IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI; *et al.*, Plaintiffs, v. Herbert H. SLATERY III, Attorney General of Tennessee, in his official capacity; *et al.*, Defendants.	CASE NO. 3:20-cv-00740 JUDGE CAMPBELL MAGISTRATE JUDGE NEWBERN

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION IN LIMINE TO EXCLUDE THE TESTIMONY OF DR. HARRISON AND LIMIT THE TESTIMONY OF DR. BOLES AND DR. DELGADO

Pursuant to Federal Rules of Evidence 702 and 402, Plaintiffs respectfully move to exclude the testimony of Dr. Donna Harrison as well as portions of the proposed testimony of Drs. Brent Boles and George Delgado.

INTRODUCTION AND SUMMARY OF ARGUMENT

Defendants offer Drs. Harrison, Boles, and Delgado as both fact and expert witnesses, with each of the three witnesses expected to testify concerning, *inter alia*, medical ethics, informed consent, and scientific research methods, as well as results from "relevant studies and articles." *See* Parties' Witness Lists & Joint Mot. to Extend Deadlines 2–3, ECF No. 47 ("Witness List"). Plaintiffs object to the broad categorization of these witnesses' expertise, object specifically to certain expert designations for Drs. Boles and Delgado, and object to the designation of Dr. Harrison as either a fact or expert witness. Dr. Harrison lacks personal knowledge of any facts relevant to this case, lacks expertise in the relevant fields, and her testimony lacks the indicia of

credibility necessary for her expert testimony to be admissible. As discussed in detail below, Dr. Harrison's penchant for mischaracterizing and exaggerating facts and sources has led other courts to find her testimony unreliable, including specifically on the issue of medication abortion.[1]

ARGUMENT

I. Standard of Review

Federal Rule of Evidence 702 imposes three distinct substantive restrictions on the admission of expert testimony. *See In re Scrap Metal Antitrust Litig.*, 527 F.3d 517, 528–29 (6th Cir. 2008) (quoting Fed. R. Evid. 702); *United States v. Mallory*, 902 F.3d 584, 592 (6th Cir. 2018) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993)). First, the testimony must be relevant, meaning that it "help[s] the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702(a); *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 147 (1999).[2] Second, an expert witness may testify only if she is qualified, as demonstrated

[1] *See MKB Mgmt. Corp. v. Burdick*, 855 N.W.2d 31, 68 (N.D. 2014) (case concerning regulations on the provision of medication abortion) ("Dr. Harrison's opinions lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence. To the extent she referenced published studies during her testimony, Dr. Harrison tended to present the results in an exaggerated or distorted manner."); *Planned Parenthood Ark. & E. Okla. v. Jegley*, No. 4:15-cv-00784, 2018 WL 3029104, at *42 (E.D. Ark. 2018) (noting the opinion she offered "appears inaccurate and incomplete"); *Little Rock Fam. Plan. Servs. v. Rutledge*, 397 F. Supp. 3d 1213, 1268, 1300, 1323 (E.D. Ark. 2019) (noting that Dr. Harrison "cite[d] no source material or scientific studies" in support of an assertion in her declaration; filed a supplemental declaration "in response to cross examination" that added 162 articles, "more than half of [which] were published over 20 years ago," but did "not point[] the Court to any language in any particular study as supporting her position"; and submitted declarations that were "generalized and provide[d] the Court with no basis to determine" the issues in question); *see also* Order Granting in Part & Denying in Part Pls.' Mot. to Strike Third Aff. of Donna Harrison, M.D., & Mot. to Strike Fourth Aff. of Donna Harrison, M.D. 2, *Okla. Coal. for Reprod. Just. v. Cline*, No. CV-2014-1886 (Dist. Ct. Okla. Cnty. Sept. 6, 2017) [hereinafter "Order Granting in Part"] (striking, *inter alia,* twenty-two full paragraphs from her declaration in case concerning regulations on the provision of medication abortion).

[2] Rule 402 makes such irrelevant evidence inadmissible as well. *See* Fed. R. Evid. 402 ("Irrelevant evidence is not admissible."); *see also* Fed. R. Evid. 401 ("Evidence is relevant if: (a) it has any

by her "knowledge, skill, experience, training, or education" in the purported area of expertise. Fed. R. Evid. 702; *see also Daubert*, 509 U.S. at 589–90. Third, her testimony must be reliable, meaning it is "based on sufficient facts or data"—not subjective beliefs or speculation—and is "the product of reliable principles and methods." Fed. R. Evid. 702(b), (c); *see also Daubert*, 509 U.S. at 589–90. The party moving for admission of the testimony must also demonstrate that the expert "reliably applied th[ose] principles and methods to the facts of the case." Fed. R. Evid. 702(d). The burden of proving admissibility rests on the party seeking to admit the expert witness. *Sigler v. Am. Honda Motor Co.*, 532 F.3d 469, 478 (6th Cir. 2008) (quoting *Pride v. BIC Corp.*, 218 F.3d 566, 578 (6th Cir. 2000)).

A district court acts properly by excluding opinions that are beyond the witness's expertise. *See Smelser v. Norfolk S. Ry. Co.*, 105 F.3d 299, 305 (6th Cir. 1997), *abrogated on other grounds by Morales v. Am. Honda Motor Co.*, 151 F.3d 500, 515 (6th Cir. 1998). Even in the absence of a jury, "*Daubert*'s standards must still be met." *Att'y Gen. of Okla. v. Tyson Foods, Inc.*, 565 F.3d 769, 779 (10th Cir. 2009); *Seaboard Lumber Co. v. United States,* 308 F.3d 1283, 1302 (Fed. Cir. 2002); *see also Bradley v. Brown*, 42 F.3d 434, 435 (7th Cir. 1994) (affirming district court's exclusion of two physicians' expert testimony in the context of a bench trial).

II. Defendants' Expert Testimony Does Not Satisfy Rule 702

A. Dr. Donna Harrison

Dr. Harrison is currently scheduled to testify on December 14, 2020. Defendants expect her to testify about "medical ethics, informed consent, scientific research methods and study designs, and the biological plausibility of avoiding, ceasing, or reversing the intended effects of a

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tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action."); *United States v. LeBlanc*, 45 F. App'x 393, 400 (6th Cir. 2002) ("Obviously, expert testimony is subject to the same relevancy constraints as all other kinds of evidence."); *United States v. Geiger*, 303 F. App'x 327, 332 (6th Cir. 2008).

medication abortion through progesterone supplementation and the supporting results from relevant studies and articles." Witness List at 3. Dr. Harrison has not practiced clinical medicine in two decades and has no medical or scientific training or expertise beyond that of the ordinary formerly practicing OB-GYN. Decl. of Christine Clarke in Supp. of Pls.' Mot. to Exclude Test. of Dr. Harrison & Limit Test. of Dr. Boles & Dr. Delgado ("Clarke Decl.") Ex. A, Rough Tr. of Nov. 13, 2020, Dep. of Donna Harrison ("Harrison Dep. (Rough)") 16:5–6, 17:11–17; Harrison Decl. Ex. 1 ("Harrison CV"), ECF No. 16-2. While Dr. Harrison has spent two decades working at an anti-abortion advocacy organization (of which she is currently executive director), *see id.* at 16:23–17:1, 17:11–17, that does not constitute medical or scientific expertise.[3] Moreover, the substantial misrepresentations and mischaracterizations that appear throughout her declaration undermine her credibility so severely that her testimony should be excluded in its entirety.

1. Lack of Expertise

Despite the sweeping topics on which Defendants propose to proffer her testimony, Dr. Harrison herself claims expertise only in "the effects of Mifeprex on progesterone receptors and the biological plausibility of the use of progesterone to displace Mifeprex from progesterone receptors and that effect in early pregnancy." Harrison Dep. (Rough) 67:23–68:7 ("Q. And what are you an expert in on this case? A. I'm an expert in the effects of Mifeprex on progesterone receptors and the biological plausibility of the use of progesterone to displace Mifeprex from progesterone receptors and that effect in early pregnancy. Q. Is that all, for the purposes of this case? A. I think so."). Moreover, during her deposition, counsel for Defendants objected to a line

[3] As the North Dakota Supreme Court found before declining to credit her testimony because it was biased and contradictory, *see supra* note 1,"Dr. Harrison is opposed to abortion in all forms [and] [i]n 2000, she left her medical practice in order to devote all of her time and energy to the American Association of Pro-life Obstetricians and Gynecologists." *MKB Mgmt. Corp.*, 855 N.W.2d at 68.

of questioning concerning informed consent on the grounds that, *inter alia*, such areas were outside her expertise. *Id.* at 142:19–145:25 ("[W]ould you be willing to agree that I've got a continuing objection to any hypotheticals [about informed consent] since at this point, as Dr. Harrison has testified, her expertise lies in progesterone receptors and Mifeprex and the like[?]").

Dr. Harrison neither claims nor has any expertise in the remaining fields cited by Defendants: "medical ethics, informed consent, scientific research methods and study designs" and "results from relevant studies and articles." Witness List at 3; *see* Harrison CV at 2–3. She has published no articles, conducted no research, and obtained no advanced training in any of those fields. Harrison CV at 2–3.

Even in the field in which Dr. Harrison claims expertise—i.e., the "biological plausibility" of abortion "reversal"—she has never conducted or published any research on the topic. Harrison Dep. (Rough) 68:8–69:16; Harrison CV at 3. She has received no advanced training or expertise in either biology or endocrinology, nor has she published or taught any courses on the subjects. *See* Harrison CV at 2–3. Indeed, neither of the only two papers Dr. Harrison has published concerning mifepristone reflect any clinical or research. *Id.*[4] While she serves as an adjunct professor at Trinity International University in Deerfield, Illinois, her responsibilities are limited to teaching a single workshop once per year in the summers. Harrison CV at 1; Harrison Dep. (Rough) 16:7–22.[5]

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[4] Clarke Decl. Ex. I, Byron C. Calhoun & Donna J. Harrison, *Challenges to the FDA Approval of Mifepristone*, 38 Annals of Pharmacotherapy 163, 163 (2004), (describing supposed "deviations from the normal Food and Drug Administration (FDA) requirements for drug approval [that] led to legal challenge"); Clarke Decl. Ex. J, Margaret M. Gary & Donna J. Harrison, *Analysis of Severe Adverse Events Related to the Use of Mifepristone as an Abortifacient*, 40 Annals of Pharmacotherapy 191, 191 (2006) (analyzing data in "[s]ix hundred seven unique mifepristone [adverse event reports] submitted to the FDA over a 4 year span").

[5] Dr. Harrison's profile from the Charlotte Lozier Institute, discussed in more detail *infra* at n.6, notes that the workshops she teaches are at the "Center for Bio Ethics and Human Dignity summer

As a result, Dr. Harrison's testimony in each of the areas on which Defendants have proffered her "is plainly inadmissible." *H.C. Smith Invs., L.L.C. v. Outboard Marine Corp.,* 181 F. Supp. 2d 746, 752–53 (W.D. Mich. 2002) (finding expert testimony "plainly inadmiss[i]ble" where "[n]one of the witnesses are qualified by sufficient 'knowledge, skill, experience, training or education' to venture their opinions[,]" and "[t]he witnesses have not published papers nor done any other scholarly work" in the relevant field and "there is also no scientific consensus as to the opinions they offer"; holding that admitting such testimony "would be to treat the truth with such reckless abandon as to wholly forsake the truth gathering process of the trial" (quoting Fed. R. Evid. 702)). To the extent that Dr. Harrison's work as an anti-abortion advocate involves "compil[ing]" abortion-related medical literature, Harrison Dep. (Rough) 19:3–11,[6] a "course of self-study is not adequate . . . to create an expert," *Taylor v. Watters*, 655 F. Supp. 801, 805 (E.D. Mich. 1987).

Ultimately, Dr. Harrison does not have any more specialized training or expertise than any other formerly practicing OB-GYN in *any* of the multiple topics on which Defendants proffer her testimony. "[M]erely possessing a medical degree is not sufficient to permit a physician to testify concerning any medical-related issue." *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965, 970 (10th Cir. 2001); *see also Christophersen v. Allied–Signal Corp.*, 939 F.2d 1106, 1113 (5th

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workshops." Charlotte Lozier Inst., *Donna Harrison, M.D., Associate Scholar*, https://lozierinstitute.org/team-member/donna-harrison/ (last visited Nov. 24, 2020).

[6] Dr. Harrison is also an Associate Scholar at the Charlotte Lozier Institute, "the research arm of the Susan B. Anthony List, which is an organization dedicated to electing candidates and pursuing policies that will reduce and ultimately end abortion." Tr. of July 22, 2019, Hr'g on Mot. for TRO/Prelim Inj., *Little Rock Fam. Plann. v. Rutledge*, No. 4:19-cv-00449 (E.D. Ark. July 25, 2019), ECF No. 84 (testimony of Dr. Harrison). However, this position does not appear to involve engaging in original research. Dr. Harrison testified that this position involves "participat[ing] in talking about the research for the life issues and what is published and what needs to be published and what could be published . . . ." Harrison Dep. (Rough) 41:8–16.

Cir. 1991) (same); *Berry v. City of Detroit*, 25 F.3d 1342, 1352 (6th Cir. 1994) (reversing district court decision that admitted opinions of expert where doing so would be "like declaring an attorney an expert in the 'law'"); *Rheinfrank v. Abbott Labs., Inc.*, 680 F. App'x 369, 380 (6th Cir. 2017) (unpublished).

Nor can Dr. Harrison make up for her lack of academic expertise with clinical experience, as she has not obtained informed consent for *any* procedure in twenty years since she has not practiced during that time, Harrison Dep. (Rough) 16:5–6, and has never provided "reversal" treatment, *id.* at 76:23–25, 80:18–21. She is unsure whether she has ever even referred someone for such treatment. *Id.* at 77:1–6. For these reasons, Dr. Harrison also lacks any personal knowledge that would permit her to provide factual testimony relevant to this case, as Defendants indicate she intends to do. *See* Witness List at 3.

2. Unreliability of Testimony

Dr. Harrison's testimony must also be excluded because the number and nature of misrepresentations and mischaracterizations in her sworn declaration undermine her credibility to the point where her opinions "lack any of the indicia of reliability required under Fed. R. Evid. 702 and *Daubert*, and consequently, should not be considered by the Court." *In re Ohio Execution Protocol Litig.*, No. 2:11-CV-1016, 2019 WL 3821786, at *4 (S.D. Ohio Aug. 15, 2019) (excluding testimony of proposed expert witness who "include[d] no citations to scientific publications or experimental results to support [his] statements[,]" and failed to explain "why he is qualified to draw that conclusion . . . as he does not appear to have training" in the field).

Indeed, multiple federal and state courts have stricken or declined to credit Dr. Harrison's testimony in favor of abortion restrictions, including specifically restrictions on medication abortion. For example, in declining to credit Dr. Harrison's opinions about medication abortion

complications, the Supreme Court of North Dakota noted that "Dr. Harrison's opinions have shifted dramatically over time, and appear to be shaped primarily by the position she is advocating at the moment,"[7] and that they "lack scientific support, tend to be based on unsubstantiated concerns, and are generally at odds with solid medical evidence." *MKB Mgmt. Corp.*, 855 N.W.2d at 68. The court further noted that "[t]o the extent she referenced published studies . . . Dr. Harrison tended to present the results in an exaggerated or distorted manner" and that "her demeanor on the stand was guarded and defensive." *Id.* For these reasons, the court did not find Dr. Harrison to be a credible witness. *Id* at 68–69.

Similarly, in declining to credit Dr. Harrison's testimony in the preliminary injunctive context, an Arkansas federal district court noted Dr. Harrison's full-time focus on her American Association of Pro-Life Obstetricians and Gynecologists ("AAPLOG") activities and lack of clinical experience connected to the opinions she offered, and concluded that "Dr. Harrison's statements regarding the incidence of complications from medication abortions must be rejected" and that her other testimony "appears inaccurate and incomplete." *Jegley*, 2018 WL 3029104, at *42; *see also Little Rock Fam. Plan.*, 397 F. Supp. 3d at 1268, 1300 (noting a variety of concerns with Dr. Harrison's declarations); Order Granting in Part, *supra* note 1, at 2 (striking, *inter alia,* twenty-two full paragraphs from Dr. Harrison's declaration).

Dr. Harrison's declaration in the instant case is replete with mischaracterizations and unsubstantiated claims. For example, Dr. Harrison's declaration is rife with citations that do not mention, much less support, the claims for which she cites them. Dr. Harrison's declaration twice

[7] More specifically, the North Dakota Supreme Court noted that Dr. Harrison reversed course on the safety of the FDA-approved regimen for medication abortion; she had previously "argued vehemently" that the regimen posed unacceptable risks to women's health, but abandoned that position entirely when it no longer served her litigation interests. *See MKB Mgmt. Corp.,* 855 N.W.2d at 68.

cites a book without providing page numbers. Decl. of Dr. Donna Harrison ("Harrison Decl.") ¶¶ 8 n.2, 16 n.8, ECF No. 16-2. When asked under oath to identify which *chapter* in the book she had intended to cite, she was unable to do so, despite having testified that she reviewed all her scientific citations in preparation for her deposition. Harrison Dep. (Rough) 10:1–5, 189:23–191:18. The book references nowhere in its 347 pages the possibility that "mifepristone is reversible by progesterone," as Dr. Harrison claims. Harrison Dep. (Rough) 191:19–22; Clarke Decl. Ex. B, *The Antiprogestin Steroid RU 486 and Human Fertility Control* (Etienne-Emile Baulieu & Sheldon J. Segal eds., 1985).[8] Additionally, Dr. Harrison cites to two sources, which she blatantly mischaracterizes as government studies (*see infra*), for the proposition that the "blockade of mifepristone at the glucocorticoid receptor 'can be reversed' by the administration of additional glucocorticoids." Harrison Decl. ¶ 16 (emphasis omitted). Neither of the cited sources says anything of the sort.[9] Even Dr. Harrison's citations to publicly available websites are misleading

[8] In the single instance where Dr. Harrison she does provide a more specific citation, *see* Harrison Decl. ¶ 19, the source *still* does not support the claims for which she cites it, and indeed appears to demonstrate the opposite. Clarke Decl. Ex. B, at 90–91 & Fig. 3 (showing that mifepristone disassociates from receptors much more slowly than progesterone, and noting that disassociation of each radioactive compound was initiated by adding 1,000x the amount of that same non-radioactive compound).

[9] One source specifically notes that when glucocorticoid receptors are deactivated, glucocorticoids *do not* reverse certain side-effects of mifepristone in animals "at the glucocorticoid receptor," contrary to Dr. Harrison's claims. Clarke Decl. Ex. C, Tr. of May 11, 2006, Esther M. Sternberg, Expert Panel Member at the Dept. of Health & Hum. Servs. Emerging Clostridial Disease Workshop, at 116; Harrison Decl. ¶ 16. The other source discusses *concurrently* treating rats with mifepristone and glucocorticoids prior to exposing them to various toxins, rather than administering "additional glucocorticoids" to "reverse" mifepristone's effects, as Dr. Harrison claims. Clarke Decl. Ex. D, Jeanette Webster & Esther M. Sternberg, Review, *Role of the Hypothalamic-Pituitary-Adrenal Axis, Glucocorticoids and Glucocorticoid Receptors in Toxic Sequelae of Exposure to Bacterial and Viral Product*, 181 J. Endocrinology 207, 212 (2004); Harrison Decl. ¶ 16.

Similarly, Dr. Harrison described a study on rats as involving treatments similar to so-called "reversal," writing that rats were given "mifepristone *followed by* natural progesterone." Harrison Decl. ¶ 17 (emphasis added). During her review of the study at her deposition, however, it became

and inaccurate. Dr. Harrison cites the Society for Assisted Reproductive Technology website for the claim that "the IVF industry has looked carefully to see if there are any indications of an increased risk from natural progesterone and have found none," Harrison Decl. ¶ 29, when in fact the website in question simply states "[w]hile long-term adverse consequences of progesterone therapy have not been identified in humans and appear unlikely, the safety of this or any drug cannot be absolutely guaranteed. . . . [s]ynthetic progestins may not be safe in pregnancy."[10]

While Dr. Harrison cites sources that do not relate to her claims, she simultaneously fails to provide attribution for the large portions of her declaration that were copied *verbatim* from an AAPLOG publication, which she admits she did not author. C*ompare* Harrison Decl. ¶¶ 13, 17, 26–28 *with* Clarke Decl. Ex. F, AAPLOG, *Practice Bulletin 6: The Reversal of the Effects of Mifepristone by Progesterone* (2019), at 2–5; *see* Harrison Dep. (Rough) 180:17–22, 186:3–7.

Not only did Dr. Harrison misleadingly cite her sources, she mischaracterized them in such a way as to lend them an artificial air of credibility or institutional backing. For example, Dr. Harrison refers to a paper as a "National Institutes of Health (NIH) stud[y]" based solely on the fact that one of the paper's authors has worked at the NIH.[11] Harrison Decl. ¶ 16; Harrison Dep. 192:19–193:10. The second citation Dr. Harrison gives for a supposed NIH study is neither a study nor published by the NIH. Harrison Dep. (Rough) 193:24–194:12; Harrison Decl. ¶ 16 n.9. Despite

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clear that this was not the case—the study involved injecting rats with a *mixture* of mifepristone and progesterone and thus the substances were administered *simultaneously*, unlike so-called reversal treatments. Harrison Dep. (Rough) 187:25–188:5.

[10] Clarke Decl. Ex. E, Soc'y for Assisted Reprod. Tech., *Progesterone: Risks and Benefits*, https://www.sart.org/patients/a-patients-guide-to-assisted-reproductive-technology/stimulation/progesterone/ (2020), at 3.

[11] The paper in question was in fact published in the Journal of Endocrinology and the author in question appears at the time to have been working at the NIH's mental health arm, the National Institute of Mental Health. Harrison Decl. ¶ 16 n.9; Clarke Decl. Ex. D, at 207.

citing that source as being authored by "Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and National Institutes of Health (NIH)," in reality the source is the transcript of a joint agency workshop and includes, *inter alia,* statements given by members of the public. Clarke Decl. Ex. C at 1–4. Similarly, Dr. Harrison's declaration cites "manufacturer studies" concerning mifepristone. Harrison Decl. ¶ 16. While such a phrase implies that the studies were conducted by mifepristone manufacturers, Dr. Harrison testified that her usage of the phrase merely meant that the manufacturers of mifepristone have *cited* those studies at some point in time. Harrison Dep. (Rough) 188:20–189:16. She admitted that she did not know whether the manufacturers of mifepristone conducted the studies in question and that she did not know where the studies were conducted. *Id.*

Dr. Harrison's misrepresentations and her misleading use of sources are sufficient grounds to exclude her testimony. *See United States v. Taylor*, 704 F. Supp. 2d 1192, 1199 (D. N.M. 2009) (excluding testimony from proposed expert who "took a quotation from another publication so far out of context as to completely reverse its meaning and cause it to be misleading" and who "not only mischaracterize[d] as a 'study' something that is actually a one-page technical note, but also misrepresent[ed] the underlying thesis of that note").

Ultimately, Dr. Harrison's opinions on the "reversibility" of mifepristone derive from Dr. Delgado's papers. Her opinions are entirely derivative of the opinions of Dr. Delgado and thus must be excluded. *See In re Ohio Execution Protocol Litig.*, 2019 WL 3821786, at *4 (excluding testimony of expert where "the only source he cites in support of [his] conclusion" is a paper submitted by another expert in the case and thus was "derivative" of the other expert's work).[12]

[12] Though Dr. Harrison lacks the expertise to comment on Dr. Delgado's work, she has a professional interest in doing so. AAPLOG, the anti-abortion organization of which she is the

Because Dr. Harrison lacks relevant expertise, has no personal knowledge of the facts at issue in this case, her testimony lacks indicia of credibility, and her opinions are derivative of those of another witness in this case, Dr. Harrison's testimony must be excluded.

B. Dr. Brent Boles

Dr. Boles is scheduled to testify on December 2, 2020. Defendants expect Dr. Boles to testify concerning, *inter alia*, the theory and practice of abortion "reversal," medical ethics, and "scientific research methods and study results related to some of the relevant studies and articles." Witness List at 2–3.

As to abortion "reversal," though Dr. Boles has some limited personal experience with providing abortion "reversal" to pregnant patients, he has no expertise in either the theory or practice of abortion "reversal." Dr. Boles has testified that his knowledge of the reversal theory comes primarily from pro-life media as well as a "package of information" he received after contacting the Abortion Pill Rescue Network ("APRN"). Clarke Decl. Ex. H, Tr. of Nov. 6, 2020, Dep. of C. Brent Boles, M.D. ("Boles Dep.") 316:15–317:15. Specifically, he testified:

> I've seen stories about it in the pro-life literature and on social media and —because I do follow pro-life news very closely. So I just thought to myself, I need to look into this and figure out where the organization was that was providing this as a service. And I contacted them. They sent me their information and I discussed it with them and decided to make myself available as [] one of their panel of providers. . . .
>
> [T]hey have a standard package of information which includes the—the research that's been done so far; the current protocol, how it works; the information that they

Executive Director, both funds Dr. Delgado's research and sponsors the journal in which he published his 2018 case series, the article that forms the foundation of Defendants' scientific claims. *See* Harrison Dep. (Rough) 20:4–10, 56:17–57:1 (explaining that Dr. Harrison is the executive director of AAPLOG, that the Watson Bowes Institute is a pseudonym of AAPLOG, and that the Watson Bowes Institute co-sponsors *Issues in Law and Medicine*); Clarke Decl. Ex. G, Tr. of Nov. 17, 2020, Dep. of George Delgado ("Delgado Dep. (Rough)") 115–16 (noting receipt of funds from Watson Bowes Institute to study abortion reversal). Indeed, Dr. Harrison is not only the Associate Editor of that journal, but she was also personally involved in getting Dr. Delgado's work published. Delgado Dep. (Rough) 129; Harrison Dep. (Rough) 228:3–7.

> want communicated to the patient . . . . it's just a pretty standard, you know, package of information that anyone who wants to provide these services would want to know.

Id. Dr. Boles's first-hand experience providing progesterone to try to reverse medication abortion is also limited, as he has provided these "reversal" treatments to "probably more than 20" women and is only aware of the pregnancy outcomes of approximately six of them. Boles Dep. (Rough) 324:3–9, 324:25–325:4. Dr. Boles has no other knowledge of or independent expertise in either the theory or practice of abortion "reversal."

As to "scientific research methods and study results," Dr. Boles has never conducted his own scientific or medical research, conducted a peer review of medical research, or authored peer-reviewed articles, other than a handful of articles for which he was listed as co-author during medical school, but for which he was neither the principal author nor principal researcher. *See* Decl. of Brent Boles ("Boles Decl.") Ex. 1 ("Boles CV")), ECF No. 16-1; Boles Dep. 53:6–54:5, 55:22–24. Dr. Boles currently participates as an investigator in pharmaceutical research studies, but his "involvement is not in the study design." Boles Dep. 124:22. Pharmaceutical companies design the studies, and Dr. Boles "review[s] the protocol that is expected to be followed, and then follow[s] it." *Id.* at 124:23–24. He oversees the "medical aspects" of the studies and "review[s] and sign[s] off on" patient data and provides gynecological care to patients who request it. *Id*. at 120:19–23, 122:3–25. While this may give Dr. Boles some expertise concerning the reporting of adverse events in medical studies on human subjects, it does not constitute experience or training in "scientific research methods."

With respect to medical ethics, Dr. Boles has admitted that he has no expertise "[o]ther than what is required for any current practitioner of medicine." *Id.* at 54:24–55:11, 57:18–22.

Defendants offer Dr. Boles as an expert witness in the theory and practice of abortion "reversal," medical ethics, and "scientific research methods and study results related to some of the relevant studies and articles." Witness List at 2–3. But because Dr. Boles's training and experience in these areas does not extend further than that of any practicing physician, Dr. Boles cannot be considered an expert in these areas. *See Ralston*, 275 F.3d at 970; *Berry*, 25 F.3d at 1351.

C. Dr. George Delgado

Dr. Delgado is scheduled to testify on December 2, 2020. Defendants expect Dr. Delgado to testify concerning, *inter alia*, "medical ethics, informed consent, scientific research methods and study designs, and the biological plausibility of avoiding, ceasing, or reversing the intended effects of a medication abortion through progesterone supplementation and the conduct and supporting results from relevant studies and articles." Witness List at 3. Because Dr. Delgado is not qualified as an expert in medical ethics, informed consent, or scientific research methods and study designs, his testimony on those subjects must be excluded.

Dr. Delgado has never published any peer-reviewed articles or conducted any research on medical ethics, informed consent, or research methods and study designs.[13] Indeed, Dr. Delgado has only ever published three articles, all of which concern his theory that medication abortions are reversible via progesterone. Delgado Decl. Ex. 1 ("Delgado CV"), at 3, ECF No. 16-4. Dr. Delgado is a family medicine doctor; he is not an OB-GYN, biologist, or endocrinologist, *id.* at 1,

[13] Plaintiffs do not concede that Dr. Delgado has any expertise in any of the underlying medical or scientific issues related to his abortion "reversal" theory. Indeed, he lacks relevant training and experience and his declaration and published works all suffer from basic methodological flaws sufficient to disqualify him as an expert. *Newell Rubbermaid Inc. v. Raymond Corp.*, 676 F.3d 521, 528 (6th Cir. 2012) (listing "red flags" such as "anecdotal evidence, improper extrapolation, failure to consider other possible causes, and, significantly, a lack of testing"). That being said, Plaintiffs recognize that this Court may wish to hear from Dr. Delgado as he has authored the only papers claiming to prove his abortion "reversal" theory and therefore is one of the few people who can testify about his own deeply flawed research.

and thus lacks expertise to offer an opinion on the "biological plausibility" of reversing mifepristone, or indeed to offer opinions about mifepristone or progesterone. Dr. Delgado has never served as a peer reviewer for any medical publication, nor has he ever served on an institutional review board. Delgado Dep. (Rough) 10. Dr. Delgado admitted that he is not an expert in the design of medical studies and that the only experience he has comes from working on two of his three published papers and assisting in designing two studies that have not yet begun. *Id.* at 10–11, 13–14, 15 ("I would say, I have developed expertise. I would not say I'm an expert. There's a difference."); *see also id.* at 17. Ultimately, Dr. Delgado has no more training or expertise in these fields than any other general practice physician. *Id.*; *see Berry*, 25 F.3d at 1351.

Dr. Delgado's qualifications do not provide the foundation for him to offer expert opinions concerning medical ethics, informed consent, scientific research methods, or study designs and thus his expert testimony on these subjects must be excluded.[14]

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the testimony of Dr. Harrison be excluded in its entirety; that Dr. Boles not be qualified as an expert in and permitted to offer opinion testimony concerning the theory and practice of abortion "reversal," medical ethics, and "scientific research methods and study results related to some of the relevant studies and articles"; and that Dr. Delgado not be qualified as an expert in and permitted to offer opinion testimony concerning medical ethics, informed consent, scientific research methods, or study designs.

[14] The single court to have addressed the validity of Dr. Delgado's expert opinions has refused to credit his testimony, finding that he sought to opine on matters outside his expertise and that he lacked adequate data to support his conclusion. *S. Bay United Pentecostal Church v. Newsom*, No. 20-cv-865, 2020 WL 6081733, at *14 (S.D. Cal. Oct. 15, 2020).

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Respectfully submitted,

By: */s/ Thomas H. Castelli*

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CERTIFICATE OF SERVICE

I, the undersigned, do hereby certify that on November 24, 2020, a true and correct copy of the foregoing was served on the Tennessee Attorney General's Office, counsel for all Defendants, via the Court's ECF/CM system.

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