

No. 22-1721

**IN THE UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT**

MAXWELL KADEL, *et al.*,
Plaintiffs-Appellees
v.
DALE FOLWELL, *et al.*,
Defendants-Appellants

On Appeal from the United States District Court
for the Middle District of North Carolina at Greensboro,
No. 1:19-cv-00272

**BRIEF OF THE STATES OF MISSOURI, ALABAMA, ALASKA, ARKANSAS,
FLORIDA, GEORGIA, INDIANA, IOWA, KANSAS, KENTUCKY, LOUISIANA,
MISSISSIPPI, MONTANA, NEBRASKA, NORTH DAKOTA, OHIO,
OKLAHOMA, SOUTH CAROLINA, TEXAS, UTAH, AND VIRGINIA, AS AMICI
CURIAE IN SUPPORT OF DEFENDANTS-APPELLANTS AND REVERSAL**

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INTRODUCTION AND INTEREST OF AMICI CURIAE

The States of Missouri, Alabama, Alaska, Arkansas, Florida, Georgia, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Montana, Nebraska, North Dakota, Ohio, Oklahoma, South Carolina, Texas, Utah and Virginia, submit this brief to explain their strong interest in preserving the prerogative of States to make decisions “in areas fraught with medical and scientific uncertainties.” *Dobbs v. Jackson Women’s Health Organization*, [142 S. Ct. 2228, 2268](#) (2022) (quoting *Marshall v. United States*, [414 U.S. 417, 427](#) (1974)); *see also* *Gonzales v. Carhart*, [550 U.S. 124, 163](#) (2007) (States have “wide discretion” to regulate “in areas where there is medical and scientific uncertainty”). Making policy decisions in an area of scientific uncertainty is a core, sovereign, democratic function.

The States file this amicus brief in two cases, Nos. 22-1927 and 22-1721, both of which involve similar issues. The decisions by both district courts threaten this democratic prerogative. Taken together, the decisions wrongly assume that the science is settled and fully supports the routine use of puberty blocking drugs, cross-sex hormones, and surgeries to treat gender dysphoria. To the contrary, countries across Europe—the UK, France, Finland, Norway, and Sweden—have recently declared these interventions to be “experimental” procedures, “lacking”

in evidentiary support, whose “risks ... currently outweigh the possible benefits.” Agencies on this side of the Atlantic have concluded the same.

Even the organizations proffered by the plaintiffs and favorably cited by the district courts—such as WPATH and the Endocrine Society—muster only half-hearted recommendations, not the full-throated endorsement the district courts suggest. The Endocrine Society admits that its relevant recommendations are “weak recommendations” because the quality of evidence is “low” or “very low,” and WPATH admits that the model it advocates is unproven and that it merely “is *hoped* that future research will explore the effectiveness of this model.”

In light of the medical uncertainty acknowledged across the globe, *Amici* States have taken a variety of approaches to the issue of using puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria. Some States decline to pay for these chemical and surgical interventions through state-funded healthcare programs. Some States—having compared the known, irreversible side-effects to the unknown, speculative benefits—have gone further and passed laws prohibiting these interventions in certain circumstances. Others have passed laws barring these interventions only temporarily—until policymakers obtain the benefit of more scientific studies. And still other States have allowed

these interventions only after individuals have first been provided adequate counseling care and psychological support.

In light of Supreme Court precedent giving States wide authority in areas of uncertainty, this Court should permit the States wide latitude to respond to these scientifically unsettled issues.¹

ARGUMENT

I. Chemical and surgical interventions cannot be assessed separately from the conditions to be treated.

At the outset, both district courts made an initial error that affected the rest of their analyses: They wrongly assumed that a procedure used to treat one condition is no different from the same “technical” procedure used to treat a different condition—that is, if a procedure is effective for one condition (such as precocious puberty), it is equally appropriate for treating gender dysphoria. The district court in West Virginia, for example, concluded that the State could not deny coverage of surgery for gender dysphoria “based solely on diagnosis” because the “technical act” of a surgery “can be performed to treat both a non-gender dysphoria related diagnosis and a gender dysphoria related diagnosis.” No. 3:20-cv-

¹ No counsel for a party in this case authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation of this brief. No person other than *Amici* States made a monetary contribution to the preparation or submission of this brief.

00740, ECF No. 271, at 8, 28 (S.D.W.Va., Aug. 2, 2022). Similarly, the district court in North Carolina equated providing hormones to treat, say, a damaged pituitary gland with hormones to treat gender dysphoria. No. 1:19-cv-00272, ECF No. 234, at 42 (M.D.N.C., June 10, 2022).

This assumption readily falters. A procedure that is effective for one diagnosis quite often is inappropriate—if not downright harmful—for another, regardless of whether the “technical” details of the procedure remain the same. To the diabetic patient, injecting insulin is life saving. To the hypoglycemic patient, it is life ending.

Surgeries plainly are not appropriate to treat gender dysphoria just because they are appropriate to treat some other, unrelated diagnosis. The district court in West Virginia said the “technical act of a mastectomy can be performed to treat both a non-gender dysphoria related diagnosis and a gender dysphoria related diagnosis.” No. 3:20-cv-00740, ECF No. 271, at 8 (internal quotation marks omitted). But there is a world of difference between using a mastectomy to remove *unhealthy* tissue (such as cancerous cells) and using a mastectomy to remove *perfectly healthy* tissue (physiologically speaking) that a patient says is causing inner, psychological distress.

So too with hormones. When a natal male receives a testosterone infusion to treat issues relating to his pituitary gland, the hormonal

infusion raises levels to normal. But when a natal female seeks to treat gender dysphoria with testosterone, that individual already has testosterone levels that are normal for a natal female. Indeed, because gender dysphoria is distress related to a person's "*internal* sense" of gender, No. 1:19-cv-00272, ECF No. 234, at 7 (emphasis added), a natal female who suffers from gender dysphoria is physiologically the same as a natal female who does not. For that individual, testosterone infusion raises testosterone levels *not* to normal, but to up to 10 times what is physiologically normal for a natal female. *Practical Guidelines for Transgender Hormone Treatment*, Boston University School of Medicine.² There is no reason to believe that hormonal infusion will have anything close to the same effect when used to treat a pituitary disorder as when used to treat gender dysphoria.

Indeed, it is precisely because the effect of chemical or surgical intervention is expected to be different that guidelines for gender interventions exist at all. The district courts touted the Endocrine Society's Guidelines for Treatment of Gender Dysphoria and WPATH's Standards of Care. But if the expected effect of a treatment were the same regardless of diagnosis, as the district courts suggested, then there would be no need for either organization to promulgate its guidelines.

² <https://www.bumc.bu.edu/endo/clinics/transgender-medicine/guidelines> (last visited May 10, 2023)

II. Health authorities across the globe consider the gender transition interventions at issue here to be “experimental” and unproven.

Both district courts suggested that using puberty blockers, cross-sex hormones, and surgeries to treat gender dysphoria is well established and medically necessary. The district court in West Virginia, for example, said that doubts about the efficacy of these interventions are “wholly unsupported” and in fact “refuted” by the evidence. No. 3:20-cv-00740, ECF No. 271, at 21–22.

A. But in fact, there is a robust international consensus that when it comes to these interventions, “the evidence is lacking.” *What America Has Got Wrong About Gender Medicine*, The Economist (Apr. 5, 2023).³ Countries across Europe—the UK, France, Finland, Norway, and Sweden—“have raised the alarm,” expressing concern that the harms “outweigh the benefits.” *Id.* Finland recently described these interventions in minors as “experimental” and said “treatment should seldom proceed beyond talking therapy.” *The Evidence to Support Medicalised Gender Transitions in Adolescents is Worryingly Weak*, The Economist (Apr. 5, 2023).⁴ Other countries are no different. In April,

³ <https://www.economist.com/leaders/2023/04/05/what-america-has-got-wrong-about-gender-medicine>

⁴ <https://www.economist.com/briefing/2023/04/05/the-evidence-to-support-medicalised-gender-transitions-in-adolescents-is-worryingly-weak>

Sweden’s health authority issued a systematic review of the evidence, concluding that puberty blockers for gender dysphoria “should be considered experimental” and that the evidentiary support was “insufficient” to back claims that cross-sex hormones are beneficial. Ludvigsson, et al., *A Systematic Review of Hormone Treatment for Children with Gender Dysphoria and Recommendations for Research*, *Acta Paediatrica*, 3–4 (Apr. 17, 2023).⁵ The BMJ (formerly British Medical Journal) reported in February that, because of the lack of evidence, “European countries have issued guidance to limit medical intervention in minors” and are instead “prioritizing psychological care.” Block, *Gender Dysphoria in Young People is Rising—and so is Professional Disagreement*, *BMJ*, 1 (Feb. 23, 2023).⁶

Activists tend to frame these interventions as evidence-based and established. The British Medical Journal, however, put it best when it said that these interventions can be called many things, “[b]ut don’t call them evidence based.” *Id.* at 6.

Consider a small sample of statements from European authorities:

- **Finland:** *Recommendation of the Council for Choices in Health Care in Finland: Medical Treatment Methods for*

⁵ <https://doi.org/10.1111/apa.16791>

⁶ <https://www.bmj.com/content/bmj/380/bmj.p382.full.pdf>

Dysphoria Related to Gender Variance in Minors,
PALKO/COHERE Finland (2020)⁷

- “In light of available evidence, gender reassignment of minors is an experimental practice.... Information about the potential harms of hormone therapies is accumulating slowly and is not systematically reported.”
 - “As far as minors are concerned, there are no medical treatment[s] that can be considered evidence-based.”
 - “It is not known how the hormonal suppression of puberty affects young people’s judgement and decision-making.”
 - Hormonal intervention may be considered only “if the need for it continues after other psychiatric symptoms have ceased and adolescent development is progressing normally.”
 - “Surgical treatments are not part of the treatment methods for dysphoria caused by gender-related conflicts in minors.”
- **Sweden:** *Care of Children and Adolescents with Gender Dysphoria*, Socialstyrelsen: The National Board of Health and Welfare (2022)⁸

⁷ https://ago.mo.gov/docs/default-source/press-releases/guidelines_minors_finland_certified-translation.pdf

⁸ <https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/kunskapsstod/2022-3-7799.pdf>

- “For adolescents with gender incongruence, the . . . risks of puberty suppressing treatment with GnRH-analogues [puberty blockers] and gender-affirming hormonal treatment [cross-sex hormones] currently outweigh the possible benefits.”
- “[H]ormonal treatments (i.e., puberty blocking and cross-sex hormones) will not be initiated in gender dysphoric patients under the age of 16.”
- **Sweden:** Gauffin, et al., *Systematic Review, Guideline Regarding Hormonal Treatment of Minors with Gender Dysphoria at Tema Barn – Astrid Lindgren Children’s Hospital (ALB)* (2021)⁹
 - “[T]he studies conducted to date are small, uncontrolled observational studies providing low quality evidence that the treatments have the desired effect, and that we have very little knowledge about their safety in the long term.”
 - “[T]he ALB will not initiate hormonal treatment [puberty blockers and cross-sex hormones] for patients with gender dysphoria.”
- **Norway:** *Report from the Norwegian Healthcare Investigation Board*, UKOM (2023)¹⁰

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<https://ia802301.us.archive.org/4/items/gov.uscourts.ared.128159/gov.uscourts.ared.128159.45.8.pdf>

¹⁰ <https://ukom.no/rapporter/pasientsikkerhet-for-barn-og-unge-med-kjonnsinkongruens/sammendrag>

- “[P]uberty delaying treatment (puberty blockers) and hormonal and surgical gender confirmation treatment for children and young people are defined as experimental treatment.”
- **United Kingdom:** *Evidence Review: Gender-Affirming Hormones for Children and Adolescents with Gender Dysphoria*, National Inst. for Health and Care Excellence (2020); *Evidence Review: Gonadotrophin Releasing Hormone Analogues for Children and Adolescents with Gender Dysphoria*, National Inst. for Health and Care Excellence (2020)¹¹
 - “The results of the studies that reported impact [of puberty blockers] on the critical outcomes of gender dysphoria and mental health (depression, anger and anxiety), and the important outcomes of body image and psychosocial impact (global and psychosocial functioning) in children and adolescents with gender dysphoria are **of very low certainty** using modified GRADE.” (emphasis added).
 - “The key limitation to identifying the effectiveness and safety of gender-affirming hormones for children and adolescents with gender dysphoria is the lack of reliable comparative studies. All the studies included in the evidence review are uncontrolled observational studies, which are subject to bias and confounding and were of very low certainty using modified GRADE.”

¹¹ <https://cass.independent-review.uk/nice-evidence-reviews/>

- **France:** *Medicine and Gender Transidentity in Children and Adolescents*, French National Academy of Medicine (2022)¹²
 - “[G]reat medical caution must be taken in children and adolescents, given...the many undesirable effects, and even serious complications, that some of the available therapies can cause.”
 - For puberty blockers and cross-sex hormones, “the greatest reserve is required in their use, given the side effects.”
 - “It is essential to provide, first of all, a medical and psychological support to these children or adolescents ... especially since there is no test to distinguish a ‘structural’ gender dysphoria from transient dysphoria in adolescence. Moreover, the risk of over-diagnosis is real, as shown by the increasing number of transgender young adults wishing to ‘detransition.’ It is therefore advisable to extend as much as possible the psychological support phase.”
 - “The vigilance ... underlining the addictive character of excessive consultation of social networks which is ... responsible, for a very important part, of the growing sense of gender incongruence.”

B. It is not just European authorities. American authorities likewise have noted that these interventions lack evidentiary support. The U.S. Agency for Healthcare Research and Quality agrees: “There is

¹² <https://www.academie-medecine.fr/la-medecine-face-a-la-transidentite-de-genre-chez-les-enfants-et-les-adolescents/?lang=en>

a lack of current evidence-based guidance for the care of children and adolescents who identify as transgender, particularly regarding the benefits and harms of pubertal suppression, medical affirmation with hormone therapy, and surgical affirmation.” *Topic Brief: Treatments for Gender Dysphoria in Transgender Youth*, AHRQ, Nom. No. 0928, at 2 (2021).¹³ And earlier this year, the Florida Boards of Medicine responded to this medical evidence by finalizing regulations that ban puberty blockers and cross-sex hormones for treating gender dysphoria in minors. Fla. Admin. Code R. 64B8-9.019; 64B15-14.014. These are just a few of the authorities that recognize that there is no solid evidence. There are many more.

C. The district court in West Virginia touted a few nongovernmental organizations that recommend these interventions, No. 3:20-cv-00740, ECF No. 271, at 20–21, but even these organizations have conceded that the evidence is lacking. As *The Economist* put it, “America’s professional bodies acknowledge the science is low quality.” *What America Has Got Wrong About Gender Medicine*, *supra*.¹⁴

¹³ <https://effectivehealthcare.ahrq.gov/system/files/docs/topic-brief-gender-dysphoria.pdf>

¹⁴ <https://www.economist.com/leaders/2023/04/05/what-america-has-got-wrong-about-gender-medicine>

For example, the Endocrine Society has recommended using puberty blockers and cross-sex hormones, but the relevant recommendations are tepid: the organization offers “weak recommendations” because the quality of the evidence is “low” or “very low.” Hembree, et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons*, 102(11) J. Clinical Endocrinology & Metabolism 3869, at 3871–72 (Nov. 2017) (“Endocrine Society Guidelines”).¹⁵ Similarly, the self-described advocacy organization WPATH,¹⁶ which advocates what it calls a “gender-affirming care model,” found only “scant, low-quality evidence.” The Economist, *The Evidence to Support Medicalised Gender Transitions in Adolescents is Worryingly Weak*, *supra*.¹⁷ In its most recent guidelines, WPATH even admits that its model is unproven, and that “it is *hoped* that future research will explore the effectiveness of this model.” WPATH, *Standard of Care 8*, at S33 (2022) (emphasis added).¹⁸

D. As is clear from the sources cited above, any claim that chemical or surgical intervention to treat gender dysphoria is “evidence-based” or

¹⁵ <https://academic.oup.com/jcem/article/102/11/3869/4157558>

¹⁶ World Professional Association for Transgender Health.

¹⁷ <https://www.economist.com/briefing/2023/04/05/the-evidence-to-support-medicalised-gender-transitions-in-adolescents-is-worryingly-weak>

¹⁸ <https://www.tandfonline.com/doi/pdf/10.1080/26895269.2022.2100644>

settled within the medical community is simply wrong. For these interventions, the evidence is lacking.

Activists and some media outlets sometimes claim otherwise and have tried to bully dissenting voices into silence. These suppression attempts have become so bad that prominent practitioners in the field are starting to expose them. Dr. Erica Anderson, who identifies as transgender and is a prominent clinical psychologist in San Francisco, has expressed concern that activists routinely hamper medical development by silencing and shaming critics. As Anderson said, “The pressure by activist medical and mental health providers, along with some national LGBT organizations to silence the voices of detransitioners and sabotage the discussion around what is occurring in the field is unconscionable.” Edwards-Leeper & Anderson, *The Mental Health Establishment Is Failing Trans Kids*, Washington Post (Nov. 24, 2021).¹⁹ “[T]he treatment pushed by activists, recommended by some providers and taught in many training workshops is to affirm without question.” *Id.* Providers who do not do so risk being “cast as transphobic bigots.” *Id.* This pressure has caused the field to “move[] from a more nuanced, individualized and developmentally appropriate assessment

¹⁹ <https://www.washingtonpost.com/outlook/2021/11/24/trans-kids-therapy-psychologist/>

process to one where every problem looks like a medical one that can be solved quickly with medication or, ultimately, surgery.” *Id.*

III. Unlike puberty blockers, cross-sex hormones, and surgeries, counseling care enjoys widespread support and has no physical side effects.

The purported benefits of chemical and surgical interventions are hypothetical. Unfortunately, the side effects are not. They are both known and severe. Premature mortality. Sterilization. Interference with brain development. Loss of bone density. Hypertension. Shockingly high suicide rates *after* chemical or surgical intervention. Surgeries in particular are known to have very high complication rates and low evidence of efficacy. *See, e.g., Wang, et al., Outcomes Following Gender Affirming Phalloplasty: A Systematic Review and Meta-Analysis*, 10 Sexual Medicine Reviews 499 (2022)²⁰ (reporting complication rates of 76.5% and noting that “current evidence” of surgical “outcomes is weak”).

Fortunately, a different treatment is well established—one with no physical side effects. Counseling care (sometimes called “talk therapy” or “psychotherapy”) has been “highly recommended” by WPATH and other groups. *E.g., WPATH, Standard of Care 7*, at 28 (2012).²¹ That is because, according to WPATH, counseling care can “greatly facilitate the

²⁰ <https://doi.org/10.1016/j.sxmr.2022.03.002>

²¹ https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English.pdf

resolution of gender dysphoria,” and through this care, many “individuals integrate their trans- or cross-gender feelings into the gender role they were assigned at birth and do not feel the need to feminize or masculinize their body.” *Id.* at 8, 25.

In other words, a method of treatment with *no* physical side effects has been recognized—even by prominent proponents of chemical and surgical intervention—as an effective clinical response to gender dysphoria. One reason for this recommendation is that gender dysphoria is often either caused by or aggravated by mental health conditions. WPATH has put it this way: gender dysphoria can be “secondary to, or better accounted for, by other diagnoses.” *Id.* at 23–24. Around 70% of individuals with gender dysphoria have serious mental health comorbidities, such as severe anxiety and depression or eating disorders. The Economist, *The Evidence to Support Medicalised Gender Transitions in Adolescents is Worryingly Weak*, *supra*.²² When those mental health comorbidities are treated, it often “greatly facilitate[s] the resolution of gender dysphoria.” *Standard of Care 7, supra*, at 25.²³

²² <https://www.economist.com/briefing/2023/04/05/the-evidence-to-support-medicalised-gender-transitions-in-adolescents-is-worryingly-weak>

²³ https://www.wpath.org/media/cms/Documents/SOC%20v7/SOC%20V7_English.pdf

Unfortunately, some providers of gender transition interventions skip this “highly recommended” process altogether and go straight to chemical and surgical interventions. Although many providers still provide talk therapy, some providers refuse. Planned Parenthood in Missouri, for example, skips this process. Indeed, the organization does not even appear to require a *diagnosis* of gender dysphoria before issuing chemical interventions.²⁴

The failure in recent years to provide basic counseling care to all individuals presenting with gender dysphoria has been disastrous for the growing number of individuals who detransition. As many as 20-30 percent of patients desist within a few years. Block, *The BMJ*, *supra* at 2.²⁵ In a recent study of detransitioners, 55% reported that they “did not receive an adequate evaluation from a doctor or mental health professional before starting transition,” and 38% said their gender dysphoria had been caused by some secondary factor. Edwards-Leeper & Anderson, *Washington Post*, *supra*.²⁶ These individuals were unnecessarily subjected to irreversible interventions. Notably, although

²⁴ <https://www.plannedparenthood.org/planned-parenthood-st-louis-region-southwest-missouri/patients/our-services/hormone-therapy> (last visited May 15, 2023).

²⁵ <https://www.bmj.com/content/bmj/380/bmj.p382.full.pdf>

²⁶ <https://www.washingtonpost.com/outlook/2021/11/24/trans-kids-therapy-psychologist/>

a few studies have found detransition rates lower than 20-30 percent, those studies all involved patients who “had undergone comprehensive assessments, lasting a year on average, before being recommended for treatment.” Terhune, *As More Transgender Children Seek Medical Care, Families Confront Many Unknowns*, Reuters (Oct. 6, 2022).²⁷ That is not the typical patient seen in America today.

Indeed, the typical patient today is far different from those in the medical literature that clinics use to try to justify their practices. Clinics typically cite the famous Dutch protocol, which they say found positive effects from these interventions. But “the patients passing through modern clinics are strikingly different from those assessed in” the Dutch protocol. The Economist, *The Evidence to Support Medicalised Gender Transitions in Adolescents is Worryingly Weak*, *supra*.²⁸ Dutch study patients were mostly male. All patients experienced persistent gender dysphoria since before completion of puberty, had responded well to puberty blockers, and were receiving continuous counseling. None experienced mental health comorbidities. *Id.* But in clinics today, patients are mostly female with an onset of gender dysphoria *after*

²⁷ <https://www.reuters.com/investigates/special-report/usa-transyouth-outcomes/>

²⁸ <https://www.economist.com/briefing/2023/04/05/the-evidence-to-support-medicalised-gender-transitions-in-adolescents-is-worryingly-weak>

puberty, and “70% or more of the young people seeking treatment suffer from mental-health problems.” *Id.*

The decisions of the States of West Virginia and North Carolina are thus justified for two reasons. First, because these procedures are experimental, the States need not fund them. *See* [42 U.S.C. § 1395y\(a\)\(1\)](#); *Rush v. Parham*, [625 F.2d 1150, 1156](#) (5th Cir. 1980) (holding that States “can reasonably exclude experimental treatment”). Second, declining to fund these procedures will cause greater reliance on tried-and-true methods of treatment, such as basic counseling care, that many clinics across the country are currently sidelining in favor of lucrative chemical and surgical interventions. Just as “European countries have issued guidance to limit medical intervention in minors” who have gender dysphoria and are instead “prioritizing psychological care,” Block, *The BMJ*, *supra*,²⁹ so too may North Carolina and West Virginia.

²⁹ <https://www.bmj.com/content/bmj/380/bmj.p382.full.pdf>

CONCLUSION

Gender dysphoria is a serious condition, and all individuals struggling with it deserve compassionate, evidence-based care. Disregarding the science and the harms is not compassionate. The evidence from the last decade suggests that today's common gender transition interventions are at best experimental and at worst deeply harmful. Policymakers in West Virginia and North Carolina are entitled to act accordingly.

The Court should reverse the judgments of both district courts and rule in favor of the States.

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Respectfully submitted,
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CERTIFICATE OF COMPLIANCE

1. This response brief complies with Fed. R. App. P. 29 and 32(a)(7)(B) because it contains 3,511 words.

2. This response brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Century Schoolbook font.

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