HONORABLE JUDGE ROBERT J. BRYAN

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT TACOMA

C. P., by and through his parents, Patricia Pritchard and Nolle Pritchard; and PATRICIA PRITCHARD, Plaintiffs, vs. BLUE CROSS BLUE SHIELD OF ILLINOIS, Defendant.	Case No. 3:20-cv-06145-RJB **DECLARATION OF MICHAEL K. LAIDLAW, M.D. IN SUPPORT OF BLUE CROSS BLUE SHIELD OF ILLINOIS'S SUPPLEMENTAL DECERTIFICATION BRIEF** **NOTE ON MOTION CALENDAR: November 20, 2023**

Pursuant to 28 U.S.C. § 1746, I, Michael K. Laidlaw, M.D., hereby declare as follows:

1. My name is Michael K. Laidlaw. I am over the age of eighteen and submit this expert declaration based on my personal knowledge and experience.

2. I am a board-certified endocrinologist. I received my medical degree from the University of Southern California in 2001. I completed my residency in internal medicine at Los Angeles County/University of Southern California Medical Center in 2004. I also completed a fellowship in endocrinology, diabetes, and metabolism at Los Angeles County/University of Southern California Medical Center in 2006.

3. I am board certified by (1) the National Board of Physicians and Surgeons for Endocrinology, Diabetes & Metabolism, (2) the National Board of Physicians and Surgeons for

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Internal Medicine, and (3) the American Board of Internal Medicine for Endocrinology, Diabetes and Metabolism.

4. The reason that endocrinologists become involved in the treatment of gender dysphoria is that gender dysphoria, a psychiatric issue, may be interrelated with hormone and gland disorders. The Endocrine Society has issued guidelines for the diagnosis and treatment of gender dysphoria.

5. On August 3, 2022, I offered an expert opinion in the above-referenced action. *See* Dkt. 88-1, Ex. K. That declaration contains my qualifications in more detail.

6. I have reviewed the documents that BCBSIL has related to plaintiff S.L. *See* BCBSIL_CP_0023389-BCBSIL_CP_0023632.

7. To determine whether S.L.'s requested treatment is medically necessary, a number of factors need to be considered, including a diagnosis of gender dysphoria by a qualified medical health professional; an examination of the patient's psychological health, family and social situation; the pubertal stage of the patient; an examination of the informed consent procedures that were followed prior to administering medication or performing surgeries related to gender dysphoria; and an individualized assessment of the potential health risks of medications and/or surgeries considered for the treatment of gender dysphoria.

S.L.'s Gender-Affirming Care Treatment

8. S.L. was born on August 30, 2011. Based on demographic information, S.L. was identified at birth to have genitalia corresponding to the male sex. (BCBSIL_CP_0023392.) According to the records, on March 30, 2022, when S.L. was 10 years old, procedure code J1950 was performed, which represents an injection of 3.75 mg of the puberty blocker leuprolide acetate known as Lupron Depot (AbbVie, 2023). The accompanying diagnosis code of F642 on that date stands for "gender identity disorder of childhood." From this evidence, we can infer that the puberty blocker leuprolide was injected into the patient at age 10 for the purpose of blocking normal adolescent pubertal development. There are a number of important health implications to blocking normal puberty, particularly at that age, discussed in further detail below.

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Diagnosis of Gender Dysphoria

9. There is no evidence from the documents I reviewed that S.L. received a psychological evaluation by a qualified mental health professional before receiving a diagnosis of gender dysphoria.

10. The Endocrine Society in 2017 issued a guideline for the treatment of gender dysphoric persons ("Endocrine Society Guidelines" or "ESG") (Hembree et al., 2017). With respect to adolescents, the Endocrine Society Guidelines state as follows:

> We advise that only MHPs [mental health professionals] who meet the following criteria should diagnose GD [gender dysphoria]/gender incongruence in children and adolescents: (1) training in child and adolescent developmental psychology and psychopathology, (2) competence in using the DSM and/or the ICD for diagnostic purposes, (3) the ability to make a distinction between GD/gender incongruence and conditions that have similar features (e.g., body dysmorphic disorder), (4) training in diagnosing psychiatric conditions, (5) the ability to undertake or refer for appropriate treatment, (6) the ability to psychosocially assess the person's understanding and social conditions that can impact gender-affirming hormone therapy, (7) a practice of regularly attending relevant professional meetings, and (8) knowledge of the criteria for puberty blocking and gender-affirming hormone treatment in adolescents.

(Hembree et al., 2017).

11. Similarly, the World Professional Organization of Transgender Health ("WPATH") issued a guideline in 2012 called the WPATH Standards of Care 7 ("SOC 7")[1] (Coleman et al., 2012). The SOC 7 states that "[b]efore any physical interventions are considered for adolescents, extensive exploration of psychological, family, and social issues should be undertaken." (*Id.*)

12. There is no evidence from the documents I reviewed that a qualified mental health professional meeting the ESG criteria has diagnosed S.L. with gender dysphoria. There is also no evidence from the records I reviewed that "extensive exploration of psychological, family, and social issues" has been undertaken for S.L., as recommended by the WPATH SOC 7.

[1] The SOC 7 was in effect when S.L. was initially treated.

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13. Likewise, WPATH's Standards of Care 8 ("SOC 8"), published in 2022, recommend ensuring the following criteria have been fulfilled for adolescents before initiating puberty blockers:

- A comprehensive biopsychosocial assessment has been undertaken, including relevant mental health and medical professionals;
- Gender diversity/incongruence is marked and sustained over time;
- The adolescent meets the diagnostic criteria of gender incongruence in situations where a diagnosis is necessary to access health care; and
- Mental health concerns (if any) that may interfere with diagnostic clarity, capacity to consent, and gender-affirming medical treatments have been sufficiently addressed so that gender-affirming medical treatment can be provided optimally (Coleman et al., 2022, p. S256)

14. Evidence has not been provided that the criteria of SOC 8 were fulfilled prior to SL beginning puberty blocker treatment.

15. Without a diagnosis of gender dysphoria by a qualified mental health professional, it would be inappropriate to determine the medical necessity of a puberty blocking medication like Lupron Depot to block S.L.'s normal pubertal development.

Determination of Pubertal Stage

16. The ESG state that puberty blockers may be started "after girls and boys first exhibit physical changes of puberty." (Hembree et al., 2017, p. 3871) Furthermore, the ESG recommends "against puberty blocking and gender-affirming hormone treatment in prepubertal children with GD/gender incongruence." (*Id.*) The SOC 7 states that "[i]n order for adolescents and their parents to make an informed decision about pubertal delay, it is recommended that adolescents experience the onset of puberty to at least Tanner Stage 2." (Coleman et al., 2012) Similarly, SOC 8

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recommends that the patient has "[r]eached Tanner stage 2" prior to initiating puberty blockers (Coleman et al., 2022).

17. There is no evidence in the documents I reviewed describing S.L.'s stage of pubertal development preceding the leuprolide injection at age 10.[2] Therefore, medical necessity cannot be determined with respect to the stage of pubertal development. For example, if S.L. were found to be pre-pubertal as of the day of injection, then, per the ESG, puberty blocking medication would not be indicated based on the stage of sexual development.

Side Effects of Lupron Depot

18. The prescribing information for Lupron Depot contains a long list of potential side effects. It is important to rule out any side effects of a medication prior to providing subsequent doses or to changing to another similar puberty blocking medication like Histrelin.

19. The documents I reviewed state that S.L. received an injection of Lupron Depot on or around March 30, 2022.

20. On April 2, 2022, just three days after the Lupron injection, S.L. was seen for a new patient office visit (BCBSIL_CP_0023632, "Line by Line"). Multiple diagnostic codes were attached to the visit:

- Segmental and somatic dysfunction of thoracic region (Diagnosis Code M99.02)
- Segmental and somatic dysfunction of cervical region (Diagnosis code M 9901)
- Segmental and somatic dysfunction of lower extremity (Diagnosis code M 9906)
- Segmental and somatic dysfunction of lumbar region (Diagnosis code M 9903)

[2] From a medical perspective, it is important to know the stage of pubertal development of the developing adolescent. This can be determined through a physical examination of the body. The female will have changes in breast characteristics and pubic hair development. Similarly, the male will have changes in testicular size and pubic hair development. These findings can be compared to the Tanner staging system, which is divided into five stages. Stage 1 is the pre-pubertal state before pubertal development of the child begins. Stages 2 through 4 are various phases of pubertal development. Stage 5 is full adult sexual maturity. (Greenspan and Gardner, 2004).

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21. These various forms of dysfunction refer to disorders involving impairment or altered function of the body framework. These types of dysfunction may present after an injection of leuprolide and correlate with side effects described in the product labeling, including leg cramps and paresthesias, peripheral neuropathy, paralysis, symptoms consistent with fibromyalgia, and tenosynovitis-like symptoms (AbbVie Inc., 2023). In my opinion, any of these side effects could lead to a preliminary diagnosis of segmental and somatic dysfunction.

22. With respect to medical necessity, it would be important to rule out the injection of Lupron Depot as a cause of these diagnoses, given the close proximity in time of the April 2, 2022 office visit to the March 30, 2022 injection. To determine medical necessity, medical record evidence would help clarify the nature of the office visit, including the history and physical exam findings.

Surgical Procedure for the Introduction of Histerelin

23. According to the claims data for S.L., on May 24, 2022, when S.L. was age 10, a surgical procedure was performed on S.L. for the introduction of a Histrelin implant.

24. The Histrelin implant is a puberty blocking medication "indicated for the treatment of children with central precious puberty." (*Id.*) According to the product labeling, "[e]ach implant contains 50 mg histrelin acetate. The implant is inserted subcutaneously in the inner aspect of the upper arm and provides continuous release of histrelin acetate (65 mcg/day) for 12 months of hormonal therapy," after which it is removed. (*Id.* at 2) The implant is inserted by a surgical procedure. (*Id.* at 2)

25. According to the prescribing information, the implant is placed subcutaneously (under the skin) of the inner aspect of the upper arm by means of a surgical procedure that involves typical surgical aspects, including setting up a sterile field, swabbing the area with a topical antiseptic, supplying local anesthesia (or general anesthesia), making a surgical incision with a sterile scalpel, and closing the incision with absorbable sutures or adhesive surgical strips. (*Id.*, p 3-8)

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26. The diagnostic code for this procedure was F642, which stands for "Gender identity disorder of childhood." From this diagnostic code, we can infer that the puberty blocking implant Histrelin was surgically implanted in the patient at age 10 for the purpose of blocking normal adolescent pubertal development. The Histrelin implant could not have been implanted for the FDA-indicated treatment of central precocious puberty because S.L. was already beyond the age of that diagnosis, which means the Histrelin implant was implanted off-label.

27. Similar to the Lupron Depot injection, prior to implantation of the Histrelin implant it is crucial that a minor patient's stage of sexual development be determined by physical exam. There is no evidence from the documents I reviewed that such a physical exam was conducted.

28. To establish medical necessity of the Histrelin implant, it is also essential that a qualified mental health professional conduct a psychological evaluation prior to implantation. It is also important to ensure that an "extensive exploration of psychological, family, and social issues" is undertaken, as recommended by the WPATH SOC 7, or a "comprehensive biopsychosocial assessment including relevant mental health and medical professionals" and mental health concerns have been addressed "so that gender-affirming medical treatment can be provided optimally," as per the SOC 8. There is no evidence from the documents I reviewed that the criteria set forth in either the ESG or WPATH's SOC 7 or SOC 8 had been fulfilled prior to S.L.'s Histrelin implant surgery.

Informed Consent

29. The ESG states that before starting puberty blocking medication, in order to determine eligibility, a medical provider must ensure that the patient:

> has been informed of the effects and side effects of treatment (including potential loss of fertility if the individual subsequently continues with sex hormone treatment) and options to preserve fertility,
>
> has 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.

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(Hembree et al., 2017). SOC 7 states that prior to initiating puberty blockers it must be ensured that "[t]he adolescent has given informed consent and, particularly when the adolescent has not reached the age of medical consent, the parents or other caretakers or guardians have consented to the treatment and are involved in supporting the adolescent throughout the treatment process." (Coleman et al., 2012) Similarly, SOC 8 recommends ensuring that the patient "demonstrates the emotional and cognitive maturity required to provide informed consent/assent for the treatment" (Coleman et al., 2022, p. S257) There is no evidence from the documents I reviewed that such informed consent procedures had taken place for S.L.

Iatrogenic Harm

30. The term "iatrogenic" is used in medicine to describe harms or newly created medical conditions that are the result of a treatment. For example, if an individual with normal blood pressure was prescribed a blood pressure medication, subsequently developed low blood pressure, and then fell as a result of the wrongly-prescribed medication, the resulting harm would be called iatrogenic because it occurred due to a medication prescribed when it was not medically necessary or indicated.

31. On August 16, 2023, records indicate that S.L. had a venous procedure to draw blood for various labs including FSH, LH, and testosterone. These labs would typically be drawn to ensure that these levels are sufficiently low after administering puberty blocking medication. In this case, without evidence that the administration of Histrelin was medically necessary, the labs were drawn as a result of iatrogenic injury. Specifically, the puberty blocking medication Histrelin iatrogenically causes hypogonadotropic hypogonadism. This condition is diagnosed by performing a laboratory exam of these same tests for LH, FSH, and testosterone. Had S.L. not received Histrelin, there would be no need to draw blood to perform these tests.

Health Implications of Blocking Normal Puberty

32. It is particularly important that these steps (pubertal staging, psychiatric evaluation, informed consent, and analysis of side effects) be followed prior to surgically implanting the Histrelin implant because the medication will be effective for an entire year. This means that an

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entire year of normal adolescent pubertal development will be put on hold while a hormonal medication takes effect, which can have negative health impacts on fertility, bone, density, and mental health and brain development.

Negative Effects of Blocking Normal Puberty on Fertility

33. There are a number of serious health consequences that occur as the result of blocking normal puberty, including infertility.

34. Gonadotropin Releasing Hormone Analogues ("GnRHa") such as Lupron Depot and Histerelin freeze the maturation and release of mature eggs in the female and stop testicular development and the production of mature sperm in the male. Therefore, GnRHAs immediately cause infertility, but the impact could be transient if the person discontinues the medication.[3] However, even greater concern arise when a minor's puberty is stopped at an early stage and then opposite sex hormones are administered in gender affirmative therapy ("GAT"). This combination of treatments has profoundly negative effects on fertility.

35. The Endocrine Society Guidelines recommend beginning puberty blockers as early as Tanner stage 2. As discussed earlier, this is the very beginning of puberty, and fertility development typically happens later, in Tanner stage 4. For example, if a minor receives puberty blockers at Tanner stage 2 or 3 as advocated by the ESG, the minor would not yet be fertile and the gonads would remain in an immature, undeveloped state.

36. If the gonads remain blocked in an early pubertal stage, then even the addition of opposite sex hormones will not allow for the development of fertility. In fact, high dose opposite sex hormones may permanently damage the immature sex organs leading to sterilization. And it is without question that the removal of the gonads by surgery would ensure sterilization.

37. For example, in a Dutch study by de Vries et al., seventy adolescents who took puberty blockers progressed to taking hormones of the opposite sex. (de Vries, et al. 2011) In a

[3] However, there are no studies that I am aware of containing adolescents who had puberty stopped at Tanner Stage II by GnRHa and then remained on this medication for an extended period of time to see if puberty would progress normally.

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follow-up study by de Vries et al., the overwhelming majority went on to have sex reassignment surgery by either vaginoplasty for males or hysterectomy with ovariectomy for females. (de Vries, et al. 2014) These surgeries resulted in sterilization. This is why puberty blockers, rather than being a "pause" to consider aspects of mental health, are instead a pathway towards potentially sterilizing hormonal treatments and sterilizing surgeries.

38. As mentioned previously, the ESG recommends that the informed consent process for puberty blockers describe the potential loss of fertility and address options for fertility preservation. (Hembree et al., 2017). SOC 8 advises the patient be "[i]nformed of the reproductive effects [of puberty blockers], including the potential loss of fertility and the available options to preserve fertility" (Coleman et al., 2022, p. S256). However, though procedures to preserve fertility are available, studies show that less than 5% of adolescents in North America receiving GAT in late pubertal stages (Tanner 4 and 5) even attempt fertility preservation ("FP") (Nahata, 2017). Moreover, for those in early pubertal stages (Tanner 2 and 3), "ovarian tissue cryopreservation is still considered experimental in most centers and testicular tissue cryopreservation remains entirely experimental. These experimental forms of FP would be the only options in children [with puberty] blocked prior to spermarche and menarche and are high in cost and limited to specialized centers. Even with FP there is no guarantee of having a child." (Laidlaw, Cretella, et al., 2019)

Negative Effects of Hypogonadotropic Hypogonadism on Bone Density

39. Puberty is a time of rapid bone development. This time period is critical in attaining what we call "peak bone mass," or the maximum bone density that one will acquire in their lifetime. (Elhakeem, 2019) Peak bone mass is typically achieved in the early to late twenties in males and females. (Lu et al., 2016) It is well established that "[p]eak bone mass is a strong predictor of osteoporosis in later life." (Kralick et al., 2020). Therefore, factors which lead to a lowering of peak bone mass will predispose a person to future osteoporosis.

40. Adolescence is the critical time period when large amounts of bone accumulate rapidly. This rapid accumulation is referred to as peak bone velocity. In fact, "about 26% of final

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adult bone is accumulated during the two years surrounding peak bone velocity...These two critical years correspond to ages 11.5–13.5 for girls (Tanner stages 2–4) and 13.05–15.05 in boys (Tanner stages 3–5)." (MacKelivie et al., 2002) (citations omitted). Unfortunately, this is precisely the time when puberty blocking hormones are being recommended as part of GAT, which leads to lower levels of sex hormones for adolescents.

41. Any abnormal lowering of sex hormones during this critical time will stop the rapid accumulation of bone and lower adult bone density. As a result, allowing a "pause" in puberty for any period of time leads to an inability to attain peak bone density. If a person does not achieve peak bone density, they will be at future risk for osteoporosis and the potential for debilitating spine and hip fractures as adults. Hip fractures for older patients significantly increase the risk of major morbidity and death. (Bentler, 2009).

42. DEXA scans are used to evaluate changes in bone density and to help evaluate risk for future fractures. The Z-score of a DEXA scan is used to compare a patient's bone density to the same population based on age and sex. Puberty blockers used in adolescence will inhibit the normal accrual of bone density, which can be evaluated by DEXA scan.

43. In a study in the United Kingdom, 44 patients aged 12-15 with gender dysphoria were given puberty blockers and tests of bone density were done at baseline, 12 months, 24 months and 36 months. (Carmichael, 2021). The study examined the bone density percentile of the study participants at 12, 24, and 36 months and determined that the average baseline Z-score was about 32% compared to peers of similar age and sex. At 12 months the Z-score had decreased to about 15%, and by 24 months it had declined further to about 5% compared to their peers of similar age and sex.

44. This pattern of diminishing bone density is similar to the hypogonadotropic hypogonadism often attributed to a pituitary injury.[4] However, in these cases, the

[4] Hypogonadotropic hypogonadism is an endocrine condition in which the pituitary fails to send signals to the gonads, thereby preventing the testicle of the male from making testosterone or the ovary of the female from making estrogen.

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hypogonadotropic hypogonadism was caused by the GnRH analogues (such as Lupron Depot or Histerelin) that led to greatly diminished bone density compared to their peers of the same age and sex.

Negative Effects of Puberty Blockers on Psychosocial Development, Mental Health and Brain Development

45. Adolescence is a critical time of physical, mental, and emotional changes for an adolescent. It is important that they develop socially in conjunction with their peers.

46. While I am not a psychologist, I am familiar with and rely upon the literature in this area to support the treatment of precocious puberty. It is generally accepted in endocrinology that there are psychological benefits to adolescents who go through puberty around the same time as their peers, which is one reason why puberty blockers in central precocious puberty are sometimes used to delay a child's abnormally early pubertal development to a more age-appropriate time.

47. The development of adolescents along with their peers is also well recognized in the psychological literature: "For decades, scholars have pointed to peer relationships as one of the most important features of adolescence." (Brown, 2009). If one is left behind for several years under the impression that they are awaiting opposite sex puberty, they will miss important opportunities for socialization and psychological development. Psychosocial development will be necessarily stunted as they are not developing with their peers. This is a permanent harm as the time cannot be regained.

48. Aside from multiple, serious problems associated with blocking normal puberty, there are independent risks of the puberty blocking medication themselves. For example, the label of a common puberty blocking medication called Lupron Depot-Ped warns of the following: "emotional lability, such as crying, irritability, impatience, anger, and aggression. Depression, including rare reports of suicidal ideation and attempt. Many, but not all, of these patients had a history of psychiatric illness or other comorbidities with an increased risk of depression." (Lupron, 2022). This is particularly concerning given the high rate of psychiatric comorbidity with gender dysphoria. (Kaltiala-Heino, 2015).

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49. The impact on the maturation of the human brain is another consideration of the use of puberty blockers in adolescents and late teens. The impact on brain development is still relatively unknown; however, we do know that "sex hormones including estrogen, progesterone, and testosterone can influence the development and maturation of the adolescent brain." (Arain, 2013). Therefore, there are unknown, but likely negative, consequences to blocking normal puberty with respect to brain development.

Conclusion

50. Multiple factors must be considered to determine medical necessity prior to administering medication or performing surgeries as part of gender affirmative therapy. These factors include (but are not limited to) an examination of the patient's psychological health, family and social situation; the pubertal stage of the patient; an examination of the informed consent procedures performed prior to administering medication or performing surgeries related to gender dysphoria; and an individualized assessment of the potential health risks of medications and/or surgeries considered for the treatment of gender dysphoria. Given the evidence provided, with respect to S.L., medical necessity has not been established for medications and procedures related to the diagnosis of gender dysphoria.

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

DATED this 7th day of November 2023, at Rocklin, CA.

/s/ Michael K. Laidlaw
Michael K. Laidlaw

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EXHIBIT A

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CERTIFICATE OF SERVICE

I certify that on the date indicated below I electronically filed the foregoing, DECLARATION OF MICHAEL K. LAIDLAW IN SUPPORT OF BLUE CROSS BLUE SHIELD OF ILLINOIS'S SUPPLEMENTAL DECERTIFICATION BRIEF with the Clerk of the Court using the CM/ECF system which sent notification of such filing to the following:

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