, Visual Cortex, and Anxiety* Department of Radiology Beijing Normal University	2013
Invited Speaker: *Threat Detection, Visual Cortex, and Anxiety* Department of Psychiatry China Medical University	2013

MEDICAL STUDENT TEACHING EXPERIENCE:

Guest Lecturer: *Neuromodulatory Interventions in Mood Disorders* 2022
Neuroscience Area of Concentration Seminar Series
University of Pittsburgh School of Medicine

Guest Lecturer: *Building Trust with your Transgender Patients* 2021,2022
Texas Christian University School of Medicine

Instructor of Record: *Introduction to Scientific Writing* 2016
China Medical University

Guest Lecturer: *Clinical and Biobehavioral Features of Autism* 2016
Clinical Medicine 400
China Medical University

Guest Lecturer: *Building an Inclusive Practice for LGB and T Patients* 2015
First Year Seminar
Meharry Medical College

Guest Lecturer: *Community Models for Improving Trans Healthcare* 2015
Intercession Course
Meharry Medical College

Guest Lecturer: *Providing Excellent Care for LGBT People* 2015
Capstone Series
Meharry Medical College

GRADUATE AND UNDERGRADUATE TEACHING EXPERIENCE:

Guest Lecturer: *Neuromodulation interventions for threat sensitivity* 2022
Biomedical Sciences First Year Seminar
Graduate School of Biomedical Sciences
UMass Chan Medical School

Guest Lecturer: *Impulsivity and reward-related activity: Predicting mania* 2021
Undergraduate Research Methods
Department of Psychology
University of California San Diego

Guest Lecturer: *Transgender people and neuroimaging: a critical review* 2021
Department of Psychology
Mount Holyoke College

Instructor of Record: PSY0205 Psychopathology 2021
Department of Psychology
University of Pittsburgh

Guest Lecturer: *Transgender People and Healthcare Systems* 2015
MHS 2110: American Medicine and the World

Laura Stark, PhD, Vanderbilt University

Guest Lecturer: *Transgender People and Healthcare Systems* 2015
MHS 3890: Documenting the Body
Odie Lindsey, PhD, Vanderbilt University

Guest Lecturer: *Introduction to Social Neuroscience* 2014
PSY3609: Educational Cognitive Neuroscience
Sasha Key, PhD, Vanderbilt University

Guest Lecturer: *Imagining Transgender Bodies in Healthcare* 2013
WGS 290: Theories of the Body
Aimi Hamraie, PhD, Vanderbilt University

Introduction to Cognitive Neuroscience 2013-2014
Vanderbilt Neuroscience Graduate Program Boot Camp

The Center for Teaching, Vanderbilt University 2013
Scholarship of Teaching and Learning Certificate

Teaching Assistant: NSC201 Introduction to Neuroscience 2011
Department of Neuroscience, Vanderbilt University

TRAINEE MENTORSHIP, CERTIFICATION, AND SUPERVISION:

Culturally Aware Mentorship Workshop 2022
University of Wisconsin Madison School of Medicine

Tiffany Nhan (post bac lab assistant) 2022-present

M. Ali Aslam (undergraduate lab assistant) 2022

Paloma Rueda (undergraduate lab assistant) 2020-2021

Shelby Gardner (undergraduate lab assistant) 2020

Kristie Mak (undergraduate lab assistant) 2019-2020

Taylor Pagliosotti, BA (graduate student, Department of Public Health) 2018-2019

Zhiqiang Sha, PhD (post doc, Mood and Brain Laboratory, PI: Phillips) 2019

Alicyn Simpson, BA (research assistant, Adolescent Medicine) 2018-2019

Hana Choi, BA (intern, The Trans Buddy Program) 2016

William Horn, BA (intern, The Trans Buddy Program) 2015

RJ Robles, BA (student worker, Program for LGBTI Health) 2015-2016

Keanan Gottlieb, BA (summer intern, The Trans Buddy Program) 2014

Cameron Donald, BA (summer intern, Program for LGBTI Health) 2014

Jamieson Jann, BA (summer intern, Program for LGBTI Health) 2014

SERVICE

CURRENT MEMBERSHIPS:
Society of Biological Psychiatry

DEPARTMENTAL, INSTITUTIONAL, AND DISCIPLINARY SERVICE:

Editorial Board, *Journal of Mood and Anxiety Disorders* 2023-present

Member, Grand Rounds Committee 2023-present
Department of Psychiatry, UMass Chan Medical School

Interviewer, Graduate School of Biomedical Sciences 2023-present
UMass Chan Medical School

Co-Director, NeuroNexus Institute 2022-present
UMass Chan Medical School

Co-chair, Diversity, Equity and Inclusion Committee 2021-present
Society of Biological Psychiatry

Member, LGBTQIA+ Task Force 2021-present
American College of Neuropsychopharmacology

Editorial Board, *Bulletin of Applied Transgender Studies* 2021-present

Grant Reviewer, Lesbian Health Fund, GLMA 2021

Member, Diversity, Equity, and Inclusion Committee 2019-2021
Department of Psychiatry University of Pittsburgh School of Medicine

Chapter Author, Assessment of Adults with Gender Dysphoria 2018-2022
WPATH Standards of Care 8 Committee

Member, Diversity and Inclusion Committee 2018-2021
Society of Biological Psychiatry

Ad Hoc Member, Diversity and Inclusion Task Force 2020-2021
American College of Neuropsychopharmacology

Member, Cross-Network Transgender Working Group, 2017-2019
NIH Office of HIV/AIDS Network Coordination

Co-Founder, Trans Buddy Pittsburgh 2016-2018

Student Representative, Vanderbilt Brain Institute Diversity Committee 2015-2016

Founding Director, The Trans Buddy Program Nashville 2014-2016

Co-Director, Vanderbilt School of Medicine Program for LGBTI Health 2014-2015

Assoc. Director, Vanderbilt School of Medicine Program for LGBTI Health 2013-2014

Associate Editor, *Vanderbilt Reviews Neuroscience*	2013-2014
President, Vanderbilt Neuroscience Student Organization	2013-2014
Member, Vanderbilt Neuroscience Organization Academic Committee	2012-2013
Board Member, Vanderbilt School of Medicine Program for LGBTI Health	2012-2013
Affiliate, Vanderbilt Kennedy Center	2011-2016

AD HOC PEER REVIEW:
Acta Psychologica; American Journal of Psychiatry; American Journal of Sexuality Education; Annals of Internal Medicine; Biological Psychiatry: Cognitive Neuroscience Neuroimaging; BJOG: An International Journal of Obstetrics and Gynaecology; Bipolar Disorder; Brain and Behavior; Child Abuse & Neglect; Development and Psychopathology; Developmental Cognitive Neuroscience; Frontiers in Neuroscience; Frontiers in Sociology; Human Brain Mapping; Journal of Affective Disorders; Journal of Autism and Developmental Disorders; Journal of Homosexuality; Journal of Medical Systems; Journal of Neuroscience Research; Journal of Psychiatry, Depression, and Anxiety; LGBT Health; Molecular Autism; NeuroImage; Neuropsychologia; Neuropsychopharmacology; Neuroscience Letters; Psychiatry Research: Neuroimaging; PLOS One; Psychological Medicine; Psychology of Violence; Psychoneuroendocrinology; Scientific Reports; Schizophrenia Research; Transgender Health

REFERENCES

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Exhibit B

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August Dekker

vs.

Jason Weida

CONFIDENTIAL - ATTORNEY'S EYES ONLY

Deposition of:

E. Kale Edmiston, Ph.D

March 23, 2023

Vol 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
TALLAHASSEE DIVISION
CASE NO. 4:22-CV-00325-RH-MAF

AUGUST DEKKER, et al.,

Plaintiffs,

v.

JASON WEIDA, et al.,

Defendants.
_____/

VIDEO-RECORDED DEPOSITION OF E. KALE EDMISTON, Ph.D.

Thursday, March 23, 2023
10:07 a.m. - 11:43 a.m.

VIA ZOOM

Stenographically Reported By:
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ALSO PRESENT:
Zack Bennington, paralegal
Randy Wright, videographer

INDEX OF PROCEEDINGS

E X H I B I T S

Thereupon,
the following proceedings began at 10:07 a.m.:

* * *

THE VIDEOGRAPHER: We are now on the record. The time is 10:07 a.m. This is the video-recorded deposition of Dr. Kale Edmiston in the matter of August Dekker et al. versus Jason Weida, et al.

This deposition is being held remotely via Zoom meetings on March 23rd, 2023. The videographer is Randy Wright, and the stenographer is Barbie Gallo, both in association with Lexitas.

Will counsel please announce their appearance for the record.

MR. BEATO: Good morning. This is Michael Beato on behalf of the defense.

MS. RIVAUX: Good morning. This is Shani Rivaux with Pillsbury, Winthrop, Shaw, Pittman on behalf of the plaintiffs, and with me is Gary Shaw.

MR. GONZALEZ: This is Omar Gonzalez on behalf of the plaintiffs. I'm with Lamda Legal.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness.

THE STENOGRAPHER: Do we need an appearance from Mr. Bennington?

If you would, Doctor --

MR. BENNINGTON: I'm --

THE STENOGRAPHER: I'm sorry.

MR. BENNINGTON: That's okay.

Good morning. I'm a paralegal appearing here from Holtzman Vogel.

THE STENOGRAPHER: Dr. Edmiston, do you consent to my administering the oath to you remotely this morning since we are not all in person?

THE WITNESS: Yes.

THE STENOGRAPHER: If you would raise your right hand, I'll swear you in. Do you swear the testimony you're about to give in this matter will be the truth, the whole truth and nothing but the truth so help you God.

THE WITNESS: Yes.

THE STENOGRAPHER: Thank you.

THEREUPON,

E. KALE EDMISTON, Ph.D.,

Being by me first duly sworn to tell the whole truth, as hereinafter certified, testified as follows:

DIRECT EXAMINATION

BY MR. BEATO:

Q. All right. Perfect.

Good morning, Doctor. Again, my name is Michael Beato, and I represent the defendants in this case. Before we begin, let me ask you, have you ever been deposed before?

A. No.

Q. Okay. So let me go over some ground rules. So, number one, for the benefit of the court reporter when answering a question, please verbally state "yes" or "no" if the question so desires instead of nodding "yes" or "no."

A. (Nodding head).

Q. Also, a deposition is not an endurance contest. If you need a break at any time, please let me know, and I think we can accommodate that.

Moreover, for the benefit of the court reporter, we can endeavor to limit crosstalk, so I will not speak when you're speaking and vice versa. And if you don't understand any of my questions, please let me know. I'm more than happy to clarify or restate the question.

With that said, let me ask you some preliminary questions. Are there any notes or

documents in front of you right now?

A. I have my -- my report in front of me right now.

Q. Perfect. Any other documents?

A. I have a tablet, but I can put it away.

Q. I'm just curious.

Have you talked to anyone about this deposition?

MS. RIVAUX: I'm going to object to form. Go ahead, you can answer.

A. I -- my -- my partner is aware that I'm doing it.

BY MR. BEATO:

Q. Okay. What is your current occupation?

A. I am an associate professor.

Q. At what university?

A. UMass Chan School of Medicine.

Q. When did you start this job?

A. September.

Q. And you are a professor of what area?

A. Psychiatry.

Q. What does your job entail?

A. My job entails conducting research and mentoring students.

Q. What specific research?

A. I conduct research in anxiety and depression.

Q. Where do you currently live?

A. I live in Worcester, Massachusetts.

Q. And could you describe to me your educational background.

A. Yeah, I completed a bachelor's degree at Hampshire College, and from there I worked at a neuroscience or psychiatry lab at the Yale School of Medicine.

Then I went on to earn a Ph.D. in neuroscience from Vanderbilt University. And then after that, I did two post docs, one at China Medical University and the other at university of Pittsburgh.

Q. Thank you, Doctor.

And this is a standard deposition question. Are you taking any medications that would affect your memory today?

A. No.

Q. Perfect. So for the purposes of this deposition I'm going to define the firm "gender-affirming care" as puberty blockers, cross-sex hormones, surgeries and treatments to alter primary or secondary sex characteristics for gender dysphoria. Does that work for you, Doctor?

A. I think those are all very different things, so I would actually appreciate specificity.

Q. Okay. Fair enough. But in terms of the blanket term, it's our understanding that it would incorporate those four different treatments. When greater specificity is warranted, I can clarify.

A. Okay.

Q. Are you a psychiatrist?

A. No.

Q. Are you a neurologist?

A. No.

Q. Are you an endocrinologist?

A. No.

Q. Are you a surgeon?

A. No.

Q. In your medical opinion, what is your definition of gender dysphoria?

A. Well, I don't have a medical opinion because I'm trained as a scientist, not a medical provider.

Q. All right. So what is your going definition of gender dysphoria?

A. I would probably -- probably lean on the language that's used in the DSM-5.

Q. And what is your definition of gender identity?

A. A sense of one's self as being a particular gender.

Q. Can one change one's gender identity throughout one's life?

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. You can answer.

A. I don't really feel that it's my place to determine that for another person.

Q. Fair enough.

So based on your previous answers you haven't diagnosed anyone with gender dysphoria?

A. No.

Q. Never prescribed puberty blockers for an individual with gender dysphoria?

A. No. I have a Ph.D., not an M.D.

Q. So cross-sex hormone surgeries, haven't prescribed or performed that for an individual with gender dysphoria?

A. No.

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. So now I'm going to pull up a document. Hopefully this works. I am not good with technology, so please bear with me, Doctor.

Tell me if you see this document.

A. Yes.

Q. Okay. Perfect. What is this document?

A. That is my rebuttal report.

MR. BEATO: So, court reporter, I'm going to mark this as Exhibit 1.

(Defendants' Exhibit Number 1 for i.d.)

BY MR. BEATO:

Q. So, Doctor, does this document fairly and accurately state your expert opinions in this case?

A. Yes.

Q. Are all of the studies and evidence you relied on contained in the bibliography in this report?

A. Yes.

Q. So I'm scrolling down on page 1. The title says "corrected." Why is this a corrected copy?

MS. RIVAUX: Objection. You can answer.

A. Can you sort of -- can you restate that?

BY MR. BEATO:

Q. Oh, sure. What does the title of this document say?

A. Corrected Expert Rebuttal Report of E. Kale Edmiston, Ph.D.

Q. Thank you, Doctor. And why does it say "corrected"?

A. Because it was corrected.
Q. Did you submit an earlier version of an expert rebuttal report in this case?
A. Yes.
Q. What is the difference between Exhibit 1, the corrected one, and the previous one?
A. The previous one cited a Soleman 2013 study where I should have cited a Soleman 2016 study, and there are two instances where that's the case.
Q. Thank you, Doctor.
Could you just quickly specify, do you recall which paragraphs?
A. Paragraphs 26 and 29.
Q. Okay. Excellent memory, by the way. It's impressive.
So here's another question. Have you conducted any empirical research on gender dysphoria?
A. Can you define what you mean by "empirical"?
Q. What does empirical research mean to you?
A. All -- if you mean by empirical, original research with data than I've collected, I have. But I have not -- my publications have been reviews of the extant literature.
Q. So to clarify, you have original research with data; is that correct?

A. I'm sorry?

Q. I apologize, Doctor. So am I correct so for empirical research on gender dysphoria you have original research with data?

MS. RIVAUX: Objection. Form.

You can answer.

A. I have done studies related to gender dysphoria, but those studies haven't been published to date.

BY MR. BEATO:

Q. So could you -- oh, I apologize, Doctor.

A. I've also -- but I have published studies that have reviewed the literature on specific topics related to gender dysphoria.

Q. Thank you for the clarification. Could you describe those for us?

MS. RIVAUX: Objection. Form.

You can answer.

A. Yeah. What do you mean by "describe"?

BY MR. BEATO:

Q. Can you explain what you are studying in those studies you referenced?

A. So there is review study that I published some years ago that reviews the primary care literature among transgender people. There is a review paper that

is currently in press that reviews the neuro -- the sort of biological basis for a trans identity. And then I have another paper that has been submitted related to adolescent decision making and brain development as it pertains to gender dysphoria.

Q. Thank you. Are those documents mentioned in your bibliography?

A. They are. There's also another paper that I'm revising that's in the bibliography as well that is about development and mental health in trans adolescents.

Q. In your opinion, what makes a treatment experimental?

MS. RIVAUX: Objection. Form.

A. I would say that that designation is outside of -- that's not my responsibility to determine, but I would say that -- I'll leave it at that.

BY MR. BEATO:

Q. Okay. And you collect research, Professor?

A. Yes.

Q. And you deal with -- do you deal with studies that are high quality and low quality?

A. Yes.

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. So what is -- so what makes evidence low quality?

A. There are a lot of different reasons why a study might be low quality. However, all studies have limitations, and so as a scientist my job is to review all of the literature and look at it as a whole because any one study will necessarily have limitations, so you can't look at any one study to sort of draw a definitive conclusion.

Q. So in your answer, Doctor, you mentioned limitations. What are the limitations that you're thinking of?

A. I mean, I think any study can have limitations, and there are so many different sorts of limitations. It can be related to study design or available data. No one study can do everything, so, you know, resources are always finite.

Q. Understood. Could you think of any other limitations besides those two?

A. It -- there are -- I mean, there are numerous possible limitations. That's sort of the nature of science, so I couldn't possibly begin to list every limitation or every possible limitation of a scientific study.

Q. Okay. And, Doctor, how did you learn about this case?

A. I was aware of the law from the news, and I assumed that there would be a challenge to it. And then I was approached by Lambda Legal, and that's how I learned about this specific case.

Q. And in preparing your expert rebuttal report, what defendants' reports did you read?

A. I read Dr. Scott's and Biggs', Dr. Levine's, several others. I don't recall all of them at this time.

Q. So I'm going down on Exhibit 1 to page 3, paragraph 7 which I'm highlighting. Doctor, could you read the highlighting. Don't read the highlight, but can you see the highlighting? It doesn't make the text darker?

A. Yes.

Q. Perfect.

Is that an accurate statement, Doctor?

A. Yes.

Q. Did you rely on the WPATH Standards of Care 8 in making conclusions in your expert report?

MS. RIVAUX: Objection. Form.

A. I relied on my expertise on the topic.

BY MR. BEATO:

Q. Is it your opinion that WPATH sets the professional standards of care for treatments for gender dysphoria?

MS. RIVAUX: Objection. Form.

You can answer.

A. They are one organization. There are other medical organizations that also have standards of care.

BY MR. BEATO:

Q. And what are those medical organizations?

A. Well, the Endocrine Society comes to mind.

Q. Did you review any Endocrine Society documents in making this expert report?

A. No.

Q. In paragraph 7, it states that you were a chapter author for the Assessment chapter; is that correct?

A. Yes.

Q. Does the Assessment chapter involve treatments for adults?

MS. RIVAUX: Objection. Form.

A. The Assessment chapter outlines the assessment process for adults.

BY MR. BEATO:

Q. Does your expert report concern treatment

for adults?

A. No.

MS. RIVAUX: Objection. Form.

BY MR. BEATO:

Q. Do your conclusions reached in the Assessment chapter fairly and accurately describe your opinions and conclusions about gender-affirming care?

MS. RIVAUX: Objection. Form.

A. The Assessment chapter is a consensus document of many experts.

BY MR. BEATO:

Q. Is that a "yes"?

MS. RIVAUX: Objection. Form.

A. I -- you know, my -- I stand by the standards of care as the gold standard for treatment guidelines.

BY MR. BEATO:

Q. Why do you say that?

MS. RIVAUX: Objection. Form.

You can answer.

A. Yeah, because it -- because of the process through which it was created.

BY MR. BEATO:

Q. And what was the process in which it was created?

MS. RIVAUX: Objection. Form.

I'm also going to object to the extent that it would address any issues that are covered by the stay that you -- in this case that you do not go into any of that.

So I'm assuming, Michael, that you're not asking anything that's privileged information as it relates to that.

MR. BEATO: So let me ask you -- let me ask you, Shani, is it plaintiffs' position that I cannot ask any WPATH-specific question to the doctor?

MS. RIVAUX: No, I'm not suggesting you can't ask WPATH questions, but just you can't go into the issues that are currently addressed in the order that stays the discovery relating to internal processes of WPATH. So as long as it's not going into that, it's fine just depending on the question, but I guess that's the concern that I have is just not to violate that court order or to violate any nondisclosure agreement. You can ask anything that's about public information but nothing internal or private to WPATH that would violate that court order or require Dr. Edmiston to violate his

confidentiality agreement.

MR. BEATO: So, for example, asking about how the doctor went about and revised the assessment chapter to Standard of Care 8 I cannot, according to plaintiffs, I cannot ask questions relating to that?

MS. RIVAUX: Ask -- say that again. I'm not sure I understood.

MR. BEATO: Sure. I'll break it down. So in paragraph 7 the doctor states that the doctor was an author for the Assessment chapter for Standards of Care 8. And in revising the standards of care, specifically the Assessment chapter, I cannot ask any questions as to what was the consensus; how did you come up with revisions; what was the process like, I cannot --

MS. RIVAUX: I -- so I think it's going to be tough to -- I'm not giving you any blanket prohibition or objection, so it may be easier just to go question by question.

But I think to the extent it doesn't reveal information that seeks confidential information, then that's fine. So I think the limitation and the instruction is just not to reveal

confidential information.

MR. BEATO: Okay. I'm a little --

MS. RIVAUX: If you want to ask -- ask the question, and then we can, you know -- to the extent it doesn't seek information, my instruction is going to be to the extent it doesn't reveal confidential information or information that would otherwise be barred by the current stay and order, then Dr. -- then Dr. Edmiston can certainly answer the question.

MR. BEATO: Sure. And I'm happy to seek additional court guidance on this particular issue too.

MS. RIVAUX: I'm sorry?

MR. BEATO: I'm happy to seek additional court guidance on this issue too because we believe it goes to credibility.

MS. RIVAUX: Right. Well, I think here really the issue is he's here to take about his expert report, not WPATH. And if there's specific questions that you want to ask about it, you know, we could go about it individually. But, as I mentioned, there's a stay in place as it relates to specific areas relating to WPATH that you're aware of, and, you know, there's a

confidentiality agreement. So to the extent that it doesn't violate those, you can ask the questions. And if we need to seek additional guidance from the court, we certainly can do that.

MR. BEATO: Okay. How about -- okay. How about this? I ask my questions. You can instruct the witness not to answer any questions you believe he should not answer.

MS. RIVAUX: Okay.

MR. BEATO: Okay. Perfect.

BY MR. BEATO:

Q. So, Doctor, how does the -- well, let me take a step back before I take a step forward.

Does WPATH standards of care have a process in which those standards of care are revised?

MS. RIVAUX: Objection. Form.

You can answer.

A. What do you mean by "revised"?

BY MR. BEATO:

Q. So in terms of making a new version.

A. Oh. So the shift -- the drafting of version 8?

Q. Precisely. Perfectly.

A. All right. Yes.

Q. What is that process?

MS. RIVAUX: Objection. Form.

You can answer to the extent it doesn't violate your confidentiality agreement or the stay entered by the Appellate Court relating to the subpoenas to WPATH.

A. I would refer you to the WPATH SOC8 website which outlines that process.

(Defendant's Exhibit Number 2 for i.d.)

BY MR. BEATO:

Q. So I'm going to pull up another document. I'm mark this as Exhibit 2. So I will scroll down. It's six pages. And I will ask if this document looks familiar to you.

A. No, I have not seen it before.

Q. Could you read the title for me?

A. "Establishing the SOC8 Revision Committee and Meet the Chairs and Lead Evidence Team."

Q. And I can represent that this was on the website.

So I'm going to page 3. Doctor, were you a chapter lead when the Assessment chapter was being revised or reviewed?

MS. RIVAUX: Objection. Form.

A. I was a chapter co-author.

BY MR. BEATO:

Q. What's the difference between the two?

A. A chapter lead, I don't believe I can answer a specific question about roles.

Q. Okay. Based on what counsel said?

A. Yes.

Q. Who was the chapter lead during the revision process for the Assessment chapter?

A. Christina. I'm sure she's listed on the website.

(Defendant's Exhibit Number 3 for i.d.)

BY MR. BEATO:

Q. I'm going to pull up another document. This is Exhibit 3. It's a little bit longer than the other one, but I'm going to scroll down. I will also represent that this is from the WPATH website.

Does this document look familiar to you, Doctor?

A. No.

Q. So I'm scrolling down to page 12, and I'll represent that there are individuals under the Assessment Of Adults With Gender Diversity/Dysphoria.

Doctor, do these individuals look familiar to you?

A. Yes.

MS. RIVAUX: Objection. Form.
BY MR. BEATO:
Q. How do you know these individuals?
MS. RIVAUX: Objection. Form.
You can answer.
A. I worked with them to write the chapter.
BY MR. BEATO:
Q. Are there any individuals who worked with you who are not listed here?
MS. RIVAUX: Objection. Form. And objection to the extent you can't answer without violating a confidentiality agreement or any stay in this case.
A. The authors list for SOC8 is very long. Many different people were involved in it, and the document was written collaboratively.
BY MR. BEATO:
Q. And earlier in the deposition you said that the standards of care is a consensus document. What does that mean?
A. I would refer you to the process, the consensus process that is outlined on the website.
Q. Can you describe the process just generally?
A. There --
MS. RIVAUX: I'm going to object, again,

only to the extent that you can answer the question -- I mean to the extent the question is asking generalities and not asking specifics into the process or things that would be violated, then that's fine, you can answer.

BY MR. BEATO:

Q. Let me clarify. Generally speaking.

A. Yes, there was a lit review that was conducted externally, and then there were grievance statements, and then the authors all had to build a consensus around the statements.

Q. Understood.

Doctor, are you a member of WPATH?

A. I was. I believe my membership -- I might be overdue on my dues, but, yes, I was at one time.

Q. When did you start being a member of WPATH?

A. I don't recall at this time exactly.

Q. Ballpark range?

A. Probably around probably 2017, I would guess.

Q. And so this is another general question. Looking at Exhibit Number 3 for the individuals listed here -- and, again, you recall working with these individuals?

A. Yes.

Q. Are any of them endocrinologists, to your memory?

MS. RIVAUX: Objection. Form.

A. No.

BY MR. BEATO:

Q. Are any of them surgeons?

MS. RIVAUX: Objection. Form.

A. There are endocrinologists and surgeons involved in SOC8 for the hormone and surgery chapters of SOC8.

BY MR. BEATO:

Q. And how would you describe each of these individual's areas of expertise?

MS. RIVAUX: Objection. Form.

A. I think that the document describes their areas of expertise.

BY MR. BEATO:

Q. Fair enough. So I'm going back to Exhibit Number 2, and I'm scrolling down to page 4, chapter stakeholder members. Again, this is on the public website. Does WPATH when it's revising its standards of care, to your knowledge, employ the help of nonmedical professionals in that process?

MS. RIVAUX: Objection. I'm going to give the same instruction. And also just to the

extent that Dr. Edmiston is also not here, doesn't speak on behalf of WPATH. But to the extent that Dr. Edmiston has personal knowledge that doesn't violate any confidentiality agreement or the order, then you may answer.

A. Can you define "medical professional"?

BY MR. BEATO:

Q. Sure. So, for example, an M.D., an endocrinologist, psychiatrist, someone who's gone to medical school.

A. There are certainly people involved in drafting the standards of care who have expertise who did not go to medical school because obviously there are lots of different manners to become educated and gain expertise on this topic.

Q. And this topic is?

A. Transgender healthcare.

Q. And you mentioned or counsel mentioned a confidentiality agreement.

A. Yes.

Q. As a member of WPATH you signed a confidentiality agreement?

A. No, as a --

MS. RIVAUX: Objection. Form.

Sorry.

BY MR. BEATO:

Q. I'm sorry.

MS. RIVAUX: I'm raising an objection only to the extent you're not going to violate any agreement.

BY MR. BEATO:

Q. No, do not violate anything. I'm just asking what's with the confidentiality?

A. The chapter authors all signed it.

Q. I see.

A. We were asked to. I don't know what anyone else did.

Q. Understood. So WPATH asked you to sign that confidentiality agreement?

MS. RIVAUX: Objection to form.

A. I signed a confidentiality statement.

BY MR. BEATO:

Q. Understood. And, again, Doctor, we're just building the record. I don't want you to violate anything or make you feel uncomfortable in answering any questions.

So let me scroll up on Exhibit 2. I know, Doctor, you said you weren't a chapter lead. But looking at the criteria for chapter leads, WPATH full member in good standing. What do you think that means?

MS. RIVAUX: Objection. Form.
A. I assume it means that you're a member of WPATH.
BY MR. BEATO:
Q. A well-recognized advocate for WPATH and the standards of care?
MS. RIVAUX: Objection. Form.
A. I'm not sure what you're asking me. Are you asking me what a -- like what the word "recognized" means? I'm not sure what you're asking.
BY MR. BEATO:
Q. Sure, what does recognize mean in this context, in your opinion?
MS. RIVAUX: Objection to form.
A. That -- that you are known to people in this area.
BY MR. BEATO:
Q. Understood.
So, Doctor, we're going to move away from the process questions.
So now let me see if I can move this.
(Defendant's Exhibit Number 4 for i.d.)
BY MR. BEATO:
Q. I'm now going to introduce this as Exhibit 4. Doctor, does this look familiar?

A. Yes.
Q. What is this document?
A. This is the Standards of Care 8.
Q. Excellent.
So -- well, let me ask you this.
Do you think WPATH is an advocacy organization?
MS. RIVAUX: Objection. Form.
A. No.
BY MR. BEATO:
Q. Why?
MS. RIVAUX: Objection, form.
You can answer.
A. The purpose of WPATH is to gather the scientific evidence and expertise of scientists and clinicians to -- to develop the standards of care and to disseminate research.
BY MR. BEATO:
Q. And what kind of evidence does WPATH collect?
MS. RIVAUX: Objection. Form.
A. So, again, I would refer you to the website which outlines the process for drafting the standards of care.

BY MR. BEATO:

Q. And in terms of the chapter that you assisted with authoring, which chapter is that?

MS. RIVAUX: Objection. Form.

A. I am co-author of the Assessment of Adults chapter.

BY MR. BEATO:

Q. And that is Chapter 5?

A. Yes.

Q. I am now going on Exhibit 4 to page 33. I'm scrolling to the -- now I'm on page 34. I'm scrolling to the bottom of page 34. Doctor, I just have a few questions.

If you look at 5.4, it says, "We suggest..." and 5.5, "We recommend..."

A. Um-hum.

Q. Is there a difference between "suggest" and "recommend" here?

A. Yes.

Q. What is that difference?

A. They are different words.

Q. Okay. Do they convey anything differently? So there is -- strike that.

So they're used synonymously?

A. No.

Q. So what are their differences?

A. The WPATH document has graded evidence, so the language there is specific to the strength of evidence.

Q. And what kind of evidence grading systems does WPATH use?

A. I'm sorry. Can you repeat the question?

Q. Sure. So what kind of evidence grading system does WPATH use?

So, for example, I believe the Endocrine Society uses the GRADE system.

A. I would refer you to the website for that information.

Q. Understood. So now I'm going to go back to page 33, Doctor. One moment, Doctor.

33, I'm highlighting a section. It begins, "For TGD..." and goes all the way to "... required."

So, Doctor, I highlighted this sentence. Just so the record is clear, what does TGD mean in this chapter?

A. I would suggest that you scroll up to the top. It will be defined there.

Q. Right up here (indicating)?

A. Yes.

Q. Transgender and gender diverse?

A. Yes.
Q. So in this highlighted section can you elaborate on that sentence?
MS. RIVAUX: Objection. Form.
A. No.
BY MR. BEATO:
Q. It says what it says?
A. If you have a specific question, I'm happy to, you know -- if you have a specific question. But I -- I don't know what you -- you'll have to ask me a specific question.
BY MR. BEATO:
Q. Sure. So when it says "...less common treatments..." what does less common treatments mean?
MS. RIVAUX: Objection. Form. You can answer.
A. I think if an adult was to ask for an intervention that was nonstandard.
BY MR. BEATO:
Q. As an example, what would that be?
A. I wouldn't really want to speculate.
Q. Can you provide an example, though?
MS. RIVAUX: I'm going to object on the grounds of scope, but you can go ahead and answer.

A. Yeah, I mean, it's a -- it is a bit outside of the scope of, you know, my rebuttal. Sometimes people ask for -- they might ask for a surgical intervention that's nonstandard for as an example.

BY MR. BEATO:

Q. And limited research evidence, what does that mean?

MS. RIVAUX: Objection. I'm going to object on both form and scope here, but you can answer.

A. I mean, somebody -- it's -- there's always a possibility that someone might request an intervention that hasn't been researched before or has been researched very little.

BY MR. BEATO:

Q. Can you provide an example, Doctor?

MS. RIVAUX: Objection. Form and scope. You can answer.

A. I think the same -- the same answer. So if someone were to ask -- if an adult were to ask for a nonstandard surgical intervention, for example.

BY MR. BEATO:

Q. Scrolling to page 34, I'm highlighting another sentence beginning with, "The statements below..." and ending with "...consensus of professional best practice."

Doctor, what does the phrase "consensus of best" -- strike that -- "consensus of professional best practice" mean?

MS. RIVAUX: Objection. Form and scope.

You can answer.

A. Yeah, I mean, again, I would refer you to the WPATH website where they outline a lot of sort of the process and the specific terminology that they use in this document.

BY MR. BEATO:

Q. With that in mind, could you today provide me with what your opinion as an author of this section, what consensus of professional best practice means?

MS. RIVAUX: Objection to both form and scope.

You can answer.

A. The consensus of ex -- people with expertise on the topic.

BY MR. BEATO:

Q. And how would you define expertise on the topic?

MS. RIVAUX: Objection. Form and scope.

But you can answer.

A. I would, again, refer you to the WPATH website where they talk about the -- they outline the

sort of selection process for authors and how they determine expertise.

BY MR. BEATO:

Q. Okay. So I'm going back to Exhibit -- bear with me. This is now Exhibit 3. Again, we're still on page 12 and 13. Do all of these individuals support gender-affirming care?

MS. RIVAUX: Objection. Form; scope.

And to the extent it doesn't violate your confidentiality agreement or the stay, you can answer and if you know.

A. These individuals support the care that is -- has an evidence -- that -- you know, your question is very broad because gender-affirming care is very broad.

BY MR. BEATO:

Q. It is.

A. And the SOC8 guidelines recommend an individualized approach to care. So I think everyone involved in -- for those individuals they support quality healthcare.

Q. Going back to Exhibit 4, this sentence, Doctor, "The empirical evidence base for the," scrolling to page 35 -- "assessment of TGD adults is limited."

My question is, in the sentence, what does "empirical evidence base" mean?

MS. RIVAUX: Objection. Form and scope. You can answer.

A. So I would have to re-read the chapter in context. I do not want to define what a specific word means in a specific sentence without reading the context in which it occurs.

BY MR. BEATO:

Q. Fair enough. And would that same answer be true for "limited" in this sentence?

A. Yes.

MS. RIVAUX: Objection. Form; scope.

BY MR. BEATO:

Q. Doctor, I apologize. I did not hear an answer.

A. Oh. Yes.

Q. Let's go to the next page. This sentence, Doctor, "Some TGD individuals will have the capacity to grant consent immediately during the assessment."

What does that mean?

MS. RIVAUX: Objection. Form and scope.

A. This is about the assessment of adults and is about the assessment process being individualized.

BY MR. BEATO:

Q. So in an individualized scenario, can an individual be given puberty blockers for gender dysphoria after one medical treatment?

MS. RIVAUX: Objection. Form.

A. I would ask you to restate the question with a little bit more specificity.

BY MR. BEATO:

Q. Fair question, Doctor. Fair question. Let me -- let me go back to these questions. Scrolling down to the next page, statement 5.3A, Doctor, what does this sentence mean?

MS. RIVAUX: Objection. Form and scope.

A. So this is a sentence from the adult chapter that says "To access GAMSTs, a TGD person's gender incongruence must be marked and sustained."

So that means that part of the assessment process is to determine sort of the duration of the feelings of gender incongruence and the degree to which they are distracting or upsetting or troubling.

BY MR. BEATO:

Q. Scrolling a little bit further down, while marked and sustained gender incongruence is present, going all the way down to access gender-affirming care, Doctor, what does that sentence mean?

MS. RIVAUX: I'm going to object to form and scope.

A. That if a person -- it just means that -- it's not -- there's not some threshold of suffering that someone -- you know, that someone needs to suffer a certain amount before they're allowed to access healthcare.

BY MR. BEATO:

Q. Okay. Moving to page --

Well, actually, Doctor, we've been going for about an hour. Would you like a five-minute break?

A. No, I'm okay.

Q. Okay. Okay. And, once again, if you'd like a break at any time, please let me know. More than happy to accommodate.

A. Sure.

Q. So this is on Page 38 highlighting the sentence -- oops, no -- I -- I apologize.

Page 39, "in rare cases..." Doctor, in this sentence what does "rare cases" mean?

MS. RIVAUX: Objection. Form and scope.

A. So in rare cases would mean a nontypical instance.

BY MR. BEATO:

Q. And in the context of this sentence what

would that nontypical instance be?

MS. RIVAUX: Objection. Form and scope.

A. So I would have to review the Hembree citation there. I mean, one example could be if someone had an estrogen receptor positive cancer.

BY MR. BEATO:

Q. And generally speaking, Doctor, when you were authoring this section, did you read all of these cases that are mentioned in this chapter?

MS. RIVAUX: Objection. Form; scope.

And to the extent it doesn't violate any of the stay order that we discussed or the confidentiality order, you may answer.

A. I have reviewed much of this literature. If you have a specific question about a specific paper, then I would request that you give me a break to review the specific paper.

BY MR. BEATO:

Q. Understood. And perfectly reasonable. I just had a broad general question.

And within the literature that you have reviewed when authoring this chapter, do you know if any of those studies were low evidence?

MS. RIVAUX: Objection. Form; scope.

You can answer.

A. I think that you would have to describe what you mean by "low evidence." I recall you asked me that question before, and I answered that all studies have limitations, and that's why we look at the literature as a whole to draw conclusions.

I'm sure you're aware, there's quite a bit of evidence cited in SOC8. I'm not sure off the top of my head how many citations there are, but it's quite a few.

BY MR. BEATO:

Q. So earlier in the deposition I think you provided examples of low-quality evidence or limitations. Do you recall saying study design could lead to evidence being low quality?

MS. RIVAUX: Objection. Form.

A. I believe I said that that is an example of a limitation. I didn't -- I do not think I said that it was an example of low quality.

BY MR. BEATO:

Q. Okay. And -- okay. And as of right now, you do not recall if any of those citations mentioned in Chapter 5 have low-quality evidence?

MS. RIVAUX: Objection. Form; scope.

A. I -- I take -- I sort of -- I challenge the premise of the idea of low quality. I am instead

talking about the limitations that occur with any scientific study, which is why we do lots of different studies to draw conclusions.

So I sort of -- or not sort of. I object to the premise of the question.

BY MR. BEATO:

Q. So still on page 39, sentence, "Because of the possible harm..." all the way down to "...is important," Doctor, what does this sentence mean?

MS. RIVAUX: Objection. Form and scope.

A. Again, I would ask that if you want me to discuss specific sentences from a very large document that I would be given time to review the document in its entirety to ensure that I am fully representing the context of any particular sentence.

BY MR. BEATO:

Q. Fair enough. And, again, you authored this document, or at least this chapter in the Standards of Care 8?

MS. RIVAUX:

A. I --

MS. RIVAUX: Objection to form; scope and the other restrictions that we've talked about before relating to your confidentiality agreement and the stay order in place.

A. Yes, I was a co-author of SOC8.
BY MR. BEATO:
Q. And this chapter?
A. Yes.
Q. Any other chapters, Doctor?
MS. RIVAUX: Objection. Form; scope; and same objections relating to the confidentiality agreement and the violation of -- and any -- and not to violate the stay in place.
A. I would, again, refer you to the WPATH website which outlines the process by which this document was drafted. It was written via consensus and was drafted collaboratively.
BY MR. BEATO:
Q. Okay. So I don't think you answered my question. Did you -- again, noting the objections, did you contribute in authoring any other chapters in WPATH?
MS. RIVAUX: I'm going to object to form; scope.
Again, do not violate your confidentiality agreement or the stay that's in place.
A. Yeah, that would -- that would -- discussing that would be in violation of the confidentiality agreement.

BY MR. BEATO:

Q. All right. I'll move on.

Doctor, to the best of your knowledge in Chapter 5, does Chapter 5 discuss any negative health risks of gender-affirming care?

MS. RIVAUX: Objection. Form; scope.

You can answer.

A. The Assessment chapter discusses the types of assessments that are necessary to determine eligibility and readiness for gender-affirming care.

BY MR. BEATO:

Q. Does it also talk about risks involved?

MS. RIVAUX: Objection. Form and scope.

You can answer.

A. I would ask what you mean by "talk about." It outlines what assessments need to be or should be done to determine the readiness for care.

BY MR. BEATO:

Q. And if I understand this correctly, part of the assessments involve evaluating benefits and risks?

MS. RIVAUX: Objection. Form and scope.

You can answer.

A. Broadly, yes.

BY MR. BEATO:

Q. And in evaluating the risks, does that

also -- in evaluating -- sorry.

In evaluating risks, do you also have to weigh irreversible potential medical consequences?

MS. RIVAUX: Objection. Form; scope.

You can answer.

A. This is very standard healthcare. All healthcare interventions have outcomes associated with them, and this is no different from any other type of health intervention.

BY MR. BEATO:

Q. So, Doctor, I would like to take a five-minute break if you don't mind.

A. Sure.

MR. BEATO: Would you mind if we reconvene, just because I like base-five numbers, how about 11:15?

THE WITNESS: Sounds good.

MR. BEATO: Thank you very much.

THE VIDEOGRAPHER: Stand by. We're going off video record. The time is 11:08 a.m.

(A recess was taken from 11:08 a.m. to 11:16 a.m.)

THE VIDEOGRAPHER: We are back on the video record. The time is 11:16 a.m.

BY MR. BEATO:

Q. All right. So, Doctor, let me ask you this.

And let me pull up Exhibit 1, the expert rebuttal report. Did you base any of your expert opinions on the WPATH Standards of Care Version 8?

MS. RIVAUX: Objection. Form. You can answer.

MR. BEATO: Counsel, can I have the basis for the objection?

MS. RIVAUX: It was confusing the way you worded the question.

MR. BEATO: Okay. I could rephrase.

BY MR. BEATO:

Q. Doctor, did you use WPATH's Standard of Care Version 8 recommendations as a basis for your expert report opinions?

A. I suppose I would ask what you mean by "use." I have expertise and I reviewed the relevant literature.

Q. So I'm scrolling down to page 4, paragraph 13. I highlight, "My opinions are based..." and I go down to "...including my work as a contributing author of WPATH Standards of Care 8."

Doctor, is paragraph 13 a fair and accurate representation of your opinion?

A. Yes.

Q. Is the confidentiality from WPATH, is that

preventing you from answering some of the WPATH questions in this case?

MS. RIVAUX: Objection. Form; scope; and, again, the same objections relating to the confidentiality agreement and the stay order.

A. I'm adhering to the confidentiality agreement that I signed.

BY MR. BEATO:

Q. Understood.

And, Doctor, again, in your expert report do you opine on adult treatment?

A. In the rebuttal.

Q. Right. Apologies. I can be clear. Let me rephrase.

Doctor, in your expert rebuttal report, do you discuss adult treatment?

A. It -- the primary point or one of the primary points of my report was related to adolescent brain development.

Q. Understood. So where specifically do you mention adults in your expert rebuttal report?

A. I would have to review, but I believe by and large the report is regarding adolescents because that is what is pertinent.

Q. And if you need time to review this report,

let me know. So, again, your report concerns adolescent treatment; is that correct?

A. Yes.

Q. Now, Doctor, regarding adolescent treatment and gender-affirming care, is there a lot of literature out there on the treatment?

MS. RIVAUX: Objection. Form.

MR. BEATO: Basis for objection?

MS. RIVAUX: It's a really broad, ambiguous question. There's a lot of literature out there. It's just, you know, just a broad, ambiguous question.

BY MR. BEATO:

Q. Okay. Let me rephrase.

Doctor, is there a good, a great deal of evidence on the effects of gender-affirming care on adolescents?

MS. RIVAUX: Objection. Form.

MR. BEATO: Basis, Counsel.

MS. RIVAUX: Same thing. I think it's ambiguous to say whether there's a great deal. I think it's ambiguous. But he may answer.

BY MR. BEATO:

Q. I will scroll down to, we're still on Exhibit 1, page 21.

Doctor, could you read this sentence for me?

A. "In contrast, there is a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents."

Q. Doctor, is "great deal," is that vague?

MS. RIVAUX: Objection. Form.

MR. BEATO: Basis?

MS. RIVAUX: What's the relevance?

MR. BEATO: The doctor wrote it.

MS. RIVAUX: Okay. So you can ask him about what he means by it.

BY MR. BEATO:

Q. What do you mean by "a great deal"?

A. So in this instance I'm looking at the literature, the decades of use of GnRHa treatment and the expertise of, my own expertise, the expertise of my colleagues. There's a great deal -- again, there's a great deal of evidence to support this, right. So I'm thinking broadly about evidence from clinical experience of my colleagues as well as the research literature.

Q. Okay. When you say "research literature," what do you mean?

A. Publications like peer-reviewed publications.

Q. Can you provide me examples of those?

A. I would refer to you my bibliography. I think there's quite a few citations.

Q. Can you name one off the top of your head?

A. There's a de Vries paper.

Q. And, again, Doctor, if I'm reading this correctly, "In contrast, there's a great deal of evidence supporting the mental health benefits of GnRHa treatment for transgender adolescents."

Again, that's accurate?

A. Yeah, so the sentence that that is -- so the sentence begins with the phrase, "In contrast." The sentence prior to it says, "There is little to support the defendants' designated experts' speculation about the negative effects of GnRHa treatment on the brain." So I stand by the sentence as written.

Q. Understood. I will scroll up to page 16, paragraph 31. I highlighted the first sentence. Doctor, could you please read that sentence?

A. Yes, "There is a small body of literature on the effects of gender-affirming hormone care on the brain in transgender adolescents."

So am I correct in assuming that you're trying to suggest that these two sentences are in conflict with each other?

Q. No.
A. Oh, okay. Great.
Q. Let's go to paragraph 5. I'm sorry. I misspoke. Page 5. Bear with me, Doctor. Sorry. So in chapter -- strike that. Sorry.
In paragraph 16, I believe you're responding to one of Dr. Scott's statements; is that correct?
A. Yes.
Q. I'm highlighting one sentence, I believe it's the second sentence, "That is, literature indicates that there are highly specific circumstances in which adolescents are more likely to engage in risky or impulsive behavior."
Doctor, my question is, did you provide a citation for that assertion?
A. I do later on.
Q. Where is that?
A. I believe it's -- yeah, paragraph 18.
Q. And all those cases stand for that proposition?
A. So those are references that describe the context -- the contextual nature of decision making and adolescents.
Q. And I'm scrolling back to page 5. Bear with me. The sentence, "However, none of these examples are

relevant to the issue at hand: Protracted medical decision making made in the context of adult guidance and consultation with a medical professional."

Doctor, my question is, what does protracted mean here?

A. Drawn out.

Q. So in this context, what period of time are we talking about?

A. I'm sorry. They're doing some work outside of my office and it's a little loud. Can you repeat the question?

Q. No problem whatsoever. No problem. And, again, if there's like a -- something going on in the background, more than happy to do that.

So in the final sentence of paragraph 16, "However, none of these treatments are relevant to the issue at hand: Protracted medical decision making made in the context of adult guidance and consultation with a medical professional," what does "protracted" mean? Like what kind of -- here's the question. What kind of period of time are we looking at?

A. So it could be -- you know, I think that it varies, which is why SOC8 recommends an individualized approach. It could be eight months or even years for some people.

Q. Okay. Do you have a citation or a study or some basis for that proposition?

A. I believe in the next paragraph I cite the, I think it's a Bauer study. Yeah, the Bauer 2022 study which outlines the time between an adolescent realizing that they're trans and then them coming out to a healthcare provider.

Q. All right. So the this sentence -- okay. Understood. So that citation for that's -- okay. Thank you, Doctor. That's all I wanted.

A. Um-hum.

Q. Give me one second.

Let's go to Paragraph 25. I think this is on page 10, still on Exhibit 1. I'm highlighting the second sentence in Paragraph 25, "Case studies are the lowest quality of evidence." Could you elaborate on that, Doctor?

A. Yeah, a case study is a study of a single individual, so they are generally not regarded as the type of evidence that we would want to use to make -- to inform, you know, standards of care policy, you know, the -- because it's just regarding a single person, so generally, you know, we don't think of those as being generalizable.

Q. Understood. And what limitations come with

case studies?

A. Well, it's a study of a single person, so we don't know if we can extrapolate the findings to the broader population.

Q. Are there any other limitations inherent with case studies, or it's just the focus of an individual on one person, to your knowledge?

A. I would say that's probably the primary limitation of a case study is just the, you know, questionable generalized ability of them.

Q. Understood.

In your knowledge, do you know if WPATH references any case studies in its standards of care?

A. I don't know off the top of my head, but I do know that WPATH cites a large body of literature that includes empirical studies, longitudinal studies, cross-sectional studies, cohort studies, unlike Dr. Levine who did not cite any valid literature.

Q. And in terms of the literature, does it pertain to adolescent treatments with gender dysphoria?

MS. RIVAUX: Objection. Form.

MR. BEATO: Basis?

MS. RIVAUX: I didn't understand the question.

MR. BEATO: Sure, I'll back up. I can take

a step back before taking a step forward.

BY MR. BEATO:

Q. So, Doctor, you said that in the standards of care, in WPATH there's a lot of longitudinal peer-reviewed literature, correct?

A. I said that there is a variety of different types of evidence that are informing recommendations as a whole, so that could include longitudinal cohort, cross-sectional.

Q. Could that also include case studies?

A. It may, yes.

Q. And in terms of the longitudinal cohort literature that you mentioned, does that literature reference or relate to adolescent treatment concerning gender-affirming care?

A. There have been longitudinal adolescent studies. If you're asking me to speak to a specific one, I would want to take a break and review it.

Q. Understood. Without speaking in depth about it, could you identify them for me off the top of your head, or are they mentioned in your bibliography?

A. They are mentioned in my bibliography.

Q. To your mind, does your bibliography reference all of those longitudinal cohort adolescent related studies that you're thinking of right now?

A. I cite the -- so I did a targeted literature review, and I cite the studies that I was -- that I identified that looked at mental health outcomes in transgender youth. I would hesitate to claim that I have cited every longitudinal study of transgender youth, but I did do a thorough literature review.

Q. Fair enough. Fair enough. Are there any additional reports that should be in your bibliography?

A. Not that I'm aware of.

Q. Let me go to paragraph 27 highlighting the first sentence, "Both Dr. Levine and Dr. Laidlaw state that the effects of GnRHa treatment on the brain are both 'unknown' and 'likely negative.'"

Does WPATH comment on the effects of GnRH -- I'm going to get it wrong, Doctor. I apologize.

Does WPATH opine on the effects of GnRHa treatment on the brain?

A. Not that I recall, but I would want to review the entire document before making a definitive statement.

Q. Is there a great deal of evidence on the subject?

A. There is --

MS. RIVAUX: Objection.

THE WITNESS: Sorry.

MS. RIVAUX: You can answer.
MR. BEATO: And what's the basis for the objection?
MS. RIVAUX: I'm not sure when you're saying "there's a great deal of evidence on the subject" what the subject in particular you were referring to.
MR. BEATO: The effects of GnRHa treatment on the brain.
MS. RIVAUX: Do you want to rephrase -- the way -- to me, the way it came out was a little -- is a little bit ambiguous. If you want to rephrase it that way, that's fine.
MR. BEATO: No problem whatsoever. I'm just asking for the basis of the objection so I can ask a better question.
MS. RIVAUX: Yeah, that's fine.
MR. BEATO: Perfect.

BY MR. BEATO:

Q. So, Doctor, is there a great deal of evidence on the effects of GnRHa treatment on the brain?

A. There is -- there is evidence. There are studies that look at GnRHa treatment on the brain.

Q. How many studies are you thinking of right

now?

A. In humans -- well, also, I guess it would depend. If you mean in humans, in transgender adolescents, I believe there's three neuroimaging studies. There are also animal studies as well.

Q. With, for example, I think, sheep?

A. Yes, there are some studies of sheep.

Q. Sheep and mice?

A. And a primate study also.

Q. And for those -- if I remember this -- please correct me if I'm wrong. For those three human studies, what were the results of those studies?

A. I outlined those in the report. Those studies used different imaging modalities. They found differences in brain structure function that were associated with sex assigned at birth; others that were associated with gender identity.

But when they ran correlations to determine associations between GnRHa treatment and brain structure function, they did not find any -- there were no significant findings.

Q. Okay. So no significant findings of benefits in the treatments?

A. No significant findings of any association.

Q. Understood. And for the animal studies, the

sheep, mice and primates, what were the results of those studies?

A. Well, as I outlined in my rebuttal as well as the paper, the review paper that I wrote that I cited, the problem with a lot of the animal literature is that they don't use the correct reference group for comparing. So a lot of those studies report differences with GnRH treatment, but really their difference is between natal sex, so we would expect a medication that delays puberty to have sex-specific effects. That is the desired outcome of the treatment.

Q. And I have no additional questions regarding the report. I do have additional follow-up questions, though.

Earlier in the deposition you stated that you were aware of the law in place in Florida.

A. (Nodding head).

Q. By the way, it's not a law; it's a regulation, but understood, understood.

A. All right.

Q. How did you hear about it, the at-issue regulation?

A. I don't recall.

Q. Understood. If you could think back, was it social media, the news or you don't remember?

A. I don't remember. I don't recall at this time.

Q. And for your expert report, did you review the at-issue regulations?

A. I reviewed, as I believe is stated at the beginning of the report, I reviewed the Florida Medicaid opinion.

Q. The so-called GAPMS report?

A. Yes.

Q. But not the at-issue regulation?

A. No, I did not review the text of it.

Q. But you were aware of the at-issue regulation through something?

A. (Nodding head).

Q. Okay. What is your opinion on the GAPMS report?

MS. RIVAUX: Objection. Scope.

A. I would ask that you just be a little bit more specific.

BY MR. BEATO:

Q. Sure. So in writing this expert report, you reviewed the GAPMS report with the accompanying attachments, correct?

A. Um-hum, yes.

Q. As a professor, as a scientist, what are

your opinions of the GAPMS report?

MS. RIVAUX: Objection. Scope.

You can answer.

A. I was surprised that it didn't seem to cite a lot of relevant literature.

BY MR. BEATO:

Q. What literature would you have cited?

A. All the literature that I cited in my rebuttal.

Q. And in hearing about the at-issue regulation, how do you feel about the regulation?

MS. RIVAUX: Objection.

BY MR. BEATO:

Q. What is your opinion as to the regulation?

MS. RIVAUX: Objection. Scope.

A. I believe that healthcare decisions should be made between patients and providers and their families and based on expert medical evidence and standards of care.

MR. BEATO: Doctor, I have no further questions.

Counsel can ask some follow-up questions.

MS. RIVAUX: I don't have any follow-up questions.

MR. BEATO: All right. Doctor, you're done.

THE WITNESS: All right. Thank you.
MR. BEATO: Thank you, Doctor. I know you're probably busy. And thank you for making yourself available and taking time to answer these questions. It's really appreciated.
MS. RIVAUX: Do you want to give him the instruction about reading or waiving?
MR. BEATO: Could you do that, Counsel?
MS. RIVAUX: Sure. So, Dr. Edmiston, you have the right to read your report and make any changes to the extent that there were any errors in the transcription or you can waive that. Otherwise, you'd get a copy. If you choose to read it, you'll have 30 days when you get it to review it to make any changes. There will be a form in which you can make any correction. And then that gets sent back and a corrected copy will get circulated to everybody.
THE WITNESS: Yeah, I'd like to read it.
MS. RIVAUX: Okay.
MR. BEATO: And, Doctor, just to be super cautious because I know you have a confidentiality agreement, I don't want to violate that at all. If you said something inadvertently that, you know, maybe you probably

shouldn't have said, should this deposition be under seal? We can send the court reporter the protective order. I just want to make sure.

MS. RIVAUX: Yeah, you know what? Why don't we do it that way, and then if there's any reason to unseal it or to seal any specific portion, we can go ahead and do that. And then we can -- you know, if there's anything -- so until Dr. Edmiston has an opportunity to review it, and then we can mark things confidential as appropriate later on. I appreciate that. Thank you.

MR. BEATO: No problem. Doctor, I understand. You're put in a tough position, right. You have -- you got something signed. I respect that. I wasn't trying to make you feel uncomfortable or get around that, so I just want to make sure everything is good.

I will ask, though, for an expedited transcript.

And, Doctor, I want to make sure you have sufficient time to review it, but at the same time we want to get this finalized as soon as possible.

THE WITNESS: I appreciate that.

MR. BEATO: So, Zack, are you on there? We can send over the court reporter the protective order.

THE STENOGRAPHER: I just want to remind you we're still on video record.

MR. BEATO: That's fine. This can all be on the record. That's fine.

Okay. I think we're -- I think we're good. Thank you for your time, Doctor.

THE WITNESS: You're welcome.

THE VIDEOGRAPHER: This is the videographer. Would anyone like to order a copy of the video?

MR. BEATO: A copy of the video, I don't need a copy of the video.

THE VIDEOGRAPHER: And Ms. Rivaux?

MS. RIVAUX: I don't -- I don't think we need a copy of the video at this time. But for the transcript, we'd like it at the same time, please.

MR. BEATO: Yes, expedited.

THE VIDEOGRAPHER: Is there a date for that? Just as soon as possible or --

MS. RIVAUX: As soon as possible.

THE VIDEOGRAPHER: Okay.

MR. BEATO: Thank you very much.

THE VIDEOGRAPHER: And then I'll go ahead and take us off the video record. We're going off the record in the video deposition of Dr. Kale Edmiston. We're going off the record on March 23rd, 2023 at 11:43 a.m.

(Thereupon, the proceedings concluded at 11:43 a.m.)

(The witness did not waive signature.)

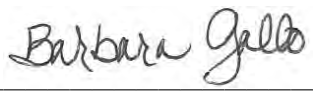
CERTIFICATE OF OATH

THE STATE OF FLORIDA)

COUNTY OF PALM BEACH COUNTY)

I, the undersigned authority, certify that E. KALE EDMISTON, Ph.D. remotely appeared before me and was duly sworn on the 23rd day of March 2023.

Signed this 23rd day of March 2023.



BARBIE GALLO, RMR-CRR
Notary Public - State of Florida
My Commission No. GG939757
My Commission Expires: December 15, 2023

CERTIFICATE OF REPORTER

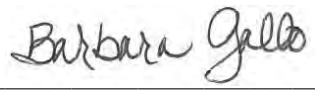
THE STATE OF FLORIDA)

COUNTY OF PALM BEACH)

I, Barbie Gallo, RMR-CRR, Registered Merit Reporter-Certified Realtime Reporter, certify that I was authorized to and did stenographically report the deposition of E. KALE EDMISTON, Ph.D., pages 1 through 69; that a review of the transcript was requested; and that the transcript is a true and complete record of my stenographic notes.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorney or counsel connected with the action, nor am I financially interested in the action.

DATED this 23rd day of March 2023.



Barbie Gallo, RMR-CRR

Thursday, March 23rd, 2022

E. Kale Edmiston, Ph.D. c/o Shani Rivaux
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(786) 913-4900
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IN RE: DEKKER vs WEIDA
CASE NO.: CASE NO. 4:22-CV-00325-RH-MAF

Please take notice that on the 23rd day of March 2023, you gave your deposition in the above cause. At that time you did not waive your signature.

The above-addressed attorney has ordered a copy of this transcript and will make arrangements with you to read their copy. Please execute the Errata Sheet, which can be found at the back of the transcript, and have it returned to us for distribution to all parties.

If you do not read and sign the deposition within 30 days, the original, which has already been forwarded to the ordering attorney, may be filed with the Clerk of the Court.

If you wish to waive your signature now, please sign your name in the blank at the bottom of this letter and return it to the address listed below.

Very truly yours,

Barbie Gallo, RMR-CRR
Phipps Reporting, Inc.
1551 Forum Place, Suite 200-E
West Palm Beach, Florida 33401

I do hereby waive my signature.

_____
E. KALE EDMISTON, Ph.D.

ERRATA SHEET
DO NOT WRITE ON TRANSCRIPT - ENTER CHANGES HERE
IN RE: DEKKER vs WEIDA
CASE NO.: CASE NO. 4:22-CV-00325-RH-MAF
WITNESS: E. KALE EDMISTON, PH.D.
TAKEN: 03/23/2023

PAGE	LINE	CHANGE	REASON FOR CHANGE

Under penalties of perjury, I declare that I have read the foregoing document and that the facts stated in it are true.

_____ _____
Date E. KALE EDMISTON, Ph.D.

C

E

From: Borgert, Rebecca
Sent: Monday, August 29, 2016 3:03 PM EDT
To: Craig, Sara
CC: Moore, Elboni A.
Subject: FW: guidelines
Attachments: Endocrine Society Guidelines 2009_Transgender_highlighted.pdf, image001.png, image002.jpg

Sara,
Well, it looks like Arlene beat me to the punch. This does seem to be the guideline that AHCA would want to use as a basis for criteria. I was surprised that it was so old (2009) and that it hasn t been updated but I checked the Endocrine Society website and this is the most recent version.

I highlighted the PDF I have attached in terms of things I think would be relevant to consider in the development of the criteria. I m not sure if you ve had a chance to read this or not but in a nutshell they recommend:

- Diagnosis of gender identity disorder (GID) must be made by a mental health professional and confirmed by treating endocrinologists based on the DSM-IV-TR diagnostic criteria for GID
- GnRH therapy to suppress puberty in kids that are at least Tanner stage 2. Table 5 in the document has a list of some other eligibility requirements (adequate psychosocial support, etc) that we may want to include. Definition of Tanner stages is in Table 6
- Giving estradiol or testosterone to induce opposite-sex puberty should be initiated at the age of 16 (Doses are available in Table 9)

Let me know if I can help in any other way.

Thanks,
Becky

From: Elliott, Arlene [mailto:Arlene.Elliott@ahca.myflorida.com]
Sent: Monday, August 29, 2016 2:05 PM
To: Craig, Sara; Borgert, Rebecca
Cc: Williams, Susan C.
Subject: RE: guidelines

Summary of recommendations endocrine society:

http://press.endocrine.org/doi/full/10.1210/jc.2009-0345

Arlene Elliott - AGENCY FOR HEALTH CARE ADMINISTRATOR-SES

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412-4152 (Office)
Arlene.Elliott@ahca.myflorida.com

From: Elliott, Arlene
Sent: Monday, August 29, 2016 1:33 PM
To: Craig, Sara <Sara.Craig@ahca.myflorida.com>; 'RJBorgert@magellanhealth.com' <RJBorgert@magellanhealth.com>
Cc: Williams, Susan C. <Susan.Williams@ahca.myflorida.com>
Subject: guidelines

http://transhealth.ucsf.edu/tcoe?page=guidelines-youth

Arlene Elliott - AGENCY FOR HEALTH CARE ADMINISTRATOR-SES

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