

**IN THE
INDIANA SUPREME COURT
CASE NO. _____**

COURT OF APPEALS CASE NO. 49A04-1611-JP-002474

IN RE: THE PATERNITY OF G.G.B.W.,)	
a minor child)	Appeal from the Marion Circuit
)	Court, Paternity Division
JAMES BARNHART)	
(Appellant/Petitioner Below),)	Trial Court Cause No.
v.)	49C01-1101-JP-003803
)	
SARA E. DAVIS WHITCOMB,)	The Honorable Sheryl Lynch,
(Appellee/Respondent Below).)	Judge
)	

**BRIEF OF *AMICUS CURIAE*
PHYSICIANS FOR INFORMED CONSENT
IN SUPPORT OF PETITION TO TRANSFER**

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STATEMENT OF INTEREST OF AMICUS CURIAE

For the public benefit, Physicians for Informed Consent (“PIC”) is a nationally recognized 501(c)(3) nonprofit organization dedicated to preserving the fundamental right and medical ethic of informed consent in vaccination. PIC members include practicing physicians, PhD biomedical research scientists, and members of the public throughout North America, including in the State of Indiana. Their mission is to unite doctors for preservation of informed consent in vaccination and educate the public on infectious disease, the immune system, and informed consent. PIC does not provide vaccine recommendations or any personal medical advice, but rather focuses on peer-reviewed education and safeguarding informed consent in vaccination.

Lawyer staff for PIC has provided thousands of families with legal guidance on informed consent in vaccination and best practices guidance to physician members as well. PIC’s regular Speaker Seminars and educational materials keep PIC physician members informed, and PIC’s online Physicians’ Forum provides a wealth of clinical resources regarding vaccine adverse events. Individually and collectively, PIC physician and PhD members have a wealth of experience regarding vaccination, infectious disease, and the immune system. PIC is uniquely qualified and situated to assist this Court by presenting the legal and public health policy concerns involved in this case.

The interest of PIC in this case arises from its members’ interests in safeguarding medical, personal belief, and religious exemptions to childhood vaccination. PIC members work daily to protect the medical ethic of informed consent, a basic virtue of a civilized society. PIC also has interest in promoting consistent recognition of informed consent law nationally. Here, PIC is concerned by the practical and ethical consequences that will result from the Court of

Appeals' disregard for Mother's right of informed consent and Father's desire to forcefully vaccinate the Child, despite Father's lack of even basic knowledge about vaccine and disease risk.

SUMMARY OF ARGUMENT

This Court should grant transfer and reverse the Court of Appeals' decision because it departed from accepted law and practice and improperly engaged in a reweighing of the evidence. Had the proper tests and scrutiny been applied in the Opinion, it would have recognized: (1) the known gaps in vaccine adverse event data collection affecting the accuracy of estimates of risks of vaccination relative to the small (in the U.S.) risks of the corresponding diseases and (2) the violation of the medical ethic of informed consent, should the vaccination of the Child be carried out against the custodial parent's consent.

ARGUMENT

III. THE OPINION PROPERLY ARTICULATED THE STANDARD OF REVIEW, BUT THEN DEMONSTRATES A DEPARTURE FROM ACCEPTED LAW AND PRACTICE AND IMPROPERLY ENGAGES IN A REWEIGHING OF THE EVIDENCE.

Articulating the proper standard of review, the Opinion in this case recognizes the obligation to determine whether the evidence supports the findings and then whether findings support the judgment. *In re the Paternity of G.G.B.W, J.B. v. S.W.*, 80 N.E.3d 264, 268 (Ind. Ct. App. 2017) (hereinafter "the Opinion") (citing *K.I. ex rel. J.I. v. J.H.*, 903 N.E.2d 453, 457 (Ind. 2009)). It further properly states the Court of Appeals will "not set aside the findings or judgment unless clearly erroneous" and will give "due regard" to "the opportunity of the trial court to judge the credibility of the witnesses." *Id.* (citing Ind. Trial Rule 52(A)).

On the contempt issue, the Opinion properly provides it is the trial court who has discretion to determine the contempt and that such judgment is reviewed solely under an abuse

of discretion standard. *Id.* at 268-69 (citing *Reynolds v. Reynolds*, 64 N.E.3d 829, 832 (Ind. 2016)). Reversal of a trial court's contempt judgment is therefore only proper where neither evidence nor inferences drawn therefrom can support it. *Id.* at 269 (citing *Hamilton v. Hamilton*, 914 N.E.2d 747, 755 (Ind. 2009)). Finally, the Opinion articulates, because Father appeals from a negative judgment, it should be reversed only where it is contrary to law and where the evidence leads to one conclusion alone. *Id.* (citing *Comm'r, Dep't of Env'tl. Mgmt. v. RLG, Inc.*, 755 N.E.2d 556, 559 (Ind. 2001)). The evidence is to be viewed in the light most favorable to the appellee. *Id.*

Despite the well-articulated and proper standards for review, the Court of Appeals thereafter engaged in a reweighing of the evidence. The Opinion's reversal of the trial court's decision improperly ignored the well-established fact that the school did not deny the Child enrollment based upon the submission of the religious exemption form. Appellant's App. Vol. II, p. 28. Likewise, the Opinion improperly ignored the abundance of evidence setting forth the known scientific dangers and risks of vaccination. Nowhere in the Opinion are the known risks and spectrum of danger acknowledged in any manner. The trial evidence provides that Mother's decision was respected by the Child's primary care physician and that Mother exercised the right and responsibility of the medical ethic of informed consent (the right to refuse a medical procedure after being informed of its risks). The trial court found this conduct was in the Child's best interest, and within Mother's rights as the Child's sole legal guardian with medical decision-making authority. Courts do not traditionally intervene in parent-doctor decisions, so it raised a red flag when the Court of Appeals intervened here. *See e.g., Troxel v. Granville*, 530 U.S. 57, 68 (2000) ("[T]here is a presumption that fit parents act in their children's best interests.... Accordingly, so long as a parent adequately cares for his or her children (*i.e.*, is fit), there will

normally be no reason for the State to inject itself into the private realm of the family to further question the ability of that parent to make the best decisions concerning the rearing of that parent's children").

Had the Court of Appeals applied the proper standard, it would have found, as the trial court did, abundant evidence that (1) vaccination carries substantial risk of harm and (2) vaccination efficacy is complex. For example:

92. The risks from vaccines include anaphylactic shock, brachial neuritis, encephalitis and death.

93. Vaccines are legally classified as "unavoidably unsafe."

94. "Vaccine Court," as it is commonly known, was established by Congress in 1986, in response to landmark case law that protects vaccine manufacturers from lawsuits associated with vaccine injuries.

95. A "table of injuries" was established, based upon the 14 vaccines that were being administered at that time. Since then, the number of vaccines administered in the US has grown to 59; the table of injuries has not been updated to include injuries from these new vaccines.

96. \$6 billion dollars has been collected for that fund thus far, with approximately \$3.2 billion having been paid out due to vaccine related injuries.

97. Many vaccine injury cases do not make it to court and many go unreported. The majority of doctors and health officials are unaware of the reporting system (VAERS, Vaccine Adverse Event Reporting System).

99. The United States requires more vaccines than any other countries and has a higher infant mortality rate. While the correlation between the two is not clear, it is part of the information available to Mother that forms the basis of her decision to not vaccinate the child.

252. Mother has clearly done extensive research into the medical efficacy of vaccines and the possible negative side effects; whether or not the Court agrees with Mother's position is not the issue, as there is at least information to make one stop and pause for a moment, before making a decision. Mother has taken the time to become informed and has relied upon the information she has gathered. This Court cannot say that Mother has failed to act in the parties' child's best interests with regard to her decisions on medical care. The Court's position might be different if Mother had not researched the matter thoroughly and weighed the pros

and cons, but it is clear that this is something Mother has given a great deal of thought and consideration to when making decisions on the parties' child's behalf.

Appellant's App. Vol. II, pp. 21-22, 44-45.

Likewise, the Court of Appeals would have found, as did the trial court, that Mother's preventative care plan with the Child's primary care physician should be respected. For example:

129. The parties' child's primary care physician is Dr. Ashlee Olp and she has treated the minor child since she was born. Dr. Olp is a family practitioner.

58. The parties' child has been generally healthy her whole life and only been seen by her doctor for a yeast infection, ear infection, and wart treatment. The parties' child has seen her family doctor seven times.

60. No evidence was presented that the examinations revealed any medical issue for the parties' child.

64. Mother is agreeable to the parties' child receiving regular preventative care, but she and Father are unable to agree upon vaccinations.

71. [I]f the parties' child did not show any active symptoms of infection or disease, she would not pose a health risk to James.

81. Mother has made a medical decision not to vaccinate the child due to her belief that the risk associated with vaccines outweighs the benefits, based upon the research she has done.

82. Mother has also chosen not to vaccinate the child based on her family medical history of diabetes, Alzheimer's, ovarian cancer and autoimmune dysfunction.

84. Family medical history can form the basis for a medical waiver for vaccinations.

Appellant's App. Vol. II, pp. 18, 20-21, 26. These examples show evidence presented which supported the trial court findings.

In contrast to these findings, the Opinion implicitly favored the opinion of Father's physician, Dr. Mastropietro, who was of the "strong opinion that all children should be vaccinated." Tr. Vol. III, p. 210. There are multiple issues with reliance on Dr. Mastropietro for

specific medical advice with respect to the Child. The first issue is simply logistical: Dr. Mastropietro was the medical doctor for only two of Father's children (sadly, one of whom is now deceased), yet Father attempted to rely on Dr. Mastropietro's advice for three of his children: the third being the Child at issue in this case. There was no evidence that Dr. Mastropietro ever examined the Child or was authorized to do so. The second issue is with Dr. Mastropietro's level of expertise in recognizing and reporting vaccine adverse events, as evidenced by the trial court record here:

77. Dr. Mastropietro advocated for vaccines; however, he had no specific expertise about vaccine safety and efficacy. He also had little knowledge of the risks of vaccines.

79. Dr. Mastropietro testified that the only reactions they are trained to spot are injection site redness and influenza-like symptoms, following the administration of vaccines.

98. Father's expert, Dr. Mastropietro, was unaware of VAERS or an obligation to report vaccine related injuries, at the time of his testimony.

Appellant's App. Vol. II, pp. 20, 22.

PIC is well-equipped to advise this Court, whereas Dr. Mastropietro's belief that "all children should be vaccinated" is based upon a lack of sufficient education and contradictory to the requirement of individualized informed consent. *See e.g.*, Paul Thomas & Jennifer Margulis, *The Vaccine-Friendly Plan* (2016). Due to undereducation, there is extreme underreporting of vaccine adverse events to the Vaccine Adverse Event Reporting System (VAERS). An HHS-funded review of vaccine adverse events over a three-year period by Harvard Medical School involving 715,000 patients found that "fewer than 1% of vaccine adverse events are reported." *Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS), Grant Final Report (R18 HS 017045)* (2011), <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>.

The Opinion’s failure to acknowledge, in any manner, the evidence in support of the trial court findings and judgment is inapposite the established and properly articulated standard of review. Findings of fact are clearly erroneous when there is no support for them in the record, either directly or by inference. *Steele-Giri v. Steele*, 51 N.E.3d 119, 125 (Ind. 2016). Likewise, a judgment is clearly erroneous when there is no evidence supporting the findings, the incorrect legal standard is applied to the facts, or the findings fail to support the judgment. *In re Adoption of O.R.*, 16 N.E.3d 965, 973 (Ind. 2014); *In re D.J. v. Ind. Dep’t of Child Servs.*, 68 N.E.3d 574, 578 (Ind. 2017). In spite of the ample evidence, the Opinion resulted from a reweighing of the evidence and improperly ignored the abundant scientific dangers and risks of vaccination.

IV. HAD THE PROPER LEGAL STANDARD BEEN APPLIED, THE OPINION WOULD HAVE RECOGNIZED: (A) THE KNOWN GAPS IN VACCINE ADVERSE EVENT DATA COLLECTION AFFECTING THE ACCURACY OF ESTIMATES AND RISKS OF VACCINATION RELATIVE TO THE SMALL (IN THE U.S.) RISKS OF THE CORRESPONDING DISEASES AND (B) THE VIOLATION OF THE MEDICAL ETHIC OF INFORMED CONSENT, SHOULD THE VACCINATION OF THE CHILD BE CARRIED OUT AGAINST THE CUSTODIAL PARENT’S CONSENT.

A. The Opinion Shows a Failure to Consider the Known Gaps in Vaccine Adverse Event Data Collection Affecting the Accuracy of Estimates of Risks of Vaccination Relative to the Small (in the U.S.) Risks of the Corresponding Diseases.

In 2012, the IOM published a report, *Adverse Effects of Vaccines: Evidence and Causality*, and acknowledged that there are risk factors not yet identified by medical science that can increase “individual susceptibility” to vaccine reactions:

Both epidemiologic and mechanistic research suggests that most individuals who experience an adverse reaction to vaccines have a pre-existing susceptibility. These predispositions can exist for a number of reasons – genetic variants (in human or microbiome DNA), environmental exposures, behaviors, intervening illness or developmental stage, to name just a few, all of which can interact. Some of these adverse reactions are specific to the particular vaccine, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine; others, at least with current technology and practice, are not.

Institute of Medicine Committee to Review Adverse Effects of Vaccines. *Id.* at Chap. 3, p. 82.

The trial court recognized there is a wide spectrum of vaccine complications identified and acknowledged by the top scientific authorities in America, such as the Institute of Medicine (IOM), a component of the U.S. National Academy of Sciences. Without giving any explanation, the Opinion ignored the entire body of scientific analysis of vaccination risks, which constitutes a significant departure from law and practice.

As a matter of vaccine public policy, because the risk of a severe vaccine adverse event is currently highly unpredictable on an individual basis prior to vaccine administration, it is inherently problematic for courts to establish what is in the true medical “best interest” of any individual child. Where there is unpredictable risk from (and not a fully guaranteed protective effect of) a preventative medical procedure, such as vaccination, there must be free and informed consent of a custodial parent. This is especially so where a parent is exercising Constitutional rights, as here, with freedom of religion and the due process right of bodily integrity.

Physicians are required by federal law to make a report to the federal Vaccine Adverse Events Reporting System (VAERS) of serious health problems, hospitalizations, injuries and deaths that occur following vaccinations, but it is estimated that only between one and ten percent of all vaccine adverse events are reported to VAERS. *See e.g.*, Steven Rosenthal & Robert Chen, *The Reporting Sensitivities of Two Passive Surveillance Systems for Vaccine Adverse Events*, 85 No. 12 *Am. Journal of Public Health* 1706 (1995), <http://ajph.aphapublications.org/doi/abs/10.2105/AJPH.85.12.1706?view=long&pmid=750335>; M. Miles Braun, *Vaccine Adverse Event Reporting System (VAERS): Usefulness and Limitations*, Johns Hopkins Bloomberg School of Public Health (2017), <http://www.vaccinesafety.edu/VAERS-Braun.htm>.

Put into context, the underreporting statistic is eye opening: in 2016 alone VAERS received 59,117 reports of adverse reactions following vaccination, including 432 deaths, 1,091 permanent disabilities, 4,132 hospitalizations, and 10,284 emergency room visits. Centers for Disease Control and Prevention, *The Vaccine Adverse Event Reporting System (VAERS) (2017)*, <https://wonder.cdc.gov/vaers.html>. Assuming VAERS captures only 1 percent of adverse events, the number of vaccine adverse events reported to VAERS in 2016 would reflect for that year close to 5.9 million actual adverse events.

The trial court's Findings of Fact numbers 100-126 addressed specific diseases and illustrated not only the inability of vaccination to address many of Father's concerns, but the possibility of vaccination actually exacerbating his concerns. Appellant's App. Vol. II, pp. 22-25. The trial court also properly considered methods to protect the immuno-compromised, such as Finding of Fact 247, "Father's concerns over the lack of vaccinations should be diminished once his twins are vaccinated and/or by taking reasonable precautions when the parties' child demonstrates symptoms of illness." Appellant's App. Vol. II, pp. 43-44. The trial court astutely observed some of the diseases (such as tetanus) that Father is/was threatening to forcefully vaccinate the Child (based on Dr. Mastropietro's advice, not in conformance with current science, to protect the immuno-compromised child) are not even contagious.

It was implicitly and erroneously assumed that the immuno-compromised cannot be immunized and therefore personal liberties in vaccination should be removed from others as a necessary and sufficient measure of their protection, but immuno-compromised persons cannot be vaccinated only with live attenuated viral vaccines. They cannot even be around those who have been recently vaccinated with live attenuated vaccines, to avoid exposure to live vaccine-derived viruses. However, the majority of modern vaccines are not made with live viruses, and

per the CDC: “Killed or inactivated vaccines do not represent a danger to immuno-compromised persons and generally should be administered as recommended for healthy persons.” Centers for Disease Control and Prevention, *Recommendations of the Advisory Committee on Immunization Practices (ACIP): Use of Vaccines and Immune Globulins in Persons with Altered Immunocompetence*, 42 (No. RR-4) Morbidity and Mortality Weekly Report (MMWR) (1993), <https://www.cdc.gov/mmwr/preview/mmwrhtml/00023141.htm>.

As for the protection of the immuno-compromised against disease exposure for which only live attenuated vaccines are available, such as measles or varicella (chickenpox), the CDC recommends a post-exposure immuno-prophylactic measure called immune globulin (IG), which constitutes passive immunization via the transfer of ready-made virus-neutralizing antibodies. *Id.* Thus, parents can protect their own immuno-compromised children via vaccination and/or passive immunization, if they willingly consent to the potential risks of these procedures, and there is no justification for a court to consider medically violating one person (in this case the Child) under the pretext of protecting the immuno-compromised.

Here, the Opinion further sets forth error in the finding, “the Decree accordingly requires that Child be vaccinated based on her school’s requirements.” *Paternity of G.G.B.W.*, 80 N.E.2d at 270. In Indiana, schools alone do not have authority to require vaccinations, but rather it is the legislature and public health departments that set and enforce requirements and exemptions to vaccination. Moreover, the Opinion has not provided for the input of the Child’s doctor, as the Indiana statute contemplates,¹ on any vaccination requirements and exemptions. Thus, the

¹ Indiana Code § 20-34-3-3 (2017) states, “If a physician certifies that a particular immunization ... is or may be detrimental to a student's health, the requirements of this chapter or IC 20-34-4 for that particular immunization is inapplicable....”

Opinion is too sweeping and would have a potentially dangerous result for the children of Indiana.

B. The Opinion Demonstrates a Failure to Consider the Violation of the Medical Ethic of Informed Consent, Should the Vaccination of the Child Be Carried Out Against the Custodial Parent’s Consent.

The Opinion overlooked the duty of the doctor to obtain informed consent and parental responsibility to understand risk, even though Father admitted that he wanted to force vaccination on the Child in spite of his own lack of even basic knowledge about vaccine risk and disease risk.

Every state in America recognizes the individual’s right to refuse medical treatment. Informed consent is the voluntary permission granted by a patient (or parent of a patient) to a physician for the performance a medical treatment or procedure, with knowledge of the diagnosis, and treatment or no treatment risks and benefits. The United States Supreme Court has also consistently recognized the constitutional right to remain free from forced medical treatment, even life-saving treatment. *See e.g., Cruzan v. Director, Missouri Dep’t of Health*, 497 U.S. 261, 279 (1990) (“It cannot be disputed that the Due Process Clause protects an interest in life as well as an interest in refusing life-sustaining medical treatment”); *Washington v. Harper*, 494 U.S. 210, 229 (1990) (“[t]he forcible injection of medication into a nonconsenting person’s body represents a substantial interference with that person’s liberty”). Indiana has also long enshrined this rule in its courts, as well as in Indiana Code 34-18-12 (“Informed Consent”) upholding “the duty to obtain an informed consent.” *See Culbertson v. Mernitz*, 602 N.E.2d 98, 101 (Ind. 1992).

When considering vaccination for their child, to provide a truly informed consent (with an implied “informed refusal”) to their physician, first and foremost, parents need to evaluate the

risks of each disease versus the potential risks of each corresponding vaccine. Below is an example of such an analysis for measles, one of the most debated infectious diseases subject to the childhood vaccination schedule. In years preceding the introduction of the first measles vaccine, the death rate from measles in the USA was about one in 500,000 (0.2 deaths per 100,000 population). Alexander D. Langmuir, Donald A. Henderson, Robert E. Serfling & Ida L. Sherman, *The Importance of Measles as a Health Problem*, 52 No. 2 *Am. Journal of Public Health* 2 (Fig. 1) (1962), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1522578/>. This was during the time when there were an estimated four million measles cases occurring annually, although only ten percent of measles cases (about 400,000) were annually reported. Centers for Disease Control and Prevention, *Measles Prevention: Recommendations of the Immunization Practices Advisory Committee (ACIP)*, 38 (No. S-9) *Morbidity and Mortality Weekly Report (MMWR)* 1 (1989), <https://www.cdc.gov/mmwr//preview/mmwrhtml/00041753.htm>.

With 408 measles deaths recorded in the USA in 1962, the case-fatality ratio at that time was about one in 10,000 among all measles cases, with one death per 1,000 *reported* cases. Centers for Disease Control and Prevention, *Epidemiology and Prevention of Vaccine-Preventable Diseases* App. E-3 (Jennifer Hamborsky, Andrew Kroger, & Charles (Skip) Wolfe, eds., 13th ed. 2015), <https://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-e.pdf>. On the other hand, the manufacturer's package insert for the currently licensed measles-containing vaccine, M-M-R II, lists a number of serious autoimmune, neurologic, and inflammatory conditions as post-vaccinal adverse reactions. U.S. Food and Drug Administration, *M-M-R II (Measles, Mumps, and Rubella Virus Vaccine Live)* (1971), <https://www.fda.gov/downloads/biologicsbloodvaccines/vaccines/approvedproduct/ucm123789.pdf>. Finally, the risk of permanent injury or death from the measles-containing vaccine has not

been proven to be less than the risk of permanent injury or death from measles. Physicians for Informed Consent, *Measles - Vaccine Risk Statement (VRS)* (2017),

<https://physiciansforinformedconsent.org/measles/vrs/>.

In other words, parents have to weigh a known but very small risk of death or permanent injury from measles against the risk of unknown size of a serious adverse event due to the measles-containing vaccine that may lead to permanent damage or death of their child. This choice cannot be forced by the State on Mother, especially when the Child's current likelihood of measles exposure is practically nil and where Mother and Father explicitly agreed for Mother to make medical decisions for the Child.

In contrast to Mother's being informed, the trial court record clearly sets forth Father's lack of knowledge about vaccine and disease risk:

85. Mother has offered her research to Father, who has not accepted the opportunity to review it.

86. Father has relied on very general medical information that has been provided to him by those physicians treating his subsequent born children.

87. Father is not sure if vaccines prevent the transmission of a disease.

89. Father is aware that there are risks associated with vaccines, but not the specific risks thereon.

Appellant's App. Vol. II, p. 21.

The trial court record also shows Father has not met and cannot (i.e., he is not the Child's authorized representative) meet the informed consent requirements of Indiana Code 34-18-12

("Informed consent"):

Sec. 2. If a patient's written consent is:

(1) signed by the patient or the patient's **authorized representative**;

...

Sec. 3. The explanation given in accordance with section 2(3) of this chapter must include the following information:

- (1) The general nature of the patient's condition.
- (2) The proposed treatment, procedure, examination, or test.
- (3) The expected outcome of the treatment, procedure, examination, or test.
- (4) The material risks of the treatment, procedure, examination, or test.
- (5) The reasonable alternatives to the treatment, procedure, examination, or test.

Sec. 4. This chapter does not relieve a qualified health care provider of the **duty to obtain an informed consent**. [emphasis added]

Accordingly, the Opinion departed from law and practice by failure to comply with Indiana Code 34-18-12. Indeed, the Opinion puts the doctor in a difficult (unethical) position of forfeiting his or her duty to obtain an informed consent and forcing vaccination on the Child of a non-consenting parent or guardian.

CONCLUSION

For all the foregoing reasons, this Court should grant transfer, reverse the decision of the Court of Appeals, and affirm the trial court's order in all respects.

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VERIFIED STATEMENT OF WORD COUNT

Pursuant to Appellate Rule 44(E), the Brief of *Amicus Curiae* Physicians for Informed Consent contains less than 4,200 words, exclusive of the items listed in Appellate Rule 44(C), as counted by the word processing system used to prepare the Brief, MS Word 2016.

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