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

JANE DOE et al.,

Civil No. 4:23-cv-00114-RH-MAF

v.

JOSEPH A. LADAPO et al.,

Defendants.

Plaintiffs,

#### EXPERT REPORT OF BRITTANY BRUGGEMAN, M.D. ON BEHALF OF PLAINTIFFS

August 16, 2023

Prepared by Brittany Bruggeman, M.D.

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	3						

# TABLE OF CONTENTS

# PAGE

I.	INTRODUCTION AND SUMMARY OF OPINIONS			
	A.	Background and Qualifications2		
	B.	Bases for Opinions		
	C.	Prior Testimony		
	D.	Compensation		
II.	EXPERT OPINIONS			
	A.	Standards of Care for Treating Gender Dysphoria Are Well-Established		
	В.	Mental Health Evaluations Are Conducted Prior to Initiating Medical Treatment for Transgender Adolescents 10		
	C.	Extensive Requirements Must Be Met before Medical Interventions Are Initiated For Transgender Adolescents		
	D.	The Multidisciplinary Treatment Team Model12		
	E.	Puberty Blocking, Hormone Antagonist, and Hormone Therapies Are Safe and Effective Treatments for Transgender Youth		
	F.	Harms of Withholding or Terminating Treatment for Transgender Adolescents with Gender Dysphoria		
	G.	The Florida Board of Medicine Informed Consent Forms For Minors Are Medically Unsound and Misleading, Introduce Unnecessary and Harmful Requirements, Create Restrictions on Care, and Subvert The Clinician-Patient Relationship and Process of Informed Consent		
	H.	Universal Inaccuracies and Harmful Restrictions on Care Are Repeated in All Three Consent Forms for Minors,		

		Subverting a Meaningful Discussion of Risks and Benefits of Treatment	24		
	I.	Specific Inaccuracies Within the Puberty Suppression Treatment Form for Minors			
	J.	Specific Inaccuracies Within the Masculinizing Medications Form for Minors	30		
	K.	Specific Inaccuracies Within the Feminizing Medications Form for Minors	30		
III.	CON	ICLUSION	31		

# I. INTRODUCTION AND SUMMARY OF OPINIONS

1. I have been retained by counsel for Plaintiffs as an expert in connection with the above-captioned litigation. I have actual knowledge of the matters stated herein. If called to testify in this matter, I would testify truthfully and based on my expert opinion.

2. In summary, there is no medical basis for the bans on access to medical care for transgender youth diagnosed with gender dysphoria promulgated by the Florida Boards of Medicine and Osteopathic Medicine and by the Florida Legislature through SB 254 and its implementing rules. There is also no basis upon which to deny parents the right to determine appropriate medical treatment for their child and to deny qualified medical providers the right to provide evidence-based treatment aligned with authoritative standards of care. As with any treatment for a minor, treatments for gender dysphoria depend on an open informed consent discussion between a qualified medical provider, their patient, and the patient's parent or guardian. The mental health problems present in transgender youth, which are exacerbated by untreated gender dysphoria, are significant and well-documented.

3. Further, the "informed consent forms" created by the Florida Boards of Medicine communicate medically inaccurate and misleading information, require inappropriate testing and restrictions, and undermine the clinician-patient relationship and trustworthiness of the process of informed consent.

4. The Florida Boards of Medicines' bans, SB 254, and the Boards' mandatory "informed consent forms" prohibit doctors from adequately caring for their patients and meeting their Hippocratic Oath.

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# A. Background and Qualifications

5. I am a licensed physician in Florida and am Double Board Certified by the American Board of Pediatrics in Pediatric Endocrinology and Pediatrics.

6. I am a pediatric endocrinologist at the University of Florida in Gainesville, Florida, and an Assistant Professor at the University of Florida College of Medicine in the Department of Pediatric Endocrinology. I am speaking on behalf of myself as a subject matter expert and not as a representative of the University.

7. I graduated with a Bachelor of Science degree in Interdisciplinary Studies, Basic Biology and Medicine, from the University of Florida. I received my medical degree from the University of Florida College of Medicine, graduating with Honors in Research.

8. I completed my Residency in Pediatrics and a Fellowship in Endocrinology at the UF Health Shands Children's Hospital.

9. I trained under Dr. Michael Haller, M.D., Professor and Chief of Pediatric Endocrinology at UF, Dr. Janet Silverstein, M.D., founder of the UF Health Youth Gender Program, and Dr. Kristin Dayton, M.D., Director of the UF Health Youth Gender Program. Drs. Haller and Silverstein have each trained hundreds of medical providers, participated in the development of national and international guidelines, treated thousands of children, held numerous NIH grants and published more than 200 and 140 peer reviewed papers respectively.

10. As a pediatric endocrinologist working in the UF Health Youth Gender Program, I have extensive experience providing treatment for gender dysphoria to transgender minors through a multidisciplinary care model. The Youth Gender Program uses evidence-based standards and practices and has provided social, medical, and mental health support for transgender and gender diverse patients across the state of Florida since 2016.

-2-

11. During my time at UF, I received numerous scholarly awards. Most recently, I received the 2022 UF College of Medicine Exemplary Teacher Award that recognizes the top 10% of College of Medicine faculty, and the 2020 Douglas J. Barrett, MD Academic Fellowship Award that recognizes pediatric clinicians or researchers for displaying the highest qualities in research, teaching and patient care. Other awards include the Audrey Lincourt Schiebler Award for Excellence in Child Advocacy (2018), Pediatric Clerkship Excellence in Medical Student Education (2018-19), the Inaugural McJunkin Family Type 1 Diabetes Fellow (2018-19), induction into the Gold Humanism Honor Society (2015), Association of Pathology Chairs Award, UF College of Medicine (2013), Distinguished Service Award, UF College of Medicine (2013), and International Medical Outreach Service Award (2013).

12. I have been a member of the American Academy of Pediatrics (AAP) since 2011, a Diplomat and Fellow of the AAP since 2018, I am a member of the AAP Section on Endocrinology and I served as the AAP's Executive Coordinator of Resident Initiatives for the Section on Pediatric Trainees and the AAP Section on Endocrinology Executive Board fellow representative; I am also a member of the Florida Chapter of the AAP; I have been a Diplomat with the American Board of Pediatric Endocrinology since 2021 and a member of the Pediatric Endocrine Society since 2018; I am a member of the American Diabetes Association, the Florida Medical Association, the Alachua County Medical Society, and Type 1 Diabetes TrialNet, an international network of endocrinologists at the forefront of Type 1 diabetes research.

13. I have served as a Pediatric Attending Physician with the Equal Access Clinic of the UF College of Medicine, a free healthcare clinic, and I have served as both a Camp Physician and volunteer at the Florida Diabetes Camp since 2012.

14. In 2018 as a pediatric endocrinology fellow I began working with transgender children, adolescents and young adults through a multidisciplinary youth gender program. I have provided care for approximately two-hundred transgender young people for gender dysphoria. The best current estimate of the number of transgender patients the multidisciplinary clinic itself has cared for is approximately five-hundred patients. The number of adolescent patients who have been prescribed hormone blocking medications and/or hormone therapy represent only a portion of all young people who are seen by the clinical team. Therapeutic decisions are individualized- some adolescents are seen in clinic and never receive these treatments, and others are not ready for, or are not candidates for, these medications.

15. Multidisciplinary youth gender clinics provide social, medical and mental health support to gender-diverse youth and young adults and their families. We educate our patients and their families about gender identity development and gender nonconformity, and help empower our patients and families to make informed decisions with accurate information. Teams of professionals include pediatric endocrinologists, psychologists, psychiatrists, pediatricians, social workers, medical-legal partners, and patient care advocates. The care provided is consistent with the World Professional Association for Transgender Health (WPATH) Standards of Care and focuses on the biological, psychological, as well as social (biopsychosocial) components of transgender health. Services provided include consultation, psychotherapy, and assessment of medical indication for hormone blocking medications and/or hormone therapy. In addition to providing expert care, one goal is to provide a safe environment where patients and their families can receive social and emotional supports.

16. In my practice, I strive to provide the highest quality, evidence-based, individualized and compassionate care for my patients and their families.

-4-

Ultimately, I strive to empower each patient to achieve their optimal physical, mental, emotional and social health, and want each person to feel that they are accepted and valued for who they are.

17. The information provided regarding my professional background, experiences, publications, and presentations is detailed in my curriculum vitae, a true and correct copy of the most up-to-date version of which is attached as **Exhibit A**.

# **B.** Bases for Opinions

18. In preparing this report, I have relied upon my training and clinical experience, as set out in my curriculum vitae, and on the materials listed therein. I have also reviewed the materials listed in the attached bibliography, Exhibit B. The sources cited therein are authoritative, scientific peer-reviewed publications. These are the same types of materials that experts in my field of study regularly rely upon when formulating opinions on the subject.

19. I reserve the right to revise and supplement the opinions expressed in this report or the bases for them if any new information becomes available in the future, including as a result of new scientific research or publications or in response to statements and issues that may arise in my area of expertise.

20. In addition, I have reviewed the rules promulgated by the Florida Board of Medicine, Rule 64B8-9.019, *Standards of Practice for the Treatment of Gender Dysphoria in Minors*, Fla. Admin. Code (effective March 16, 2023), and the Florida Board of Osteopathic Medicine, Rule 64B15-14.014, *Standards of Practice for the Treatment of Gender Dysphoria in Minors*, Fla. Admin. Code (effective March 28, 2023), which restrict the ability of Florida physicians from providing treatments for gender dysphoria to minors. I have also reviewed SB 254, and its implementing emergency rules and the "informed consent forms" promulgated by the Florida Boards of Medicine pertaining to minors ("Masculinizing Medications for Patients with Gender Dysphoria Patient Information and Informed Parental Consent and Assent for Minors" (DH5081-MQA (Rev. 06/23); "Feminizing Medications for Patients with Gender Dysphoria Patient Information and Informed Parental Consent and Assent for Minors" (DH5080-MQA (Rev. 06/23); and "Puberty Suppression Treatment for Patients with Gender Dysphoria Patient Information and Informed Parental Consent and Assent for Minors" (DH5079-MQA (Rev. 06/23)).

21. My opinions are based solely on my extensive background and experience treating transgender patients.

# C. Prior Testimony

22. I have not testified as an expert at trial or by deposition in the past four years.

# **D.** Compensation

23. I am being compensated for my work on this matter at an hourly rate of \$350.00 for preparation of declarations and expert reports, and deposition and trial testimony. My compensation does not depend on the outcome of this litigation, the opinions I express, or the testimony I may provide.

# **II. EXPERT OPINIONS**

# A. Standards of Care for Treating Gender Dysphoria Are Well-Established

24. According to the 2022 *Diagnostic and Statistical Manual of Mental Disorders*, *Fifth Edition (DSM-V)*, *Text Revision*, gender dysphoria is a diagnosis defined as an individual having clinically significant psychological distress or impairment in social, occupational or other important areas of functioning that results from a marked incongruence between their sex assigned at birth and the

person's gender identity (the gender with which the individual identifies). Gender dysphoria may manifest in childhood, at the onset of puberty, or in adulthood, and when left untreated it can result in adverse mental health outcomes such as severe anxiety, depression, suicidal ideation and self-harm.

25. I stay updated on the latest medical science and treatment protocols for the treatment of gender dysphoria in adolescents and young adults to ensure that I am providing the highest quality evidence-based care for my patient population. The available treatments for gender dysphoria are well established in the medical profession and the potential benefits of treatments are well-documented in the literature.

26. Comprehensive standards of care and clinical practice guidelines directing this treatment have been developed by the World Professional Association for Transgender Health (WPATH)<sup>1</sup> and by the Endocrine Society.<sup>2</sup> These guidelines have been adopted into practice by the profession as a standard of care. These standards of care are based on decades of scientific and medical research representing the best evidence-based practice information available for treating this condition. The treatment of gender dysphoria with transition-related care is recognized by nearly every major medical professional association, including the American Medical Association, American Academy of Pediatrics, Society for Adolescent Health and Medicine, American Psychiatric Association, and the American Academy of Family Physicians, among others.

<sup>&</sup>lt;sup>1</sup> WPATH was founded in 1979 and aims to promote evidence-based care, education, research, public policy, and respect in transgender health. Internationally a ccepted Standards of Care (SOC) for health professionals are updated and revised as new scientific information becomes available. SOC8 was informed by a systematic review of the evidence and assessment of benefits and harms of alternative care options. Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *Int J Transgend Health*. 2022 Sep 6;23(Suppl 1):S1-S259.

<sup>&</sup>lt;sup>2</sup> Specifically, an Endocrine Society-appointed task force whose Clinical Practice Guidelines were published in The Journal of Clinical Endocrinology & Metabolism in 2017. Hembree WC, Cohen-Kettenis PT, Gooren L, et al Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017 Nov 1;102(11): 3869–3903.

27. The current version of the WPATH Standards of Care for the Health of Transgender and Gender Diverse People, Version 8 (SOC-8), was released in September 2022. The prior SOC, Version 7, had been in place for more than a decade. Standards of care for treating gender dysphoria differ for prepubertal children (minors who have not started puberty), adolescents, and adults.

28. Treatment for gender dysphoria is aimed at eliminating the clinically significant distress that patients suffer by helping them explore, define, and express their gender identity openly and respectfully. This care model is referred to as "transition-related care," "gender transition," or "gender-affirming care."

29. Medications for treating gender dysphoria are not recommended for or prescribed to prepubertal children. Instead, support for a prepubertal transgender child may include social transition, which means allowing a child to live and be socially recognized in accordance with their gender identity rather than their sex assigned at birth. The social transition may include allowing the child to choose clothing, hairstyle, name, pronouns, and activities that correspond to that individual's gender identity.

30. Many transgender minors experience exacerbation of gender dysphoria when puberty begins. The development of secondary sex characteristics – breast development, body fat redistribution, facial changes, and onset of menses for transgender boys; androgenized hair growth, voice deepening, facial changes, and increased musculature for transgender girls – has caused significantly heightened stress and anxiety in many of my transgender adolescent patients. In my experience treating transgender adolescents, without treatment for their gender dysphoria many patients can experience anxiety, interpersonal conflicts, depression, academic decline, social withdrawal, disordered eating patterns, and suicidal thoughts and attempts.

-8-

#### Case 4:23-cv-00114-RH-MAF Document 176-3 Filed 11/06/23 Page 12 of 58

31. Once a transgender adolescent begins puberty, medications can be prescribed to temporarily halt the physical changes of puberty, avoiding the exacerbation of gender dysphoria and mitigating harms that can accompany the development of secondary sex characteristics. Then, if later in adolescence the patient, family, and healthcare team decide that initiation of hormone therapy is in the patient's best interest, they may be able to avoid physical changes inconsistent with their gender identity.

32. Puberty is initiated by the pulsatile release of the hormone GnRH from the hypothalamus. GnRH then stimulates the pituitary gland to produce Follicle Stimulating Hormone (FSH) and Luteinizing Hormone (LH). These hormones, FSH and LH, then lead to the production of estrogen and testosterone in individuals with ovaries and testes, respectively. Pubertal suppression involves the administration of a medication that prevents the release of FSH and LH, thereby inhibiting the production of estrogen and testosterone. By inhibiting that production, the further development of secondary sex characteristics halts. This pause in puberty limits the further influence of a person's endogenous sex hormones on the body. Stopping the medication resumes the production of FSH and LH and allows puberty to resume with no residual effects on fertility or secondary sex characteristics.

33. For some transgender adolescents, undergoing pubertal development consistent with their gender identity through hormone therapy may also be medically necessary and in their best interest. When prescribed hormone therapy—testosterone for transgender boys, and estrogen in combination with a testosterone-suppressing medication for transgender girls—adolescents experience physical changes consistent with their gender identity.

-9-

# **B.** Mental Health Evaluations Are Conducted Prior to Initiating Medical Treatment for Transgender Adolescents

WPATH SOC-8 recommends a multidisciplinary assessment that 34. involves several domains for the patient seeking treatment for gender dysphoria. A licensed mental health professional with expertise in the treatment of transgender and gender diverse adolescents assesses the patient's gender identity development, social development, and the support structure for the patient, including an investigation of the effects of gender minority stress, family dynamics and any other aspect that might contribute to the individual's social development. Additionally, co-occurring mental health and/or developmental concerns are addressed. The mental health professional also assesses whether the minor has the emotional and cognitive maturity to provide informed assent for any treatment. This process of consent and assent involves an evaluation of the minor's and guardian's understanding of the medical information and treatment, including the option to not receive treatment, risks and reversible and irreversible effects of treatment, and fertility options and considerations during an open discussion about the patient's goals and expectations of treatment.

35. The Endocrine Society Guideline specifies that mental health clinicians who diagnose gender dysphoria should be trained "in child and adolescent developmental psychology and psychopathology," competent in using the DSM and/or ICD diagnostically, and able to understand the individual's mental health, social conditions and ability to consent. This process is highly individualized; a nuanced approach is indicated as each patient has unique medical needs.

# C. Extensive Requirements Must Be Met before Medical Interventions Are Initiated For Transgender Adolescents

36. Medications for the treatment of gender dysphoria are not appropriate for every patient. The WPATH SOC-8 advises that "it is important to establish the

-10-

young person has experienced several years of persistent gender diversity/incongruence prior to initiating less reversible treatments such as gender-affirming hormones "<sup>3</sup> Similarly, the Endocrine Society Guideline provides that prior to the initiation of any medical intervention, "transgender individuals should be encouraged to experience living in the new gender role and assess whether this improves their quality of life."<sup>4</sup>

37. Pursuant to the Endocrine Society Guideline, transgender adolescents with gender dysphoria may be eligible for pubertal blocking medication if a qualified mental health professional has confirmed that: (i) the adolescent has demonstrated a long-lasting and intense pattern of gender nonconformity or gender dysphoria (whether suppressed or expressed); (ii) gender dysphoria worsened with the onset of puberty; (iii) any coexisting psychological, medical, or social problems that could interfere with treatment (e.g., that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start treatment; and (iv) the adolescent has sufficient mental capacity to give informed consent to this (reversible) treatment.

38. Further, the adolescent must: (i) have been informed of the effects and side effects of treatment (including potential impacts on fertility *if* the individual subsequently continues with life-long sex hormone treatment) and options to preserve fertility; and (ii) has given informed consent and the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.

39. Lastly, a pediatric endocrinologist or other clinician experienced in pubertal assessment should: (i) agree with the indication for GnRH agonist

<sup>&</sup>lt;sup>3</sup> Coleman E, Radix AE, Bouman WP, et al. Standards of Care for the Health of Transgender and Gender Diverse People, Version 8. *Int J Transgend Health*. 2022 Sep 6;23(Suppl 1):S60.

<sup>&</sup>lt;sup>4</sup> Hembree WC, Cohen-Kettenis PT, Gooren L, et al. Endocrine Treatment of Gender-Dysphoric/Gender-Inconguent Persons: An Endocrine Society Clinical Practice Guideline. *J Clin Endocrinol Metab.* 2017 Nov 1;102(11): 3876.

treatment; (ii) confirm that puberty has started in the adolescent; and (iii) confirm that there are no medical contraindications to GnRH agonist treatment.<sup>2</sup>

40. For transgender adolescents to be eligible for hormone therapy, the Endocrine Society Guideline directs that a qualified mental health professional confirms: (i) the persistence of gender dysphoria; (ii) any coexisting psychological, medical, or social problems that could interfere with treatment (*e.g.*, that may compromise treatment adherence) have been addressed, such that the adolescent's situation and functioning are stable enough to start hormone therapy; and (iii) the adolescent has sufficient mental capacity to estimate the consequences of this treatment, weigh the benefits and risks, and give informed consent to this treatment.<sup>2</sup>

41. Further, the adolescent needs to have: (i) been informed of the effects and side effects of treatment (including options to preserve fertility); (ii) given informed consent and (particularly when the adolescent has not reached the age of legal medical consent, depending on applicable legislation) the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process.

42. And lastly, a pediatric endocrinologist or other clinician experienced in pubertal induction: (i) agrees with the indication for hormone therapy; and (ii) has confirmed that there are no medical contraindications to hormone therapy.<sup>2</sup>

# **D.** The Multidisciplinary Treatment Team Model

43. I treat transgender patients as part of a multidisciplinary treatment team, which includes psychologists, psychiatrists, pediatricians, pediatric endocrinologists, medical-legal partners, and patient care advocates, all of whom are experienced in providing care to transgender minor patients.

44. We follow the process outlined in the WPATH SOC-8 and the Endocrine Society Guidelines.

45. Keeping with the American Medical Association's Code of Medical Ethics, I follow a comprehensive informed consent process prior to initiating treatment.

46. Some patients are referred to the clinic by a mental health provider with expertise in transgender health, while others are referred by their pediatrician or another provider. If the patient does not already have a mental health provider, I refer the patient to one to begin the mental health evaluation prior to providing any treatment. We then work together collaboratively to assess the patient in accordance with the WPATH standards and Endocrine Society guidelines.

47. The mental health provider assesses the patient in the domains described in paragraph 33 and 36. I then review the mental health assessment and confirm that there is a diagnosis of gender incongruence and that it has been consistent, persistent and insistent, along with confirming other relevant criteria. For most of my patients, gender dysphoria has been present for years prior to their first visit with the youth gender clinic. I further assess the patient for any medical or psychosocial conditions that might affect treatment. My interview with the patient and parent or guardian includes a thorough discussion of the patient's individual needs, goals, and their process of coming to understand and live in accordance with their gender identity.

48. Once both a mental health professional and I have each confirmed the diagnosis of gender dysphoria, I meet with the patient and parent or guardian as many times as is necessary for them to fully understand the risks and benefits of treatment options in their individual circumstance and come to an informed decision. As part of my evaluation, I order bloodwork, and in some circumstances a DEXA scan or other necessary evaluation to assess the general health of the

-13-

patient prior to initiating therapy. I also thoroughly discuss the potential impacts on fertility, fertility preservation options, and make appropriate referrals as necessary.

49. As part of my informed consent process, I fully review a packet of information with the adolescent and guardian, which discusses in detail the risks, benefits, and reversible and long-term effects of the relevant medications (pubertal suppressants and/or hormone therapies), and alternatives to treatment. As part of this process, I ask detailed questions to the patient and guardian to ensure understanding of the range of potential treatment options and outcomes. Additional resources and a follow-up protocol are also items in the packet that are reviewed.

50. The patient and guardian then take the informational packet home for self-study. I offer additional reading material when necessary. Once a full evaluation has been completed; the patient, family, and healthcare team are all in agreement that a treatment is in the best interest of the patient; and risks and benefits are well understood, informed consent and assent are obtained and treatment can commence.

51. Once the patient begins their medical treatment as prescribed, I meet with the patient and family for follow up on a regular basis and their progress is monitored at regular intervals. I assess the patient's progress, presence of gender dysphoria, physical and mental health, efficacy of the treatment, satisfaction with the treatment, side effects, and hormone levels and laboratory screening for treatment side effects. At these follow-up appointments, we carefully reassess patient progress and make medication adjustments as appropriate. The patients are strongly encouraged to remain in therapy with a mental health provider throughout this process.

52. Consistent with the established treatment guidelines described above, I consider prescribing puberty blocking treatment starting at pubertal Tanner Stages

-14-

II–III. Please refer to paragraph 52 for a detailed discussion of pubertal timing and other uses of pubertal suppressive medications. Depending on the needs of the patient, the pubertal stage they are in, and any changes that may have already resulted from endogenous puberty, patients may first initiate puberty blocking medication, followed by hormone therapy *if and when* it is medically indicated and the patient and family desire this treatment; or they may initiate hormone therapy alone or in conjunction with androgen receptor antagonists or pubertal suppressants at later stages of puberty. The goal of the treatment is to minimize the patient's gender dysphoria and to allow the patient to experience secondary sex characteristics consistent with their gender identity if medically indicated and agreed upon by the healthcare team, patient and family.

53. In my clinical experience, I have witnessed first-hand the significant and substantial benefits that access to puberty blocking, hormone antagonist, and hormone therapies, when medically necessary for the individual, can have on an adolescents' overall health and well-being.

# E. Puberty Blocking, Hormone Antagonist, and Hormone Therapies Are Safe and Effective Treatments for Transgender Youth

54. I have read the Florida Boards of Medicine and Osteopathic Medicine rules that bar doctors from prescribing puberty blocking, hormone antagonist, and hormone therapies for transgender youth. I have also read SB 254, which takes the further extraordinary step of criminalizing doctors like myself for prescribing these evidence-based treatments for transgender youth. These bans stand in direct contrast to the authoritative standards of care for the treatment of gender dysphoria. Based on my expert opinion, unless enjoined these bans will continue to cause harm to my patients and countless other transgender adolescents in the state of Florida.

55. The Endocrine Society's and WPATH's treatment protocols for prescribing puberty blocking medications and hormone therapies provide an

-15-

evidence-based, safe and effective treatment approach for gender dysphoria. The American Academy of Pediatrics, which was founded in 1930 and represents more than 67,000 pediatricians in this country, is one of many reputable medical associations in the United States which supports the use of puberty blocking medications and hormone therapy to treat gender dysphoria in adolescent patients when medically indicated.

56. Puberty blocking treatment works by pausing endogenous puberty at whatever stage it is at when the treatment begins, limiting the further influence of endogenous hormones until the treatment is ended. Puberty blocking medications are not new for the treatment of gender dysphoria, as their use began in Amsterdam in 1998 and expanded to the United States in 2010. There is over 30 years' worth of data on the safety of puberty blockers regarding children who experience precocious puberty that can be applied to the transgender population. In appropriate candidates, the benefits of treating gender dysphoria with puberty blocking medication can greatly outweigh the small potential for short- or long-term side effects. Moreover, for youth with gender dysphoria, as compared to those treated for precocious puberty, the treatment is typically used for a much shorter period to pause development before either initiating puberty with hormone therapy or resuming endogenous puberty.

57. Pubertal development has a wide variation among individuals. The onset of puberty in individuals whose sex assigned at birth is male begins, on average, at age 11-12 but can range from age 9 to 14. In those whose sex assigned at birth is female, the onset of puberty typically begins at age 10-11, but can range from age 8 to 13. Once puberty begins, completion on average occurs 3.5–4 years later. Generally speaking, pubertal suppression occurs for up to 2-3 years. The use of puberty blockers in transgender males (whose sex assigned at birth is female) allows for decreased chest development, reducing the need for breast binding and

potential surgical intervention in adulthood. The use of puberty blockers in transgender females (whose sex assigned at birth is male), limits facial and body hair growth, voice deepening, and testosterone-driven cartilage and bone structure changes, which greatly reduce distress both at the time of treatment and later in life reduce the need for future interventions such as voice therapy, hair removal, and facial feminization surgery.

58. The use of puberty blocking medications are safe and effective, and the rare side effects are thoroughly discussed with the patient and their family prior to starting any treatment. To address the risk of lower bone mineral density that can be associated with prolonged use of puberty blockers, we conduct regular screening for vitamin D and calcium deficiency (and treat deficiencies when needed), advise regular weight-bearing exercise, conduct bone mineral density scans at regular intervals, and limit the number of years a patient is on puberty blocking medication. Decades of data on the use of puberty blockers as treatment for precocious puberty has demonstrated that puberty blocking medication does not have long-term implications for fertility.<sup>56</sup>

59. Puberty blocking medications may also be used by transgender females (whose sex assigned at birth is male) in conjunction with estrogen therapy to suppress that individual's endogenous production of testosterone. It is standard protocol to include a testosterone-suppressive agent when an individual begins estrogen. Hormone receptor antagonist therapies can also be used to suppress the endogenous action of testosterone. There are some instances where pubertyblocking medications are used in the latter stages of puberty to prevent unwanted secondary sex characteristics such as an Adam's apple, increased facial hair, a lower

<sup>&</sup>lt;sup>5</sup> Guaraldi F, Beccuti G, Gori D, Ghizzoni L. MANAGEMENT OF ENDOCRINE DISEASE: Long-term outcomes of the treatment of central precocious puberty. *Eur J Endocrinol*. 2016 Mar;174(3):R79-87.

<sup>&</sup>lt;sup>6</sup> Martinerie L, de Mouzon J, Blumberg J, di Nicola L, Maisonobe P, Carel JC; PREFER study group. Fertility of Women Treated during Childhood with Triptorelin (Depot Formulation) for Central Precocious Puberty: The PREFER Study. *Horm Res Paediatr.* 2020;93(9-10):529-538.

voice or late-stage breast development, depending on the individualized needs and assessment of the patient.

60. In a 2020 study published in the American Academy of Pediatrics' official journal *Pediatrics*, researchers queried a group of 20,619 transgender individuals and found a lower odds of lifetime suicidal ideation for those who received pubertal suppression when they were adolescents compared with a group that desired pubertal suppression but did not receive it.<sup>7</sup> Suicidality is of particular concern because the estimated lifetime prevalence of suicide attempts among the transgender population is as high as 40%.

61. Under the Endocrine Society Guidelines and WPATH SOC-8, hormone therapy is appropriate for transgender adolescents with gender dysphoria when their experience of gender incongruence is marked and sustained over time, the adolescent demonstrates emotional and cognitive maturity required to provide informed consent/assent for treatment, other mental health concerns (if any) that may interfere with diagnostic clarity and capacity to consent have been addressed, and the adolescent has discussed reproductive options with their provider. For adolescents who meet these criteria, it may be in the patient's best interest to provide hormone therapy to initiate puberty consistent with the patient's gender identity. The parent or guardian is critical to the assessment and treatment process for minors and must provide informed consent for any individual under the age of majority.

62. Hormone therapy is safe and has been used in non-transgender patients for reasons unrelated to the treatment of gender dysphoria. There are a variety of medical conditions in childhood and adulthood where estrogen or testosterone are prescribed, such as polycystic ovary syndrome, menorrhagia (heavy menstrual bleeding), acne, contraception, menopause, post-chemotherapy, premature ovarian

<sup>&</sup>lt;sup>7</sup> Turban JL, King D, Carswell JM, Keuroghlian AS. Pubertal Suppression for Transgender Youth and Risk of Suicidal Ideation. *Pediatrics*. 2020 Feb;145(2):e20191725.

failure, pubertal delay, and testosterone deficiency. Patients with various intersex conditions, such as Turner Syndrome or Klinefelter Syndrome, also often receive hormone therapy. Those individuals with the conditions described often need hormone therapy for the duration of their entire lives.

63. As with puberty blocking medications, I discuss the risks and benefits of hormone therapy at length with adolescent patients and their families prior to initiation of treatment. Potential impact on fertility is always discussed along with fertility preservation options. If desired after our discussion, patients are referred to a reproductive endocrinologist for further discussion of fertility preservation, a procedure that also may be recommended prior to certain chemotherapy regimens or due to ovarian or testicular insufficiency.

64. Many transgender adults have been on hormone therapy for decades. No reputable medical organization or reliable study has concluded that the risk of any negative outcome would categorically outweigh the substantial benefit of treatment in appropriate candidates for therapy.

65. The goal of hormone therapy is to lessen gender dysphoria, improve functioning and avoid unwanted secondary sex characteristics while developing characteristics that align with gender identity. Studies have showed improved psychological functioning, body image and mental health, and less gender dysphoria, suicidality, depression and anxiety with treatment for gender dysphoria. Some of my patients who are receiving medical treatment for gender dysphoria experienced suicidal ideation and attempts prior to beginning treatment. I have witnessed patients transform from individuals with significant levels of psychological distress to functional, psychologically stable, thriving individuals. I fear that categorically denying puberty blockers, hormone antagonists, and hormones to transgender adolescents who meet criteria for care will lead to distress and psychological harm.

#### Case 4:23-cv-00114-RH-MAF Document 176-3 Filed 11/06/23 Page 23 of 58

66. After medications are initiated, the patient's functioning, psychosocial situation, physical changes, satisfaction with therapy, hormone levels, and treatment side effects are assessed frequently. Patient care is individualized and in consultation with their doctor, patients may decide to stop therapy, continue, or be evaluated for adjustment of their medication in response to medical need.

67. In summary, the interventions described above are effective and safe, and access is essential for the wellbeing of those transgender adolescent patients for whom they are indicated. The treatments are provided only with assent from the patient and consent from the parent or guardian. My patients who receive medically necessary treatment for gender dysphoria often experience significant improvement in their mental health and quality of life. Medical treatment recommended for and provided to transgender adolescents with gender dysphoria can substantially reduce lifelong gender dysphoria and can eliminate the potential need for later, more invasive treatments. Access to medications to treat gender dysphoria is vital and can improve the short- and long-term health outcomes for transgender adolescents.

# F. Harms of Withholding or Terminating Treatment for Transgender Adolescents with Gender Dysphoria

68. I have reviewed the medical bans promulgated by the Florida Boards of Medicine and Osteopathic Medicine and by the Florida Legislature (SB 254). Based on my review, I understand those bans to prohibit board-certified physicians like myself from following accepted standard of care in providing medical treatment for gender dysphoria for minors who had not received treatment prior to March 16, 2023 and March 28, 2023 (Boards of Medicine and Osteopathic rules, respectively) and May 17, 2023 (SB 254).

69. Puberty blocking medications and hormone therapies have improved the physical and mental well-being of many of my patients. Withholding this wellestablished, necessary medical care from patients will worsen their mental health outcomes. Being denied the only medical therapies that can legitimately treat their gender dysphoria will render their conditions more recalcitrant. Refusing medical care in this way without a sound medical basis violates my professional and ethical obligations by forcing me to withhold necessary treatment from my patients.

70. Since the Boards' rules have become effective, I have met with numerous new patients who were candidates for puberty blocking medication or hormone therapy, but physicians, including myself, are not permitted to prescribe them under the law. The parents of these adolescents are angry and concerned for their children. They want to ensure their children get the medical care that they need to live happy, productive and healthy lives. There are several families who are taking active steps to move out of the state of Florida. It is devastating that these parents feel that they have no other option but to leave and find a safe place for their children, who will be denied critical medical treatment if they remain in Florida.

71. In my clinical experience, I can attest that medications to treat gender dysphoria significantly improve the health and well-being of adolescents who are transgender, and for whom the care is medically indicated. I have witnessed the tremendous impacts of treatment on my transgender patients, including developing improved relationships with their family members and peers, improved academic performance and feelings of belonging at school, the ability to develop healthy romantic relationships with their partners, and feeling hopeful about their future and the opportunities life has to offer.

72. Many of my transgender patients' anxiety, depression, and selfharming behaviors have improved following the initiation of treatment for gender dysphoria. I have witnessed myriad patients transform from being withdrawn, sullen, and unable to connect, to thriving socially, developing self-confidence, and developing close friendships. Not only have I seen this growth in my patients during our clinical visits, but many of my patients' parents have expressed to me how their teenage child blossomed and came out of their shell after receiving treatment for gender dysphoria. Many of my patients' parents have also shared with me how crippling and painful it was as a parent to watch their child struggle without access to necessary medical care, and it haunts me to know that under the medical care bans created by the Boards of Medicine and the Florida Legislature, so many more parents are going to have to watch their children suffer without access to effective treatment for their gender dysphoria.

# G. The Florida Board of Medicine Informed Consent Forms For Minors Are Medically Unsound and Misleading, Introduce Unnecessary and Harmful Requirements, Create Restrictions on Care, and Subvert The Clinician-Patient Relationship and Process of Informed Consent

73. The "Informed Consent" forms were created by the Boards of Medicine pursuant to SB 254, which required the Boards to "consider requirements for physicians to obtain informed consent from such patient's parent or legal guardian[.]"

74. Further, SB 254 required that "consent must be voluntary, informed, and in writing on forms adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine[;]" and "[c]onsent to sex-reassignment prescriptions or procedures is voluntary and informed only if the physician who is to prescribe or administer the pharmaceutical product or perform the procedure has, at a minimum, while physically present in the same room:

(a) Informed the patient of the nature and risks of the prescription or procedure in order for the patient to make a prudent decision;(b) Provided the informed consent form, as adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine, to the patient; and

(c) Received the patient's written acknowledgment, before the prescription or procedure is prescribed, administered, or performed, that the information required to be provided under this subsection has been provided."

75. Pursuant to SB 254, the Boards of Medicine created the following forms for the treatment of gender dysphoria in minors: "Masculinizing Medications for Patients with Gender Dysphoria Patient Information and Informed Parental Consent and Assent for Minors" (DH5081-MQA (Rev. 06/23); "Feminizing Medications for Patients with Gender Dysphoria Patient Information and Informed Parental Consent and Assent for Minors" (DH5080-MQA (Rev. 06/23); and "Puberty Suppression Treatment for Patients with Gender Dysphoria Patient Information and Informed Parental Information and Informed Parental Consent and Assent for Minors" (DH5080-MQA (Rev. 06/23); and "Puberty Suppression Treatment for Patients with Gender Dysphoria Patient Information and Informed Parental Consent and Assent for Minors" (DH5079-MQA (Rev. 06/23).

76. Informed consent for treatment is a fundamental process of communication within the clinician-patient relationship that allows patients, and in the case of pediatrics, their parents or legal guardians, to receive accurate information that a reasonable person would want to know prior to making a healthcare decision.<sup>8</sup>

77. Informed consent discussions include a dialogue between the clinician and patient about the medical condition being treated, potential treatment options, and potential risks and benefits of these treatment options. Clinicians must ensure that the patient and parents of minor patients have the capacity to understand risks and benefits and agree to a treatment plan.

78. The consent forms created by the Florida Board of Medicine communicate medically inaccurate and misleading information, require inappropriate testing and restrictions on care, and undermine the clinician-patient

<sup>&</sup>lt;sup>8</sup> AMA Code of Medical Ethics Opinion 2.1.1: Informed Consent. <u>https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent</u>

relationship and trustworthiness of the process of informed consent. For this reason, these forms subvert informed consent rather than promoting it.

79. By providing inaccurate and misleading information, creating restrictions on care and introducing needless medical procedures and testing, and subverting the process of informed consent, these "consent forms" breach the ethical principles of patient autonomy and provider non-maleficence. The process of informed consent as distorted by the mandatory forms is no longer an honest, accurate, and compassionate dialogue between clinician and patient, but rather a "form [that] contains information required to be disclosed to you by Florida law and does not necessarily reflect the views or opinions of your physician."

80. The clinical practice guidelines and standards of care published by the World Professional Association for Transgender Health (WPATH) and the Endocrine Society provide context for my specific comments related to the content of the Board of Medicine consent forms.

# H. Universal Inaccuracies and Harmful Restrictions on Care Are Repeated in All Three Consent Forms for Minors, Subverting a Meaningful Discussion of Risks and Benefits of Treatment

81. Each of the three consent forms for minors (hereinafter, referred to as "Minor Consent Forms" when referencing all three) begins by stating that "medical treatment of people with gender dysphoria is based on very limited, poor-quality research with only subtle improvements seen in some patient's psychological functioning in some, but not all, research studies. This practice is purely speculative..." (Minor Consent Forms, at p.1). This paragraph is inaccurate and misleading- medical treatment of people with gender dysphoria is evidence-based and associated with significant improvements in psychosocial outcomes. It is not speculative but is well-established and based on decades of clinical experience and data.

82. Each form presents pubertal suppression and hormone therapies prescribed for gender dysphoria as "not being used for their intended purpose." (Minor Consent Forms, at p. 1). This statement is misleading and likely to confuse patients. Off-label use of medications, especially within pediatrics, is common. In fact, one in five prescriptions written today are for off-label use.<sup>9</sup> The FDA states that a healthcare provider may prescribe a drug off-label when "there might not be an approved drug to treat your disease or medical condition."

83. Each form requires that Tanner staging be confirmed by a physician before proceeding with treatment. (Minor Consent Forms, at p. 3). This is not supported by guidelines, which state that "a pediatric endocrinologist or other clinician experienced in pubertal assessment" may confirm.<sup>10</sup> Other clinicians such as APRNs may meet this qualification and be able to perform this exam in accordance with clinical practice guidelines.

84. Each form requires the clinician to discuss "the medical and social risks and benefits of sex reassignment surgery." (Minor Consent Forms, at p. 3). It is inappropriate and unnecessary to discuss the risks and benefits of a procedure that is not being recommended within the informed consent discussion about a completely different treatment.

85. The forms for masculinizing and feminizing medications require that a psychological and social evaluation be performed by a Florida licensed boardcertified psychiatrist or a Florida licensed psychologist prior to beginning treatment. Additionally, all three forms require annual mental health assessments by a boardcertified Florida licensed psychiatrist or psychologist. (Minor Consent Forms, at p. 3). There is no medical reason for this requirement, which serves as an unnecessary

<sup>&</sup>lt;sup>9</sup>https://www.ahrq.gov/patients-consumers/patient-involvement/off-label-drugusage.html#:~:text=Off%2Dlabel%20prescribing%20is%20when,are%20for%20off%2Dlabel%20use.

<sup>&</sup>lt;sup>10</sup> Supra FN 4, Hembree et al. ("Endocrine Society Clinical Practice Guideline"), at p. 3878.

and potentially insurmountable barrier to care. There is a severe shortage of child and adolescent psychiatrists in Florida, with only 12 available per 100,000 Florida children.<sup>11</sup> There is also a severe shortage of board-certified psychologists in the state of Florida. Healthcare professionals evaluating patients for medical treatment of gender dysphoria should have expertise in mental health across the developmental spectrum, in gender diversity across the lifespan, and in assessing capacity to consent/assent.<sup>12</sup> This may include therapists or licensed social workers in addition to psychologists or psychiatrists. Indeed, therapists and licensed social workers may have a deeper understanding of their patient's gender dysphoria than the patient's psychiatrist, who is often primarily managing psychotropic medications rather than facilitating exploration of gender identity which may be primarily the therapist's role.

86. Relatedly, each form requires that a suicide risk assessment be performed by a licensed mental health care professional at least every three months. (Minor Consent Forms, at p. 3). The frequency of mental health evaluations for patients undergoing medical treatment for gender dysphoria should be individualized according to the needs of the patient. It is inappropriate to mandate assessments every three months for all patients.

87. SB 254 mandated that physicians execute the informed consent forms "while physically present in the same room" as the patient. (Fla Stat 456.52(2)). However, there is no medical justification for this requirement. Pursuant to SB 254, each form requires that the consent form be signed "*in person*" (Minor Consent Forms, at p. 1), and also requires "in-person" evaluations by the prescribing physician at least every 6 months (*id.*, at p. 3). There are few clinicians across

<sup>&</sup>lt;sup>11</sup> The American Academy of Child and Adolescent Psychiatry, Practicing Child and Adolescent Psychiatrists (AACAP Workforce Maps by State), available at: <u>https://www.aacap.org/aacap/Advocacy/Federal\_and\_State\_Initiatives/Workforce\_Maps/Home.aspx</u> (last accessed

August 16, 2023).

<sup>&</sup>lt;sup>12</sup> Supra FN 3, Coleman et al. ("Standards of Care V. 8")

Florida who provide medical treatment for gender dysphoria in minors. Requiring all patients to complete the consent forms in person, and to have in-person visits every 6 months, rather than allowing for telehealth visits when appropriate, creates a barrier to care for patients, who may have to travel up to 5-6 hours to receive care from their nearest clinic. Further, there is no medical justification for these in-person requirements.

88. Each form requires laboratory assessments at least every 4 months. (Minor Consent Forms, at p. 3). This interval is not supported by clinical practice guidelines - the Endocrine Society guidelines suggest, but do not mandate, laboratory testing every 6-12 months during pubertal suppression and for masculinizing therapy and every 3 months in the first year and then annually for feminizing therapy.<sup>13</sup> The frequency of laboratory testing should be individualized according to the needs of the patient.

89. Each form requires a bone age x-ray be obtained at least once yearly if the minor is still growing. (Minor Informed Consent Forms, at p. 3) (the forms for masculinizing and feminizing medications impose the requirement "at least once a year if the minor is still growing" while the form for puberty suppression medication imposes this requirement "no less than once a year."). This is often unnecessary unless there is a concern for the patient's final adult height, and not recommended in Endocrine Society guidelines unless clinically indicated. Exposing patients to unnecessary laboratory draws and x-rays violates the ethical principle of nonmaleficence.

90. Each form also requires annual DEXA scans to evaluate bone mineral density. (Minor Consent Forms, at p. 3). This is not supported by clinical practice guidelines. Endocrine Society guidelines suggest, but do not mandate, DEXA scans

<sup>&</sup>lt;sup>13</sup> Supra FN 4, Hembree et al. ("Endocrine Society Clinical Practice Guideline"), at p. 3871, 3888-89.

every 1-2 years.<sup>14</sup> In fact, as bone mineral density changes very slowly over time, annual DEXA scans may not show meaningful change, and scans performed every other year may be more appropriate. The frequency of imaging for bone mineral density should be individualized according to the needs of the patient.

91. Each form states that medical treatment for gender dysphoria "will not prevent serious psychiatric events such as suicide." (Masculinizing medication form, at p. 7; feminizing medication form, at p. 6; puberty suppressing medication form, at p. 4). Medications for the treatment of gender dysphoria are associated with improved mental health outcomes. A categorical statement that these medications will not prevent serious psychiatric events for an individual patient is not consistent with individualized informed consent.

92. Each form contains an inordinate number of points that patients must initial individually, including obvious statements already previously covered. For example, the Masculinizing medication form states that "[t]aking testosterone causes changes that other people will notice" (at p. 7), and also contains information about drug interactions with blood thinners such as Warfarin, which are very infrequently used in the pediatric population (*id.* at 4); and contraindications to treatment including uncontrolled coronary artery disease (*id.* at 6), which I have never seen in an adolescent population throughout my years of medical practice. Similarly, the Feminizing Medication Form discusses estrogen-dependent cancers (at p. 6), which are also exceedingly rare in the adolescent population. This serves to lengthen the form, seemingly to serve the purpose of intimidating patients with an extensive and unwieldly document that must be initialed 44 times by both the parent and the patient in the case of the Feminizing Medications Consent form. This does not facilitate informed consent, and instead focuses the patient on potential

<sup>&</sup>lt;sup>14</sup> Id. at 3883-84.

risks that are not applicable to their individual care, usurping a discussion of the actual risks and benefits of treatment.

93. The Masculinizing and Feminizing Medication Forms for minors state that "this medicine and dose that is recommended is based solely on the judgement and experience of the minor's prescribing physician." (at, p. 6). This is inaccurate, as clinical practice guidelines including the Endocrine Society Guidelines are followed by myself and other clinicians to guide treatment regimens.

94. The Masculinizing and Feminizing Medication Forms for minors state that "taking too much" medication "will not make changes happen more quickly or more significantly." (masculinizing medication form, at p. 7; feminizing medication form, at p. 6). While not recommended, this statement is inaccurate.

# I. Specific Inaccuracies Within the Puberty Suppression Treatment Form for Minors

95. On Page 4 of the document, it states that the puberty blocking effect may be permanent even after stopping medical treatment. This is incorrect and is never part of the informed consent discussion for patients with precocious puberty or for patients with gender dysphoria, as it is false information.

96. Also on Page 4, the document states that "it cannot be predicted how quickly or slowly or even if a minor's body will respond to the medication." The effect of GnRH agonists on pubertal suppression is very predictable and the physiologic impact is well understood.

97. Also on Page 4, the document states that "puberty blockers can interfere with fertility." Puberty blockers themselves have no long-term impact on fertility once they are stopped; this statement is misleading and inaccurate.

98. Also on Page 4, the document states that "the adverse effects and safety of puberty blockers used for the treatment of gender dysphoria in minors is not well known." This is inaccurate, as described in Paragraphs 55-57.

99. The laundry list of side effects included on Pages 5-6 of the form is misleading. These are side effects that were reported most commonly for the 6-month GnRH agonist (which, interestingly, is not listed as a treatment option on the consent form itself), but may have been reported equally among the treatment and placebo group in clinical trials.<sup>15</sup> In fact, the only commonly listed side effects for the 3-month GnRH agonist formulation, which is most commonly prescribed, are injection site reactions, weight gain, headache, and mood changes.<sup>16</sup> Having a laundry list of potential side effects without highlighting the most common or potentially severe again disrupts a meaningful discussion of risks and benefits of treatment.

# J. Specific Inaccuracies Within the Masculinizing Medications Form for Minors

100. The document states on page 5 that "the following changes could be permanent, but may improve if I stop taking testosterone." However, many of these changes are known to be non-permanent, and so this paragraph is inaccurate.

101. Currently, data do not support that testosterone increases the risk of endometrial, ovarian, or breast cancer, and so stating definitively that treatment does increase these risks is inaccurate. Testosterone also does not cause or worsen migraines. (Page 7).

# K. Specific Inaccuracies Within the Feminizing Medications Form for Minors

102. On Page 4, it states that "If a minor takes estrogen, the following changes in a minor's breast will occur," and then lists "a milky discharge from the nipples." This is not an expected change from estrogen therapy and should not be listed within this paragraph.

<sup>&</sup>lt;sup>15</sup> <u>https://www.lupron.com/isi.html</u>
<sup>16</sup> *Id*.

103. On Page 5, it states that "Even if a minor stops taking feminizing medications, the following changes may occur." However, the changes listed are reversible, and not irreversible, effects of estrogen therapy.

104. On Page 7, it states that "Estrogen should be used **WITH CAUTION** and only after a full discussion of risks by anyone who… has high levels of cholesterol." However, in most studies estrogen therapy does not increase levels of LDL and can result in a more favorable lipid profile.<sup>17</sup>

105. Also on Page 7, it states that "Taking estrogen can increase the deposits of fat around internal organs, which increases the risk for diabetes and heart disease, which in turn increases the risk of heart attack and stroke." However, recent studies show no change in visceral fat with estrogen therapy.<sup>18</sup>

106. Also on Page 7, it states that "Taking estrogen can raise blood pressure, which increases the risk of heart attack and stroke." However, recent studies show that estrogen therapy actually tends to lower systolic blood pressure.<sup>19</sup>

# **III. CONCLUSION**

107. Transgender persons account for 0.6% of our population in the United States. This marginalized population has had the misfortune of having their medical care targeted and banned despite the existence of evidence-based medical standards that have been reviewed and adopted by major medical organizations and providers with extensive expertise in this field of medicine. As with any treatment for a minor, treatments for gender dysphoria rely on an open informed consent discussion

<sup>&</sup>lt;sup>17</sup> Masumori N, Nakatsuka M. Cardiovascular Risk in Transgender People With Gender-Affirming Hormone Treatment. Circ Rep. 2023 Mar 28;5(4):105-113. doi: 10.1253/circrep.CR-23-0021. PMID: 37025940; PMCID: PMC10072899.

<sup>&</sup>lt;sup>18</sup> Klaver M, van Velzen D, de Blok C, Nota N, Wiepjes C, Defreyne J, Schreiner T, Fisher A, Twisk J, Seidell J, T'Sjoen G, den Heijer M, de Mutsert R. Change in Visceral Fat and Total Body Fat and the Effect on Cardiometabolic Risk Factors During Transgender Hormone Therapy. J Clin Endocrinol Metab. 2022 Jan 1;107(1):e153-e164. doi: 10.1210/clinem/dgab616.

<sup>&</sup>lt;sup>19</sup> Banks K, Kyinn M, Leemaqz SY, Sarkodie E, Goldstein D, Irwig MS. Blood Pressure Effects of Gender-Affirming Hormone Therapy in Transgender and Gender-Diverse Adults. Hypertension. 2021 Jun;77(6):2066-2074. doi: 10.1161/HYPERTENSIONAHA.120.16839.

between a qualified medical provider, their patient, and the patient's parent or guardian. There is no sound medical justification for prohibiting the medical treatment provided to this one particular population, and no basis upon which to deny parents the right to determine appropriate medical treatment for their child and to deny qualified medical providers the right to provide evidence-based treatment aligned with authoritative standards of care. Further, the "informed consent forms" created by the Florida Boards of Medicine communicate medically inaccurate and misleading information, require potentially inappropriate testing and restrictions on care, and undermine the clinician-patient relationship and trustworthiness of the process of informed consent. The mental health disparities present in this population that are exacerbated by untreated gender dysphoria are significant and well-documented. The Florida Boards of Medicine's bans, SB 254, and the recently promulgated "informed consent forms," prohibit doctors from caring for their patients and abiding by the Hippocratic Oath.

I declare under penalty of perjury that the foregoing is true and correct. Executed this 16th day of August, 2023.

BRITTANY BRUGGEMAN, M.D.

Case 4:23-cv-00114-RH-MAF Document 176-3 Filed 11/06/23 Page 36 of 58

# Exhibit A

PL000661

# Brittany S. Bruggeman

Curriculum Vitae Assistant Professor of Pediatric Endocrinology *E-mail:* bruggemanbr@gmail.com *Phone:* 321-537-8832 UF Health Shands Children's Hospital University of Florida Gainesville, FL 32608

<b>Education</b>	<b>University of Florida</b> , Gainesville, FL <b>B.S.</b> , Basic Biology and Medicine Minor, Music Performance <i>Summa cum laude</i>	2008-2012	
	Summa cum laude Thesis: "Development and Optimization of a Bioartificial Pancreas as a Therapy for Type 1 Diabetes."		
	M.D., College of Medicine Medical Honors Program With Honors in Research	2011-2015	
	<b>UF Health Shands Children's Hospital,</b> Gainesville, F <b>Pediatric Residency</b> <i>Research Track</i>	L 2015-2018	
	Endocrinology Fellowship	2018-2021	
Oualificatio	ons & Licensure		
	USMLE Step 1: 247	2013	
	USMLE Step 2: 267	2014	
	USMLE Step 3: 242	2015	
	Diplomat, American Board of Pediatrics	2018-present	
	Fellow, American Academy of Pediatrics	2018-present	
	Florida Medical Licensure: ME 137728	2018-present	
	Diplomat, American Board of Pediatric Endocrinology	2021-present	
Current A	<u>opointments</u>		
	Assistant Professor of Pediatric Endocrinology, Tenure-eligible University of Florida   Gainesville, FL J	uly 2021-present	
Honors and	d Awards		
Internal			
	<b>UF College of Medicine Exemplary Teacher Award</b> Annual award that recognizes the top 10% of College of Medicin teaching excellence and mentorship.	2022 e faculty in	

**2020 Douglas J. Barrett, MD Academic Fellowship Award** 2020-2021

Awarded to one rising third or fourth year pediatric clinical or research fellow displaying the highest qualities of scholarly activity in research, teaching and patient care. Funds one year of fellowship training.

**Pediatric Clerkship Excellence in Medical Student Education** x3, 2018-2019 Medical students recognize one resident or faculty who most positively impacted their education during their pediatric clerkship.

Inaugural McJunkin Family Type 1 Diabetes Fellow2018-2019Awarded to fellows committed to careers as clinician-scientists in type 1 diabetes.Funds one year of pediatric endocrinology fellowship.

**Audrey Lincourt Schiebler Award for Excellence in Child Advocacy** 2018 Awarded to one UF pediatric trainee for superior efforts in child advocacy.

Best Resident/Fellow Poster, UF Pediatric Science DayMay 2017"Prevalence and Characterization of Retinopathy in Children with Type 1Diabetes Using a Non-mydriatic Fundus Camera."

**Gold Humanism Honor Society, UF Chapter** Jan. 2015- present 15% of the fourth-year medical school class selected for exemplary behavior that promotes humanism in medicine.

Association of Pathology Chairs Award, UF College of Medicine May 2013Distinguished Service Award, UF College of Medicine (COM)May 2013International Medical Outreach Service Award, UF COMMay 2013

#### External

**NIH NIDDK Travel Award** June 2022 One of six abstracts chosen for oral presentation at the "Integrated Physiology of the Exocrine and Endocrine Compartments in Pancreatic Diseases Workshop." **CAPER 2022** PancreasFest Travel Grant May 2022 Awarded to trainees and early career faculty dedicated to pancreatic research. **Runner-Up, Best Case Presentation ISPAD Science School** May 2021 Awarded to the top five case presentations at the ISPAD Science School for Physicians in May 2021. Winning presentations were developed into modules on the ISPAD e-learning platform. American Academy of Pediatrics (AAP) Top Ten Resolution 2019 First-authored resolution, "Affordable Insulin Access for All Children with Diabetes" voted by AAP leadership to be a top 10 policy priority in 2019 out of 60+ accepted proposals.

Endocrine Society Presidential Poster Competition Participant March 2019

First-authored top-scoring abstract for presentation at the Annual Meeting.

# Third Place Oral Presentation, FCAAP Pediatric Medical Student Research Forum Aug. 2014 "Comparison of effectiveness of Glulisine, Lispro, and Aspart in decreasing postprandial hyperglycemia in a real-world setting."

# Service and Leadership

#### Internal

External

<b>Equal Access Clinic, UF College of Medicine</b> Pediatric Attending Physician UF College of Medicine student-run free healthcare cl	2018-present
Gainesville Healthy Smiles Day Founder and Organizer	April 2016 & June 2017
Pediatric Residents trained in oral health exams and pr care, education, and referrals in an underserved area o	ovided free basic dental
Global Health Outreach Medical Missions	
Trip Member, Nicaragua	2012, 2014, 2015
Trip Leader, Nicaragua	2013
PACE Center for Girls	
UF College of Medicine Careers in Medicine Day	July 2022
UF College of Medicine	
LCME Accreditation Review	Jan. 2023
Pediatric Residency Advocacy Rotation Co-Director	July 2022-present
Research Accountability Team member	December 2021-present
Collaborative Learning Group Leader	July 2021-present
Team Lead, FL DOH CMS Endocrine Disease Mgmt. C	
Pediatric Interest Group Treasurer	2012-2013
UF College of Medicine White Coat Company	
Vocal coach and participant	Aug. 2011-May 2013
Alachua County Medical Society	
Secretary/Treasurer	May 2021-present
Trainee Advisory Board Member	2018-2021

**American Academy of Pediatrics** 

Type 1 Diabetes TrialNet	2022-present
The Environmental Determinants of Diabetes i Diet Committee	in the Young Study 2022-present
Camp Physician	July 2018, 2022
	ly 2012, 2014, 2016 & 2017
Florida Diabetes Camp	
Legislative Committee Co-Chair	Nov. 2022-present
Early Career Committee Member	2019-2021
Florida Chapter of the American Academy of l	Pediatrics
Call to Congress Participant	April 2019
Legislative and Regulatory Subcommittee Member	2019-2020
Early Career Advisory Group Member	March 2021-present
National Advocacy Committee Member	Jan 2021-present
American Diabetes Association	
Residency Program Delegate	2015-2018
District X Assistant District Coordinator, SOPT	2010-2017
Resolutions Task Force, SOPT District X Resident Representative, SOPT	2017-2018 2016-2017
Executive Coordinator of Resident Initiatives, SOPT	E 2017-2018 2017-2018
(SOPT) Executive Coordinator of Resident Initiatives, SOPT	2018-2019
Executive Coordinator of Internal Process for the Security	
Section on Endocrinology Executive Board Fellow M	
Contran an Lindo ann a litr to art litr any ture Dooud Lindows M	Aug. 2021 ember 2019-2021

# American Academy of Pediatrics (AAP)

Washington, DC Legislative Office Internship	Apr	il 2018
Annual Legislative Conference	201	7, 2018
Section on Pediatric Trainees Planning Meeting	2016, 201	8, 2019
District IX/X Annual Meeting	201	6, 2017
National Conference and Exhibition	Annually 201	2-2020
Florida Chapter of the AAP		
Annual Meeting Residency Brain Bowl Participant	2016	<b>&amp;</b> 2017
Annual Conference	2014, 2016-2018, 202	20-2022
American Diabetes Association		
Focus on Fellows Annual Meeting	Annually 201	8-2021
Scientific Sessions	Annually 201	8-2022
American Pediatric Society/Society for Pediat	ric Research	
APS SPR Journeys & Frontiers in Pediatric Research		-2022
Association for Clinical and Translational Sci	ence	
Annual Meeting		2022
Mock NIH K Study Section		2022
Children with Diabetes Friends for Life		
Fellows Program		2018
Annual Meeting		2018
Collaborative Alliance for Pancreatic Educat	ion and Research	
CAPER PancreasFest Annual Meeting		2022
The Endocrine Society		
Fellows Series: Type 1 Diabetes Care and Manager	ment Conference	2019
Annual Meeting		2019
Florida Medical Association		
Legislative Visitation Program	Apr	il 2019
Annual Conference Delegate	201	7, 2022
International Society for Pediatric and Adoles	scent Diabetes	
Science School for Physicians	Ma	y 2021
Network for Pancreatic Organ Donors with D	viabetes (nPOD)	
Annual Meeting	2020, 202	2, 2023
NIH NIDDK		
Integrated Physiology of the Exocrine and Endocrin	e Compartments in Par	ocreatic
Diseases Workshop	-	2022

	<b>Pediatric Academic Societies</b> Annual Conference	2013
	Pediatric Endocrine Society Annual Meeting	2019, 2021, 2022
	Southern Pediatric Endocrine Society Annual Meeting	2019
	The Environmental Determinants of Diabetes in the Y Steering Committee Meeting	Zoung (TEDDY) 2022
	Type 1 Diabetes TrialNet Steering Committee Meeting	2019, 2020, 2022
	UF Graduate-Level Research Courses Completed GMS6945 Team Science PHC6052 Introduction to Biostatistical Methods GMS6875 Ethical/Policy Issues in Clinical Research GMS6885 Translational Health Research Design	Fall 2021 Fall 2021 Spring 2022 Fall 2022
<u>Reviewer</u>	Alachua County Medical Society ACMS Poster Symposium Judge	2021, 2022
	<b>American Academy of Pediatrics</b> Legislative Conference Scholarships, Section on Pediatric T	
	(SOPT) Anne E. Dyson Child Advocacy Award, SOPT National Conference Resident Clinical Case Presentations	2017, 2018 2017, 2018 2016- 2018
	Pediatric Endocrine Society 2023 Annual Meeting Abstracts	2023
	Ad hoc reviewer for: Case Reports in Endocrinology Diabetes Care Diabetes Technology and Therapeutics Diabetes Therapy Diabetes UK Diabetologia JMIR Diabetes Pediatric Diabetes Pediatrics	2020-present 2018-present 2019-present 2019-present 2022-present 2019-present 2021-present 2018-present 2020-present

Pediatrics in Review

2021-present

#### **Mentorship**

#### University of Florida Undergraduate Research Assistants

Logan Brunson	Oct. 2018-May 2020
McKayla Massey	Oct. 2018-May 2020
Daniel Rodriguez	Oct. 2018-May 2020
Michael Guyot	June 2022-present
Christopher Georgas	Nov. 2022-present
Danielle Elliott	Nov. 2022-present

#### **UF COM Medical Student Research Assistants**

Savanna Gornisiewicz	June 2022-present
Ryan Grabau	June 2022-present
Camila Sarcone	June 2022-present
Rebecca Oyetoro	June 2020-March 2021
Amanda LaPorte	June 2015-Dec. 2018

#### UF Pediatric Residency Intern Mentorship Program

Iriyise Oloruntoba-Oju

July 2021-present

# UF Pediatric Endocrinology Fellow Scholarship Oversight Committee Israa Ismail October 2021-present

#### **Mentee Awards**

Savanna Gornisiewicz, 2022 Alachua County Medical Society Poster Symposium finalist, "Serum Exocrine Enzymes as Biomarkers of Response to Immunotherapy in Type 1 Diabetes." Received \$500 scholarship.

Camila Sarcone, 2022 Medical Student Research Program Symposium semifinalist, "Chronic pancreatitis and acinar atrophy by histopathology characterize young nPOD donors with reduced pancreas organ weight and may precede this finding in the progression to type 1 diabetes." Received \$100 prize.

Michael Guyot, 2023-2024 University of Florida AI Scholars Program, "The development of a MACSima imaging cyclic staining (MICS) panel to evaluate exocrine pancreatic pathology in type 1 diabetes (T1D)." Received \$1750 scholarship.

# **Invited Panels**

Internal

#### **UF College of Medicine**

BMS 6091: Health Outcomes and Policy 1, Expert Panel Consult Jan. 2020, 2021Intern 101 Pediatric Pathway: LGBTQ PanelMay 2022

#### External

#### American Academy of Pediatrics

National Conference and Exhibition Residency Admissions Panel Nov. 2018

#### Network for Pancreatic Organ Donors with Diabetes (nPOD)

15<sup>a</sup> Annual Scientific Meeting "WIELD panel: What Brings You Joy? How to Choose a Career Path in T1D Women in Diabetes Research" March 2023

# WGCU Public Media

"Blood Sugar Rising" Panel Discussion	Nov. 2020
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# **Invited Lectures**

#### Internal

Medi-Gators Virtual Shadowing Program	
"A Day in the Life of a Pediatric Endocrinologist."	October 2021
UF Child & Adolescent Psychiatry Fellowship Program	
"Hormonal Treatment for Gender Dysphoria."	March 2022
UF College of Medicine	
BMS 6632: "Intro to Diabetes: Types, Stigma, & Complications."	2022, 2023
BMS 6632: "DKA & HHS: Case-based Learning."	2022, 2023
Intern 101 Pediatric Pathway: "Diabetes in Children."	May 2022
UF Neonatal Grand Rounds	
"Sexual Differentiation and Related Disorders." Nov. 202	1, March 2023
UF OB/GYN Grand Rounds	
"OB/GYN care of transgender and gender-diverse patients."	Nov. 2021
UF OB/GYN Clerkship	
Case-based conference: "Amenorrhea and delayed puberty."	March 2023
UF Pediatric Grand Rounds	
"Hot Topics- 3 Minute Talks. Natural History and Mechanisms of	Exocrine
Dysfunction in Pre-Type 1 Diabetes."	May 2021
"Pediatric Obesity: Avoiding the Pitfalls of Stigma, Bias, and Iner	
Care."	October 2021
UF Pediatric Endocrinology Core Lectures	

	"Placental Passage of Hormones"	February 2022
	"Sexual Differentiation and Related Disorders."	March 2023
	UF Pediatric Residency Program "Diabetes Logistics" "Precocious Puberty"	July 2019 July 2019, Aug 2022
	UF Pensacola Pediatric Residency Program "Cushing Syndrome"	March 2021
External		
LAICIMU	American Academy of Pediatrics	
	Section on Oral Health Webinar "Adding Oral Health to Yo	ur Advocacy
	Agenda."	Feb. 2018
	National Conference and Exhibition Section on Pediatric Trainees Resident	
	Breakout, "SOPT Delegate 101."	Nov. 2018
	American Diabetes Association	
	ADA Focus on Fellows, "Patient Advocacy."	June 2021
	ADA Focus on Fellows, "Identifying Funding."	June 2021
	Webinar, "Standards of Care in Diabetes 2023 Update for I	Early Career
	Professionals."	Jan. 2023
	Lohman Family Diabetes & Wellness Conference	
	"Advancements & Opportunities in the Care of Children with Diabetes" Nov 20	
	Right Care Alliance	
	UF Town Hall, "Insulin Access and Affordability."	July 2018
	UF Diabetes Awareness Fair, "Insulin Access and Affordab	oility." Nov. 2018
	Southern Pediatric Endocrine Society	
	Annual Meeting, "Insulin Affordability for Pediatric Diabete	es Patients." Feb. 2019
	Rotary Club of Marco Island	
	"The COVID-19 Pandemic and Diabetes Care"	Jan. 2021

# **Bibliography**

# **Peer-Reviewed Manuscripts**

 Bruggeman BS, Walker AF, Peters AL, D'Avolio LW, Haller MJ. "Blue Circle Health: A novel patient-centered model of health care delivery for lowincome patients with type 1 diabetes." *J Diabetes Sci Technol.* 2023;0(0). https://doi.org/10.1177/19322968221149008

- So M, O'Rourke C, Ylescupidez A, Bahnson HT, Steck AK, Wentworth JM, Bruggeman BS, Lord S, Greenbaum CJ, Speake C. "Characterizing the Agedependent Effects of Risk Factors on Type 1 Diabetes Progression." *Diabetologia* 2022 Apr;65(4):684-694. <u>https://doi.org/10.1007/s00125-021-05647-5</u>
- Crossen SS, Bruggeman BS, Haller MJ, Raymond JK. "Challenges and Opportunities in Utilizing Telehealth for Diabetes Care." *Diabetes Spectr*. 2022 Feb 15;35(1):33-42. <u>https://doi.org/10.2337/dsi21-0018</u>
- Zimmerman C, Ilstad-Minnihan A, Bruggeman B, Bruggeman B, Dayton K, Joseph N, Moas D, Rohrs H. "Thyroid Storm Caused by Hyperemesis Gravidarum." AACE Clin. Case Rep. 2022 Jan 3;8(3):124-127. https://doi.org/10.1016/j.aace.2021.12.005
- Bruggeman BS, Campbell-Thompson M, Filipp SL, Gurka MJ, Atkinson MA, Schatz DA, Jacobsen LM. "Substance use affects type 1 diabetes pancreas pathology: implications for future studies." *Front Endocrinol.* 2021 Nov;12:1553. <u>https://doi.org/10.3389/fendo.2021.778912</u>
- Bruggeman BS, Bernier A. "Hirsutism and Menstrual Irregularity in a 16year-old Girl." *Pediatr Rev.* 2021 Aug;42(8):449-452. https://doi.org/10.1542/pir.2020-002089
- Lin AS, Mack JA, Bruggeman B, Jacobsen LM, Posgai AL, Wasserfall CH, Brusko TM, Atkinson MA, Gitelman SE, Gottlieb PA, Gurka MJ, Mathews CE, Schatz DA, Haller MJ. "Low-dose ATG/GCSF in Established Type 1 Diabetes: A Five-Year Follow-up Report." *Diabetes*. 2021 May;70(5):1123-1129. <u>https://doi.org/10.2337/db20-1103</u>
- Bruggeman B,\* Zimmerman C,\* LaPorte A, Stalvey M, Filipp SL, Gurka MJ, Silverstein JH, Jacobsen LJ. "Barriers to Retinopathy Screening in Youth and Young Adults with Type 1 Diabetes." *Pediatr Diabetes.* 2021 May;22(3):469-473. <u>https://doi.org/10.1111/pedi.13171</u> \*Equal first authorship
- Foster TP, Bruggeman B, Guedes B, Dayton K. "Seizure Activity in a 3-yearold Girl." *Pediatr Rev.* 2021 Jan;42(S1):S85-S88. https://doi.org/10.1542/pir.2019-0252
- Foster TP, Bruggeman B, Campbell-Thompson M, Atkinson MA, Haller MJ, Schatz DA. "Exocrine Pancreas Dysfunction in Type 1 Diabetes." *Endocr Pract.* 2020 Dec;26(12):1505-1513. <u>https://doi.org/10.4158/EP-2020-0295</u>
- 11. **Bruggeman BS,** Vincent HK, Chi X, Filipp SL, Mercado R, Modave F, Guo Y, Gurka MJ, Bernier A. "Simple tests of cardiorespiratory fitness in a

pediatric population." *PLOS ONE*. 2020 Sep;15(9):e0238863. https://doi.org/10.1371/journal.pone.0238863

- 12. Zimmerman C,\* Bruggeman B,\* LaPorte A, Kaushal S, Stalvey M, Beauchamp G, Dayton K, Hiers P, Filipp SL, Gurka MJ, Silverstein JH, Jacobsen LJ. "Real-world Screening for Retinopathy in Youth with Type 1 Diabetes Using a Non-mydriatic Fundus Camera." *Diabetes Spectr.* 2020 Sep; ds200017. <u>https://doi.org/10.2337/ds20-0017</u> \*Equal first authorship
- Morris HL, Donahoo WT, Bruggeman B, Zimmerman C, Hiers P, Zhong VW, Schatz D. "An Iterative Process for Identifying Pediatric Patients with Type 1 Diabetes: Retrospective Observational Study." *JMIR Med Inform.* 2020 Sep;8(9):e18874. <u>https://doi.org/10.2196/18874</u>
- Walker AF, Haller MJ, Gurka MJ, Bruggeman B, Miller K, Foster N, Anez Zabala C, Schatz DA. "Addressing Health Disparities in Type 1 Diabetes through Peer Mentorship." *Pediatr Diabetes*. 2020 Feb;21(1):120-127. https://doi.org/10.1111/pedi.12935
- 15. Bruggeman BS, Albanese-O'Neill, A. "From Pediatric to Adult Diabetes Care: Strategies for Success." *Practical Diabetology*. 2019 Aug. Retrieved from: <u>https://www.diabetesselfmanagement.com/practical-diabetology/newstools/pediatric-adult-diabetes-care-strategies-success/</u>
- 16. Bruggeman BS, Schatz DA. "Enhanced Understanding of the Natural History of Pre-Type 1 Diabetes: Fundamental to Prevention." *Pediatr Endocrinol Rev.* 2019 Mar;16(3):359-368. https://doi.org/10.17458/per.vol16.2019.bs.pretype1diabetes

## Expert Commentary

- Bruggeman BS, Schatz DA. "The ISPAD Clinical Practice Consensus Guidelines 2022: how far we have come and the distance still to go." *Lancet Diabetes Endocrinol.* 2023 Mar 24;S2213-8587(23)00083-9. https://doi.org/10.1016/S2213-8587(23)00083-9
- Bruggeman BS, Campbell-Thompson MC. Expert Commentary, "2-Year Remission of Type 2 Diabetes and Pancreas Morphology." *Practice Update* October 2020. <u>https://www.practiceupdate.com/content/2-year-remission-of-</u> type-2-diabetes-and-pancreas-morphology/107876
- 3. Bruggeman BS. "Fertile, fat, and forty." The Yale Journal for Humanities in<br/>Medicine.11May2014.http://yjhm.yale.edu/essays/bbruggeman20140511.htm

# Peer-Reviewed Conference Proceedings and Abstracts

**International/National Presentations** 

- Guyot M, Williams M, Bumgarner BM, Brusko M, Campbell-Thompson M, Wasserfall C, Bruggeman B. "The development of a MACSima imaging cyclic staining (MICS) panel to evaluate exocrine pancreatic pathology in type 1 diabetes (T1D)." Poster at Network for Pancreatic Organ Donors with Diabetes 15<sup>th</sup> Annual Meeting, February 2023.
- Sarcone C, Turk L, Jacobsen L, Campbell-Thompson M, Bruggeman B. "Chronic Pancreatitis and Acinar Atrophy by Histopathology Characterize Young nPOD Donors with Reduced Pancreas Organ Weight and May Precede this Finding in the Progression to Type 1 Diabetes." Poster at Network for Pancreatic Organ Donors with Diabetes 15<sup>th</sup> Annual Meeting, February 2023.
- 3. Bruggeman BS, Gomisiewicz S, McGrail K, Gonzalez N, Wasserfall C, Campbell-Thompson M, Atkinson M, Haller M, Schatz D. "Serum Exocrine Enzymes as Biomarkers of Response to Immunotherapy in Type 1 Diabetes." Oral presentation at *NIH NIDDK Integrated Physiology of the Exocrine and Endocrine Compartments in Pancreatic Diseases Workshop*, June 2022.
- 4. **Bruggeman BS**, McGrail K, Gonzalez N, Wasserfall C, Campbell-Thompson M, Atkinson M, Haller M, Schatz D. "A Serum Exocrine Enzyme as a Biomarker of Response to Immunotherapy in Type 1 Diabetes." Poster at *CAPER PancreasFest*, July 2022.
- 5. Bruggeman BS, Gomisiewicz S, McGrail K, Gonzalez N, Wasserfall C, Campbell-Thompson M, Atkinson M, Haller M, Schatz D. "Serum Exocrine Enzymes as Biomarkers of Response to Immunotherapy in Type 1 Diabetes." Oral presentation at NIH NIDDK Integrated Physiology of the Exocrine and Endocrine Compartments in Pancreatic Diseases Workshop, June 2022.
- Gornisiewicz S, McGrail K, Gonzalez N, Wasserfall C, Campbell-Thompson M, Atkinson M, Haller M, Schatz D, Bruggeman BS. "Serum Exocrine Enzymes as Biomarkers of Response to Immunotherapy in Type 1 Diabetes." Poster at NIH NIDDK Integrated Physiology of the Exocrine and Endocrine Compartments in Pancreatic Diseases Workshop, June 2022.
- Bruggeman BS, McGrail K, Gonzalez N, Wasserfall C, Campbell-Thompson M, Atkinson M, Haller M, Schatz D. "A Serum Exocrine Enzyme as a Biomarker of Response to Immunotherapy in Type 1 Diabetes." Poster at Association for Clinical and Translational Science Annual Meeting, April 2022. <u>https://doi.org/10.1017/cts.2022.192</u>
- Bruggeman BS, McGrail K, Gonzalez N, Wasserfall C, Campbell-Thompson M, Atkinson M, Haller M, Schatz D. "A Serum Exocrine Enzyme as a Biomarker of Response to Immunotherapy in Type 1 Diabetes." Poster at *Pediatric Endocrine Society Annual Meeting*, April 2022.

- Zimmerman C, Ilstad-Minnihan A, Bruggeman B, Bruggeman B, Dayton K, Joseph N, Moas D, Rohrs H. "Thyroid Storm Caused by Hyperemesis Gravidarum." Poster at American Association of Clinical Endocrinology Annual Meeting 2021: Envision. Virtual. May-June 2021.
- 10. Bruggeman B. "Mechanisms of Exocrine Dysfunction in Type 1 Diabetes." Oral Presentation at *Seventh Annual Endocrine Fellows Foundation Diabetes, Obesity, and Metabolism Research Forum.* February 2021.
- Bruggeman BS, Beachy D, Jacobsen LM, Nick HS, Atkinson MA, Schatz D, Wasserfall C. "Role of mTORC1 Regulation in the T1D Organ Donor Pancreas." Poster at *American Diabetes Association Annual Meeting*, June 2020. <u>https://doi.org/10.2337/db20-1637-P</u>
- 12. Bruggeman BS, Bernier A. "Ovarian Venous Sampling Supports the Diagnosis of a Rare Virilizing Tumor in a Pediatric Patient." Poster at *Pediatric Endocrine Society Annual Meeting*, April 2020 (meeting canceled).
- Bruggeman BS, Campbell-Thompson MA, Posgai AL, Atkinson MA, Schatz D, Jacobsen LM. "Effect of Substance Use on Type 1 Diabetes Pancreas Histopathology." Poster at *American Diabetes Association Annual Meeting*, June 2019. <u>https://doi.org/10.2337/db19-1366-P</u>
- Bruggeman BS, Vincent HK, Chi X, Filipp SL, Mercado R, Modave F, Guo Y, Gurka MJ, Bernier A. "Simple Tests of Cardiorespiratory Fitness in a Pediatric Population: A Feasibility Study." Poster at *Pediatric Academic Society Annual Meeting*, April 2019.
- 15. Bruggeman B, Dayton K. "An Unusual Presentation of Pseudohypoparathyroidism Type 1a Associated with a Novel GNAS Mutation and Vitamin D Deficiency." Guided Presidential Poster Session at Endocrine Society Annual Meeting, March 2019. <u>https://doi.org/10.1210/js.2019-MON-252</u>
- Morris HL, Donahoo WT, Bruggeman B, Zimmerman C, Hiers P, Zhong VW, Schatz D. "Development of a Computable Phenotype for Youth with Type 1 Diabetes." Poster at *American Public Health Association Annual Meeting*, Nov. 2018.
- Walker AF, Haller MJ, Gurka MJ, Morris HL, Anez-Zabala C, Bruggeman BS, Guiffre D, Rohrs H, Atkinson MA, Schatz D. "Promoting Health Equity in Type 1 Diabetes through Peer Mentorship-Findings from the All for ONE Randomized Controlled Trial." Moderated Poster Discussion at *American Diabetes Association Annual Meeting*, June 2018. <u>https://doi.org/10.2337/db18-1371-P</u>

- Walker AF, Johnson C, Anez-Zabala C, Dorvil SR, Haller MJ, Gurka MJ, Bruggeman BS, Guiffre D, Atkinson MA, Schatz I, Schatz D. "A Content Analysis of Text Messages in a Type 1 Diabetes Peer Mentoring Program-The Importance of Shared Interests." Poster at *American Diabetes Association Annual Meeting*, June 2018. <u>https://doi.org/10.2337/db18-844-P</u>
- Zimmerman C, Bruggeman B, LaPorte A, Kaushal S, Stalvey M, Beauchamp G, Dayton K, Hiers P, Filipp SL, Gurka MJ, Silverstein JH, Jacobsen LJ. "Prevalence and Characterization of Retinopathy in Children with Type 1 Diabetes Using a Non-mydriatic Fundus Camera." Poster at American Diabetes Association Annual Meeting, Aug. 2017.
- 20. Sorensen B, Silverstein J. "Comparison of effectiveness of Glulisine, Lispro, and Aspart in decreasing post-prandial hyperglycemia in a real-world setting." Poster at *Pediatric Academic Societies Annual Meeting*, May 2013.

#### **Regional Presentations**

- Gornisiewicz S, McGrail K, Gonzalez N, Wasserfall C, Campbell-Thompson M, Atkinson M, Haller M, Schatz D, Bruggeman BS. "Serum Exocrine Enzymes as Biomarkers of Response to Immunotherapy in Type 1 Diabetes." Poster at FCAAP 8<sup>th</sup> Annual Pediatric Research Forum for Medical Students, September 2022.
- Bruggeman B, Zimmerman C, LaPorte A, Kaushal S, Stalvey M, Beauchamp G, Dayton K, Hiers P, Filipp SL, Gurka MJ, Silverstein JH, Jacobsen LJ. "Prevalence and Characterization of Retinopathy in Children with Type 1 Diabetes Using a Non-mydriatic Fundus Camera." Poster at *Children with Diabetes Friends for Life Conference*, July 2018.
- Bruggeman B, Zimmerman C, LaPorte A, Kaushal S, Stalvey M, Beauchamp G, Dayton K, Hiers P, Filipp SL, Gurka MJ, Silverstein JH, Jacobsen LJ. "Prevalence and Characterization of Retinopathy in Children with Type 1 Diabetes Using a Non-mydriatic Fundus Camera." Poster at *Florida Medical Association David A. Paulus, MD Poster Symposium*, Aug. 2017.
- 4. **Bruggeman B.** "Comparison of effectiveness of Glulisine, Lispro, and Aspart in decreasing post-prandial hyperglycemia in a real-world setting." Oral presentation at *FCAAP Pediatric Medical Student Research Forum*, Aug. 2014.
- 5. **Sorensen B**, Simpson N. "Developing methods to optimize efficacy of a bioartificial pancreas as a therapy for type 1 diabetes in a C3H/HeN mouse model." Poster at *Furman Engaged Research Symposium*, April 2011.

 Sorensen B, Simpson N. "Developing methods to optimize efficacy of a bioartificial pancreas as a therapy for type 1 diabetes in a C3H/HeN mouse model." Poster at *Florida Statewide Student Research Symposium*, March 2011.

#### **Local Presentations**

- Guyot M, Williams M, Bumgarner BM, Brusko M, Campbell-Thompson M, Wasserfall C, Bruggeman B. "The development of a MACSima imaging cyclic staining (MICS) panel to evaluate exocrine pancreatic pathology in type 1 diabetes (T1D)." Poster at 2023 Spring Undergraduate Research Symposium, April 2023.
- 2. Guyot M, Williams M, Bumgarner BM, Brusko M, Campbell-Thompson M, Wasserfall C, **Bruggeman B**. "The development of a MACSima imaging cyclic staining (MICS) panel to evaluate exocrine pancreatic pathology in type 1 diabetes (T1D)." Poster at *STEM at UF Research Symposium*, March 2023.
- Guyot M, Williams M, Bumgarner BM, Brusko M, Campbell-Thompson M, Wasserfall C, Bruggeman B. "The development of a MACSima imaging cyclic staining (MICS) panel to evaluate exocrine pancreatic pathology in type 1 diabetes (T1D)." Poster at 13<sup>th</sup> annual UF College of Medicine Celebration of Research, February 2023.
- 4. Sarcone C, Turk L, Jacobsen L, Campbell-Thompson M, Bruggeman B. "Chronic Pancreatitis and Acinar Atrophy by Histopathology Characterize Young nPOD Donors with Reduced Pancreas Organ Weight and May Precede this Finding in the Progression to Type 1 Diabetes." Poster at 13<sup>th</sup> annual UF College of Medicine Celebration of Research, February 2023.
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- 6. Bruggeman BS. "Exocrine Pancreas Pathology in Type 1 Diabetes." Oral Presentation at *UF Pediatrics Fellows Research Conference*, January 2021.
- 7. Bruggeman BS. "Exocrine Pancreas Pathology in Type 1 Diabetes." Oral Presentation at *UF Pediatrics Fellows Research Conference*, May 2020.
- Bruggeman BS, Campbell-Thompson MA, Posgai AL, Atkinson MA, Schatz D, Jacobsen LM. "Effect of Substance Use on Type 1 Diabetes Pancreas Histopathology." Poster at UF Diabetes Institute World Diabetes Day Poster Session, Nov. 2019.

- 9. Bruggeman BS. "Simple Tests of Cardiorespiratory Fitness in a Pediatric Population: A Feasibility Study." Oral Presentation at *UF Pediatric Science Day*, June 2019.
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- Zimmerman C, Morris HL, Donahoo WT, Bruggeman B, Hiers P, Zhong VW, Schatz D. "Development of a Computable Phenotype for Youth with Type 1 Diabetes." Poster at UF Pediatric Science Day, June 2018.
- 12. Bruggeman B, Guiffre D, Walker A. "Improving Type 1 Diabetes Compliance Using a Mentorship Program." Poster at UF Health Pediatric Residency Quality Improvement Symposium, Aug. 2017.
- Bruggeman B, Zimmerman C, LaPorte A, Kaushal S, Stalvey M, Beauchamp G, Dayton K, Hiers P, Filipp SL, Gurka MJ, Silverstein JH, Jacobsen LJ. "Prevalence and Characterization of Retinopathy in Children with Type 1 Diabetes Using a Non-mydriatic Fundus Camera." Poster at UF Pediatric Science Day, May 2017.
- Bruggeman BS, Zimmerman C. "Prevalence and Characterization of Retinopathy in Children with Type 1 Diabetes Using a Non-mydriatic Fundus Camera." Oral Presentation at UF Pediatrics Fellows Research Conference, Nov. 2016.
- 15. **Sorensen B**, Silverstein J. "Comparison of effectiveness of Glulisine, Lispro, and Aspart in decreasing post-prandial hyperglycemia in a real-world setting." Poster at *University of Florida Medical Student Research Day*, April 2013.
- 16. Sorensen B, Simpson N. "Developing methods to optimize efficacy of a bioartificial pancreas as a therapy for type 1 diabetes in a C3H/HeN mouse model." Poster at *Junior Honors Medical Program Research Symposium*, April 2011.
- 17. **Sorensen B**, Simpson N. "Developing methods to optimize efficacy of a bioartificial pancreas as a therapy for type 1 diabetes in a C3H/HeN mouse model." Poster at *HHMI Creativity in the Arts and Sciences Event*, Jan. 2011.

# **Ongoing Research Support**

#### NIH NIDDK K23 Career Development Award

Role: Mentored PIJanuary 2023-November 2026Title: "Natural History and Mechanisms of Exocrine Pancreatic Dysfunction in<br/>Pre-Type 1 Diabetes."

This project aims to investigate the natural history and role of exocrine loss in pre-T1D while cultivating the skills and experience necessary to establish an independent career as a physician scientist in T1D clinical and translational research.

# Georgia Center for Diabetes Translation Research 2022 Pilot and Feasibility Program Cycle

Role: PI

February 2023-January 2024

Title: "A Provider-Facing EHR-Based Dashboard to Improve Health Equity in Type 1 Diabetes."

This project aims to conceptualize and create capacity for a T1D Technology Health Equity Dashboard within the University of Florida and Emory University Health systems.

# NIH NIDDK Extramural Loan Repayment Program for Pediatric

#### Research

Role: Mentored PI

July 2022-June 2024

Title: "Natural History and Mechanisms of Exocrine Pancreatic Dysfunction in Pre-Type 1 Diabetes."

This project aims to investigate the natural history of exocrine loss in T1D by measuring fecal elastase throughout the course of pre-T1D and to investigate exocrine autoimmunity as a potential mechanism for exocrine dysfunction in T1D while cultivating the skills and experience necessary to establish an independent career as a physician scientist in T1D clinical and translational research.

# NIH NIDDK R03: New Investigator Gateway Awards for Collaborative T1D Research

Role: PI

September 2021-August 2023

Title: "Natural History and Mechanisms of Exocrine Dysfunction in Pre-Type 1 Diabetes."

This project aims to investigate the natural history of exocrine loss in T1D by measuring fecal elastase throughout the course of pre-T1D within two different cohorts: The Environmental Determinants of Diabetes in the Young (TEDDY) study and a T1D TrialNet prospective ancillary study.

## Pediatric Endocrine Society Clinical Scholar Award

Role: Mentored PIJuly 2021-June 2023Title: "Natural History and Mechanisms of Exocrine Dysfunction in Pre-Type 1Diabetes."

This project aims to investigate the natural history of exocrine loss in T1D by measuring fecal elastase throughout the course of pre-T1D and to investigate exocrine autoimmunity as a potential mechanism for exocrine dysfunction in T1D.

# **Completed Grants**

# University of Florida Clinical and Translational Research Institute KL2 Career Development Award

Role: Mentored PI

July 2021-June 2023

Title: "Natural History and Mechanisms of Exocrine Dysfunction in Pre-Type 1 Diabetes."

This project aims to investigate the natural history of exocrine loss in T1D by measuring fecal elastase throughout the course of pre-T1D and to investigate exocrine autoimmunity as a potential mechanism for exocrine dysfunction in T1D while cultivating the skills and experience necessary to establish an independent career as a physician scientist in T1D clinical and translational research.

# UF Medical Student Research Program Grant June 2011-July 2011 Role: Mentored PI

Title: "Comparison of Effectiveness of Glulisine, Lispro, and Aspart in decreasing post-prandial hyperglycemia in a real-world setting."

This project was a randomized, open-label trial that aimed to compare the glycemic excursion following food intake and post-meal injection of Apidra, Humalog, and Novolog insulins in a diabetes camp for children.

# American Academy of Pediatrics Community Access to Child Health<br/>(CATCH) Resident GrantJune 2018-August 2019

Role: Mentored co-PI

Title: "Health Smiles Day Initiative."

This project trained pediatric residents in oral health exams and provide free basic dental care, education, and referrals in an underserved area of Gainesville on an annual to biannual basis.

# UF Children's Miracle Network Fellow Grant June 2018-June 2019

Role: Mentored co-PI

Title: "Fundal Photography as a Screening Tool for Diabetic Retinopathy in Pediatric Type 2 Diabetes."

This project aimed to assess the feasibility of screening for retinopathy in the pediatric type 2 diabetes patient population using a non-mydriatic fundus camera.

# **Inaugural McJunkin Family Type 1 Diabetes Fellow** July 2018-July 2019 Role: PI

Awarded to fellows committed to careers as clinician-scientists in type 1 diabetes. Funds one year of pediatric endocrinology fellowship.

UF Children's Miracle Network Fellow Grant June 2019-June 2020 Role: Mentored PI Title: "Mechanisms of Exocrine Dysfunction in Type 1 Diabetes." This project aims to elucidate the relationship between AUC C-peptide, markers of immune function, and serum markers of exocrine pancreatic function in subjects enrolled in the clinical trial: "Antithymocyte Globulin (ATG) and pegylated granulocyte colony stimulating factor (GCSF) in New Onset Type 1 Diabetes."

# Pediatric Endocrine Society Rising Star AwardJan. 2019-March 2021Role: Mentored PI

Title: "Mechanisms of Exocrine Dysfunction in Type 1 Diabetes." This project aims to elucidate the relationship between AUC C-peptide, markers of immune function, and serum markers of exocrine pancreatic function in subjects enrolled in the clinical trial: "Antithymocyte Globulin (ATG) and pegylated granulocyte colony stimulating factor (GCSF) in New Onset Type 1 Diabetes."

# University of Florida Clinical and Translational Research Institute Pilot Award July 2019-June 2021

Role: Mentored PI

Title: "Mechanisms of Exocrine Dysfunction in Type 1 Diabetes." This project aims to elucidate the relationship between AUC C-peptide, markers of immune function, and serum markers of exocrine pancreatic function in subjects enrolled in the clinical trial: "Antithymocyte Globulin (ATG) and pegylated granulocyte colony stimulating factor (GCSF) in New Onset Type 1 Diabetes."

## **Douglas J. Barrett, MD Academic Fellowship Award** June 2020-June 2021 Role: PI

Title: "Mechanisms of Exocrine Dysfunction in Type 1 Diabetes." Awarded to one fellow per year for highest qualities of scholarly activity in research, teaching, and patient care. Funds one year of pediatric endocrinology fellowship.

## **Endocrine Fellows Foundation Research Grant** Jan. 2019-Dec. 2021 Role: Mentored PI

Title: "Mechanisms of Exocrine Dysfunction in Type 1 Diabetes."

This project aims to elucidate the relationship between AUC C-peptide, markers of immune function, and serum markers of exocrine pancreatic function in subjects enrolled in the clinical trial: "Antithymocyte Globulin (ATG) and pegylated granulocyte colony stimulating factor (GCSF) in New Onset Type 1 Diabetes."

Case 4:23-cv-00114-RH-MAF Document 176-3 Filed 11/06/23 Page 56 of 58

# Exhibit B

PL000681

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