IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN and SHAUNTAE ANDERSON*;* individually and on behalf of all others similarly situated*,*

Plaintiffs,

v.

WILLIAM CROUCH, *et al.,*

Defendants.

CIVIL ACTION NO. 3:20-cv-00740
HON. ROBERT C. CHAMBERS

PLAINTIFFS' REPLY MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY OF STEPHEN B. LEVINE, M.D.

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I. INTRODUCTION

Defendants' opposition fails to meaningfully grapple with the deficiencies described in Dr. Levine's testimony. Instead, Defendants attempt to shift, or in some cases, remove the legal goal posts altogether. Specifically, Defendants suggest that what is at issue is not whether their discriminatory exclusion violates the Equal Protection Clause, Section 1557 ("Section 1557") of the Patient Protection and Affordable Care Act ("ACA") or the Medicaid Act's Comparability and Availability requirements but whether gender affirming surgeries are "medically necessary," and claim this justifies admitting Dr. Levine's opinions wholesale. ECF No. 260 at 3. Defendants misconstrue the relevant *Daubert* standard and willfully ignore the Fourth Circuit's most recent and relevant affirmation of "the indispensable nature of district courts' Rule 702 gatekeeping function in all cases in which expert testimony is challenged." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 284 (4th Cir. 2021). Finally, Defendants attempt to rehabilitate Dr. Levine's testimony from the damage done by his own concessions at deposition by rewriting the record. But even this attempt at revisionist history cannot overcome the witness's myriad inconsistencies, methodological failures and scientifically unsupported conclusions. The Court should disregard Defendants' plea for lackadaisical gatekeeping and instead exclude the challenged expert's testimony because of his lacking qualifications, and the fact that his testimony is neither relevant nor scientifically reliable.

II. ARGUMENT

Though Defendants would have this Court ignore Fourth Circuit precedent, it is well established that when considering expert testimony, "[t]he party offering the expert carries the burden of establishing admissibility by a preponderance of the evidence." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001); *see also Smith v. Wyeth-Ayerst Lab'ys Co.*, 278

F. Supp. 2d 684, 691 (W.D.N.C. 2003) ("The proponent of expert testimony has the burden of establishing its admissibility by a preponderance of proof.") Defendants fail to meet this burden, however, and are unable to overcome Plaintiffs' specific challenges to Dr. Levine's qualifications and the scientific reliability of his methods and proffered opinions.

As Plaintiffs noted in their opening brief in support of the instant motion, other federal courts have resoundingly dismissed Dr. Levine's opinions about transgender people and the treatment of gender dysphoria. This occurred as recently as 11 days ago, by a federal district court within the Fourth Circuit. On June 10, 2022, Judge Loretta C. Biggs of the Middle District of North Carolina issued a ruling in the *Kadel v. Folwell*, No. 1:19-CV-272, 2022 WL 1046313 (M.D.N.C. Apr. 7, 2022), where transgender plaintiffs challenged a similar exclusion of coverage of gender affirming care within the North Carolina State Employee Health Insurance Plan. Ruling on a motion to exclude the expert testimony of Dr. Levine, the Court held that "notably, Levine does not testify that medical and surgical care for gender dysphoria is categorically inappropriate." Memorandum Opinion and Order at 33, Kadel v. Folwell, No. 1:19-CV-272, 2022 WL 1046313 (M.D.N.C. Apr. 7, 2022), ECF No. 234. The Court also held that "Levine's testimony regarding desistance rates does not appear to be based on reliable methodology." *Id*. at 36. Like Levine's testimony in this case, the Court found that:

> [I]t does not appear that he offers any *categorical opinion* as to the medical necessity of medical and surgical treatments of gender dysphoria, nor does he testify that healthcare providers are prescribing such treatment without due caution and informed consent beyond his anecdotal "experience." To the extent that Defendants seek to introduce testimony from Levine to that effect, he has not provided the Court with any data or methodology from which such claims could be made. Levine has conducted no research to identify which physicians are proceeding as he does, and which do not, rendering any broader opinion about the practice of such healthcare providers pure speculation. *Id*. at 37 (emphasis added).

Finally, *Kadel* also found that Levine's references to a "'Transgender Treatment Industry'

does not appear to be based on any science whatsoever" and is "nothing more than rank speculation designed to distract or inflame the jury and has no business in expert testimony." *Id.* at 37, 32.[1] After narrowing the scope of admissible testimony by Dr. Levine, *Kadel* rejected Defendants' argument Levine's testimony created "a genuine issue of material fact as to whether the Plan's exclusion substantially excludes ineffective treatments." *Id.* at 50. There, as here, Defendants pointed to Dr. Levine's testimony to argue that medical treatments for gender dysphoria are categorically ineffective. But the Court rejected that argument based on *Levine's own testimony*:

> [T]hat is not Levine's testimony. He testifies that the available research is not sufficiently reliable to prove that treatments are effective, but repeatedly and emphatically testifies that this lack of high-level research is not reason to justify withholding treatment from all gender dysphoric patients. Rather he testifies that doctors and patients, when fully aware of the risks and elusive benefits of available treatments, should decide if medicine or surgery is necessary, as he does *in his own practice*. This is Plaintiffs' request: that they and their doctors, not their sex or transgender status, determine when their treatments are appropriate. Levine does not and cannot reliably testify as to how often doctors prescribe unnecessary treatments or fail to obtain informed consent. *Id.* (emphasis in original).

So too here, Levine's proposed opinions are undercut by his own testimony under oath, a blow from which Defendants cannot recover. Dr. Levine Fain Dep. Tr. 88:10-13, ECF No. 254-03; Dr. Levine Kadel Dep Tr. at 73:4-7 ("Q: Is the worrisomeness about a patient's future health, is that a reason to ban all medical care for gender dysphoria? A: Absolutely not."); 84:21-85:1 ("Q: Given all those concerns you have, is that a reason to deny all medical interventions to people with gender dysphoria? A: No …."); 85:4-11 ("Q: Are those concerns you raised justifications in your mind for denying medical interventions to people who have gender dysphoria? A: You know, I'm not advocating denying endocrine treatment or surgical treatment."); 152:1-6 ("Q: Do you think

[1] Dr. Levine's similar proposed testimony here lacks any scientific basis and should be excluded by this Court as similarly based on nothing more than "conspiratorial accusations": "There is also an entire industry of mental health clinicians, hormone prescribers, surgeons and even hospitals who have built lucrative lines of business from scaling the costly 'transgender healthcare' model." Dr. Levine Expert Disclosure ¶10, ECF No. 254-02.

because that study showed that some people committed suicide after gender affirming surgery that no patient should be able to access gender affirming surgery? A: That would be illogical"); 154:3-5 ("Q: But you're not recommending total bans on gender affirming surgery? A: I'm not recommending total bans."); 160:23-25 ("I did not say that gender affirming treatment in general should be stopped. I've never said that."), ECF No. 254-04. Thus, Levine's testimony also does not create a genuine issue of material fact as to whether the Plan's exclusion substantially excludes ineffective treatments.

A. Defendants' Attempt to Rewrite Dr. Levine's Report in Their Response, Misquote Plaintiffs' Memorandum of Law, and Mischaracterize Fourth Circuit Precedent Does Not Make Dr. Levine's Testimony Admissible.

Defendants' opposition grasps for straws in response to Plaintiffs' motion to exclude Dr. Levine's irrelevant opinions about how a person is "biologically defined," his personal and scientifically unsupported opinions "gender exploratory psychotherapy" as a treatment for gender dysphoria, and the Fourth Circuit's observations about the medical community's consensus about appropriate treatment protocols for gender dysphoria. In response, Defendants attempt to rewrite their own expert witness's testimony, including by suggesting his opinions are scientifically supported when they are not, misquoting Plaintiffs' arguments, and mischaracterize the controlling Circuits Court of Appeals decision.

First, Defendants argue that Dr. Levine's scientifically unsupported opinion that biology is defined only by chromosomes, regardless of any other sex related characteristics, is relevant because it is the basis for another of his opinions. ECF No. 260 at 10. Putting aside Defendants' assertion that Dr. Levine relies on an unsupported opinion of *his own* for another of his opinions, Defendants then troublingly state that Dr. Levine has offered the opinion that "gender affirming surgeries do not and cannot fully achieve the results desired by patients." *Id*. But Defendants cite

no portion of Dr. Levine's report or deposition to support this assertion. To the extent they intend to invoke Dr. Levine's distasteful suggestion that no transgender person can ever become a "complete man" or a "complete woman," that is scientifically unsupported and rooted in disrespectful stereotypes that transgender men are not men, and that transgender women are not women. This is not expert testimony. Nor could Dr. Levine purport to offer such an opinion given that he cannot possibly assert specialized knowledge about what results are desired by Plaintiffs here, the class they represent, or even any patients with whom he has not directly discussed the matter.[2]

Second, instead of meaningfully confronting Dr. Levine's admitted lack of scientific evidence for his assertions that "gender exploratory psychotherapy" is the only appropriate treatment for gender dysphoria, Defendants employ several unsuccessful arguments. First, Defendants mischaracterize Plaintiffs' motion to accuse Plaintiffs of "attempting to make Dr. Levine a pariah." ECF No. 260 at 11. Such an ad hominem attack is unfounded and not reflected anywhere in Plaintiffs' brief. Dr. Levine's meaning of the term "gender exploratory psychotherapy" as set out in his testimony is wholly at odds with the way that other professional agencies and behavioral health organizations define that term, such as the Substance Abuse and Mental Health Services Administration ("SAMHSA")[3] and the American Academy of Child and

[2] Defendants make the first of several peculiar attempts to respond to Plaintiffs' well-supported arguments by suggesting that if certain opinions of Dr. Levine's must be excluded, so too must Plaintiffs' experts on the same category. ECF No. 260 at 10, 19-20. By doing so, Defendants suggest this "tit for tat" is the standard by which the Court should evaluate the exclusion of Dr. Levine's opinions. This is also not the appropriate venue for such arguments about Plaintiffs' experts. Defendants could have filed similar motions to exclude the testimony of Plaintiffs' experts, but notably, did not. These arguments are therefore untimely and improperly raised.

[3] Substance Abuse and Mental Health Servs. Admin., Ending Conversion Therapy: Supporting and Affirming LGBTQ Youth (2015), available at https://store.samhsa.gov/sites/default/files/d7/priv/sma15-4928.pdf

Adolescent Psychiatry. Those agencies and professional organizations recognize that, properly done, such therapies "foster healthy development, especially for sexual and gender diverse youth, as they *integrate their sexual orientation, gender identity, and/or gender expression, into their overall identity without any pre-determined outcome*." *Conversion Therapy*, https://www.aacap.org/aacap/Policy_Statements/2018/Conversion_Therapy.aspx (last visited June 20, 2022). In stark opposition, Dr. Levine clearly favors placing a thumb on the scale to try to persuade younger patients through "gender exploratory therapy" to no longer be transgender, or that the cause of their gender dysphoria is related to their race, developmental disability, their residence in a foster home, their status as an adoptee, their history of psychiatric illness, or even having been assigned female at birth, rather than simply their being transgender. Dr. Levine Expert Disclosure ¶¶10, 87, 88, 156, 157, 160, 164, ECF No. 254-02. Notably, "conversion therapy" is defined by the American Academy of Child and Adolescent Psychiatry as "any therapeutic intervention operating under the premise that a specific gender identity and/or expression is pathological" and "imposed with the intent of promoting a particular…gender as a preferred outcome." That is Dr. Levine's preferred outcome as well. Indeed, in each of the articles that Dr. Levine cites to about the supposed impact of "gender exploratory therapy" each young person's gender dysphoria is treated by the young person "reinvesting" in their assigned sex at birth, not by continuing to assert a gender identity different from the one they were assigned at birth. ECF No. 254-02 Dr. Levine Expert Disclosure ¶37. If Dr. Levine's characterization of "gender exploratory therapy" were in line with its widely accepted clinical meaning, he would not rely on sources that have as their goal causing the patient to identify with their birth assigned sex. These unreliable opinions present by Dr. Levine throughout his testimony do not pass the rigorous gatekeeping requirements of FRE 702 and *Daubert* standards.

Third, Defendants return to their tried-and-true strategy of rewriting Dr. Levine's testimony and misrepresenting which of his opinions have scientific support in the hopes the Court will ignore its gatekeeping obligations in this dispute. Defendants allege that Dr. Levine "cites to peer-reviewed literature showing … a growing consensus supporting the use of psychotherapy as a first treatment modality for gender dysphoria." But whether therapy is an initial treatment option for transgender people says nothing about the categorical ban Defendants maintain on surgical care, and indeed, Dr. Levine has testified repeatedly that he does not support such bans. Dr. Levine Fain Dep. Tr. 88:10-13, ECF No. 254-03; Dr. Levine Kadel Dep Tr. at 73:4-7 ("Q: Is the worrisomeness about a patient's future health, is that a reason to ban all medical care for gender dysphoria? A: Absolutely not."); 84:21-85:1 ("Q: Given all those concerns you have, is that a reason to deny all medical interventions to people with gender dysphoria? A: No …."); 85:4-11 ("Q: Are those concerns you raised justifications in your mind for denying medical interventions to people who have gender dysphoria? A: You know, I'm not advocating denying endocrine treatment or surgical treatment."); 152:1-6 ("Q: Do you think because that study showed that some people committed suicide after gender affirming surgery that no patient should be able to access gender affirming surgery? A: That would be illogical"); 154:3-5 ("Q: But you're not recommending total bans on gender affirming surgery? A: I'm not recommending total bans."); 160:23-25 ("I did not say that gender affirming treatment in general should be stopped. I've never said that."), ECF No. 254-04. Contrary to Defendants' suggestion, Dr. Levine provided no other citation or scientific support for this assertion in his report or elsewhere. Dr. Levine Expert Disclosure ¶ 160, ECF No. 254-02. Regardless, this opinion is simply irrelevant both to Dr. Levine's own clinical practices, and to the issues in the case. Dr. Levine himself does not preclude his own patients from receiving this care and writes letters of authorization so they can obtain it. Dr. Levine Fain Dep. Tr. at 84:4-85:4;

139:14-19, ECF No. 254-03; Dr. Levine Kadel Dep. Tr. at 55:13-17; 56:2-5; 112:16-21; 176:8-16, ECF No. 254-04; Soneeya Bench Trial Day 1 Tr. at 1-100:15-22, ECF No. 254-05. Additionally, as Plaintiffs explained in their summary judgment opposition brief, concerns about medical necessity are indisputably post-hoc, and therefore irrelevant under the heightened scrutiny Grimm requires for Plaintiffs' Equal Protection claims, and for Plaintiffs' Medicaid Act claims. Pls.' Summ. J. Opp. at 12-13, ECF No. 262; see also *Flack v. Wisconsin Dep't of Health Servs.*, 395 F. Supp. 3d 1001, 1020-21 (W.D. Wis. 2019) (finding that lack of evidence of any systematic review of medical necessity before or after adopting exclusion renders the concern post-hoc), 1021 n.28 (same for expert testimony constructed for litigation and not considered by decision-makers).

Finally, Defendants would have this Court ignore Fourth Circuit precedent about "the indispensable nature of district courts' Rule 702 gatekeeping function" as well as its persuasive and informative observations about accepted treatment protocols. As such, the Fourth Circuit has observed in *Grimm* that,

> Fortunately, we now have modern accepted treatment protocols for gender dysphoria. Developed by the World Professional Association for Transgender Health (WPATH), the Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People (7th Version 2012) (hereinafter "WPATH Standards of Care") represent the *consensus approach of the medical and mental health community*, Br. of Medical Amici 13, and have been recognized by various courts, *including this one*, as the authoritative standards of care, *see De'lonta v. Johnson*, 708 F.3d 520, 522–23 (4th Cir. 2013); *see also Edmo*, 935 F.3d at 769; *Keohane v. Jones*, 328 F. Supp. 3d 1288, 1294 (N.D. Fla. 2018), vacated sub nom. *Keohane v. Fla. Dep't of Corrs. Sec'y*, 952 F.3d 1257 (11th Cir. 2020). "There are no other competing, evidence-based standards that are accepted by any nationally or internationally recognized medical professional groups." *Edmo*, 935 F.3d at 769 (quoting *Edmo v. Idaho Dep't of Corr.*, 358 F. Supp. 3d 1103, 1125 (D. Idaho 2018)).

Grimm v. Gloucester Cnty. Sch. Bd., 972 F.3d 586, 595-96 (4th Cir. 2020) (emphasis added). Ultimately, Defendants' attempts to shoehorn Dr. Levine's irrelevant testimony within the zone of admissibility fail and must be denied.

B. Defendants' Attempts to Rehabilitate Dr. Levine's Methodologically Unreliable and Scientifically Unsupported Testimony Fail.

Defendants "say so" that Dr. Levine's opinions should be admitted, and that his proposed testimony will survive the Court's gatekeeping duties under Rule 702 and *Daubert* and its progeny, including *Sardis*, is not enough.

1. Dr. Levine's Unsupported Criticisms of the WPATH SOC Make Him An Outlier in This Field and Render His Proposed Testimony Unreliable.

It is worth noting at the outset that the only Fourth Circuit case Defendants cite in their response to Plaintiffs' instant motion runs contrary to their arguments about Dr. Levine's criticisms of the WPATH SOC. ECF No. 260 at 2-3. Specifically, a challenged expert's disagreement with what is otherwise the recognized medical and scientific consensus calls into question *their reliability* because general acceptance in the relevant scientific community is an important element of reliability. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017). As Plaintiffs have explained at length in their opening brief, the WPATH SOC are the generally accepted and recognized protocols for the treatment of gender dysphoria in the United States and elsewhere, and Dr. Levine testified in this case and others[4] that he generally abides by them in his clinical practice. ECF No. 255 at 5. Even still, Defendants argue that because Dr. Levine's report mischaracterizes the findings of the Dahlen et al. article, quotes statements from the incoming WPATH president Dr. Marci Bowers that she has since clarified and disavowed, and "includes citations" that his testimony about WPATH SOC is reliable. These arguments simply do not survive this Court's gatekeeping inquiry, or the standards set forth in FRE 702 and *Daubert.*

[4] Contrary to Defendants' assertion, the previous testimony given under oath of any expert witness, including Dr. Levine, in other similar cases is directly relevant to the reliability of the opinions he proposes to offer in this case.

Defendants repetition of Dr. Levine's mischaracterization of the Dahlen et al. article is not a rebuttal to Plaintiffs' argument. ECF No. 260 at 14. Plaintiffs take issue with, and Defendants have no response for, Dr. Levine's inaccurate characterization that "[a] recently published systematic review found the current WPATH SOC7 (sic) guidelines to be of very low quality and unfit tools for clinical decision making," a statement found nowhere in the Dahlen article, nor a conclusion supported by the article itself. *Id*. Defendants notably have no response to the article's significant qualification that "evaluations of clinical practice guidelines in other medical areas including cancer, diabetes, pregnancy, and depression" "tend to show room for improvement," and that "finding poor quality CPGs is not confined to this area of healthcare." Dahlen Article at 8-9, ECF No. 254-08. Dr. Levine's suggestion that this is somehow uniquely true for the WPATH SOC is unsupported, and it simply cannot be that such a methodologically unsound conclusion is admissible under FRE 702 and *Daubert*. The article's authors also note that "[i]ncluding gender minority/trans people in guidelines can be considered a matter of health equity, where CPGs have a role to play. GRADE suggests that CPG developers consider equity at various states in creating guidelines..." *Id*. This recommendation runs directly counter to Dr. Levine's assertion that because attendance at WPATH's "biennial meetings has been open to trans individuals who are not licensed professionals" that "WPATH can no longer be considered a purely professional organization." Dr. Levine Expert Disclosure at ¶ 68, ECF No. 254-02. Indeed, the Dahlen et al. article does not support the reliability of Dr. Levine's testimony in the ways that Defendants allege.

"[A] reliable expert would not ignore contrary data, misstate the findings of others, make sweeping statements without support, and cite papers that do not provide the support asserted." *Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 520 (S.D.W. Va. 2014). And yet, Defendants attempt to justify Dr. Levine's ignoring the subsequent statements of Dr. Marci Bowers that

disavow statements quoted by Dr. Levine for the purpose of undermining WPATH. Dr. Bowers' Statement, ECF No. 254-09. Dr. Bowers says that what she hopes for "most of all, is that my out-of-context comments will not be excerpted to weaponize ongoing attacks on transgender persons," and that "we are best served by our support of WPATH and its goal of establishing evidence-based care that affirms gender identity as another important aspect of global diversity." *Id*. at *3. Defendants believe Dr. Levine's failure to account for these subsequent statements by Dr. Bowers has "no bearing on the admissibility of Dr. Levine's opinions." ECF No. 260 at 14. This Court disagrees. *Tyree*, 54 F. Supp. 3d at 520 (cleaned up) ("An expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead "selectively [chooses] his support from the scientific landscape.").

Finally, Defendants misunderstand their burden in submitting reliable and methodologically sound expert testimony when they assert that Dr. Levine's opinion that "a growing number of countries are deviating from WPATH and Endocrine Society guidelines" should not be excluded because "Dr. Levine's report includes citations[5] to support his opinions." ECF No. 260 at 14-15. Plaintiffs have already explained that the citations Dr. Levine provides are not from peer-reviewed, scientific sources, and the even *the sources themselves* do not stand for the proposition Dr. Levine alleges. In fact, those sources admit instead that Sweden, Finland, and the UK still allow access to puberty blockers, hormone therapy and other medical interventions, which Dr. Levine also conceded when pressed at deposition. Dr. Levine Fain Dep. Tr. 106:4-

[5] Defendants assert that the number of citations Dr. Levine includes in his report helps to establish Dr. Levine as qualified and his testimony as reliable and relevant under FRE 702 and *Daubert* standards. ECF No. 260 at 7, 13 ("Dr. Levine's opinions are supported by 242 citations"). Defendants point to no authority for this assertion, including nothing within Rule 702, *Daubert,* or its progeny. Indeed, quantity is not the same as quality in the admissibility of proposed expert testimony.

108:8;191:20-192:16, ECF No. 254-03. Likely because Dr. Levine's citations fail to support his opinion, Defendants cite in their reply to a source Dr. Levine did not identify in his report or at deposition as a source upon which he relied in forming his opinions. ECF No. 260 at 15. Defendants' untimely inclusion of this source should not be allowed as it violates the expert witness' obligation under Rule 26 that their expert disclosure include all sources upon which they have relied in forming their opinions. However, even if the Court found this source admissible at this juncture, the article simply does not support Dr. Levine's asserted opinion. It states that the Swedish National Board of Health and Welfare "recommends restraint when it comes to hormone therapy," but defendants omitted the sentence that immediately follows: "[a]t the same time, it is important that children and young people suffering from gender dysphoria are taken seriously, well treated and offered adequate care measures." ECF No. 252-07. It is worth noting that Defendants already provide coverage for hormone therapy in their Medicaid program, so this articles' recommendations have no relevance to the surgical care exclusion at the center of this case. Finally, the article does not conclude that Sweden, or a "growing number of countries," are deviating from providing the medical care in accordance with WPATH, or the Endocrine Society guidelines, protocols that Dr. Levine continues to generally adhere to in his own clinical practice.

2. Dr. Levine's Failure to Account for Contrary Scientific Literature and His Misrepresentation of Existing Data About Gender Affirming Medical Care Renders His Related Opinions Unreliable.

At the outset it must be noted that Defendants mischaracterize Plaintiffs' arguments and misquote their opening brief in support of the instant motion.[6] Plaintiffs do not seek only to exclude Dr. Levine's opinions included in the non-exhaustive list of paragraphs from his report on page 15

[6] Defendants write that "Plaintiffs specifically cite to Paragraphs 23, 39, 51, 55 and 118 through 124 of Dr. Levine's Report…" Plaintiffs cite these as a non-exhaustive list of examples of Dr. Levine's unreliable opinions in this vein.

of their memorandum, but instead to exclude *all* of Dr. Levine's opinions that assert that gender affirming medical care is "experimental, risky and without lasting benefit." Nevertheless, Defendants again misunderstand the preponderance of evidence burden they bear in proving the admissibility of Dr. Levine's opinions in this case. Defendants suggest that the mere fact that Dr. Levine provides "support" for his opinions is sufficient to survive this Court's rigorous gatekeeping role under Rule 702. ECF No. 260 at 15. But "if the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Tyree*, 54 F. Supp. 3d at 520 (cleaned up). Such is the case here. As Plaintiffs discussed in their opening brief, Dr. Levine fails to acknowledge or account for "recent studies demonstrating that medical treatments for transgender adolescents and adults have favorable outcomes across many measures." ECF No. 255 at 11. Defendants make no attempt to explain or defend Dr. Levine's omissions in this regard. Defendants also notably offer no response to Plaintiffs' arguments about Dr. Levine's misrepresentation about two key studies showing positive long-term outcomes for transgender people who underwent gender reassignment via surgical interventions. ECF No. 255 at 11-12.

3. Defendants' Attempts to Address the Methodological Flaws in Dr. Levine's Report by Rewriting it Must Fail.

Defendants attempt to rehabilitate another of Dr. Levine's unreliable opinions regarding "desistance" by ignoring Plaintiffs' arguments about specific methodological flaws and again attempting to introduce a source not found in Dr. Levine's report or deposition transcript. ECF No. 260 at 17. To begin, Defendants turn to their oft-repeated refrain that because Dr. Levine provides *any support* for his opinions whatsoever, regardless of whether the support is legitimate, that his opinions should be admitted in this case. Fortunately, that is not the standard by which expert testimony is evaluated and "proposed testimony must because supported by appropriate

validation—i.e., 'good grounds' based on what is known." *Tyree*, 54 F. Supp. 3d at 526 (citing *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 590 (U.S. 1993)). Defendants fail to address Plaintiffs' arguments that Dr. Levine's sources to support this opinion are not "good grounds," nor based on what is known. Specifically, Defendants have *no answer* for Dr. Levine's failure to rely on *any data or scientific literature* that studied transgender children or adolescents diagnosed under the current DSM V criteria for gender dysphoria other than to admit that "some of the literature cited to by Dr. Levine did analyze treatment outcomes using diagnostic criteria from the DSM-IV," which differed in significant ways from the current diagnostic criteria. ECF No. 260 at 17. Defendants go no further than this before attempting to distract the court with a key misrepresentation. Defendants state that "most of the literature cited to by Dr. Levine is from 2020 and 2021…Levine Report ¶90 (ECF 252-11)." While two of the three articles Dr. Levine relies on were published in 2020 and 2021, all three of articles use the same data collected from children whose gender non-conforming behavior was diagnosed between *1952 and 2008*, not 2020 or 2021. ECF No. 255 at 13. As Plaintiffs have already discussed in their opening brief, Dr. Levine points to no "recent available literature in the field" that analyzes data from children diagnosed with "Gender Dysphoria in Children" using the current and authoritative DSM-V which was released in 2013. ECF No. 255 at 17. Dr. Levine's citations to "papers that do not provide the support asserted" cannot be used to establish his opinion as reliable in this case.

Further, Defendants should not be permitted to submit in their reply to the instant motion a source that Dr. Levine did not include in his expert disclosure nor identify at deposition as a basis for this opinion. ECF No. 260 at 17 (citing De Vries, et al., *Reliability and Clinical Utility of Gender Identity-Related Diagnoses: Comparisons between the ICD-11, ICD-10, DSM-IV, and DSM-5*, 8(2) LGBT HEALTH 133 (2021)). Even if the Court does consider this improperly cited

source, it does not stand for the proposition that Defendants allege, nor provide any additional support for Dr. Levine's challenged opinion. First, Defendants omit from their description that the study's purpose was to assess the "reliability and clinical utility" of the ICD-11, which has not yet been adopted in the United States, in comparison to other criteria. Defendants also omit the methods which involved sixty-four health care providers assessing videos of two children, two adolescents, and two adults for gender incongruence. This study notably did not purport to actually diagnose any of the six individuals, nor did it engage in long-term follow-up of the children and adolescents to see if they continued to experience gender incongruence or any other data points beyond "clinicians evaluating all four systems as convenient and easy to use." De Vries, et al., *Reliability and Clinical Utility of Gender Identity-Related Diagnoses: Comparisons between the ICD-11, ICD-10, DSM-IV, and DSM-5*, 8(2) LGBT HEALTH 133 (2021). No matter how Defendants try to slice it, Dr. Levine's reliance on data collected under sweeping, outdated diagnostic criteria of the DSM III, III-R, IV and IV-R cannot pass muster to support this opinion and therefore it must be excluded.

4. Defendants Fail to Establish Dr. Levine's Unsupported Opinions About "Rapid Onset Gender Dysphoria" and "Detransition" As Reliable or Supported by Scientific Evidence.

In the service of attempting to salvage Dr. Levine's opinions from exclusion by this Court's gatekeeping obligations under Rule 702, Defendants misstate Plaintiffs' arguments, attempt to introduce a source that Dr. Levine did not include in his report or deposition testimony, and simply repeat Dr. Levine's unsupported opinions. Defendants' first sleight of hand to defend Dr. Levine's opinions about "rapid onset gender dysphoria" conflates an increase in the number of children and adolescents reporting to clinics for treatment of gender dysphoria with the scientifically unsupported hypothesis known as "rapid onset gender dysphoria." Dr. Levine Expert Disclosure

¶92, ECF No. 254-02.[7] Such a manipulation does not comport with the scientific method. "Rapid onset gender dysphoria" as a clinical term has not been "documented in the literature," contrary to Defendants' (and Dr. Levine's) assertions. This hypothesis was first posited in an article based on what parents, *not the adolescents themselves*, described as their view that their adolescent experienced a "sudden onset of gender dysphoria." ECF No. 260 at 18. The researcher who introduced the term had to correct and republish the article, explicitly admitting that "rapid onset gender dysphoria is not a formal mental health diagnosis," and that "the report did not collect data from adolescents and young adults or clinicians and therefore *does not validate the phenomenon*." Correction to Littman Article, ECF No. 254-18. Dr. Levine's report points to *no evidence* to validate this hypothesis. Significantly, Dr. Levine did not cite in his report or discuss at deposition the one study to investigate the "rapid onset gender dysphoria hypothesis" that did use adolescent clinical data—and which found no evidence to support the hypothesis. Bauer Article, ECF No. 254-19. "[I]f the relevant scientific literature contains evidence tending to refute the expert's theory and the expert does not acknowledge or account for that evidence, the expert's opinion is unreliable." *Tyree*, 54 F. Supp. 3d at 520 (cleaned up). Nor do Plaintiffs' experts support this hypothesis, and Defendants misrepresent their testimony by suggesting otherwise. ECF No. 260 at 18-19. Dr. Olson-Kennedy testified regarding a demographic shift seen at some gender clinics, but in no way suggested that it is accounted for by so-called "rapid onset gender dysphoria," and to the contrary suggested that other dynamics are likely the cause instead. Declaration of Carl S. Charles, Ex. U at 23:23-25:20; 55:6-56:10.

[7] Dr. Levine also attempts to use the WPATH SOC Version 8 draft's omission of "rapid onset gender dysphoria" and "detransition" as reasons to discredit the group and the forthcoming standards. For reasons discussed above, WPATH is under no obligation to include unscientific hypotheses and unverified reports from the internet in its internationally used Standards of Care.

Defendants repeat Dr. Levine's unsupported opinion that "a growing number of individuals are coming out publicly to discuss their own detransition." ECF No. 260 at 19. Dr. Levine conceded at deposition that he has no scientific evidence to support his opinion that the number of people "detransitioning" is growing, or that the number of people who report "detransition" is greater now that it has even been historically. Dr. Levine Fain Dep. Tr. at 158:8-159:2, 160:25-161:9; 163:9-24, ECF No. 254-3. Defendants offer no explanation for why any of Dr. Levine's scientifically unsupported opinions should be admitted under the Rules of Evidence or *Daubert* standards as applied to proposed testimony in this case. As such, these and others of Dr. Levine's opinions must stop at the gates of this Court.

C. Defendants Cannot Tout Dr. Levine as a Qualified Expert Based on His Experience and Then Dismiss that Experience When It Contradicts Their Arguments.

Defendants take a "have their cake and eat it too" approach to the application of Dr. Levine's experience to the admissibility of his testimony in this case. They recite Dr. Levine's credentials at length and argue that has the requisite "education, training, experience, and knowledge" required by Rule 702 and *Daubert*, and highlight his "50 years of clinical practice." ECF No. 260 at 6-7. As a preliminary matter, credentials alone are "insufficient to support [an expert's] testimony." *Belk, Inc. v. Meyer Corp.,* U.S., 679 F.3d 146, 162 (4th Cir. 2012) (cleaned up). But when it comes time to reconcile the factual reality of Dr. Levine's years of clinical experience as described at his deposition in this and many other cases, Defendants suddenly deem that experience "irrelevant to the issues of this case." ECF No. 260 at 7. The undisputable reality of Dr. Levine's experience is that he has, for the entirety of his nearly 50-year clinical practice, written letters of approval for transgender patients in his care to access endocrine and surgical treatment and does not believe those treatments should be categorically denied. ECF No. 255 at 4-

5. This practice continues even to the present: in the last few months he approved surgical interventions for *several* incarcerated transgender people at Framingham Prison in Massachusetts, people who otherwise could not access this care and must rely on the State to provide them access to it. Dr. Levine Fain Dep. Tr. at 84:4-85:4, ECF No. 254-03. Similarly, Defendants concede, as they must, that Dr. Levine has rarely treated a pre-pubescent child in his 50-year practice. ECF No. 260 at 20. Despite this fatal blow to Dr. Levine's qualifications and the reliability of his testimony in this area, Defendants claim *exactly the opposite*: that Dr. Levine has "education, training, experience and knowledge in the field of psychiatry and treating gender dysphoric children." *Id*. Dr. Levine conceded otherwise. Dr. Levine Fain Dep. Tr. at 28:23-29:6; 62:6-14, ECF No. 254-03; Dr. Levine B.P.J. Dep. Tr. at 87:1-7, ECF No. 254-21. "[A]ny expert, including physicians, must have the specialized knowledge or skill in the specific area in which the testimony is proffered." *Smith*, 278 F. Supp. 2d at 698 (emphasis added); *see also Elegant Massage, LLC v. State Farm Mut. Auto. Ins. Co.*, 2022 WL 433006, at *9 (E.D. Va. Feb. 11, 2022) ("the Fourth Circuit has recognized that experience and expertise in one area does not automatically qualify someone as an expert in another similar area"); *Maldonado v. Apple*, *Inc*., 2021 WL 1947512, at *17 (N.D. Cal. May 14, 2021) (chemical engineer not qualified to opine about "reliability engineering," because "slapping the label 'engineering' on an expert or opinion is insufficient to show expertise across that expansive field"). As Plaintiffs have already demonstrated, Dr. Levine lacks both specialized skill or knowledge about the treatment and diagnosis of pre-pubescent children and he does not write, research or publish about them. ECF No. 255 at 18-20. Defendants' vague references to "his own published works and the works of others" do not address this failure. ECF No. 260 at 20. Defendants simply cannot have it both ways: either Dr. Levine is a qualified expert with experience that contradicts Defendants' arguments about the relevance and reliability

of his testimony in this case, or he is not. Either way, the Court must exclude his testimony.

In Defendant's efforts to diminish the fact that Dr. Levine's clinical practice supports the relief Plaintiffs seek, they obfuscate the meaning of "medical necessity" and fail to stretch Dr. Levine's testimony to cover the gap. ECF No. 260 at 7. Defendants suggest, without evidence or citation to the record, that Dr. Levine's provision of approval letters for surgery, a practice consistent with the WPATH SOC Version 7 is not "an admission of medical necessity." *Id*. While this may be Defendants' opinion, it does not comport with the reality that Dr. Levine's letters (and those of other psychiatrists in this field) are used to support determinations of medical necessity for insurance coverage. Indeed, those determinations cannot be made without a provider's "letter of approval," as Defendants own internal documents confirm. Defs' InterQual Sheets, ECF No. 254-17. Additionally, nowhere in Dr. Levine's report does he demonstrate "experience, education, training or knowledge" about the concept of "medical necessity" beyond suggesting repeatedly that it should not be conflated with gender-affirming medical care. Dr. Levine Expert Disclosure ¶¶81, 82, 84, ECF No. 254-02. Instead, Dr. Levine alleges that establishing a basis for medical necessity for gender affirming medical care is "challenging" because science hasn't established a "causal mechanism" of gender dysphoria and because "the nature of the diagnosis is in flux." *Id*. at ¶94. Yet again, this unsupported opinion fails the tests for relevance and reliability. Dr. Levine cites to *no scientific authority* for the idea that the cause of an illness or medical condition must be "scientifically established" for treatment to be medically necessary. If that dubious standard were used by West Virginia Medicaid to determine medical necessity then they would decline to treat a host of debilitating and widespread conditions with no "scientifically established" cause including

pediatric cancers[8], Type 1 Diabetes[9], and multiple sclerosis.[10] Plaintiffs already dispensed with Dr. Levine's unsupported and unreliable opinion that the diagnosis of gender dysphoria is in flux in their opening brief. ECF No. 254 at 14. At base, treatments for gender dysphoria under West Virginia Medicaid have already been established to be a medically necessary service, given the range of treatments Defendants already cover for gender dysphoria. ECF No. 261 at 1. Dr. Levine's scientifically unsupported personal beliefs about "medical necessity" are irrelevant and unreliable, and the Court should find them inadmissible under FRE 702 and *Daubert* and progeny.

III. CONCLUSION

Accordingly, Plaintiffs respectfully request that this Court grant the instant motion and exclude Dr. Levine's purported expert testimony as inadmissible under *Daubert* and the Federal Rules of Evidence.

* * *

[8] Risk Factors and Causes of Childhood Cancer, Am. Cancer Soc'y (Oct. 15, 2019), https://www.cancer.org/cancer/cancer-in-children/risk-factors-and-causes.html#:~:text=But%20the%20causes%20of%20DNA,without%20having%20an%20outside%20cause.

[9] Diabetes, Mayo Clinic (Oct. 30, 2020), https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444#:~:text=Causes%20of%20type%201%20diabetes,with%20little%20or%20no%20insulin.

[10] What Causes M.S.?, Nat'l Multiple Sclerosis Soc'y, https://www.nationalmssociety.org/What-is-MS/What-Causes-MS#:~:text=The%20cause%20of%20MS%20is,of%20the%20body's%20immune%20system).

Dated: June 21, 2022

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN, *et al.*, individually and on behalf of all others similarly situated,

Plaintiffs,

v.

WILLIAM CROUCH, *et al.*,

Defendants.

CIVIL ACTION NO. 3:20-cv-00740
HON. ROBERT C. CHAMBERS

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, and any attachments, were served electronically on June 21, 2022, on the following counsel for Defendants in this case:

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Dated: June 21, 2022

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN and SHAUNTAE ANDERSON*;* individually and on behalf of all others similarly situated*.,* *Plaintiffs*, v. WILLIAM CROUCH, *et al.,* *Defendants*.	CIVIL ACTION NO. 3:20-cv-00740 HON. ROBERT C. CHAMBERS

DECLARATION OF CARL S. CHARLES

Pursuant to 28 U.S.C. § 1746, I, Carl S. Charles, do hereby declare as follows:

1. I am over 18 years of age.

2. I am a Senior Attorney at Lambda Legal Defense and Education Fund, Inc. and serve as counsel of record for the plaintiffs in the above-captioned matter.

3. I have personal knowledge of the facts stated herein, except those stated upon information and belief, and if called upon, could and would testify competently to them.

4. I submit this declaration in support of Plaintiffs' Motion to Exclude Expert Testimony of Stephen B. Levine, M.D. ("Dr. Levine.").

5. Attached as **Exhibit U** is a true and correct copy of excerpts of the transcript of the deposition of Dr. Joanna Olson-Kennedy, taken on April 25, 2022, in relation to the above captioned matter.

I declare under the penalty of perjury that the foregoing is true and correct. Dated this 21st day of June 2022.

Carl S. Charles

Exhibit U

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
HUNTINGTON DIVISION

CHRISTOPHER FAIN; ZACHARY MARTELL; BRIAN MCNEMAR, SHAWN ANDERSON a/k/a SHAUNTAE ANDERSON and LEANN JAMES, individually and on behalf of all others similarly situated,

Plaintiffs,

vs.

WILLIAM CROUCH, in his official capacity as Cabinet Secretary of the West Virginia Department of Health and Human Resources; CYNTHIA BEANE, in her official capacity as Commissioner for the West Virginia Bureau for Medical Services; WEST VIRGINIA DEPARTMENT OF HEALTH AND HUMAN RESOURCES, BUREAU FOR MEDICAL SERVICES; JASON HAUGHT, in his official Capacity as Director of the West Virginia Public Employees Insurance Agency; and THE HEALTH PLAN OF WEST VIRGINIA, INC.,

Defendants.

Civil Action No.

3:20-cv-00740

REMOTE VIDEOTAPED DEPOSITION OF

JOHANNA OLSON-KENNEDY, M.D.

April 25, 2022

Reported By: Amy E. Simmons, CSR, RPR, CRR, CRC

REMOTE VIDEOTAPED DEPOSITION OF
JOHANNA OLSON-KENNEDY, M.D.

BE IT REMEMBERED that the remote videotaped deposition of JOHANNA OLSON-KENNEDY, M.D., was taken via videoconference by the Defendants before Veritext Legal Solutions, Amy E. Simmons, Court Reporter and Notary Public in and for the County of Ada, State of Idaho, on Monday, the 25th day of April, 2022, commencing at the hour of 8:39 a.m. Pacific Daylight Time in the above-entitled matter.

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Videographer: Jonathan Hernandez

Also Present: Michele Clanton-Lockhart

Plaintiffs.

THE WITNESS: My name is Johanna Olson-Kennedy. I am the expert witness here on behalf of the Plaintiffs.

THE VIDEOGRAPHER: Thank you. Now will the court reporter please administer the oath.

OHANNA OLSON-KENNEDY, M.D.,

a witness having been first duly sworn remotely to tell the truth, the whole truth and nothing but the truth, was examined and testified as follows:

MS. BORELLI: And before Mr. David begins his questions, we'd like to put a stipulation on the record.

The stipulation is that for purposes of this deposition, an objection to form will preserve all objections to form without needing to specifically state them.

Mr. David, is that agreeable to you?

MR. DAVID: That is agreeable to me.

MS. BORELLI: Thank you.

MR. DAVID: And, Tara, before I get going, do we want to note Walt's appearance? I just wanted to make sure.

MS. BORELLI: Sure. Walt, do you want to state your appearance?

MR. AUVIL: Walt Auvil for the Plaintiffs.

gender dysphoria in a patient, do you use the DSM-5 criteria for diagnosis?

MS. BORELLI: Objection; form.

THE WITNESS: Yes.

Q. (BY MR. DAVID) Are there any other criteria that you rely upon in making the diagnosis outside of the DSM-5?

MS. BORELLI: Objection; form.

THE WITNESS: I think that making the diagnosis in addition to what's in the DSM, I lean on my clinical experience, 16 years of doing this work, to facilitate that diagnosis.

Q. (BY MR. DAVID) Are there other diagnostic criteria other than what's listed in the DSM-5?

MS. BORELLI: Objection; form.

THE WITNESS: No. Those are the diagnostic criteria.

Q. (BY MR. DAVID) And I believe you just said that you have 16 years of clinical experience; is that correct?

A. That's correct.

Q. Over your 16 years of clinical experience, have you seen a shift in the patient population from primarily individuals who were

assigned male at birth to now individuals who were assigned female at birth?

MS. BORELLI: Objection; form.

THE WITNESS: We have seen a shift in that ratio.

Q. (BY MR. DAVID) Do you have an explanation for why that shift is occurring?

MS. BORELLI: Objection; form.

THE WITNESS: I have thoughts about it, yes.

Q. (BY MR. DAVID) Okay. And I'll ask you your thoughts in a second.

Are you aware of any literature that has looked into that specific shift and determined why that shift has occurred?

MS. BORELLI: Objection; form.

THE WITNESS: No.

Q. (BY MR. DAVID) And now can you tell me your thoughts on why that shift has occurred?

MS. BORELLI: Objection; form.

THE WITNESS: I think that there are many things that have to be considered. The first is, you know, I work in a youth clinic. So I see people that primarily are accessing services at around the age of 16. And their experiences are

of gender dysphoria -- their gender dysphoria is emerging around the time that they start puberty.

I think that it is critical to understand that the development of chest tissue is the first beginnings of puberty for people designated female at birth.

Because of that, it is likely that that change of puberty is the thing that is either exacerbating or creating the experience of gender dysphoria for them in a way that they can verbalize and talk about.

Q. (BY MR. DAVID) Okay. So would the rise in individuals who were assigned female at birth coming out as transgender in recent years compared to previously be more or less that that population has always existed, but now it's more acceptable from society's point of view to come out as transgender?

MS. BORELLI: Objection; form.

THE WITNESS: Yes, I believe so.

Q. (BY MR. DAVID) Okay. And so as a result of that, individuals who were assigned male at birth were, I guess, overrepresented in the ratio because those who were assigned female at birth were not comfortable coming out as transgender

been a shift in the ratio with more individuals presenting with -- who were assigned female at birth than previously were presenting --

MS. BORELLI: Objection; form.

I apologize, Caleb.

MR. DAVID: You're okay. I'm being a little clumsy with this, so I'll start over.

Q. (BY MR. DAVID) We previously talked at the beginning of your deposition about there is a shift in the ratio of your patient population from primarily those who were assigned male at birth to now a greater number who were assigned female at birth; is that right?

MS. BORELLI: Objection; form.

THE WITNESS: Well, let me clarify. There was not a time -- we -- there was not a time -- I'm going to go back because the historical context is important.

We've been providing services at our division of adolescent medicine since the '90s. But since we started tracking our new referrals, we -- in 2010 to 2015, there was an equal ratio.

And then in -- sorry, 2014-2015, we started getting a higher number of people designated female at birth new for consultation.

Q. (BY MR. DAVID) Okay. Has that population that you've seen starting to shift from 2014-2015, has it continued to today?

MS. BORELLI: Objection; form.

THE WITNESS: We still have -- it evened out a little bit -- at our center it evened out a little bit over the last year or two years, but we still have -- more than 50 percent of the people seeking services are designated female at birth, but it has evened out a little bit more.

Q. (BY MR. DAVID) Okay. Has that cohort of patients that has shifted that ratio been involved in studies regarding the efficacy of the services that you specifically provide, puberty blockers and hormone therapy? And we'll leave out the oral contraceptives.

But for puberty blockers and for the hormone therapy, has that cohort of patients been studied?

MS. BORELLI: Objection; form.

THE WITNESS: In -- are you talking about just broadly speaking, or in our program?

Q. (BY MR. DAVID) Well, let's start broadly speaking.

MS. BORELLI: Same objection.

REPORTER'S CERTIFICATE

STATE OF IDAHO)
) ss.
COUNTY OF ADA)

I, AMY E. SIMMONS, Certified Shorthand Reporter and Notary Public in and for the State of Idaho, do hereby certify:

That prior to being examined, the witness named in the foregoing deposition was by me duly sworn remotely to testify to the truth, the whole truth and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named and thereafter reduced to typewriting under my direction, and that the foregoing transcript contains a full, true and verbatim record of said deposition.

I further certify that I have no interest in the event of the action.

WITNESS my hand and seal this 10th day of May, 2022.

AMY E. SIMMONS
CSR, RPR, CRR, CRC and Notary Public in and for the State of Idaho.

My Commission Expires: 06-13-2022