

686 F.3d 889
 United States Court of Appeals,
 Eighth Circuit.

PLANNED PARENTHOOD MINNESOTA,
 NORTH DAKOTA, SOUTH DAKOTA; Carol
 E. Ball, M.D., Appellees/Cross Appellants,
 v.

Mike ROUNDS, Governor; Marty J.
 Jackley, Attorney General, in their official
 capacities, Appellants/Cross Appellees,
 Alpha Center; Black Hills Crisis Pregnancy
 Center, doing business as Care Net;
 Dr. Glenn A. Ridder, M.D.; Eleanor D.
 Larsen, M.A., L.S.W.A., Appellants.
 Christian Medical & Dental Associations;
 American Association of Pro–Life Obstetricians
 & Gynecologists; Catholic Medical Association;
 Physicians for Life; National Association
 of Pro–Life Nurses; Family Research
 Council; Care Net; Heartbeat International,
 Incorporated; National Institute of Family
 and Life Advocates, Incorporated; Eagle
 Forum Education and Legal Defense Fund;
 American College of Pediatricians, Amici Curiae.

Nos. 09–3231, 09–3233, 09–3362. |
 Submitted: Jan. 9, 2012. | Filed: July 24, 2012.

Synopsis

Background: Abortion providers brought action challenging constitutionality of disclosures required by South Dakota's abortion statute. After the providers' motion for preliminary injunction was granted, 375 F.Supp.2d 881, a panel of the Court of Appeals affirmed, 467 F.3d 716, but, on rehearing en banc, 530 F.3d 724, vacated the panel decision, and reversed and remanded. On remand, the United States District Court for the District of South Dakota, Karen E. Schreier, Chief Judge, 650 F.Supp.2d 972, granted summary judgment motions in part, and parties appealed. The Court of Appeals, Diana E. Murphy, Circuit Judge, 653 F.3d 662, affirmed in part, reversed in part, and remanded.

Holdings: On partial en banc rehearing, the Court of Appeals, Gruender, Circuit Judge, held that:

[1] “increased risk,” as term was used in statute, existed if relative risk was significantly higher for one group when compared to other groups;

[2] disclosure of “increased risk” of suicidal ideation and suicide was truthful; and

[3] disclosure of “increased risk” of suicidal ideation and suicide was non–misleading and relevant to patients' decision.

Reversed.

Loken, Circuit Judge, concurred and filed opinion

Colloton, Circuit Judge, concurred in part, concurred in the judgment, and filed opinion.

Murphy, Circuit Judge, dissented and filed opinion in which Wollman, Bye, and Melloy, Circuit Judges, joined.

West Headnotes (18)

[1] **Federal Courts**

🔑 Summary judgment

Court of Appeals reviews a grant of summary judgment de novo.

Cases that cite this headnote

[2] **Federal Courts**

🔑 Statutes, regulations, and ordinances, questions concerning in general

Court of Appeals reviews constitutional challenges and questions of statutory interpretation de novo.

2 Cases that cite this headnote

[3] **Abortion and Birth Control**

🔑 Information and consent; counseling

When the government requires, as part of the informed consent process, the giving of truthful, non–misleading information about the nature of the procedure, the attendant health risks

and those of childbirth, and other information broadly relevant to the decision to have an abortion, it does not impose an undue burden on abortion rights, even if the disclosure might cause the woman to choose childbirth over abortion.

Cases that cite this headnote

- [4] **Abortion and Birth Control**
 🔑 Information and consent; counseling

Constitutional Law

- 🔑 Health care professions

With respect to First Amendment concerns, while the state cannot compel an individual simply to speak the state's ideological message, it can use its regulatory authority to require a physician to provide truthful, non-misleading information relevant to a patient's decision to have an abortion, even if that information might also encourage the patient to choose childbirth over abortion. U.S.C.A. Const.Amend. 1.

Cases that cite this headnote

- [5] **Abortion and Birth Control**
 🔑 Information and consent; counseling

Constitutional Law

- 🔑 Health care professions

To succeed on either its undue burden on abortion rights or compelled speech claims, the plaintiff challenging the constitutionality of required disclosures to patients seeking abortion procedure must show that the disclosure at issue is either untruthful, misleading, or not relevant to the patient's decision to have an abortion. U.S.C.A. Const.Amend. 1.

1 Cases that cite this headnote

- [6] **Constitutional Law**
 🔑 Making, Interpretation, and Application of Statutes
Statutes
 🔑 Language and intent, will, purpose, or policy

Intent of a statute is determined from what the legislature said, rather than what the courts think it should have said, and the court must confine itself to the language used.

Cases that cite this headnote

- [7] **Abortion and Birth Control**
 🔑 Information and consent; counseling
 Under South Dakota law, "increased risk," as that term was used in state statutory provision requiring physicians to provide suicide advisory to patients seeking abortion procedure, existed if relative risk was significantly higher for women who abort compared to women who give birth or never have children, with no requirement for proof of causation, where peer-reviewed medical literature in record on topic of suicide and abortion consistently used term to refer to relatively higher probability of adverse outcome in one group compared to other groups, and this definition was supported by parties' experts in action challenging constitutionality of statute. SDCL § 34-23A-10.1(1)(e)(ii).

Cases that cite this headnote

- [8] **Statutes**
 🔑 Natural, obvious, or accepted meaning
Statutes
 🔑 Relation to plain, literal, or clear meaning; ambiguity
 Under South Dakota law, a statutory term must be construed according to its accepted usage, and a strained, unpractical, or absurd result is to be avoided.

Cases that cite this headnote

- [9] **Abortion and Birth Control**
 🔑 Information and consent; counseling
 Phrase "to which the pregnant woman would be subjected" in South Dakota implied-consent statute, requiring physicians to provide certain advisories to patients seeking abortion procedure, modified only immediately preceding phrase "statistically significant risk factors," and not phrase "all known medical risks of the

procedure,” of which increased risk of suicide ideation and suicide was listed example. SDCL § 34–23A–10.1(1)(e).

Cases that cite this headnote

constitutional questions arise and by the other of which such questions are avoided, the court's duty is to adopt the latter construction.

Cases that cite this headnote

[10] Statutes

➤ Relative and qualifying terms and provisions, and their relation to antecedents
Limiting clause or phrase in a statute should ordinarily be read as modifying only the noun or phrase that it immediately follows.

Cases that cite this headnote

[14] Statutes

➤ Validity
In evaluating a facial challenge to a state law, a federal court must consider any limiting construction that a state enforcement agency has proffered.

Cases that cite this headnote

[11] Statutes

➤ Relationship to statute amended; clarification or change of meaning
Where the wording of an act is changed by amendment, it is evidential of an intent that the words shall have a different construction.

Cases that cite this headnote

[15] Abortion and Birth Control

➤ Information and consent; counseling
Constitutional Law
➤ Health care professions
Disclosure of “increased risk” of suicidal ideation and suicide that physicians were required to make to patients seeking abortion procedure under South Dakota implied–consent statute was truthful, as required to avoid imposing undue burden on abortion rights or improperly compelling speech in violation of First Amendment, where peer–reviewed studies demonstrated significant correlation between undergoing abortion procedure and suicidal ideation or suicide. U.S.C.A. Const.Amend. 1; SDCL § 34–23A–10.1(1)(e)(ii).

Cases that cite this headnote

[12] Abortion and Birth Control

➤ Information and consent; counseling
Sweeping changes to language of South Dakota implied–consent statute, requiring physicians to provide certain advisories to patients seeking abortion procedure, expressed legislature's intent to address much broader range of specific medical risks in required disclosure, and not to implicitly sever term “increased risk” from its accepted usage in medical field; amendment essentially effected complete rewriting of former statute by removing 13 of original 28 words and adding 70 new words, including entirely new introduction requiring description of “all known medical risks” and listing of three new specific areas of concern in new subsections. SDCL § 34–23A–10.1(1)(e).

Cases that cite this headnote

[16] Abortion and Birth Control

➤ Information and consent; counseling
Constitutional Law
➤ Health care professions
Disclosure of “increased risk” of suicidal ideation and suicide that physicians were required to make to patients seeking abortion procedure under South Dakota implied–consent statute was non–misleading and relevant to patient's decision to have abortion, as required to avoid imposing undue burden on abortion rights or improperly compelling speech in violation of First Amendment; even though record reflected medical and scientific uncertainty as

[13] Constitutional Law

➤ Avoidance of doubt
When faced with varying constructions of a statute, by one of which grave and doubtful

to whether abortion itself was causal factor in observed correlation between abortion and suicide, nothing in record suggested that abortion as cause per se had been ruled out with certainty, and physicians were capable of reviewing relevant research and explaining difference between relative risk and proof of causation to their patients. U.S.C.A. Const.Amend. 1; SDCL § 34–23A–10.1(1)(e)(ii).

Cases that cite this headnote

[17] Abortion and Birth Control

🔑 Regulation in general

State and federal legislatures have wide discretion to pass legislation in areas where there is medical and scientific uncertainty, and thus medical uncertainty does not foreclose the exercise of legislative power in the abortion context any more than it does in other contexts.

Cases that cite this headnote

[18] Abortion and Birth Control

🔑 Information and consent; counseling

Informed consent requirements must be calculated to inform a woman's free choice as to whether to undergo an abortion procedure, and not to hinder it.

Cases that cite this headnote

Attorneys and Law Firms

*891 John P. Guhin, AAG, argued, Patricia J. DeVaney, AAG, on the brief, Pierre, SD, for appellants/cross-appellees, Mike Rounds, Governor, Marty J. Jackley, Attorney General.

Harold J. Cassidy, argued, Shrewsbury, NJ, Robert W. Ruggieri, Thomas J. Viggiano, III, Derek M. Cassidy, Shrewsbury, NJ, Jeremiah D. Murphy, Sioux Falls, SD, on the brief, for appellants, Alpha Center, Black Hills Crisis Pregnancy Center, Dr. *892 Glenn A. Ridder, and Ms. Eleanor D. Larsen.

Timothy E. Branson, argued, Minneapolis, MN, Michael Drysdale, Minneapolis, MN, Steven D. Bell, Denver, CO,

Roger Evans, New York, NY, Mimi Liu, Washington, DC, on the brief, for appellees/cross-appellants, Carol E. Ball, M.D., and Planned Parenthood Minnesota, North Dakota, South Dakota.

Steven H. Aden, on the brief, Washington, DC, for amici curiae, Family Research Council, Care Net, Heartbeat International Inc., and National Institute of Family and Life Advocates, Inc.

Mailee R. Smith, William L. Saunders, Denise M. Burke, on the brief, Washington, DC, for amici curiae, Christian Medical & Dental Associations, American Association of Pro–Life Obstetricians & Gynecologists, Catholic Medical Association, Physicians for Life, and National Association of Pro–Life Nurses.

Before RILEY, Chief Judge, WOLLMAN, LOKEN, MURPHY, BYE, MELLOY, SMITH, COLLOTON, GRUENDER, BENTON and SHEPHERD, Circuit Judges, en banc.

Opinion

GRUENDER, Circuit Judge.

The Governor and Attorney General of South Dakota (“the State”), along with two intervening crisis pregnancy centers and two of their personnel (collectively “Intervenors”), appeal the district court's permanent injunction barring enforcement of a South Dakota statute requiring the disclosure to patients seeking abortions of an “[i]ncreased risk of suicide ideation and suicide,” *see* S.D.C.L. § 34–23A–10.1(1)(e)(ii) (“suicide advisory”), and the underlying grant of summary judgment in favor of Planned Parenthood of Minnesota, North Dakota, South Dakota and its medical director Dr. Carol E. Ball (collectively “Planned Parenthood”) that this advisory would unduly burden abortion rights and would violate physicians' First Amendment right to be free from compelled speech. For the reasons discussed below, we reverse.

I.

In 2005, South Dakota enacted House Bill 1166 (“the Act”), amending the requirements for obtaining informed consent to an abortion as codified in S.D.C.L. § 34–23A–10.1. Section 7 of the Act requires physicians, in the course of obtaining informed consent, to provide certain information to the patient seeking an abortion. In June 2005, Planned Parenthood sued to prevent the Act from taking

effect, contending that several of its provisions constituted an undue burden on abortion rights and facially violated patients' and physicians' free speech rights, while other provisions were unconstitutionally vague. After the district court preliminarily enjoined the Act and a divided panel of this court affirmed, this court sitting en banc vacated the preliminary injunction and remanded for further proceedings. *See Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724 (8th Cir.2008) (en banc).

On remand, the parties filed cross-motions for summary judgment with respect to the challenged provisions. The district court ruled that a biological disclosure, *see* §§ 34–23A–10.1(1)(b), 34–23A–1(4), and a medical emergency exception, *see* § 34–23A–10.1, were facially sound with respect to the First Amendment and imposed no undue burden, while disclosures regarding the protected relationship between the patient and the unborn child, *see* § 34–23A–10.1(1)(c), (d), and the suicide advisory, *see* § 34–23A–10.1(1)(e)(ii), failed to meet both constitutional requirements. The district court also held that a requirement to disclose “all known medical risks of the procedure,” *see* § 34–23A–10.1(1)(e), was not ***893** unconstitutionally vague, but that a requirement to disclose “statistically significant risk factors,” *see id.*, was.

Planned Parenthood appealed the district court's decision on the biological disclosure and the “all known medical risks” disclosure, while the State and Intervenors appealed the district court's decision on the relationship disclosures and the suicide advisory. A panel of this court affirmed unanimously with respect to the biological disclosure and the “all known medical risks” disclosure, reversed unanimously with respect to the relationship disclosures, and affirmed in a divided decision as to the suicide advisory. *See Planned Parenthood Minn., N.D., S.D. v. Rounds*, 653 F.3d 662 (8th Cir.2011). We granted this rehearing en banc solely on the issue of the suicide advisory.¹

II.

[1] [2] We review a grant of summary judgment *de novo*. *Missouri ex rel. Nixon v. Am. Blast Fax, Inc.*, 323 F.3d 649, 653 (8th Cir.2003). In addition, we review constitutional challenges and questions of statutory interpretation *de novo*. *McDermott v. Royal*, 613 F.3d 1192, 1193 (8th Cir.2010) (per curiam).

[3] [4] Planned Parenthood contends that requiring a physician to present the suicide advisory imposes an undue burden on abortion rights and violates the free speech rights of the physician. “[W]hen the government requires [as part of the informed consent process] ... the giving of truthful, nonmisleading information about the nature of the procedure, the attendant health risks and those of childbirth,” and other information broadly relevant to the decision to have an abortion, it does not impose an undue burden on abortion rights, even if the disclosure “might cause the woman to choose childbirth over abortion.” *Planned Parenthood of Se. Penn. v. Casey*, 505 U.S. 833, 882–83, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992). Moreover, “the physician's First Amendment rights not to speak are implicated, but only as part of the practice of medicine, subject to reasonable licensing and regulation by the State.” *Id.* at 884, 112 S.Ct. 2791 (citations omitted). Thus, with respect to First Amendment concerns, “while the State cannot compel an individual simply to speak the State's ideological message, it can use its regulatory authority to require a physician to provide truthful, non-misleading information relevant to a patient's decision to have an abortion, even if that information might also encourage the patient to choose childbirth over abortion.” *Rounds*, 530 F.3d at 734–35; *accord Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570, 576–77 (5th Cir.2012).

[5] In short, to succeed on either its undue burden or compelled speech claims, Planned Parenthood must show that the disclosure at issue “is either untruthful, misleading or not relevant to the patient's decision to have an abortion.” *Rounds*, 530 F.3d at 735. To evaluate the constitutional merits of the suicide advisory, we will examine first what disclosure actually is required, second whether that disclosure is truthful, and third whether it is non-misleading and relevant to the patient's decision to have an abortion.

III.

[6] Section 34–23A–10.1 requires a physician seeking to perform an abortion to present to the patient:

(1) A statement in writing providing the following information:

***894** * * *

(e) A description of all known medical risks of the procedure and statistically significant risk factors

to which the pregnant woman would be subjected, including:

- (i) Depression and related psychological distress;
- (ii) Increased risk of suicide ideation and suicide;

* * *

Planned Parenthood argues, and the district court agreed, that subsection (ii) must be construed to require a disclosure of a conclusive causal link between abortion and suicide. *See Planned Parenthood Minn., N.D., S.D. v. Rounds*, 650 F.Supp.2d 972, 982 (D.S.D.2009). However, no language in subsection (ii), or in the heading of section 10.1(1)(e), refers to such a causal link. “The intent of a statute is determined from what the legislature said, rather than what the courts think it should have said, and the court must confine itself to the language used.” *Langdeau v. Langdeau*, 751 N.W.2d 722, 727 (S.D.2008) (quoting *US W. Commc'ns, Inc. v. Pub. Utils. Comm'n*, 505 N.W.2d 115, 123 (S.D.1993)).

[7] [8] Here, the language actually used by the legislature —“medical risks,” “statistically significant risk factors,” “[i]ncreased risk”—denotes risk in a medical context. Moreover, while the heading of subsection (e) refers broadly to “all known medical risks of the [abortion] procedure ... including” those listed in its subsections, the suicide advisory is the only subsection to further incorporate the more precise phrase “[i]ncreased risk.” *See* § 34–23A–10.1(1)(e) (ii). Therefore, we must presume that the term “increased risk” has a more precise meaning than the umbrella term “risk” by itself. *See Maynard v. Heeren*, 563 N.W.2d 830, 835 (S.D.1997) (“[N]o wordage should be found to be surplus. No provision can be left without meaning. If possible, effect should be given to every part and every word.” (quoting *Cummings v. Mickelson*, 495 N.W.2d 493, 500 (S.D.1993))); *see also FCC v. AT & T Inc.*, — U.S. —, 131 S.Ct. 1177, 1183, 179 L.Ed.2d 132 (2011) (recognizing that, in construing a statute, “two words together may assume a more particular meaning than those words in isolation”). The term “increased risk” is not defined in the statute, and it has more than one reasonable definition in the medical field. South Dakota law requires that such a term “must be construed according to its accepted usage, and a strained, unpractical or absurd result is to be avoided.” *Peters v. Spearfish ETJ Planning Comm'n*, 567 N.W.2d 880, 885 (S.D.1997).

As a result, the disclosure actually required by the suicide advisory depends upon the accepted usage of the term

“increased risk” in the relevant medical field. We turn to the medical literature and expert evidence in the record to discern the accepted usage of the term “increased risk” in the applicable medical context, with an eye towards whether that accepted usage necessarily implies proof of causation.

The peer-reviewed medical literature in the record on the topic of suicide and abortion consistently uses the term “increased risk” to refer to a relatively higher probability of an adverse outcome in one group compared to other groups—that is, to “relative risk.” *See Stedman's Medical Dictionary* 1701 (28th ed. 2006) (defining relative risk as “the ratio of the r[isk] of disease among those exposed to a r[isk] factor to the r[isk] among those not exposed”). For example, one study compared the rate of suicide for women who had received an induced abortion with the rates of suicide for two other groups, women who had given birth and women who had miscarried. *See* Ex. 60, Mika Gissler *895 et al., *Suicides After Pregnancy in Finland*, 1987–94, 313 *Brit. Med. J.* 1431, 1432 (1996), ECF No. 172–3.² That study characterized its finding of a vastly higher suicide rate for women who received an induced abortion as “an increased risk of suicide.” *Id.* at 1434. Another study compared the rate of, *inter alia*, suicide ideation in women who had received an induced abortion with the rates for women who had given birth and for women who had not become pregnant. *See* Ex. 61, David M. Fergusson et al., *Abortion in Young Women and Subsequent Mental Health*, 47 *J. Child Psychol. & Psychiatry* 16, 19 (2006), ECF No. 172–4. That study concluded, “Certainly in this study, those young women who had abortions appeared to be at moderately *increased risk* of both concurrent and subsequent mental health problems when compared with equivalent groups of pregnant or non-pregnant peers.” *Id.* at 23 (emphasis added).

The discussion of risk in the medical context provided by Intervenor's expert also supports the conclusion that the term “increased risk” refers to the comparison of two groups, or relative risk:

Assessment of degree of risk is often expressed in terms of absolute risk, which relates to the chance of developing a disease over a time-period (e.g., a 10% lifetime risk of suicide) or in terms of relative risk, which is a comparison of the probability of an adverse outcome in two groups. For example, abortion

would be considered an *increased risk* for suicide if the relative risk is significantly higher for women who abort compared to women who give birth or never have children.

Coleman Decl. ¶ 6, Jul. 6, 2006, ECF No. 189 (emphases added). Based on the “accepted usage” of the term in the relevant field, *Peters*, 567 N.W.2d at 885, the term “increased risk” in subsection (ii) indicates that the “relative risk” definition is the one intended by the legislature for the suicide advisory.

Noticeably absent from the contextual definition of “increased risk” is a requirement for conclusive proof of causation. This stands to reason, because, as explained by the Intervenor’s expert:

When examining complex human psychological and physical health outcomes, such as depression and suicidal behavior, identification of a single, precise causal mechanism applicable to all situations is not possible....

Given this inherent complexity, sound epidemiological evidence is nevertheless derived by identifying those variables which are most strongly linked with adverse mental or physical health outcomes for large groups of individuals.

Coleman Decl. ¶¶ 5–6, Jul. 6, 2006. While such evidence of relative risk eventually may prove direct causation as further experiments rule out plausible competing explanations, *see id.* at ¶ 9, conclusive proof of causation is not required in order for the identification of a medical risk.

Even the evidence upon which Planned Parenthood heavily relies is consistent with the “relative risk” definition of “increased risk,” with no requirement for proof of causation. For example, the report of the American Psychological Association’s (“APA”) Task Force on Mental Health and Abortion, Branson Decl. Ex. A, Sept. 8, 2008, ECF Nos. 283–3, 283–4 (hereinafter “APA Report”), decries the “tendency to confuse a risk and a cause” as a “logical fallacy.” APA Report at 31. As another example, Planned Parenthood submitted into the record a letter to a medical ***896** journal from one of the researchers mentioned above. While the researcher emphasized that his studies linking suicide and abortion did not prove causation, he resolutely reiterated his finding of “increased risk.” Mika Gissler et al., *Letter to the Editor: Pregnancy-Related Violent Deaths*, 27 Scand. J.

Pub. Health 1:54, 55 (1999), ECF No. 206–10. It would be nonsensical for those in the field to distinguish a relationship of “increased risk” from one of causation if the term “risk” itself was equivalent to causation.

[9] [10] In the face of this extensive evidence of the accepted usage of the term “increased risk,” Planned Parenthood makes two arguments as to why the suicide advisory should be read to require a disclosure of proof of causation. First, it argues that the statute refers to the “increased risk of suicide ideation and suicide” as a risk “to which the pregnant woman *would be subjected*” by the abortion procedure, *see* § 34–23A–10.1(1)(e) (emphasis added), implying that the abortion procedure directly subjects the patient to, or causes, the result. A relevant rule of statutory construction, however, holds that “a limiting clause or phrase ... should ordinarily be read as modifying only the noun or phrase that it immediately follows.” *Barnhart v. Thomas*, 540 U.S. 20, 26, 124 S.Ct. 376, 157 L.Ed.2d 333 (2003). Under that rule, the phrase “to which the pregnant woman would be subjected” modifies only the immediately preceding phrase “statistically significant risk factors” (which is not at issue here), not the phrase “all known medical risks of the procedure” (of which the “increased risk of suicide ideation and suicide” is a listed example). *See* § 34–23A–10.1(1)(e).

Moreover, even if the phrase “to which the pregnant woman would be subjected” is construed to modify the “increased risk” language, it would not advance Planned Parenthood’s argument because the result to which the pregnant woman would be subjected is the *increased risk*. In other words, the abortion procedure causes the patient to become a member of a group for which an increased risk is documented relative to other groups. This does not imply proof that the abortion procedure directly causes the adverse outcome in those cases where the risk materializes. There is a very real difference between (1) a statement that an action places an individual at an increased risk for an adverse outcome, and (2) a statement that, if the individual experiences the adverse outcome, the action will have been the direct cause.³

[11] Second, Planned Parenthood relies on the “established principle of statutory construction that, where the wording of an act is changed by amendment, it is evidential of an intent that the words shall have a different construction.” *Lewis & Clark Rural Water Sys., Inc. v. Seeba*, 709 N.W.2d 824, 831 (S.D.2006) (quoting *S.D. Subsequent Injury Fund v. Federated Mut. Ins., Inc.*, 605 N.W.2d 166, 170 (S.D.2000)).

The informed-consent statute in ***897** effect prior to the Act required the disclosure of “[t]he particular medical risks associated with the particular abortion procedure to be employed including, when medically accurate, the risks of infection, hemorrhage, danger to subsequent pregnancies, and infertility.” S.D.C.L. § 34–23A–10.1(1)(b) (2004) (emphasis added). The Act expanded this subject matter into a new, four-part subsection:

(e) A description of all known medical risks of the procedure and statistically significant risk factors to which the pregnant woman would be subjected, including:

- (i) Depression and related psychological distress;
- (ii) Increased risk of suicide ideation and suicide;
- (iii) A statement setting forth an accurate rate of deaths due to abortions, including all deaths in which the abortion procedure was a substantial contributing factor;
- (iv) All other known medical risks to the physical health of the woman, including the risk of infection, hemorrhage, danger to subsequent pregnancies, and infertility[.]

§ 34–23A–10.1(1)(e) (2005). Because this provision as amended by the Act no longer includes the word “associated,” Planned Parenthood asks us to conclude that the legislature intended the term “increased risk” to imply proof of causation, rather than that the procedure and the adverse outcome are merely “associated” by a correlative relationship such as relative risk.

[12] We certainly agree that the amendments to the medical-risks provision are “evidential of an intent that the words shall have a different construction,” *Lewis & Clark Rural Water Sys.*, 709 N.W.2d at 831 (quoting *S.D. Subsequent Injury Fund*, 605 N.W.2d at 170), but in this case that different construction does not hinge on the removal of one word. Instead, the Act effects essentially a complete rewriting of the former § 34–23A–10.1(1)(b) (2004), removing thirteen of the original twenty-eight words and adding seventy new words, including an entirely new introduction requiring a description of “all known medical risks” and a listing of three new specific areas of concern in subsections (i)-(iii). Taken as a whole, these sweeping changes to the language of the provision express the legislature’s intent to address a much broader range of specific medical risks in the required disclosure, not to implicitly sever the term “increased risk” from its accepted usage in the medical field. *See Lewis &*

Clark Rural Water Sys., 709 N.W.2d at 830 (“[T]he true intent of the legislature in enacting laws ... is ascertained primarily from the language employed in the statute.” (quoting *Sanford v. Sanford*, 694 N.W.2d 283, 287 (2005))). Indeed, where only fifteen words of original language remain in an amended provision of eighty-five words, ascribing such an effect to the removal of a single word would go far beyond any use of the cited rule of statutory construction of which we are aware. *See, e.g., S.D. Subsequent Injury Fund*, 605 N.W.2d at 170–71 (applying the statutory-amendment rule of construction to a seventy-one-word statute to which four new words were added and two were changed).

[13] **[14]** Finally, even if the language of the suicide advisory also reasonably could be construed to require a disclosure of a causal link, we would be faced with “varying constructions of the South Dakota statute, ‘by [one] of which grave and doubtful constitutional questions arise and by [the other] of which such questions are avoided.’ ” *Rounds*, 653 F.3d at 669 (quoting *United States v. Adler*, 590 F.3d 581, 583 (8th Cir.2009)). In such a situation, our “duty is to adopt the latter,” *id.* (quoting *Adler*, 590 F.3d at 583), and “[t]his is ***898** especially so since ‘[i]n evaluating a facial challenge to a state law, a federal court must ... consider any limiting construction that a state ... enforcement agency has proffered,’ ” *id.* (quoting *Kolender v. Lawson*, 461 U.S. 352, 355, 103 S.Ct. 1855, 75 L.Ed.2d 903 (1983)). As a result, we would be called to apply the “relative risk” construction of increased risk over a construction that required disclosure of a causal link.

To summarize, in subsection (ii), the legislature expressly required the disclosure of an “increased risk,” not a causal link. Based on the accepted usage of the term “increased risk” in the relevant medical field, the usage of that term in the context of § 34–23A–10.1(1)(e)(ii) does not imply a disclosure of a causal relationship. Instead, subsection (ii) requires a disclosure simply that the risk of suicide and suicide ideation is higher among women who abort compared to women in other relevant groups, such as women who give birth or do not become pregnant.

IV.

[15] With regard to whether the required disclosure is truthful, *see Rounds*, 530 F.3d at 735, the State submitted into the record numerous studies published in peer-reviewed medical journals that demonstrate a statistically significant

correlation between abortion and suicide. The studies were published in respected, peer-reviewed journals such as the *Obstetrical and Gynecological Survey*, the *British Medical Journal*, the *Journal of Child Psychology and Psychiatry*, the *Southern Medical Journal*, and the *European Journal of Public Health*, and there is no indication that the peer-review process was compromised for the studies at issue. See *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 593–94, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993) (“The fact of publication (or lack thereof) in a peer reviewed journal ... [is] a relevant, though not dispositive, consideration in assessing the scientific validity of a particular technique or methodology on which an opinion is premised” because “submission to the scrutiny of the scientific community ... increases the likelihood that substantive flaws in methodology will be detected.”).

Planned Parenthood argues that these studies do not examine the correlation between abortion and suicide in sufficient detail to prove a causal link (as discussed in more detail in Part V), but, as we concluded above, the suicide advisory does not require disclosure of a causal link. With regard to the accuracy of the correlation itself, there is nothing in the record to suggest that the underlying data or calculations in any of these studies are flawed. For example, Planned Parenthood's own expert, Dr. Nada Stotland, admitted that one of the studies, which determined a suicide rate after abortion of 31.9 per 100,000 as compared to a suicide rate after live birth of 5.0 per 100,000, “indicates an association; not causation, but an association” between abortion and suicide. Stotland Dep. 283:22–284:9, ECF No. 152–12.⁴ When asked if she had “any quarrel with the validity of that association,” Dr. Stotland replied that she did not. *Id.* at 284:11–13.

Based on the record, the studies submitted by the State are sufficiently reliable to support the truth of the proposition that the relative risk of suicide and suicide ideation is higher for women who abort *899 their pregnancies compared to women who give birth or have not become pregnant. It also is worth noting that Planned Parenthood does not challenge the disclosure that “[d]epression and related psychological distress” is a “known medical risk [] of the [abortion] procedure.” S.D.C.L. § 34–23A–10.1(1)(e)(i); see also *Gonzales v. Carhart*, 550 U.S. 124, 159, 127 S.Ct. 1610, 167 L.Ed.2d 480 (2007) (noting that “[s]evere depression and loss of esteem can follow” an abortion). As a matter of common sense, the onset of depression and psychological distress also would increase one's risk of suicide and suicide ideation. See, e.g., Ottar Bjerkset et al., *Gender Differences*

in the Association of Mixed Anxiety and Depression with Suicide, 192 Brit. J. Psychiatry 474, 474 (2008) (“Depression is thought to be the most important antecedent of suicide....”). Thus, there appears to be little dispute about the truthfulness of the required disclosure.

Finally, Planned Parenthood contends that the suicide advisory is not truthful because an increased risk of suicide after abortion is not “known” as required by the statute. See S.D.C.L. § 34–23A–10.1(1)(e) (requiring disclosure of “[a]ll known medical risks of the procedure”); *Rounds*, 653 F.3d at 673 (“‘[K]nown’ means generally recognized, proved, or familiar to all.”). Once again, however, this contention is premised on Planned Parenthood's argument that the term “increased risk” implies a *causal link* that is not generally “known.” Because the statute does not require the disclosure of any causal link, Planned Parenthood's argument on this point is misdirected. The record indicates that the disclosure actually required—that the relative risk of suicide and suicide ideation is higher for women who abort compared to women in other relevant groups—is generally “known.” For example, the ninety-one-page APA Report, on which Planned Parenthood relies extensively, was commissioned for the sole purpose of analyzing that “known” risk in more detail. See APA Report at 5.

As a result, we hold that the disclosure facially mandated by the suicide advisory is truthful.

V.

[16] Despite the extensive evidence in the record of an “increased risk” of suicide, Planned Parenthood contends that disclosure of the increased risk would be misleading and irrelevant to a patient seeking an abortion, see *Rounds*, 530 F.3d at 735, because some authorities have indicated that there is no direct causal link. In particular, Planned Parenthood argues that it is more plausible that certain underlying factors, such as pre-existing mental health problems, predispose some women both to have unwanted pregnancies and to have suicidal tendencies, resulting in a misleading correlation between abortion and suicide that has no direct causal component. Under this view, the required disclosure would be misleading or irrelevant to the decision to have an abortion because the patient's decision would not alter the underlying factors that actually cause the observed increased risk of suicide.

[17] As an initial matter, the standard medical practice, as reflected in the record, is to *recognize* a strongly correlated adverse outcome as a “risk” while further studies are conducted to clarify whether various underlying factors play causal roles. *See, e.g.,* Coleman Decl. ¶¶ 9–11, Jul. 6, 2006. In contravention of that standard practice, Planned Parenthood argues that the mere existence of underlying factors *proscribes* the disclosure of suicide as a risk related to abortion. However, there is no constitutional requirement to invert the traditional understanding of “risk” by requiring, where abortion is involved, that conclusive understanding of causation be obtained first. Indeed, the Supreme *900 Court “has given state and federal legislatures wide discretion to pass legislation in areas where there is medical and scientific uncertainty,” and “[m]edical uncertainty does not foreclose the exercise of legislative power in the abortion context any more than it does in other contexts.” *Gonzales*, 550 U.S. at 163–64, 127 S.Ct. 1610. In particular, “a requirement that a doctor give a woman certain information as part of obtaining her consent to an abortion is, for constitutional purposes, no different from a requirement that a doctor give certain specific information about any medical procedure.” *Casey*, 505 U.S. at 884, 112 S.Ct. 2791. There is no basis in the “non-misleading” and “relevant” requirements of *Casey* for imposing a new, stricter definition of medical risk—a standard that requires certainty of causation—simply because the medical procedure at issue is abortion.

Thus, the truthful disclosure regarding increased risk cannot be unconstitutionally misleading or irrelevant simply because of some degree of “medical and scientific uncertainty,” *Gonzales*, 550 U.S. at 163, 127 S.Ct. 1610, as to whether abortion plays a causal role in the observed correlation between abortion and suicide. Instead, Planned Parenthood would have to show that any “medical and scientific uncertainty” has been resolved into a certainty *against* a causal role for abortion. In other words, in order to render the suicide advisory unconstitutionally misleading or irrelevant, Planned Parenthood would have to show that abortion has been ruled out, to a degree of scientifically accepted certainty, as a statistically significant causal factor in post-abortion suicides. An examination of Planned Parenthood's evidence reveals that it has not met this burden.

First, Planned Parenthood points out that the label approved by the Food and Drug Administration (“FDA”) for the abortion-inducing drug Mifeprex (mifepristone, also known as RU-486) does not list suicide or suicide ideation as a risk of using the drug, despite FDA labeling regulations requiring

the listing of, *inter alia*, all “clinically significant adverse reactions” and “other potential safety hazards.” *See* 21 C.F.R. § 201.57(c)(6)(i). However, an FDA-approved label does not represent the definitive or exclusive list of risks associated with a drug. The record before us does not show whether any evidence of the link between abortion and suicide was submitted to the FDA, nor does it provide details of the FDA's analysis, if any, of the link. Thus, the FDA-approved label for Mifeprex yields no information as to whether abortion has been ruled out as a statistically significant causal factor in post-abortion suicides.

Second, Planned Parenthood argues, and the district court found, that the American College of Obstetricians and Gynecologists (“ACOG”), a well-known professional medical organization, “rejects any suggestion that increased risk of suicide and suicide ideation are known risks of abortion.” *See Rounds*, 650 F.Supp.2d at 983. Unfortunately, there was no evidence from ACOG in the record for the district court to consider. The only evidence in the record pertaining to ACOG's position is a second-hand reference in a 2005 report by the State's expert, Dr. Elizabeth M. Shadigian, that quoted two sentences from a single ACOG Practice Bulletin: “Long-term risks sometimes attributed to surgical abortion include potential effects on ... psychological sequelae. However, the medical literature, when carefully evaluated, clearly demonstrates no significant negative impact on any of these factors with surgical abortion.” Elizabeth M. Shadigian, Report to the S.D. Task Force to Study Abortion 4, Sept. 21, 2005, ECF No. 177–4 (hereinafter “Shadigian Report”); *see also* Ex. O, Shadigian Dep. 137–38, ECF No. 147–15 (quoting the recitation of those lines in the Shadigian Report). *901 Dr. Shadigian further reported her opinion that ACOG's statement was erroneous and that “ACOG seems to claim that they have adequately evaluated the medical literature, but they do not consider our study or the many other studies we evaluated.” Shadigian Report at 5. There is no other evidence in the record as to what “medical literature” ACOG considered, in what fashion it was “carefully evaluated,” whether suicide was one of the “psychological sequelae” considered, whether ACOG's analysis received any independent peer review, or indeed whether a “Practice Bulletin” purports to be grounded in any sort of reliable scientific method at all. The two unsupported sentences from an ACOG Practice Bulletin lend no credence to the argument that abortion has been ruled out as a statistically significant causal factor in post-abortion suicides.

Third, Planned Parenthood cites the previously mentioned APA Report. The six-person Task Force on Mental Health and Abortion that authored the APA Report reviewed “50 papers published in peer-reviewed journals between 1990 and 2007 that analyzed empirical data of a quantitative nature on psychological experiences associated with induced abortion, compared to an alternative.” APA Report at 64. For some of the studies that found increased mental health risks associated with abortion, the APA Report identifies perceived methodological deficiencies, including an inability to limit the comparison group to women who carried unplanned or unwanted pregnancies to term. *See id.* at 68. Based on one study that attempted to account for that variable, the report states that “the *best* scientific evidence indicates that the relative risk of mental health problems among adult women who have an *unplanned pregnancy* is no greater if they have an elective first-trimester abortion than if they deliver that pregnancy.” *Id.* (emphases in original). In the very same sentence, however, the report states that the published literature could not provide “unequivocal evidence regarding the relative mental health risks associated with abortion per se compared to its alternatives (childbirth of an unplanned pregnancy).” *Id.*

The State and Intervenor argue that the APA Report is deficient in several respects. While the APA Report alleges methodological flaws in all of the studies that found a strong link between abortion and adverse mental health outcomes, it does not systematically list or analyze those flaws for each study considered. Instead, the report uses a handful of studies as illustrative examples. The State and Intervenor contend that this lack of rigor allowed the APA Report to analyze studies that found abortion to be “a benign experience for most women” less stringently than studies that found abortion to cause adverse effects. Coleman Decl. ¶ 14, Sept. 16, 2008, ECF No. 290–3. For example, while the APA Report suggests that the studies showing increased risk did not compare women receiving abortions to women who carried *unplanned* pregnancies to term, at least three studies purportedly considered by the task force did use such a control group, and each of those studies still “definitively indicated that abortion was associated with more mental health problems.” *Id.* at ¶ 19. The APA Report also does not acknowledge that some of the studies showing increased risk did statistically control for other potential causal factors such as history of depression, anxiety, suicide ideation, childhood sexual abuse, physical abuse, child neuroticism, and low self-esteem. *Id.* at ¶ 15(c).⁵ As another example, although a high rate of attrition (i.e., the loss of subjects from a *902 long-

term study before the study is complete) is typically regarded as a methodological weakness, the APA Report downplays the significance of attrition, possibly because “the studies with the highest attrition rates ... are also the ones that provide little evidence of negative effects” of abortion. *Id.* at ¶ 15(d). A number of published authors in the field contacted the APA to point out these problems and ask that the APA Report be retracted. *Id.* at ¶¶ 28–29.

At a minimum, it appears that many published authors in the field do not accept the opinion of the APA's six-person task force that the “best evidence” suggests that there is no real significance to the link between abortion and suicide. Even if one accepts the findings in the APA Report at face value, however, the crux of the matter is that while the APA Report states that the evidence available at the time of its review is not “sufficient to support the claim that an observed association between abortion history and mental health was *caused* by the abortion,” *id.* at 6 (emphasis added), it also concludes that the published literature is inconclusive and more research is needed “to disentangle confounding factors and establish relative risks of abortion compared to its alternatives,” *id.* at 72; *see also id.* at 68 (admitting that the published literature could not provide “unequivocal evidence regarding the relative mental health risks associated with abortion per se compared to its alternatives (childbirth of an unplanned pregnancy)”). In other words, while the APA Report finds that studies to date have not established with certainty that abortion is a causal factor in post-abortion suicide, it also acknowledges that abortion has not been ruled out as a causal factor and that currently available studies are inadequate for that purpose.⁶ Thus, the APA Report provides no support for the proposition that abortion has been ruled out as a statistically significant causal factor in post-abortion suicides.

Finally, the dissent relies on six recent publications submitted to this Court by Planned Parenthood as a supplement to the district court record. While the dissent suggests that these more recent publications have eliminated any uncertainty about the causal role of abortion in the increased risk of suicide, *post* at 909–10, the publications add little of value to the record. As an initial matter, three of the publications⁷ are not new analyses of data, *903 but rather reviews or surveys of existing studies. As with the APA Report, it is difficult to identify a solid objective basis for the criteria employed in these reviews to identify the “best” studies and discount the others, and in the fine print they sometimes remain equivocal about the role of abortion as a causal factor. *See,*

e.g., Robinson, *supra*, at 277 (“For women who have more significant [psychological] problems, the causal contribution of the abortion is not clear; a wide range of factors, both internal and external, affect women’s responses—and interact in complex ways.”).

The three remaining supplemental publications actually provide new analysis, but each suffers from apparent weaknesses. One of the publications, Julia R. Steinberg et al., *Does the Outcome of a First Pregnancy Predict Depression, Suicidal Ideation, or Lower Self-Esteem? Data from the National Comorbidity Survey*, 81 Am. J. Orthopsychiatry 193 (2011) (“Steinberg I”), compared self-reported mental health problems for women who carried their first pregnancy to term with women who aborted their first pregnancy, *see id.* at 194, while attempting to control for pre-pregnancy mental health, experience of sexual violence, and age at first pregnancy, *see id.* at 197. Mental health problems were classified as pre- or post-delivery or abortion of the first pregnancy. *Id.* at 195. Thus, if a woman delivered a first pregnancy, aborted a subsequent pregnancy, and suffered an adverse mental health outcome after the abortion, her adverse outcome nevertheless was classified by Steinberg I as belonging to the “delivery” comparison group, rather than the “abortion” comparison group. According to data from the Guttmacher Institute, however, approximately 45 to 47 percent of women obtaining their first abortion have previously carried at least one pregnancy to term. *See* Jones et al., *Repeat Abortion in the United States*, Guttmacher Institute, 18 (Nov. 2006), <http://www.guttmacher.org/pubs/2006/11/21/or29.pdf> (listing number of prior births for women having a first abortion, based on two sets of data collected by the Guttmacher Institute at abortion provider locations). As a result, Steinberg I almost certainly shifts the outcomes for a significant number of women who aborted their second or subsequent pregnancies from the “abortion” comparison group to the “delivery” comparison group, rendering its comparison of mental health outcomes unreliable.

Another study, Julia R. Steinberg & Lawrence B. Finer, *Examining the Association of Abortion History and Current Mental Health: A Reanalysis of the National Comorbidity Survey Using a Common-Risk-Factors Model*, 72 Soc. Sci. & Med. 72 (2011) (“Steinberg II”), compared self-reported mental health problems for women who had been pregnant but never aborted with those women who had aborted one or more pregnancies, while attempting to control for pre-pregnancy mental health, experience of violence, and age at first pregnancy. *See id.* at 77. However, Steinberg

II identified post-abortion or post-delivery mental health outcomes only as those problems the participants reported they were experiencing at the time of the survey, rather than considering mental health problems that participants reported as occurring at any time after an abortion or delivery. *See id.* at 76–77. Therefore, it appears that Steinberg II addresses only an arbitrarily limited *904 window of the women’s mental health histories.

Finally, Trine Munk-Olsen et al., *Induced First-Trimester Abortion and Risk of Mental Disorder*, 364 New Eng. J. Med. 332 (2011), extracted data from the Danish Civil Registration System and the Danish Psychiatric Central Register. The study considered data only for women who had no history of inpatient treatment for mental illness in their lifetime prior to the nine-month period preceding either a first abortion or a first delivery of a pregnancy. *See id.* at 334. For that group of women, the study analyzed data regarding inpatient or outpatient mental health contacts during the nine-month period preceding abortion or delivery and the twelve-month period following abortion or delivery. *See id.* While the study observed a significantly higher number of psychiatric visits after abortion as compared to after delivery, *see id.* at 335, it “found no significant increase in the incidence rate of psychiatric contact in the 12 months after an induced first-trimester abortion as compared with the 9-month period before the abortion” and concluded that the higher incidence in post-abortive women compared to post-delivery women likely was due solely to higher pre-existing levels of psychiatric problems for the women who sought abortions, *see id.* at 336. This conclusion apparently begs the question, however, by assuming that any mental distress occurring in the nine-month period prior to an abortion procedure was completely unrelated to the abortion. It seems just as plausible to assume, particularly in a population selected for having no adverse mental health history prior to that time period, that for at least some of the women, psychological distress in that time period arose in part because they had decided, or already were facing pressure from others, to undergo the abortion. Under this interpretation, the study actually tends to confirm the legislative finding that women who seek abortions are “often under stress and pressures from circumstances and from other persons, and that there exists a need for special protection of the rights of such pregnant women.” S.D.C.L. § 34–23A–1.5.

We acknowledge that these studies, like the studies relied upon by the State and Intervenor, have strengths as well as weaknesses. Like all studies on the topic, they must make

use of imperfect data that typically was collected for entirely different purposes, and they must attempt to glean some insight through the application of sophisticated statistical techniques and informed assumptions. While the studies all agree that the relative risk of suicide is higher among women who abort compared to women who give birth or do not become pregnant, they diverge as to the extent to which other underlying factors account for that link. We express no opinion as to whether some of the studies are more reliable than others; instead, we hold only that the state legislature, rather than a federal court, is in the best position to weigh the divergent results and come to a conclusion about the best way to protect its populace. So long as the means chosen by the state does not impose an unconstitutional burden on women seeking abortions or their physicians, we have no basis to interfere.

In summary, although the record reflects “medical and scientific uncertainty,” *Gonzales*, 550 U.S. at 163, 127 S.Ct. 1610, as to whether abortion itself is a causal factor in the observed correlation between abortion and suicide, there is nothing in the record to suggest that abortion as a cause *per se* has been ruled out with certainty. As a result, the disclosure of the observed correlation as an “increased risk” is not unconstitutionally misleading or irrelevant under *Casey* and *Gonzales*. Indeed, physicians who provide abortions *905 should be capable of reviewing the research in the field, understanding the difference between relative risk and proof of causation, and explaining it correctly to their patients. *Cf. Rounds*, 530 F.3d at 736 (holding that the subject matter of the biological disclosure “should be clear in context to a physician”).⁸ In the end, “[t]he point of informed consent laws is to allow the patient to evaluate her condition and render her best decision under difficult circumstances. Denying her up to date medical information is more of an abuse to her ability to decide than providing the information.” *Lahey*, 667 F.3d at 579.

Accordingly, we hold that the suicide advisory is non-misleading and relevant to the patient's decision to have an abortion.

VI.

In conclusion, we hold that the requirements of S.D.C.L. § 34–23A–10.1(1)(e)(ii) are satisfied by a disclosure that the relative risk of suicide and suicide ideation is higher for women who abort compared to women in other relevant

groups, as described in the relevant medical research. The statute does not require the physician to disclose that a causal link between abortion and suicide has been proved. The disclosure is truthful, as evidenced by a multitude of studies published in peer-reviewed medical journals that found an increased risk of suicide for women who had received abortions compared to women who gave birth, miscarried, or never became pregnant. Various studies found this correlation to hold even when controlling for the effects of other potential causal factors for suicide, including pre-existing depression, anxiety, suicide ideation, childhood sexual abuse, physical abuse, child neuroticism, and low self-esteem.

[18] Moreover, the suicide advisory is non-misleading and relevant to the patient's decision to have an abortion, as required by *Casey*. It is a typical medical practice to inform patients of statistically significant risks that have been associated with a procedure through medical research, even if causation has not been proved definitively.⁹ While Planned Parenthood points to uncertainty as to whether abortion itself is a causal factor in the observed correlation to suicide, as opposed to other underlying factors that tend to be associated independently with both abortion and suicide, the Supreme Court “has given state and federal legislatures wide *906 discretion to pass legislation in areas where there is medical and scientific uncertainty,” including “in the abortion context.” *Gonzales*, 550 U.S. at 163–64, 127 S.Ct. 1610. Thus, a truthful disclosure cannot be unconstitutionally misleading or irrelevant simply because some degree of medical and scientific uncertainty persists. To be sure, informed consent requirements “must be calculated to inform [a] woman's free choice, not hinder it,” *Casey*, 505 U.S. at 877, 112 S.Ct. 2791, but there is no unconstitutional hindrance of the woman's choice where, as here, the State merely is using “its regulatory authority to require a physician to provide truthful, non-misleading information relevant to a patient's decision to have an abortion, even if that information might also encourage the patient to choose childbirth over abortion,” *Rounds*, 530 F.3d at 735.

On its face, the suicide advisory presents neither an undue burden on abortion rights nor a violation of physicians' free speech rights. Accordingly, we reverse the district court's grant of summary judgment to Planned Parenthood with respect to S.D.C.L. § 34–23A–10.1(1)(e)(ii), direct the entry of summary judgment for the State as to that provision, and vacate the permanent injunction against the enforcement of that provision.

LOKEN, Circuit Judge, concurring.

Though I agree with the dissent that the plain language of S.D.C.L. § 34–23A–10.1(1)(e)(ii)—“known medical risks ... to which the pregnant woman would be subjected”—strongly suggest legislative intent to require that a physician make an untruthful, misleading causation disclosure, the first two sentences of Part VI of the court's opinion require only a disclosure as to relative risk that the physician can adapt to fit his or her professional opinion of the conflicting medical research on this contentious subject. With the facial constitutionality of the statute limited in this fashion, controlling Supreme Court precedent requires that I concur. *See Gonzales v. Carhart*, 550 U.S. 124, 163–68, 127 S.Ct. 1610, 167 L.Ed.2d 480 (2007).

COLLTON, Circuit Judge, concurring in part and concurring in the judgment.

I concur in Parts I through III of the court's opinion, except that I find it unnecessary to consider the meaning of the hypothetical phrase “a description of all known risks of the procedure ... to which the pregnant woman would be subjected.” *Ante*, at 896 & n. 3. The most natural reading of S.D.C.L. § 34–23A–10.1 is that it requires the physician to present “a description of all known medical risks of the procedure,” including “[i]ncreased risk of suicide ideation and suicide.” *Ante*, at 896. For the reasons set forth in Part III, the statutory language thus calls for a description of the relative risks of suicide ideation and suicide that are discussed in the peer-reviewed literature. *See ante*, at 894–96, 898. The phrase “to which the pregnant woman would be subjected” modifies “statistically significant risk factors.” The district court's order striking “statistically significant risk factors” did not rewrite the statute to cause the phrase that follows the stricken text to modify antecedent text that was not previously modified.

I concur in Part IV of the court's opinion concerning why the required disclosure is truthful. I also concur in the portion of Part V that explains why the record before the district court did not establish that the disclosure is misleading. This court took the unusual step of permitting the appellees to supplement the record on appeal, after the completion of briefing, with a 476–page supplemental appendix that includes several studies that were not presented to the district court. Without attempting to engage in a social science *907 critique of these studies in the first instance, it is sufficient to observe that the conclusions of these studies do not, on their face, eliminate the medical and scientific uncertainty

concerning the relationship between abortion and suicide ideation or suicide. *See ante*, at 904. I thus concur that the State was permitted to require a description of the relative risks as reflected in the peer-reviewed literature, with the physician free to augment that description based on his or her professional judgment. *Ante*, at 905 & n. 8.

For these reasons, I concur in the judgment.

MURPHY, Circuit Judge, with whom WOLLMAN, BYE, and MELLOY, Circuit Judges, join, dissenting.

The record before the district court supported its conclusions that South Dakota's 2005 suicide advisory is unconstitutional because it will not inform the free choice of a woman and is not consistent with the medical evidence. These conclusions have only been strengthened by the medical evidence received since then. The governing rule of law is that laid down by the Supreme Court in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833, 112 S.Ct. 2791, 120 L.Ed.2d 674 (1992), which prohibits a state from requiring an advisory which is not “calculated to inform the woman's free choice” but “hinder[s] it.” *Id.* at 877, 112 S.Ct. 2791. *Gonzales v. Carhart*, 550 U.S. 124, 127 S.Ct. 1610, 167 L.Ed.2d 480 (2007), on which the majority relies, did not address that standard.

The most reliable evidence in the record shows that abortion does not have a *causal* relationship to the risk of suicide and that South Dakota's mandated advisory is not truthful, but actually misleading. In *Casey*, the Court recognized both a woman's right “to decide to terminate a pregnancy free of undue interference by the State” and the state's “legitimate goal of ... ensuring a decision that is mature and informed” in order to “facilitate[] the wise exercise of that right.” 505 U.S. at 883, 887, 112 S.Ct. 2791. Focus on these parallel goals in *Casey* shows how carefully the Court considered the interests of both the woman and the state in that decision.

In order to be constitutional an informed consent requirement must be truthful, non misleading, and relevant. *See Casey* 505 U.S. at 882–83, 112 S.Ct. 2791; *see also Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 735 (8th Cir.2008) (en banc). Requiring physicians to provide their patients with information that does not meet this standard violates the physicians' First Amendment right against compelled speech. *Casey*, 505 U.S. at 884, 112 S.Ct. 2791; *see also Rounds*, 530 F.3d at 734–35.

The content of the 2005 suicide advisory raises constitutional problems which the prior version of the South Dakota statute did not. The previous provision required a physician to advise a patient about the “particular medical risks *associated with* the particular abortion procedure to be employed, including *when medically accurate*, the risks of infection, hemorrhage, danger to subsequent pregnancies, and infertility.” S.D.C.L. § 34–23A–10.1(1)(b) (2003) (emphasis added). In contrast, the statute before the court requires doctors to tell a pregnant woman that a greater likelihood of suicide and suicide ideation is a “*known medical risk* []” to which she “*would be subjected*” by having an abortion. S.D.C.L. § 34–23A–10.1(1)(e) (2005) (emphasis added).

The record clearly demonstrates, however, that suicide is not a known medical risk of abortion and that suicide is caused instead by factors preexisting an abortion such as a history of mental illness, domestic violence, and young age at the time of *908 pregnancy. *See, e.g.*, Julia R. Steinberg, et al., *Does the Outcome of a First Pregnancy Predict Depression, Suicidal Ideation, or Lower Self-Esteem? Data from the National Comorbidity Survey*, 81 Am. J. Orthopsychiatry 193 (2011); Gail Erlick Robinson, et al., *Is There an “Abortion Trauma Syndrome?” Critiquing the Evidence*, 17 Harv. Rev. Psychiatry 268 (2009).

As can be seen, the prior version of the South Dakota law did not carry the fatal flaw embodied in the statute now being considered. The wording of the statute under consideration conveys a causal relationship between abortion and the risk of suicide “to which the pregnant woman *would be subjected*.” The phrase to subject someone to something means “to cause to undergo or submit to.” *Webster’s Third New Int’l Dictionary* 2275 (2002). In contrast, the wording in the prior state legislation spoke of the “risks *associated with* ... abortion.” An association is defined as “the relationship of the occurrence of two events, without evidence that the event being investigated actually causes the second condition.” *Taber’s Cyclopaedic Med. Dictionary* 201 (21st ed. 2009). Legislative findings show that the statutory drafters intended that the advisory under review convey causality, for they stated that women must be informed that “procedures terminating the life of an unborn child *impose* risks to the life and health of the pregnant woman.” S.D.C.L. § 34–23A–1.4 (emphasis added); *Webster’s Third New Int’l Dictionary* 1136 (2002) (defining “impose” as “to cause to be burdened”).¹⁰

The majority concedes that there is no proof in the medical literature that abortion causes suicide, *ante* at 895–96, and

it recognizes that an advisory telling a woman that abortion causes an increased risk of suicide would be untruthful. *Ante* at 897–98. It seeks to avoid the constitutional problem created by the current statutory text by suggesting that the legislature’s amendment substituting subjected to for “associated with” should not be understood to mean causality since nearly all of the words in the advisory were changed. The new language is explained as merely informing women that their decision to have an abortion would “cause[] [them] to become a member of a group” with a statistically higher rate of suicide. *Ante* at 896. That is not what the plain language of the statute says, however, and the medical evidence shows that women sharing certain factors may have a higher rate of suicide but not that abortion causes suicide.

The evidence considered by the district court shows that an advisory informing women that abortion *causes* them to be more likely to commit suicide is untruthful and misleading. That record made clear that abortion does not *cause* a “known” risk of suicide or suicide ideation. The record included volumes of deposition testimony, published medical research, and legislative reports supporting the district court’s conclusion that the suicide advisory is unconstitutional.

One of the significant reports in the record was the American Psychological Association’s (APA) review of the medical *909 literature. That review showed only an association between women who have an abortion and woman who commit suicide. The APA’s review concluded that “the best scientific evidence indicates that the relative risk of mental health problems among adult women who have an unplanned pregnancy is no greater if they have an elective first-trimester abortion than if they deliver that pregnancy.” Brenda Major, et al., American Psychological Association, *Report of the APA Task Force on Mental Health and Abortion* 68 (2008) (APA Report).

There was also evidence from the “most recent edition of medical opinions” by the American College of Obstetricians and Gynecologists (ACOG) showing that the ACOG shared the APA’s interpretation of the medical literature and informed its members that abortion does not affect women’s subsequent mental health. The record included evidence that the label for the abortion inducing drug mifepristone was never revised to include the risk of suicide or suicide ideation. That was relevant in light of the Food and Drug Administration requirement that drug labeling must “be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a

causal relationship need not have been proved.” 21 C.F.R. § 201.80(e).

In addition the district court was made aware of the fact that the author of two of the studies, on which the state and intervenors rely, has explained that his findings did not “support the hypothesis that abortion itself causes suicide.” Mika Gissler, et al., *Letter to the Editor: Pregnancy-Related Violent Deaths*, 27 *Scand. J. Pub. Health* 54, 55 (1999). Gissler concluded that “[a] more likely explanation is that the excess risk may be due to causes related both to induced abortion and violent death.” *Id.*

The record included other criticisms of studies presented by the state and the intervenors which had used comparator groups irrelevant to a pregnant woman's decision to have an abortion. Because pregnant women can no longer choose not to become pregnant, providing them information about the relative risks of suicide for women after abortion compared with women with no pregnancy does nothing to inform their decision on whether to have an elective abortion. *See, e.g.*, Mika Gissler, et al., *Injury Deaths, Suicides and Homicides Associated with Pregnancy, Finland 1987–2000*, 15 *European J. Pub. Health* 459, 460 (2005) (comparing women electing abortion with women who are not pregnant); David M. Fergusson, et al., *Abortion in Young Women and Subsequent Mental History*, 47 *J. Child Psychol. & Psychiatry* 16, 17 (2006) (same); *see also* APA Report at 53–54, 71 (discussing this methodological problem).

Since the district court enjoined the suicide advisory and a panel of this court affirmed that decision, the United Kingdom's Royal College of Obstetricians and Gynaecologists (RCOG) has issued recommendations that women “be informed that the evidence suggests that they are no more or less likely to suffer adverse psychological sequelae whether they have an abortion or continue with the pregnancy and have the baby.” RCOG, *The Care of Women Requesting Induced Abortion* 45 (Nov. 2011). The United Kingdom's National Collaborating Centre for Mental Health arrived at the same conclusion in its report to the Academy of Medical Royal Colleges. *Induced Abortion and Mental Health: A Systemic Review of the Mental Health Outcomes of Induced Abortion, Including Their Prevalence and Associated Factors* 125 (Dec. 2011).

These conclusions are based on numerous studies which strengthen the evidence *910 on which the district court relied. The studies establish that post abortion suicide rates

are linked to preexisting mental illness and domestic violence, not to the decision to undergo an abortion. *See, e.g.*, Trine Much-Olsen, et al., *Induced First-Trimester Abortion and Risk of Mental Disorder*, 364 *New Eng. J. Med.* 332, 338 (2011); Robinson, *supra*, at 276 (“The most well controlled studies continue to demonstrate that there is no convincing evidence that induced abortion of an unwanted pregnancy is per se a significant risk factor for psychiatric illness.”). If, as the majority points out, “the standard medical practice ... is to recognize a strongly correlated adverse outcome as a ‘risk’ while further studies are conducted to clarify whether various underlying factors play causal roles,” *ante* at 899 (emphasis omitted), must not research conducted by experts in the field after the district court's decision be considered as corroboration of its findings and conclusions?

Dr. Priscilla Coleman, an expert witness produced by the state and intervenors in the district court, has recently been criticized for her study methodology and her resulting conclusions that abortion plays a causal role to increase the risk of suicide. In one study researchers used the same data and methodology Coleman had in a 2009 study discussed in one of her declarations to the district court. Guhin Decl., Exh. 87 at 13, ECF No. 290–2. The researchers found that Coleman's results were not replicable and concluded that “structural, psychological, and sociodemographic risk factors associated with both having an abortion and having poor mental health drive a relationship between abortion and mental health.” Julia R. Steinberg & Lawrence B. Finer, *Examining the Association of Abortion History and Current Mental Health: A Reanalysis of the National Comorbidity Survey Using a Common-Risk-Factors Model*, 72 *Soc. Sci. & Med.* 72, 81 (2011). The editor-in-chief of the *Journal of Psychiatric Research* subsequently concluded that Coleman's explanation for her methodology in the 2009 study was “unpersuasive” and that the analysis “does not support [Coleman's] assertions” that abortions “were associated with increased risk of lifetime mental disorders....” *Reply to Letter to the Editor: Commentary on Abortion Studies of Steinberg and Finer (Soc. Sci. & Med. 2011; 72:72–82) and Coleman (J. Psychiatric Res. 2009; 43:770–6 & J. Psychiatric Res. 2011; 45:1133–4)*, 46 *J. Psychiatric Res.* 410, 410 (2012).

The quality of the cited studies has been recognized by leading professional associations. This research also formed the basis for the opinions of these bodies that the induced abortion of an unwanted pregnancy does not cause an increased risk of mental health problems. *See, e.g.*, National Collaborating Centre for Mental Health, *supra* at 125–27.

Rather than recognizing this emerging consensus based on the scientific research in the record before the district court and all the subsequently submitted evidence by the parties to this court, the majority theorizes about the nature of an advisory. In the end it arrives at a new test divorced from the standard established in *Casey*.

The majority posits that the lack of evidence—that the correlation between abortion and suicide is due to a causal relationship—is not fatal to the advisory because the existence of a correlation for any reason makes the advisory truthful. Pointing out that Planned Parenthood does not currently challenge the state's depression advisory, it asserts that “as a matter of common sense” depression can be a precursor to suicide. *Ante* at 899. While Planned Parenthood withdrew its challenge to that section of the statute, it never conceded that “depression and related psychological *911 distress” are known medical risks of abortion nor does it inform its patients of this. Resp. Pet. for Reh'g n. 8. Even a study submitted by the intervenors admits that data do not support an association between abortion and depression. David M. Fergusson, et al. *A Further Meta-Analysis*, Br. J. of Psychiatry, Oct. 5, 2011 available at http://bjp.rcpsych.org/content/199/3/180/reply#bjprpsych_el_33839.¹¹

The majority concedes though that if the correlation between abortion and suicide were not due to a causal relationship, then the advisory “would be misleading or irrelevant to the decision to have an abortion because the patient's decision would not alter the underlying factors that actually cause the observed increased risk of suicide.” *Ante* at 899. The vast majority of researchers, however, assert that this is precisely the case. Those studies in the record show that other independent factors which co-occur with both abortion and suicide, such as pre-pregnancy mental health problems, domestic violence, and youth, account for the correlation between abortion and suicide risk.

To overcome this evidentiary problem a new standard for informed consent advisories is offered. Under this proposed test, so long as a causal link between abortion and suicide would be theoretically possible, an advisory is truthful, non misleading, and relevant unless Planned Parenthood can prove the absence of a causal link with “scientifically accepted certainty.” *Ante* at 900. In support the court turns to *Gonzales*, 550 U.S. at 163–67, 127 S.Ct. 1610, to rely on its discussion of medical uncertainty. *Ante* at 899–900, 904–05. The Court there was not considering a *Casey* issue about informed consent, however, and it was not evaluating

the information given to an individual woman to “ensur[e] a decision that is mature and informed.” See *Casey*, 505 U.S. at 883, 112 S.Ct. 2791. The Court concluded only that Congress, which was fully informed of the contradicting medical opinions, could balance the need to protect the state's interests in the “ethics of the medical profession” and “respect for dignity of human life” against the uncertain risks to women's health resulting from the ban. *Gonzales*, 550 U.S. at 157, 166, 127 S.Ct. 1610 (citation omitted).

The state's interest in this case is to promote a “wise,” “mature [,] and informed” decision by women considering abortion. *Casey*, 505 U.S. at 883, 887, 112 S.Ct. 2791. Here, any medical uncertainty as to whether abortion causes an increased risk of suicide undermines the advisory's constitutionality because a woman's ability to make a wise, mature, and informed choice is hindered by being told that the increased risk of suicide is a “known medical risk[]” “to which ... [she] would be subjected” by having an abortion when the weight of the medical research indicates the opposite and she is not informed of the debate. The state's interest is thus not furthered by such an advisory.

It is significant that the South Dakota legislature and governor amended certain abortion regulations in March 2012 in order to reflect the more accepted view in the medical community that abortion does not cause mental health problems such as suicidal ideation and suicide. In the new version of the statute, which requires a physician to meet with a pregnant woman before she can schedule an abortion, the *912 state legislature eliminated language mandating an assessment “to determine if any of the risk factors associated with abortion are present in her case.” S.D. House Bill 1254 § 2 ¶ 4 (amending S.D.C.L. § 34–23A–56). The state law now requires an assessment “to determine if any of the following preexisting risk factors associated with adverse psychological outcomes following an abortion are present in her case.” *Id.* Among the listed preexisting risk factors in South Dakota's revision are coercion, a history of mental illness, and youth. *Id.* This amendment thus brings the statute in line with the existing medical evidence which shows that an increased risk of suicide is linked not to the decision to undergo an abortion, but to preexisting risk factors that coincide with abortion.

We agree that “[t]he point of informed consent laws is to allow the patient to evaluate her condition and render her best decision under difficult circumstances” and that “[d]enying her up to date medical information is more of an abuse to her ability to decide than providing the

information.” *See ante* at 905 (quoting *Tex. Med. Providers Performing Abortion Servs. v. Lakey*, 667 F.3d 570, 579 (5th Cir.2012)) (first alteration in original). Yet, instead of recognizing that medical research has shown that South Dakota’s suicide advisory is untruthful, misleading, and irrelevant, the majority tries to shift the responsibility to attending physicians to “review[] the research in the field, understand[] the difference between relative risk and proof of causation, and explain[] it correctly to their patients.” *Ante* at 905. The statute provides only for a written transaction between doctor and patient in which explanation and clarification occur if a woman requests it, *see* S.D.C.L.

§ 34–23A–10.1 ¶¶ 2, 3, but no judicial attempt to direct the content of the conversation between a patient and her doctor can remedy the advisory’s constitutional shortcomings.

By forcing doctors to inform women that abortion subjects them to a risk which the record medical evidence refutes, the suicide advisory places an undue burden on a pregnant woman’s due process rights and violates a doctor’s First Amendment right against compelled speech. The district court’s order enjoining the suicide advisory should therefore be affirmed.

Footnotes

- 1 Apart from Section II.C of the panel opinion, which addresses the suicide advisory and was vacated by our order taking this matter en banc, the panel opinion remains in force.
- 2 All cited exhibit numbers and ECF designations refer to the summary judgment exhibit numbers and ECF document heading numbers, respectively, in the district court record, No. 05–cv–4077 (D.S.D.).
- 3 This difference may be better illustrated by an example less contentious than abortion. One recent study found that prolonged television viewing resulted in an “increased risk” of mortality for individuals in any given age group. *See* Anders Grøntved et al., *Television Viewing and Risk of Type 2 Diabetes, Cardiovascular Disease, and All–Cause Mortality*, 305 J. Am. Med. Assoc. 23:2448 (2011). We would not demand proof that television viewing itself directly caused the adverse outcome (for example, proof of an actual decline in the health of heart muscle tissue to a fatal level during viewing) before acknowledging that a prolonged television viewer is “subjected” to the increased risk of mortality. Indeed, a measure of increased risk based on a discrete, easily reportable event such as television viewing is useful precisely because of the difficulty of tracing exactly whether and how a given action combines with other factors to directly “cause” a particular death.
- 4 With regard to another potential comparison group, the cited study also determined a suicide rate among women of reproductive age who did not become pregnant as in the range of 11.8 to 13.3 per 100,000. *See* Mika Gissler et al., *Injury Deaths, Suicides and Homicides Associated with Pregnancy, Finland 1987–2000*, 15 Eur. J. Pub. Health 5:459, 460 (2005), ECF No. 147–18.
- 5 The dissent notes that one study authored by Coleman and cited in her declaration on this issue later was found to contain errors. *Post* at 910. However, Coleman’s declaration cites various studies by other authors that control for these other potential causal factors and nevertheless find a persistent link between abortion and increased mental health problems. *See* Coleman Decl. ¶¶ 22–24, Sept. 16, 2008, ECF No. 290–3. Her declaration was not rebutted with respect to those studies.
- 6 While the APA awaits methodologically perfect research on the effect of “unwanted” or “unplanned” pregnancies, others have suggested that such perfection may not be achievable, because “pregnancies that are aborted frequently were initially intended by one or both partners and pregnancies that are initially unintended often become wanted as the pregnancy progresses, rendering assessment of wantedness/intendedness [sic] subject to considerable change over time.” Coleman Decl. ¶ 15, Jul. 6, 2006. In addition, “pregnancy wantedness/intendedness is open to multiple subjective interpretations.” *Id.* at ¶ 16. The APA Report does not specify what sort of data on these variables would be acceptable to resolve the issue to the APA’s satisfaction, and the report even seems to conflate the entirely separate concepts of whether a pregnancy is “wanted” with whether it was initially “planned” or “intended.” *See, e.g.*, APA Report at 64 (“These studies were evaluated with respect to their ability to draw sound conclusions about the relative mental health risks associated with abortion compared to alternative courses of action that can be pursued by a woman facing a similar circumstance (e.g., an unwanted or unintended pregnancy).”).
- 7 National Collaborating Centre for Mental Health, *Induced Abortion and Mental Health: A Systemic Review of the Mental Health Outcomes of Induced Abortion, Including Their Prevalence and Associated Factors* (2011); Royal College of Obstetricians and Gynaecologists, *The Care of Women Requesting Induced Abortion* (2011); Gail Erlick Robinson et al., *Is There an “Abortion Trauma Syndrome?” Critiquing the Evidence*, 17 Harv. Rev. Psychiatry 268 (2009).
- 8 To the extent the dissent suggests that a patient will receive a physician’s detailed explanation of the disclosure only if she seeks additional explanation and clarification, *see post* at 911–12, we disagree. The statute requires the physician to provide, in writing, “[a] description” of the risks at issue, § 34–23A–10.1(1)(e), not just a recitation of the statutory language. Contrary to the dissent’s

reference to a “judicial attempt to direct the content of the conversation between a patient and her doctor,” *post* at 912, we recognize that the legislature left the precise content of that description to the physician's discretion.

- 9 We disagree with the dissent's suggestion that this is a new standard or theory about the nature of an informed consent advisory. *See post* at 911. Instead, statements about “increased risk” in the absence of conclusive proof of causation have been treated as material in a variety of contexts. *See, e.g., Brock v. Merrell Dow Pharms., Inc.*, 874 F.2d 307, 312 (explaining that if studies establish, within an acceptable confidence interval, that those who use a pharmaceutical have a relative risk of greater than 1.0—that is, an increased risk—of an adverse outcome, those studies might be considered sufficient to support a jury verdict of liability on a failure-to-warn claim), *modified on reh'g*, 884 F.2d 166 (5th Cir.1989); 21 C.F.R. § 201.80(e) (requiring that prescription drug “labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved”). The decision of the South Dakota legislature that the increased risk at issue here likewise merits an advisory is not atypical.
- 10 The majority states that the statutory phrase “to which a pregnant woman would be subjected” attaches to “statistically significant risk factors.” *Ante* at 896. The phrase “statistically significant risk factors” was permanently enjoined by the district court as unconstitutionally vague, *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 650 F.Supp.2d 972, 981–82 (D.S.D.2009), however, and that ruling was not appealed by the state or the intervenors. Applying the rule of the last antecedent to the enjoined text effectively reads the phrase “to which a pregnant woman would be subjected” out of the statute as well, counter to the legislature's intent as expressed in its findings.
- 11 While citing dictum from *Gonzales* that “[s]evere depression and loss of esteem can follow” abortion in support of the advisory's truthfulness, the majority ignores the Court's concession there that it “find[s] no reliable data to measure the phenomenon....” *Gonzales*, 550 U.S. at 159, 127 S.Ct. 1610. The absence of “reliable data” undermines reliance here on an isolated statement in a lengthy opinion dealing with an uncommon medical procedure.