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A Mother's Worst Nightmare, What's Left Unsaid: The Lack of Informed Consent in Obstetrical Practices

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A MOTHER'S WORST NIGHTMARE, WHAT'S LEFT UNSAID:
THE LACK OF INFORMED CONSENT IN OBSTETRICAL
PRACTICES

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INTRODUCTION

In the modern age of Western society, virtually every person moves through life's challenges with a presumption that every day practices and procedures are lawful, harmless, and have been refined to avoid personal danger. Indeed, when a couple goes to buy their first home, they will place a presumptive trust in the loan officer at the local bank who will educate them about acquiring a mortgage, and in the realtor who will tend to every aspect of the home acquisition process. The couple simply and unreservedly assumes that the law adequately requires these professionals to protect the couple's interests, to shield them from harm, to prevent the incidence of damage and, most importantly, to keep them informed, unequivocally, to make proper decisions throughout a process about which they know little.

Likewise, when this same couple conceives a child, they enter into a realm in which they are completely inexperienced and are again asked to place faith in numerous professionals. As these expectant parents navigate through this unknown journey, they submit mother and unborn child without reservation to a wide range of obstetrical medications and practices, certain that they have absolutely nothing about which to worry.

As with most Americans, this expectant couple is operating on a presumptive trust: a trust that they will learn everything they need to know to make good choices for their growing family; a trust that the mother and her unborn child's care are the primary concerns of her practitioners; and a trust that no information will be errantly advised or completely omitted from discussions, so as to endanger the lives of mother or child. Unfortunately, this presumptive trust by our expectant couple is grossly misplaced in the field of obstetrical care, for there is a great deal of information left unsaid.

While the doctrine of informed consent¹ has been continually strengthened in the fields of traditional medicine by numerous judicial decisions,² the presence of the doctrine is virtually absent from the field of obstetrics and gynecology.³ By virtually absent, it is meant that the doctrine of informed consent has not been sufficiently delineated, applied and required in the field of obstetrics.⁴ In the vast majority of jurisdictions across the United States, there is no legal compulsion placed upon an obstetrical practitioner to disclose anything more than highly significant risks.⁵ Therefore, only the most egregious

1. The doctrine of informed consent is a legal requirement for medical professionals that imposes upon a physician "the duty to explain the procedure to the patient and to warn her of any material risks or dangers inherent in or collateral to the proposed [practice or procedure], so as to enable the patient to make an intelligent and informed choice about whether to follow her physician's recommendation . . ." *Bankert v. United States*, 937 F. Supp. 1169, 1173 (D. Md. 1996). Accordingly, "[i]nformed consent is [presently] defined as 'the willing and uncoerced acceptance' of a medical intervention by a patient after adequate disclosure by the physician of the nature of the intervention, its risks and benefits, as well as of alternatives with their risks and benefits." *Id.* (second emphasis added). Perhaps the most obvious flaw with the doctrine is that only adequate disclosure of risks to the patient is required. *See id.*

2. *See, e.g., Curtis v. MRI Imaging Servs. II*, 956 P.2d 960, 960, 962 (Or. 1998) (finding that a physician may be held liable for not informing patients of the claustrophobic nature of the MRI process); *Martin v. Richards*, 531 N.W.2d 70, 72 (Wis. 1995) (holding physician liable for not informing parents of a child with a head injury after a biking accident of the availability of a CAT scan).

3. The author does not intend to imply that the doctrine of informed consent does not apply in obstetrics to establish a breach of the professional standard of care. Indeed, such a cause of action may be maintained in all fifty states. *See A Practical Guide to Informed Consent, Background: Requirements for Informed Consent*, TEMPLE U. HEALTH SYS., <http://www.templehealth.org/ICTOOLKIT/html/ictoolkitpage5.html> (last visited Mar. 30, 2012) (noting that all 50 states now have legislation requiring "some level of informed consent").

4. *See Informed Consent*, AM. CONGRESS OBSTETRICIANS & GYNECOLOGISTS, COMM. ON ETHICS (Aug. 2009), http://www.acog.org/Resources_And_Publications/Committee_Opinions/Committee_on_Ethics/Informed_Consent (explaining the difficulties and limitations of the informed consent doctrine in obstetrics cases).

5. As of the date of this article, only three jurisdictions have extended the doctrine of informed consent to such an extent in the field of obstetrics: Maryland, New Jersey, and New York. *Bankert*, 937 F. Supp. at 1173; *Draper v. Jasionowski*, 858 A.2d 1141, 1148 (N.J. Super. Ct. App. Div. 2004); *Cicione v. Meyer*, 823 N.Y.S.2d 173, 175-76 (N.Y. App. Div. 2006).

of failures to provide basic information to an expectant mother, which result in physical injury to her or her child, are likely to result in malpractice liability to the attending practitioner for want of informed consent.⁶ Consequently, expectant mothers learn only a fraction of the vital information necessary to make decisions about the various medications, practices and procedures that are commonly a component of their pregnancy.⁷

The position of this Note is clear as to what the doctrine of informed consent should be in the field of obstetrics: a woman's consent to authorize an obstetric practice or procedure is not informed unless she is provided with any and all information that is pertinent enough to have an effect on her decision-making regarding whether to undergo or forgo such a practice or procedure.⁸ The doctrine of informed consent, however, must necessarily go beyond a duty to explain procedures and warn patients of inherent risks or dangers.⁹ Indeed, informed consent must require the provision of any and all information known by the attending practitioner that is of such significant and pertinent substance that its awareness by the patient might have an effect on the patient's decision of whether to consent to a particular practice or procedure, or other medical alternative. Only then can consent by obstetrics patients be truly informed.

Part I endeavors to explore the nature of the duty to inform in obstetrics today. Given the vulnerability and the medical under-sophistication of expectant mothers, Part I observes the legal issues concerning the scope of informed consent, as applied to both the expectant mother and her child. The subject of bioethics is explored to examine when the physician's duty to inform should arise in the field of obstetrics, particularly given the numerous opportunities during

6. See *Bankert*, 937 F. Supp. at 1170 (holding that physicians at a government-operated hospital violated the mother's right to informed consent by failing to inform her of the risks of labor-inducing drugs and by not respecting her decision to deliver by Cesarean section); see also *Cicione*, 823 N.Y.S.2d at 176 (reversing the jury's verdict on appeal and finding that the plaintiffs made out "a prima facie case on the issue of whether Dr. Meyer adequately conveyed the reasonably foreseeable risks of the VBAC [vaginal birth after Cesarean section] to Denise Cicione to permit her to make an informed decision, and whether a reasonably prudent person would have elected to attempt the VBAC had she been fully informed").

7. See Wendy Woolery, *Informed Consent Issues Throughout the Birthing Process*, 21 J. LEGAL MED. 241, 255 (2000) (explicating the large information divide between practitioner and patient).

8. This demonstrates that the doctrine of informed consent requires substantial broadening so that physicians will be required to disclose more than just significant or material risks. See *Scott v. Bradford*, 606 P.2d 554, 556-57 (Okla. 1979) (finding that consent becomes informed once the patient knows all the material risks related to practice or procedure at issue).

9. Woolery, *supra* note 7, at 242 (explaining that the modern standard of informed consent "require[s] physicians to disclose all material risks to their patients").

pregnancy and labor in which the consent discussion should occur. Further, Part I opines on the practice of off-labeling and the frequent failure to disclose not only a drug's effects on the fetus that are known by medical professionals, but also concerning a drug's "areas of uncertainty" when consequences are unknown. Both practices operate in obstetrics to inhibit a complete information exchange between the mother and her practitioner, and ultimately serve to block efforts to reform obstetrical practices by increasing the disclosure and dissemination of vital information every woman needs to make an informed choice.

Part II demonstrates the direct and collateral consequences stemming from the most common procedures during pregnancy and delivery, all of which have inherent dangers, but none of which are regularly communicated from practitioner to patient. Exposed is the simple fact that expectant mothers fail to receive a complete and comprehensive discussion of underappreciated risks inherent to conventional obstetrical care because loopholes exist in the doctrine of informed consent that permit this unacceptable silence in the informational exchange. To paint the picture vividly, Part II walks through some of the various prenatal, labor and delivery procedures, from the first prenatal visit where volumes of information should be explained to the mother, all the way to the trial of labor, where the self-serving economic policies of hospitals and insurance companies virtually discourage the complete disclosure of risks of common procedures.¹⁰ Identified here are the dangers of the induction and delivery drugs, the dangers of EFMs and ultrasound usage, and how both can lead to increased rates of Cesarean sections and negative effects. The consequences resulting from the botched information exchange are shocking; indeed, it is a mother's worst nightmare. Unfortunately, these consequences are the price our society has chosen to pay by not compelling physicians to disclose the dangers associated with commonly accepted obstetrical medications, practices and procedures.

I. THE NATURE OF THE DUTY TO INFORM AND WHEN IT SHOULD ARISE

Underpinning the doctrine of informed consent is the simple principle that patients¹¹ are vulnerable and medically unsophisticated.¹²

10. See HENCI GOER, *THE THINKING WOMAN'S GUIDE TO A BETTER BIRTH* 16–17 (1999) (exacting the economic forces from insurance companies and hospitals that drive physicians to push obstetric medications, practices and procedures in the interests of profitability rather than patient necessity).

11. Uniquely in the field of obstetrics, the doctrine of informed consent has been interpreted to protect both patients: mother and child. *Draper v. Jasionowski*, 858 A.2d 1141, 1148 (N.J. Super. Ct. App. Div. 2004). An infant brought action against his mother's obstetrician and hospital for prenatal injuries he sustained during vaginal delivery that arose out of the obstetrician's alleged failure to obtain his mother's informed consent prior to delivery. *Id.*; see discussion *infra* Part I.B.

12. See Woolery, *supra* note 7, at 241, 255; see also Nancy K. Rhoden, *Informed*

Implied within the doctrine, therefore, is that patients have a right to know all the information and risks to inform their decision-making.¹³ To every extent imaginable, patients undeniably rely on the expertise and forthrightness of their physicians and other attending professionals.¹⁴ Patients carry this expectation into prenatal visits with practitioners.¹⁵ Additionally, patients carry this expectation when asked for their blanket consent upon arriving at the hospital for delivery.¹⁶ Mothers certainly expect that the care of their unborn child is the ultimate priority of the attending physicians.¹⁷ This patient expectation permeates every level and stage of care in the field of obstetrics.¹⁸ Likewise, it should exist for every practice, procedure and medication.

A. The Pregnant Patient's Bill of Rights

Acknowledging the expectations and rights of obstetrics patients, maternity care pioneer and birth expert Doris B. Haire,¹⁹ while

Consent in Obstetrics: Some Special Problems, 9 W. NEW ENG. L. REV. 67, 67–69 (1987) (recognizing the informational disadvantage between patient and practitioner).

13. See Rhoden, *supra* note 12, at 84–85 (espousing the idea that obstetricians should provide as much information to patients as possible to ensure that decisions are jointly made).

14. *Id.* at 68.

15. See *id.* at 68, 85. Rhoden even suggests that in the eyes of the expectant mother “physicians’ typical approach to uncertainty or to a crisis may be perceived not as one strategy among several, but as the only legitimate approach.” *Id.* at 68. Consequently, expectant mothers “see the physician’s recommendation as the best or only hope for the baby, and this viewpoint virtually guarantees acceptance of that recommendation, except in cases of exceedingly firm beliefs on the part of the mother.” *Id.*

16. Attempts to seek a mother’s consent to medication, practices and procedures while in, or beginning, her trial of labor should be considered invalid as it seems tantamount to obtaining consent by duress. *But see* Bankert v. United States, 937 F. Supp. 1169, 1174 (D. Md. 1996) (finding the onset of labor did not by itself render a woman incompetent to engage in decision-making); Rizzo v. Schiller, 445 S.E.2d 153, 155 (Va. 1994) (finding the plaintiff was capable of making medical decisions even after being medicated with delivery drugs).

17. See J. L. Reynolds, *Great Expectations: The Doctor-Patient Relationship in Obstetrics*, 35 CANADIAN FAM. PHYSICIAN 115, 115 (1989) (noting the high expectations that patients have for obstetric services and their outcomes).

18. See *id.*

19. Doris B. Haire serves as president of the American Foundation for Maternal and Child Health, which she founded with her husband John R. Haire, and is a former Chair of the National Women’s Health Network. *Doris B. Haire*, CHILDBIRTH CONNECTION, <http://www.childbirthconnection.org/pop.asp?ck=10101> (last updated Aug. 15, 2007). She has led the fight to increase research on the practices and effects of common obstetric drugs on infant outcome and the child’s neurological development. *Id.* Her quest has taken her to 72 countries to interview health professionals and to the halls of Congress to give her testimony in three obstetrical practices proceedings for improvements to the FDA’s drug regulating practices. Tellingly, Mrs. Haire was instrumental in the passage of the New York Maternity Information Act. *Id.* The Act requires state hospitals to disclose a myriad of obstetrical statistics and information. *Legislation Affecting Maternity Care*,

President of the International Childbirth Education Association (ICEA), published what has become “The Pregnant Patient’s Bill of Rights.”²⁰ Contained within are sixteen enumerated and purported rights of childbearing women.²¹ The first right of childbearing women appears in substance to be a rendition of the doctrine of informed consent:

*The Pregnant Patient has the right, prior to the administration of any drug or procedure, to be informed by the health professional caring for her of any potential direct or indirect effects, risks or hazards to herself or her unborn or newborn infant which may result from the use of a drug or procedure prescribed for or administered to her during pregnancy, labor, birth, or lactation.*²²

Importantly, the remainder of the rights listed explicate the patient’s access to information and medical records, patients’ safety for both mother and child, and transparency in hospital and emergency medicine practices and procedures.²³ According to Professor George Annas, chair of the Health Law Department at Boston University School of Law, rights numbered “1, 7, 8, 9, 11, 13, and 14 can properly be labeled ‘legal rights,’ and most of the remainder, including 15 and 16, can be labeled ‘probable legal rights.’”²⁴ The import is clear: patients and consumer advocates are endeavoring to supplement the doctrine of informed consent as it pertains to obstetrical care to acknowledge the rights of patient and child and thereby require physicians to increase the information exchange and risk disclosure substantially.²⁵ But why? What is wrong with the doctrine of informed consent in obstetrics? Suffice it to say, far too much seemingly “material” information is left unsaid and all too often results in serious physical harm and/or death to both patients.

ALLIANCE FOR IMPROVEMENT MATERNITY SERVICES, <http://www.aimsusa.org/laws.htm> (last visited Mar. 30, 2012).

20. GEORGE J. ANNAS, *THE RIGHTS OF PATIENTS: THE AUTHORITATIVE ACLU GUIDE TO THE RIGHTS OF PATIENTS* app. at 375–77 (S. Ill. Univ. Press, 3d ed. 2004); *The Pregnant Patient’s Bill of Rights*, ALLIANCE FOR IMPROVEMENT MATERNITY SERVICES, <http://www.aimsusa.org/ppbr.htm> (last visited Mar. 30, 2012).

21. ANNAS, *supra* note 20, app. at 375–77.

22. *Id.* app. at 375.

23. *Id.* app. at 375–76.

24. *Id.* app. at 377.

25. *See Understanding & Navigating the Maternity Care System: Informed Decision-Making*, CHILDBIRTH CONNECTION, <http://www.childbirthconnection.org/article.asp?ck=10081> (last updated Feb. 24, 2012) (noting that an improved standard of “shared decision making” should replace the current informed consent doctrine in obstetrics (internal quotation marks omitted)).

B. Legal Limits on the Duty to Inform in Obstetrics

While the premise underlying the need for informed consent lies in the vulnerability of expectant mothers, the premise underlying the right of expectant women to enjoy informed consent is founded in a principle equally as simple. Beginning with the bedrock principle that only an expectant mother can be the true advocate for her unborn child, it necessarily follows that practitioners and physicians must be under the most complete duty to inform women of every risk attendant in any drug or procedure administered. The courts seem to agree on the first component of this simple premise.

In *Modaber v. Kelley*,²⁶ a medical malpractice action was filed by a mother against her physician for personal injuries and mental anguish due to the stillbirth of her child.²⁷ In affirming that the evidence presented at trial was sufficient to support a finding that the obstetrician's conduct during the patient's pregnancy "caused direct injury to the [patient],"²⁸ the Supreme Court of Virginia held that the injury to the unborn child constituted an injury to the mother and thus she could recover damages.²⁹ Similarly, in *Castle v. Lester*,³⁰ a mother filed a medical malpractice claim against the attending physician after her child was born "neurologically impaired."³¹ In affirming her \$1.6 million jury verdict,³² the Supreme Court of Virginia held that when an unborn child sustains injuries from being born, both the mother and the unborn child have causes of action against the negligent practitioner.³³

Other courts outside the Commonwealth are in accord. In *Hilsman v. Winn Dixie Stores, Inc.*,³⁴ the Florida Fourth District Court of Appeals confirmed that an injury to an unborn child was an injury to the mother.³⁵ In *Spangler v. Bechtel*,³⁶ the Court of Appeals of Indiana held that "a mother who suffers a stillbirth due to medical malpractice qualifies as an injured patient" and is entitled to bring suit.³⁷ Similarly, in *Smith v. Borello*,³⁸ the Maryland Court of Appeals concluded

26. 348 S.E.2d 233 (Va. 1986).

27. *Id.* at 233.

28. *Id.* at 236.

29. *Id.* at 237.

30. 636 S.E.2d 342 (Va. 2006).

31. *Id.* at 343.

32. *Id.* at 342.

33. *See id.* at 350 (noting that while the child does have a cause of action for its injuries, it must be conducted separately from its mother's cause of action).

34. 639 So. 2d 115 (Fla. Dist. Ct. App. 1994).

35. *Id.* at 117.

36. 931 N.E.2d 387 (Ind. Ct. App. 2010), *vacated*, 958 N.E.2d 458 (Ind. 2011).

37. *Id.* at 397.

38. 804 A.2d 1151 (Md. 2002).

that a woman who loses her child in pregnancy may recover for demonstrable emotional distress in her own action for personal injuries.³⁹ In *Krishnan v. Sepulveda*,⁴⁰ the Texas Supreme Court permitted a mother to recover for “mental anguish” caused by the stillbirth of her child due to the negligence of her physician.⁴¹ That court reasoned that the mother should recover from the physician because the negligence was in treating the mother, and not the unborn child.⁴² The notion that a woman may recover on behalf of her unborn or stillborn child is therefore well-established.⁴³ A number of courts have additionally recognized that when a child survives a negligently performed trial of labor, even if only for a few days, the child or the child’s estate may sue independently of the mother and any claims she might have against the physician.

In *Kalafut v. Gruver*,⁴⁴ the Supreme Court of Virginia concluded that so long as the child is born alive, a physician who causes harm to the child while in utero is subject to liability to the child or child’s estate (as well as the mother) for tortious conduct causing injury.⁴⁵ In *Gonzales v. Mascarenas*,⁴⁶ the Colorado Court of Appeals held that a child who is born alive and subsequently dies is entitled to bring suit independently of its mother against the negligent practitioner.⁴⁷ In *Miccolis v. AMICA Mutual Insurance Co.*,⁴⁸ the Supreme Court of Rhode Island concluded that a child born alive is entitled to bring suit for injuries caused by tortious conduct that occurred both before and after conception.⁴⁹ Similarly, in *Draper v. Jasionowski*,⁵⁰ New Jersey’s Appellate Division held that an infant, on reaching the age of majority, has an independent cause of action against its mother’s obstetrician for any prenatal injuries.⁵¹ Furthermore, in *Schreiber v. Physicians Insurance Co. of Wisconsin*,⁵² the Wisconsin Supreme Court specifically recognized the right of a child born alive to recover for injuries suffered as a result of the obstetrician’s failure to offer its

39. *Id.* at 1163.

40. 916 S.W.2d 478 (Tex. 1995).

41. *Id.* at 482.

42. *Id.* at 479–80.

43. *See id.*

44. 389 S.E.2d 681 (Va. 1990).

45. *Id.* at 683–84.

46. 190 P.3d 826 (Colo. App. 2008).

47. *Id.* at 830.

48. 587 A.2d 67 (R.I. 1991).

49. *Id.* at 69.

50. 858 A.2d 1141 (N.J. Super. Ct. App. Div. 2004).

51. *Id.* at 1142.

52. 588 N.W.2d 26 (Wis. 1999).

mother a Cesarean section.⁵³ Courts have clearly embraced the concept that a mother can truly be the only advocate for her unborn child, and, once born, the child may be its own independent advocate.

Despite this progressive thinking by our nation's judiciary, courts have failed to make the leap in applying these principles to establish a broader, more comprehensive, doctrine of informed consent.⁵⁴ Indeed, tying the innate role women play in being responsible for their unborn child to the notion that physicians be required to divulge the whole truth, even if it is unknown, has escaped our judiciary. Although liability will apply in cases of egregious physician misconduct, it remains virtually impossible for plaintiffs to demonstrate a deviation from the standard of care for failing to disclose risks and information concerning obstetric procedures.⁵⁵ This is because the standard of care is being set, for better or for worse, by obstetricians acting in concert with one another.⁵⁶ If all the obstetricians remain silent during the information exchange on key risks, the standard of care reflects that silence and necessarily leaves mother and child in the dark, unprotected, and without malpractice recourse.

If courts are only willing to require the disclosure of "material" risks, perhaps the fight here is in advocating that the definition of "materiality" be construed to truly encompass all risks which truly might cause an expectant mother to forego a recommended drug or procedure. Logically, therefore, if courts should be expected to apply a more broad and comprehensive doctrine of informed consent, a discussion is required of when the duty to inform should arise.

C. Bioethics: When Should the Duty to Inform Arise?

Professor George Annas observes that while bioethics should govern the conduct of physicians in patient care decisions, it has "little impact on actual physician practice."⁵⁷ One reason may be because the laws governing informed consent in healthcare and obstetrics, which are almost exclusively state laws and federal enactments like the Health Insurance Portability and Accountability Act (HIPAA), "are

53. *Id.* at 26, 34–35.

54. *See* Bankert v. United States, 937 F. Supp. 1169, 1182 (D. Md. 1996) (ruling that the doctrine of informed consent, as applied in obstetrics, extends only to require that physicians disclose those risks or dangers that are material to an expectant mother).

55. *See id.* (laying out the three-pronged objective test that must be satisfied in order for a patient to prove an informed consent violation).

56. *See* Rhoden, *supra* note 12, at 72 (explaining the collective obstetrical practice of refusing to admit uncertainty to patients).

57. GEORGE J. ANNAS, AMERICAN BIOETHICS: CROSSING HUMAN RIGHTS AND HEALTH LAW BOUNDARIES 95 (2005).

aberrations to this rule.”⁵⁸ The lack of uniformity in state laws and judicial case law may be the reason why the idea of patients’ rights “remain[s] foreign to many physicians.”⁵⁹

As Professor Annas notes, “some physicians seem to believe that they can follow their own ethical compass without regard to the law.”⁶⁰ Given the currently weak state of the doctrine of informed consent in obstetrics, a physician need not do much to comport with applicable state law and judicial precedent on the subject. The inquiry of the moment is when the duty to inform should arise and how to know when consent is truly informed. Without a doubt, it should certainly arise and protect before “[b]eing killed in a hospital where you went for care, or by a drug you took for [a] cure.”⁶¹

The duty to inform in obstetrics should arise in every context prior to a medical procedure or drug administration in which the expectant mother is in a competent mental state. The reason relates back to the expectant mother’s dual role.⁶² Not only does any medication or procedure affect her, it necessarily affects her unborn child. Given that the mother is the only true advocate for her child, informed consent should be omnipresent in the context of obstetrical care.

Informed consent means that in any given medical context, whether during prenatal care, labor or delivery, the expectant mother has been informed of the following: the name and nature of a particular procedure or drug and why she should allow the procedure or drug to be administered to her and her unborn child;⁶³ the dangers or disadvantages to her and her unborn child of not receiving the procedure or drug;⁶⁴ the existence of other methods of treatment available to her and her unborn child; the risks and benefits of these other methods to her and her unborn child;⁶⁵ the benefits or advantages of this procedure or drug as it applies to both her and the unborn child;⁶⁶ an understanding of her physician’s experience in providing these procedures or drugs to people similarly situated;⁶⁷ her prognosis, and the likely

58. *Id.*

59. *Id.* at 104.

60. *Id.*

61. GEORGE J. ANNAS, WORST CASE BIOETHICS: DEATH, DISASTER, AND PUBLIC HEALTH 163 (2010).

62. See Rhoden, *supra* note 12, at 76 (“It is quite obvious that decisionmaking in obstetrics differs from decisionmaking in other areas of medicine, in that *only in obstetrics is one patient within and dependent upon another.*” (emphasis added)).

63. ANNAS, *supra* note 20, at 134.

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

outcome to her and her unborn child following the administration of the procedure or drug;⁶⁸ and all areas of uncertainty (gaps in medical knowledge) associated with the administration of the drug or procedure that are known by the physician. The expectant mother must also have had the opportunity to ask all questions with “a clear head and alert mind”;⁶⁹ have a belief that the benefits from receiving a procedure or drug “outweigh the risks” to her and her unborn child;⁷⁰ and understand that there is no obstetric related drug that has been proven safe for the fetus during the pregnancy or at term.⁷¹

Even in the advocate’s ideal view of informed consent, there would still exist two well-established justifications for withholding information from the expectant mother: (1) exigent circumstances “in which immediate treatment is needed to preserve the [mother and/or child’s] life or health and the patient is unconscious or incompetent and there is no time to locate a family member or other decision maker”;⁷² and (2) waiver of informed consent, in which the mother elects not “to know the specific risks and, understanding that there are risks of death . . . , asks not to be informed of them in detail.”⁷³ In the case of the latter, the expectant mother might be asked to sign such a waiver on behalf of herself and her unborn child.⁷⁴

By no means, however, should the use of general or “blanket” consent forms be advocated. Blanket consent forms are often utilized by practitioners and authorize them to perform and administer a wide variety of procedures and drugs deemed necessary in their own discretion.⁷⁵ “A blanket consent form,” by its very nature, “covers . . . almost everything a doctor or a hospital might do to a patient, without mentioning anything specifically.”⁷⁶ According to Professor Annas, “[m]any

68. *Id.*

69. See ANNAS, *supra* note 20, at 134–35.

70. *Id.* at 135.

71. Letter from Dr. Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, U.S. Food & Drug Admin., to Doris B. Haire, President, Am. Found. for Maternal & Child Health (June 11, 2001) (on file with author). According to Dr. Woodcock, in response to a request from the American Foundation for Maternal and Child Health for a copy of the Standards of Safety that must be met before the FDA approves a drug to be used in obstetrics, “[t]here are no written standards for safety assessments of drugs approved for obstetrics indications.” *Id.* Despite a growing concern that fetal exposure to obstetric drugs may result in neuroapoptosis, and subsequent autism in the exposed offspring, it is frightening to see that the FDA has shown little interest in curbing or minimizing such fetal exposure.

72. ANNAS, *supra* note 20, at 127.

73. *Id.*

74. *Id.*

75. See Woolery, *supra* note 7, at 253; see also *Rizzo v. Schiller*, 445 S.E.2d 153, 155–56 (Va. 1994).

76. ANNAS, *supra* note 20, at 129.

hospitals continue to require patients to sign such forms on admission.”⁷⁷ While in theory a blanket consent form is not sufficient consent for any procedure with “risks or alternatives,”⁷⁸ it would not be a far stretch to posit that physicians may be getting incentivized to take advantage of blanket consent forms signed by the expectant mother in an effort to perform procedures and administer drugs to increase personal and hospital profit.⁷⁹

When the duty to inform ideally should arise is a far cry from where the duty to inform indeed arises.⁸⁰ Perhaps this is because physicians argue they are disadvantaged by the uncertainty of knowing “what risks should be disclosed.”⁸¹ What is inherently unfortunate about this standpoint is that it makes clear the fundamental weakness of the doctrine of informed consent as applied to obstetrics: a physician is not legally required to disclose every risk of every drug or procedure.⁸² This is certainly not because the expectant mother is disinterested. In fact, it would be hard to believe that an expectant mother would be indifferent if she knew her physician was aware of risks associated with a drug or procedure and failed to convey them to her. Perhaps the only saving grace for expectant mothers currently is that physicians must present the information in language the mother can understand.⁸³

D. The Practice of Off-Labeling

Although Pfizer or Merck might try to convey that off-label uses are benefits that the U.S. Food and Drug Administration (FDA) has yet to recognize, in truth, off-labeling is the physician practice of prescribing drugs for uses, dosages and applications presently unapproved by the FDA.⁸⁴ As Consumer Reports aptly observes, “[l]ike most

77. *Id.*

78. *Id.*

79. See Henci Goer, *The Soaring Cesarean Rate: It's the Economics, Stupid*, SCI. & SENSIBILITY (May 22, 2009), <http://www.scienceandsensibility.org/?p=189> (discussing how Cesareans generate large profits for hospitals and, as a consequence, there is not a lot of incentive to reduce them regardless of the fact that they can have a negative effect on mothers and babies).

80. See *Bankert v. United States*, 937 F. Supp. 1169, 1182 (D. Md. 1996) (ruling that the doctrine of informed consent, as applied in obstetrics, extends only to require that physicians disclose those risks or dangers that are material to an expectant mother).

81. ANNAS, *supra* note 20, at 116.

82. See *id.* (observing that the only risks that physicians are required to disclose are those which are material).

83. *Id.* at 117.

84. *Off-Label Drug Prescribing: What Does It Mean For You?*, CONSUMERREPORTS.ORG (May 2009), <http://www.consumerreports.org/health/best-buy-drugs/off-label-drug-prescribing->

Americans, you probably assume that if your doctor writes a prescription for you, the drug is approved by the U.S. Food and Drug Administration for your specific condition or ailment.”⁸⁵ Of course, you would be very wrong.

Physicians in all areas of practice write, as often as one out of every five, prescriptions for off-label uses.⁸⁶ While off-labeling is not restricted by law and can be beneficial,⁸⁷ often there is not conclusive research supporting a particular off-label use,⁸⁸ and the effects can be devastating.⁸⁹ Even more shocking, while physicians may elect to discuss off-label uses with patients, they are under no legal obligation to disclose that the prescription being written is for an off-label use.⁹⁰ Drugs in obstetrics are no different, and many of the drugs that commonly are prescribed prenatally or during labor are written off-label, some with horrific obstetric implications.⁹¹

Prozac, which is an antidepressant for oral administration, is not FDA approved for pregnancy, labor, or delivery, but is frequently prescribed to, and taken by, expectant mothers.⁹² The manufacturer's package insert indicates that when Prozac is administered to an expectant mother, it “crosses the placenta” and enters the fetal circulatory system, meaning it “may have adverse effects on the newborn.”⁹³ The insert further advises that “[Prozac] should be used during labor and delivery only if the potential benefit justifies the potential risk to the

what-does-it-mean-for-you-5-09/overview/off-label-drug-prescribing.htm.

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. See Robert H. Pritchard, *Off-Label Uses of Approved Drugs: A New Compromise Is Needed*, LEDA AT HARV. L. SCH. (Mar. 25, 1999), <http://www.leda.law.harvard.edu/leda/data/130/rpritcha.html> (“[I]t cannot be denied that serious harm can occur when physicians and manufacturers abuse their bounded powers with regard to off-label drug therapies.”); see also Randall S. Stafford, *Regulating Off-Label Drug Use—Rethinking the Role of the FDA*, 358 NEW ENG. J. MED. 1427, 1427–28 (2008) (detailing the negative consequences and numerous conflicts surrounding off-label drug use).

90. *Off-Label Drug Prescribing: What Does it Mean for You?*, *supra* note 84.

91. See *Drugs Not FDA Approved for Obstetrics*, ALLIANCE FOR IMPROVEMENT MATERNITY SERVICES, <http://www.aimsusa.org/ObstetricDrugs-NotApproved.htm> (last visited Mar. 30, 2012) (providing a long list of drugs that are commonly used off-label in obstetric care).

92. *Id.*; Anne Harding, *Antidepressant Use in Pregnancy May Raise Autism Risk*, CNN HEALTH (July 6, 2011, 9:22 AM), <http://www.cnn.com/2011/HEALTH/07/04/antidepressant.pregnancy.autism.risk/index.html> (highlighting that a large study in 2005 found that 6.5 percent of pregnant women were taking antidepressants such as Prozac); *Prozac (Fluoxetine Hydrochloride) Capsule*, DAILY MED, <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=62256> (last updated Jan. 2012) (“The effect of PROZAC on labor and delivery in humans is unknown.”).

93. See *Prozac (Fluoxetine Hydrochloride) Capsule*, *supra* note 92.

fetus.”⁹⁴ And yet, there is no legal requirement for a physician to speak a word of this to the expectant mother.⁹⁵ Consequently, most do not.⁹⁶

Similarly, Valium, which is approved for the management of anxiety disorders, is not approved for use in obstetrics.⁹⁷ The package insert for Valium indicates that “[s]pecial care must be taken when Valium is used during labor and delivery, as high single doses may produce irregularities in the fetal heart rate and hypotonia, poor sucking, hypothermia, and moderate respiratory depression in the [newborn children].”⁹⁸ The insert further provides that physicians should advise patients of the desirability of ceasing use of the drug if the patient becomes pregnant or expects to become pregnant.⁹⁹ Although the manufacturer advisory is certainly a good one, there is no legal compulsion requiring physicians to disclose this information regarding Valium to the expectant mother.¹⁰⁰ Moreover, there is nothing restricting a physician from writing a prescription for Valium to an expectant mother.

Prostin E2 (Dinoprostone), which is commonly prescribed to an expectant mother in labor to prepare the cervix for birth, is also not approved for pregnancy, labor or delivery.¹⁰¹ The manufacturer cautions that “PROSTIN E2 Vaginal Suppository should [not] be used for cervical ripening”¹⁰² (“a process in which the drug causes the cervix to soften, efface and dilate”).¹⁰³ Yes, that is right, the manufacturer strongly cautions against the drug’s most common off-label use. Should our hypothetical couple be concerned yet?

Mepergan (Meperidine HCl/Prometh HCl) is also a narcotic analgesic often used in obstetrics.¹⁰⁴ The package insert cautions that when used as an obstetric analgesic, “Meperidine crosses the placental barrier and can produce [respiratory] depression . . . in the newborn.”¹⁰⁵

94. *Id.*

95. *Off-Label Drug Prescribing: What Does it Mean for You?*, *supra* note 84.

96. See Rebecca Dresser & Joel Frader, *Off-Label Prescribing: A Call for Heightened Professional and Government Oversight*, 37 J.L. MED. & ETHICS 476, 480 (2009) (“A 2006 poll suggests that much of the U.S. public is confused and ambivalent about off-label prescribing, with about half the respondents believing that physicians are permitted to prescribe drugs only for on-label indications and about half believing that physicians should be prohibited from prescribing drugs for off-label indications.” (footnote omitted)).

97. *Drugs Not FDA Approved for Obstetrics*, *supra* note 91.

98. *Valium (Diazepam) Tablet*, DAILY MED, <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=18533> (last updated Apr. 2010).

99. *Id.*

100. *Off-Label Drug Prescribing: What Does It Mean For You?*, *supra* note 84.

101. *Dinoprostone*, PUBMED HEALTH (Sept. 1, 2008), <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000698>; *Drugs Not FDA Approved For Obstetrics*, *supra* note 91.

102. *Prostin E2 (Dinoprostone) Suppository*, DAILY MED, <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=451> (last updated May 2006).

103. *Drugs Not FDA Approved For Obstetrics*, *supra* note 91.

104. *Id.*

105. *Meperidine HCL (Meperidine Hydrochloride) Tablet*, DAILY MED, <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=3790> (last updated Mar. 2007).

The insert further alerts that “resuscitation [of the newborn] may be required.”¹⁰⁶ While Mepergan is not approved for use in labor or delivery, presently there is no legal requirement preventing physicians from administering this drug during labor or delivery.¹⁰⁷

Sadly, the list goes on.¹⁰⁸ Although off-label uses can be beneficial to patients, the foregoing discussion obviates the need for regulation of off-label uses and greater disclosure through a stronger duty to inform. Clearly, practitioners should be required to engage expectant mothers in a dialogue regarding the nature and frequency of off-label use during pregnancy, labor, and delivery. Further, lawyers must repeatedly move courts in this direction and bring malpractice actions for medical damages brought on by off-label uses accompanied by a failure to inform.

E. The FDA's Areas of Uncertainty

As horrific as the reality of off-labeling is, the reality is not much better even for drugs that carry FDA approval in obstetric applications. One reason for this could be because “[t]he FDA does not guarantee the safety of any drug.”¹⁰⁹ According to Doris Haire, what this means is that “no prescription drug or over-the-counter remedy . . . is without risk, even when taken according to directions.”¹¹⁰ Thus, when informing a patient that a drug is safe, a physician is not using the common dictionary definition of the word “safe”: “free from harm or injury,” as the patient might otherwise imagine.¹¹¹ Rather, the physician simply means that the drug comes with an acceptable risk, measured not against the expectant mother’s standards of acceptability, but upon the assessments of a non-stakeholder: the FDA.¹¹² This is especially true in the field of obstetrics.¹¹³

Perhaps the other reason, even with drugs that do carry the unpersuasive FDA approval in obstetric applications, is that many of these drugs’ medical effects and consequences on the unborn or

106. *Id.*

107. *See Off-Label Drug Prescribing: What Does It Mean For You?*, *supra* note 84.

108. *See Drugs Not FDA Approved for Obstetrics*, *supra* note 91 (providing a comprehensive list of drugs frequently used “off-label” in obstetrics).

109. Letter from Dr. J. Richard Crout, Dir., Bureau of Drugs, U.S. Food & Drug Admin., to Doris B. Haire (Jan. 15, 1975) (on file with author).

110. Doris Haire, *Just How Safe Is “Safe”? How the F.D.A. Determines the “Safety” of Drugs*, ALLIANCE FOR IMPROVEMENT MATERNITY SERVICES, <http://www.aimsusa.org/howsafe.htm> (last visited Mar. 30, 2012).

111. *Id.* (internal quotation marks omitted).

112. *Id.*

113. *See id.* (noting that the “FDA has no [established] system for accurately determining the benefit/risk ratio of an obstetric drug for the offspring”).

newborn child are unknown or inconclusive.¹¹⁴ When gaps in medical knowledge exist concerning a drug's effect in a particular context, such as a drug's effect on fetal development, these unknown consequences have been denominated by the FDA as "areas of uncertainty." To protect consumers from "areas of uncertainty," Section 201.57(c)(9)(ii) of Volume 21 of the Code of Federal Regulations provides:

If the drug has a *recognized use* during labor or delivery (vaginal or abdominal delivery), whether or not the use is stated in the Indications and Usage section, this subsection must describe the available information about the effect of the drug on the mother and the fetus, on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and the effect of the drug on the later growth, development, and functional maturation of the child. If any information required under this subsection is unknown, it must state that the information is unknown.¹¹⁵

This regulation requires drug manufacturers to disclose in its package insert a drug's effects on the fetus when the drug has a recognized use in labor or delivery and, if a drug's fetal effects are unknown, manufacturers are required to acknowledge the particular areas of uncertainty.¹¹⁶ But, as with off-label uses, it appears present law imposes no obligation upon obstetricians to notify an expectant mother that the drugs she may be taking, or having administered, come with areas of uncertainty, unless the risks are objectively "material."¹¹⁷ The results seem inconsistent. If the FDA believes it is necessary to warn consumers by requiring package inserts to state fetal effects and areas of uncertainty associated with a particular drug, the disclosure of this information should also be required by the doctrine of informed consent when a physician engages in the colloquy with a patient,

114. See *FDA Approved Obstetrics Drugs: Their Effects on Mother and Baby*, ALLIANCE FOR IMPROVEMENT MATERNITY SERVICES, <http://www.aimsusa.org/obstetricdrugs.htm> (last visited Mar. 30, 2012) (observing that no conclusive studies on Pitocin have ever been produced that identify the long-term effects of the drug on the baby); Haire, *supra* note 110 (stressing that there is "[n]o FDA requirement that obstetric drugs be proven safe for the fetus or newborn"); *Prozac (Fluoxetine Hydrochloride) Capsule*, *supra* note 92 ("The effect of PROZAC on labor and delivery in humans is unknown.").

115. 21 C.F.R. § 201.57(c)(9)(ii) (2006) (emphasis added).

116. *Id.*

117. This author was unable to find a single malpractice case seeking to recover damages stemming from injuries arising out of the areas of uncertainty of a drug brought on by the administration of that drug, which was a result of the obstetrician's failure to inform regarding those areas of uncertainty.

recommending a particular course of action, procedure, or drug. Are areas of uncertainty *not* material risks?

Marcaine (Bupivacaine), for example, is a drug commonly used in epidurals and is approved by the FDA for use in obstetrics.¹¹⁸ In the insert for Marcaine, the manufacturer cautions that use on patients during uterine contractions “is *not recommended*.”¹¹⁹ Marcaine is also not recommended for use on mothers who are under the age of eighteen.¹²⁰ Most importantly, the FDA package insert states, “[t]here are no adequate and well-controlled studies in pregnant women of the effect of [Marcaine] on the developing fetus. [Marcaine] should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.”¹²¹ In this realistic example, but for the obstetrician’s disclosure, how else would an expectant mother know about Marcaine’s areas of uncertainty? Is this information not “objectively material?”¹²² Might the disclosure of this drug information cause the typical expectant mother to decline an epidural?

What is truly remarkable is that despite the simplicity of the idea that only a mother can be her unborn child’s advocate, and the natural progression of the idea that in order to advocate a mother must be completely informed, courts have remained unwilling to extend the doctrine of informed consent beyond material risks to the mother.¹²³ As a result, off-labeling and the failure to discuss significant areas of uncertainty have become commonplace, particularly in the field of obstetrics.¹²⁴ This abstraction of the doctrine of informed consent thus far, however, does not adequately portray obstetricians’ missed opportunities to truly inform a mother of many seemingly material risks. It is the absence of a strong duty to inform in the field of obstetrics that leaves much unsaid, and often with nightmarish consequences. Endeavoring

118. *FDA Approved Obstetric Drugs: Their Effects on Mother and Baby*, *supra* note 114; *Obstetric Drugs: Their Effects on Mother and Infant*, ALLIANCE FOR IMPROVEMENT MATERNITY SERVICES, <http://www.aimsusa.org/rothdrug.htm> (last visited Mar. 30, 2012).

119. *Bupivacaine (Bupivacaine Hydrochloride) Injection, Solution*, DAILY MED, <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=49075> (last visited Mar. 30, 2012) (emphasis added).

120. *Id.*

121. *Id.*

122. *See Bankert v. United States*, 937 F. Supp. 1169, 1182 (D. Md. 1996) (asserting that physicians must disclose to patients “material risks or dangers inherent in or collateral to” the administration of a drug).

123. *See id.* (emphasizing that the doctrine of informed consent requires *only* the disclosure of material risks or dangers to a patient).

124. Dresser & Frader, *supra* note 96, at 482; *see also* M.S. Henry, *Uncertainty, Responsibility, and the Evolution of the Physician/Patient Relationship*, 32 J. INST. MED. ETHICS 321, 321 (2006) (noting that a study of the informed consent process found that uncertainty was disclosed to patients only five percent of the time).

to paint this picture as vividly as possible, we once again return to our hypothetical expectant parents.

II. MISSED OPPORTUNITIES FOR INFORMED CONSENT DURING THE BIRTHING PROCESS AND THE POTENTIAL CONSEQUENCES

Our quest begins with the stigmatized importance of finding an obstetrician upon learning of pregnancy. As a product of Western society, our expectant couple is conditioned that getting an obstetrician is essentially a rite of passage upon conception of a child.¹²⁵ But rarely would they ever know to challenge that notion and ask whether alternatives exist. Indeed, alternatives to a “normal” hospital birth,¹²⁶ such as the midwifery profession or even a natural home birth, are seemingly left unconsidered.¹²⁷ The beginning of this vicious cycle appears to be the blind, presumptive trust that we instinctively place in our obstetrical practitioners.¹²⁸ As a result, our expectant couple quickly loses control and, from this point, the odds that they will ever make truly informed decisions are incredibly slim.

A. *The Laughable Information Exchange*

Once in the office with their obstetrician, a laughable information exchange takes place because obstetricians are in a business built on happy patients, not informed ones.¹²⁹ As our expectant mother gives the doctor an oral medical history, and perhaps expresses her interest in giving birth to her child naturally and without drugs, the physician tells the expectant mother what she wants to hear and gives shallow

125. From the motion picture portrayals of pregnancy, delivery and birth, to celebrations by our co-workers, family and friends, a theme is clear. Often portrayed is the ultrasound procedure during pregnancy, the eagerness to distribute ultrasound photos, and the attending obstetrician in the hospital telling the mother “everything’s A-OK.” Of course, these moments are well engrained into the American psyche because these are the norms of our culture—a culture without an effective doctrine of informed consent.

126. The irony is of course that by “normal” birth, society often thinks of a birth in a hospital by the attending obstetrician. To those in the field of maternity and obstetric care, however, a “normal” birth is a natural birth, and a natural birth can only be assured when a midwife has been engaged to deliver the child. See GOER, *supra* note 10, at 209 (emphasizing that in hospitals, birth is approached as “a medical crisis,” whereas births at birthing centers or at home are normal and healthy).

127. *Id.* at 201. For further discussion on midwifery, see *id.* at 200–18 (making the case for the continued role of midwifery in the modern age).

128. This is a theory posited by the author and is not known to have been suggested by another source.

129. See, e.g., Woolery, *supra* note 7, at 245 (describing the specificity with which patients must object to the use of forceps when there has been informed consent present in a previous procedure).

assurances:¹³⁰ “Oh, we should definitely be able to do a natural birth, and everything *should* be fine.” But, for some reason, the conversation stops here. Again, another opportunity is missed for the real conversation about hospitals, procedures, labor, delivery and drugs.¹³¹

The obstetrician should have been frank with our expectant parents about the realities of the situation, beyond simply ascertaining the mother’s medical history and desire for a natural birth. Expectant parents need the truth. The truth is that the reality of a natural birth, for a first-time mother, is not a likely reality when a hospital birth is elected.¹³² This is largely because hospitals injudiciously administer drugs to expectant mothers.¹³³ How can they do this? What expectant parents are not being told is that when the mother is eventually admitted to the hospital at term, she will likely sign a blanket consent form that enables the doctors to do anything from clipping her toenails to giving her a Cesarean section.¹³⁴ Further, our expectant couple is not told that many legal hospital policies authorize physicians to medically intervene if the pregnancy does not progress “properly.”¹³⁵

B. Economics and Cesareans

By “properly,” one may have thought the meaning to be whatever is in the best interests of mother and child. Sadly, by “properly,” what is meant is profitably.¹³⁶ All too often, under the authority of the blanket consent form, hospitals actually encourage their doctors to perform legal, but unnecessary obstetrical procedures covered by insurance in order to increase patients’ bills and maximize hospital profit from the insurance companies.¹³⁷

Hospitals also put economics over patient care by stacking the deck against patients and increasing the likelihood that “[they]’ll need

130. See, e.g., *id.* at 245–46 (citing a case in which a doctor used forceps during delivery before the mother could ask questions); see also GOER, *supra* note 10, at 1–3 (explicating the gap between patient belief and practitioner reality).

131. See Woolery, *supra* note 7, at 245–46.

132. *Id.* at 242; see also GOER, *supra* note 10, at 16–17 (articulating that the profitability to hospitals of Cesarean sections and delivery drug usage reduces a mother’s chance of having a natural birth).

133. GOER, *supra* note 10, at 205.

134. See Woolery, *supra* note 7, at 253–54 (indicating the prominent use of the blanket or general consent form and how its use does not appear to absolve physicians from all liability for lack of informed consent).

135. ANNAS, *supra* note 20, at 127. Unfortunately, when interventions become routine under the authority of blanket consent forms, then there is really no medical reason for them. GOER, *supra* note 10, at 205.

136. GOER, *supra* note 10, at 16–17.

137. Goer, *supra* note 79.

the drugs.”¹³⁸ After all, if drugs are administered during the trial of labor, insurance will pay for them and the hospitals will make more money than if an expectant mother had a natural birth and did not need them.¹³⁹ At least, that is what our expectant parents should have been told.

Henci Goer, an award winning medical writer and birth activist, suggests that unnecessary Cesarean sections are performed because they add thousands of dollars to the patient’s hospital bill,¹⁴⁰ and are procedures for which insurers will, and do, pay.¹⁴¹ In a study by Myers and Gleicher, when a hospital’s “cesarean rate [was reduced] from 17.5% to 11.5% over two years, the hospital lost \$1 million in revenue.”¹⁴² Unfortunately, Cesarean sections come with their own set of risks and have become an epidemic.¹⁴³

Between 1970 and the mid-1990s, the number of women who gave birth by Cesarean has grown exponentially from 5.5%¹⁴⁴ (about one in eighteen) to an average of 24% (about one in four).¹⁴⁵ According to Henci Goer, this makes “Cesarean section . . . *the* most common operation performed in the [United States].”¹⁴⁶ While arguably the increase could be attributable to the fact that the Cesarean section procedure itself is now rather low risk, this is not an accurate or complete explanation.

Cesareans, as surgical procedures, can be scheduled, permitting the element of convenience to enter obstetrics.¹⁴⁷ With families being more geographically spread out in the age of modern travel, scheduled deliveries are more popular.¹⁴⁸ And because Cesarean sections can be scheduled, obstetricians are led “to exaggerate the problems of vaginal birth and minimize those of cesarean delivery.”¹⁴⁹ Certainly, expectant parents would want to learn that “obstetricians are less likely to perform cesareans late at night or on weekends” because the procedure is often scheduled for the physician’s convenience.¹⁵⁰

138. Yvonne Brackbill, *Introduction*, MONOGRAPHS SOC’Y FOR RES. CHILD DEV., June 1970, at 1, 1.

139. *See* GOER, *supra* note 10, at 16–17.

140. *See* Goer, *supra* note 79.

141. *See id.*

142. HENCI GOER, OBSTETRIC MYTHS VERSUS RESEARCH REALITIES: A GUIDE TO THE MEDICAL LITERATURE 24 (1995).

143. GOER, *supra* note 10, at 11.

144. GOER, *supra* note 142, at 21.

145. *Id.*

146. *Id.* (citation omitted); *see also* GOER, *supra* note 10, at 11.

147. GOER, *supra* note 10, at 17–18.

148. *See, e.g., id.* at 17 (identifying “[c]onvenience” as a reason for the increased rates of Cesareans).

149. *Id.* at 13.

150. *Id.* at 17–18.

Perhaps the most common reason that women have Cesareans is simply because they have already had one.¹⁵¹ Many obstetricians believe that vaginal birth after Cesarean is “too dangerous.”¹⁵² Patients who have had Cesarean sections are at higher risk for uterine rupture, cephalopelvic disproportion, and failure to progress, all of which will put the unborn child in distress.¹⁵³ As a result, many hospitals will not permit the mother to have a normal vaginal birth after a Cesarean section, not because her body cannot handle it, but because insurance will not cover the delivery unless it is by Cesarean section.¹⁵⁴ This means the normal woman is virtually uninsurable for normal birth following a Cesarean section.¹⁵⁵

While clearly a majority of Cesareans are performed absent medical necessity, and have earned popularity from the convenience factor, cesareans are not without negatives. Cesareans are painful, debilitating and require a longer recovery period than a vaginal birth.¹⁵⁶ Moreover, each of these complicating factors necessarily interferes with the bonding process between mother and baby.¹⁵⁷

Cesareans also carry risks for the baby, not the least of which is that the newborn may be cut.¹⁵⁸ Because most Cesareans are performed after administering an epidural drug to the mother, such as Marcaine (Bupivacaine), the drug is certain to be passed through the bloodstream to the child prior to the procedure.¹⁵⁹ Because there are no adequate or well controlled studies on the effects of Marcaine on the fetus, a real risk is being taken during the Cesarean section procedure.¹⁶⁰ Certainly, the foregoing seems like the type of information an obstetrician should pass onto its patients. Why is our expectant couple not being told these facts?

C. *The Unnatural Amniotomy*

Another procedure from whose details expectant parents are likely to be insulated is the amniotomy procedure. This procedure involves

151. GOER, *supra* note 142, at 23.

152. *Id.* at 23–24.

153. Heidi Rinehart, *A VBAC Primer: Technical Issues for Midwives*, MIDWIFERY TODAY (2001), www.midwiferytoday.com/articles/vbacprimer.asp.

154. GOER, *supra* note 10, at 162–63.

155. *See id.* at 47 (warning patients that “[y]ou may find that your insurance plan does not include anyone who does vaginal breech births”).

156. *Id.* at 22.

157. *Id.* (reporting that many women experience difficulty in looking after the baby during recovery).

158. *Id.* at 23.

159. *Bupivacaine (Bupivacaine Hydrochloride) Injection, Solution*, *supra* note 119.

160. *Id.*

the forced breaking of the water, or amniotic sac membrane, in which the fetus is encased.¹⁶¹ To break, the doctor will snag the membrane with an amnihook tool, causing the sac to rupture and the amniotic fluid to drain.¹⁶² The procedure is often uncomfortable for the mother, but does not inflict physical pain on the child.¹⁶³ Unfortunately, “[m]any [obstetricians] consider amniotomy so trivial that they may not think to advise you that they are about to do one.”¹⁶⁴

An amniotomy can shorten labor by one or two hours.¹⁶⁵ Some obstetricians hail it as a less risky alternative to inducing labor through the use of drugs, but this is misleading as both methods are unnatural.¹⁶⁶ Obstetricians are also aware that the absence of amniotic fluid has been associated with abnormalities in the fetal heart rate.¹⁶⁷ If the membranes are intact, the baby and the umbilical cord will remain in a suspended state of floating.¹⁶⁸ But without the fluid, the fetus loses its insulation and uterine contractions may impede blood flow to the newborn.¹⁶⁹ Further, an amniotomy can result in umbilical cord prolapse, in which the cord precedes the baby from the birth canal.¹⁷⁰ Umbilical cord prolapse is an emergency requiring immediate Cesarean section to get oxygen to the newborn.¹⁷¹

Unfortunately, while all of this information is known to practitioners, it is unlikely to be shared with expectant parents. The law does not require obstetricians to disclose the information or the risks of a procedure such as this unless the risks to the mother are objectively “material.”¹⁷² Consequently, our expectant couple is likely to remain ignorant of this information, despite it being undeniably “material” to them.

D. Induction of Labor and Epidurals

This should, but likely will not, lead the obstetrician into a discussion about the common induction drug, Pitocin (synthetic oxytocin), and the common epidural drug Marcaine (Bupivacaine), for the hospi-

161. GOER, *supra* note 10, at 99.

162. *Id.* at 103.

163. *Id.*

164. *Id.* at 105.

165. *Id.* at 103.

166. *See id.* at 99.

167. GOER, *supra* note 10, at 100.

168. *Id.*

169. *Id.* at 100–01. One need not worry about involuntary rupture of the amniotic membranes, however, because “full-term babies can compensate.” *Id.* at 101.

170. *Id.* at 101.

171. *Id.*

172. *See id.* at 105.

tal will likely be “required” to administer them.¹⁷³ Epidurals are the “Cadillac of anesthesia,” and friends and family would think it crazy not to have one.¹⁷⁴ The truth is that labor induction drugs, and the epidurals that usually follow, are quite harmful and unnatural, both for mother and for baby.¹⁷⁵

As Henci Goer observes, inducing labor is intrinsically ironic.¹⁷⁶ Labor is such a delicate and biologically balanced hormonal symphony that any attempt to begin the process artificially often ends in Cesarean section.¹⁷⁷ What’s the hurry?

One answer is that obstetricians often induce labor upon concern for the fetus.¹⁷⁸ This too is ironic as induced labor is more strenuous on the fetus than natural birth and causes many of the problems it was meant to prevent.¹⁷⁹ This is largely due to the injudicious use and quantity of the induction drugs involved: Pitocin, Prostin E2, Prepidil and Cervidil.¹⁸⁰ All of these drugs are known for causing painful and elongated contractions (uterine hyperstimulation).¹⁸¹

Another answer is rooted in the infamous “twenty-four hour rule.”¹⁸² The twenty-four hour rule effectively says that if the expectant mother has experienced a measured, but only slight amount of dilation in the twenty-four hour period since her water spontaneously broke or was unnaturally broken by an amniotomy, obstetricians are authorized to give the woman drugs to induce labor in an effort to minimize the risk of infection to the unborn child.¹⁸³ Studies that initially supported this rule as the basis for hospital policies have been found to be seriously flawed.¹⁸⁴ This is not the full conversation with regard to induction medications, but explicates some of the economic forces that drive decisions in hospitals.¹⁸⁵

Another explanation for induction is for the convenience of the mother and also for the physician.¹⁸⁶ All too often, upon hearing word

173. See GOER, *supra* note 10, at 50–51 (discussing the unnecessary interventions by hospitals to induce and deliver infants absent adequate medical necessity, largely for reasons of obstetrician convenience).

174. See *id.* at 126.

175. *Id.* at 126–27.

176. See *id.* at 51.

177. *Id.* at 52.

178. *Id.* at 50.

179. GOER, *supra* note 10, at 50.

180. *Id.* at 50–51.

181. *Id.* at 51.

182. *Id.* at 52.

183. *Id.* at 52–53.

184. *Id.* at 53.

185. See GOER, *supra* note 10, at 16–17.

186. *Id.* at 51.

that her obstetrician will be leaving town, the mother elects induction.¹⁸⁷ Induction is also used to prevent the mother from being “[o]verdue,” which, in the words of Henci Goer, is like “overbaking a cake.”¹⁸⁸ So how can this be in the mother’s best interests? More importantly, why are expectant mothers being insulated from receiving this information?

Regardless of the reason for the induction, almost always part and parcel is the epidural. Almost all of the common induction drugs unfortunately cause uterine hyperstimulation, which sends a woman’s nerve endings into overdrive.¹⁸⁹ Accordingly, the administration of the induction-drug Pitocin makes labor extremely painful, while doubling the odds of a negative fetal outcome.¹⁹⁰ Enter the epidural.

The very first epidural was administered in 1885, when a New York neurologist injected cocaine into a patient’s back in an effort to relieve pain.¹⁹¹ Today, “[e]pidurals involve the injection of [drugs] into the epidural space.”¹⁹² Bupivacaine, Ropivacaine and Lidocaine are traditionally used, all of which are derivatives of cocaine.¹⁹³ Although an epidural does substantially eviscerate the pain of labor,¹⁹⁴ and the pain amplified by the induction drugs, it has two significant consequences.

First, “[e]pidural drugs] can cause profound, prolonged drops in babies’ heart rates.”¹⁹⁵ The drop can occur within thirty minutes of the epidural being administered to the mother and last as long as twenty minutes.¹⁹⁶ All too often, the fetus develops bradycardia, a neonate condition characterized by a very low-level fetal heart rate.¹⁹⁷

It is critical to remember that the labor and birth processes are biologically orchestrated, and complex with hormones. Epidurals violently interfere with this natural process in the mother.¹⁹⁸ Oxytocin, for example, is a natural hormone that causes contractions within the uterus.¹⁹⁹ As discussed, sometimes Pitocin (synthetic oxytocin) is administered to supplement the mother’s natural oxytocin and unnaturally induce labor. Epidurals, however, which are administered to

187. *Id.*

188. *Id.* at 55 (internal quotation marks omitted).

189. *Id.* at 64–66.

190. *Id.* at 65.

191. SARAH J. BUCKLEY, GENTLE BIRTH, GENTLE MOTHERING: A DOCTOR’S GUIDE TO NATURAL CHILDBIRTH AND GENTLE EARLY PARENTING CHOICES 132 (2009).

192. *Id.*

193. *Id.* at 132, 138.

194. *Id.* at 133.

195. GOER, *supra* note 10, at 126.

196. BUCKLEY, *supra* note 191, at 142.

197. *Id.*

198. *Id.* at 133–35.

199. *Id.* at 133.

eviscerate the pain now amplified by the synthetic oxytocin, lower the mother's release of natural oxytocin and block its intended induction effect if administered prior to labor.²⁰⁰ As Dr. Sarah J. Buckley observes: "Epidurals also obliterate the maternal oxytocin peak that occurs at birth—possibly the highest oxytocin activity of a mother's lifetime—that catalyzes the final powerful contractions of labor . . . helping [the mother] fall in love with her baby at first meeting."²⁰¹ This brings us to the second significant consequence of epidural administration.

Once a woman has received an epidural, labor will necessarily be slowed as the epidural decreases her natural oxytocin and effectively offsets any Pitocin (synthetic oxytocin) she has received.²⁰² Although now pain-free, synthetic oxytocin will need to be administered, or re-administered, to ensure the mother's delivery progresses.²⁰³ Failure to combat this slowing of labor caused by the epidural can lead to the need for forceps or vacuuming.²⁰⁴ Doris Haire explains the effect of synthetic oxytocin (Pitocin) on the baby: "The situation is analogous to holding an infant under the surface of the water, allowing the infant to come to the surface to gasp for air, but not to breathe."²⁰⁵

Adding depth and context, however, is the foregoing revelation that "[t]he FDA does not guarantee the safety of any [approved] drug."²⁰⁶ Additionally, federal regulations permit the prescribing of off-label uses in which the drug does not have a specific approval.²⁰⁷ Moreover, no conclusive studies on Pitocin (synthetic oxytocin) have ever been produced that identify the effect of the drug on the baby's future development.²⁰⁸ The same is of course also true of Marcaine (Bupivacaine), the drug used in epidurals.²⁰⁹ But for the obstetrician's disclosure, how else would expectant parents know?

What is significant is not simply the horrific consequences of these procedures and drugs, but rather that obstetricians fail to tell us about them.²¹⁰ Henci Goer suggests the reason is "mindset, money, or ignorance."²¹¹ Mindset, in that many obstetricians see things as black-and-white and actually believe that epidurals shield newborns from fetal

200. *Id.* at 133–34.

201. *Id.* (footnotes omitted).

202. BUCKLEY, *supra* note 191, at 135.

203. *Id.*

204. *Id.*

205. *Id.* at 111 (footnote omitted).

206. Letter from Dr. J. Richard Crout to Doris B. Haire, *supra* note 109, at 3.

207. 21 C.F.R. § 201.57(c)(9)(ii) (2006).

208. *Pitocin (Oxytocin) Injection*, DAILY MED, <http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=6365> (last updated Jan. 2008).

209. *Bupivacaine (Bupivacaine Hydrochloride) Injection, Solution*, *supra* note 119.

210. GOER, *supra* note 10, at 126.

211. *Id.*

distress brought on by a natural childbirth.²¹² Money, in that induction drugs and epidurals bring in huge revenue for obstetricians and hospitals.²¹³ And ignorance, in that obstetricians themselves may be under misinformation or belief.²¹⁴ Regardless of the reason, it is quite clear that physicians should be obligated to disclose the nature and risks of drugs and procedures in the field of obstetrics. After all, such information is likely to be “material” to the expectant mother.

E. The Ultrasound Procedure

The exchange between the expectant mother and her obstetrician should also flow to other procedures that are common during the pregnancy. Expectant parents should be advised regarding the use of ultrasound. It should not be assumed that a mother will simply submit herself to ultrasound or that the risks associated with it are too trivial to have an effect on her decision-making.

Ultrasound is a procedure that uses ultra-high frequency sound waves to scan bones, soft tissue, or fluids by producing an echo which creates a patterned image that can be used for diagnostic purposes.²¹⁵ Although the procedure has its roots in World War II when it was used by warships to detect enemy submarines, ultrasound “has become a rite of passage for pregnant women in most developed countries.”²¹⁶ In the United States, nearly seventy percent of pregnant women are scanned,²¹⁷ and in Europe the figure is as high as ninety-eight percent.²¹⁸

Although ultrasound can be useful if and when specific problems are expected, concerns loom about its safety.²¹⁹ The simple fact is that no studies have conclusively shown the effect of ultrasound waves upon the unborn child’s future development.²²⁰ Obstetricians know that ultrasound waves cause heating and cavitation of the scanned area.²²¹

212. *Id.* at 126–27.

213. *Id.* at 128. Epidural charges “range from \$500 to \$2500.” *Id.* Accordingly to one hospital consultant, “[i]n order for [some] doctors to make what they consider adequate income, the hospital has to [keep] an 80 percent epidural rate.” *Id.* at 128.

214. GOER, *supra* note 10, at 128.

215. BUCKLEY, *supra* note 191, at 80.

216. *Id.* at 79.

217. *Id.*

218. Sarah J. Buckley, *Ultrasound Scans—Cause for Concern?*, KINDRED (June 5, 2008), <http://www.kindredcommunity.com/articles/ultrasound-scans-cause-for-concern/p/1279>.

219. BUCKLEY, *supra* note 191, at 81, 86.

220. *Id.* at 74.

221. *Id.* at 85.

They also know humans exposed to ultrasound have had side effects, including premature ovulation, dyslexia, and delayed speech development.²²²

Consequently, ultrasound appears slightly effective at best, and tragic at worst.²²³ But with seventy percent of expectant Americans and nearly every expectant European subscribing to the procedure, it is hard to believe that obstetricians are disclosing these accompanying risks. This appears to be yet another missed opportunity and another failure on part of the obstetrician to obtain the expectant parents' informed consent.

F. Electronic Fetal Monitoring

Much like ultrasound usage, the practice of affixing electronic fetal monitoring (EFM) equipment to the mother has become standard practice in obstetrical care.²²⁴ Although expectant parents are almost certainly told that EFM equipment is helpful in monitoring fetal heart rate,²²⁵ the risks are equally worth mentioning. Unfortunately, despite the established premise that a mother can be the only true advocate for her unborn child, the "downsides" to the EFM procedure are unlikely topics for discussion during the prenatal visits.²²⁶

The truth about EFM is that the technology was developed to provide continuous tracing of the fetal heartbeat because it was believed that conventional intermittent listening was likely to miss changes in fetal heart rate, which might lead to fetal distress.²²⁷ This is one of the major reasons "EFM swept the marketplace."²²⁸ EFM equipment, however, has high rates of false positives, either from halving or doubling the baby's heartbeat or picking up the mother's pulse; the occurrence of these false positives is believed to contribute to the high number of Cesareans.²²⁹ Obstetricians getting a false positive from the EFM think the baby is in distress and perform a Cesarean section, when, in reality, everything is normal, and the baby is not in medical jeopardy.²³⁰

222. *Id.* at 88.

223. *Id.* at 78.

224. Myra Gerson Gilfix, *Electronic Fetal Monitoring: Physician Liability and Informed Consent*, 10 AM. J.L. & MED. 31, 31–32 (1984).

225. See GOER, *supra* note 10, at 86.

226. See, e.g., *id.* at 126–27 (describing how physicians do not discuss problems associated with certain procedures, such as epidurals).

227. *Id.* at 86–87.

228. *Id.* at 89.

229. See *id.* at 88–89.

230. *Id.*

As of 1995, eighty-one percent of all pregnant American women reported receiving EFM, perhaps because of the liability issue.²³¹ Hospital administrators assert that EFMs provide exculpatory documentation in the event of a malpractice action, and obstetricians claim that EFMs are the societal norm or standard of care.²³²

Although some hospitals have wireless EFM equipment, most do not, and the mother must remain in bed to stay hooked up to equipment in a horizontal position.²³³ The decision whether to use an internal or external EFM is another area of consideration.²³⁴ The main difference is that an internal EFM requires that the equipment be directly connected to the fetus.²³⁵ While this fact is seemingly innocuous, to perform an internal EFM, the obstetrician must perform the amniotomy if the membranes have not already naturally broken.²³⁶ This in turn sets off a “cascad[ing] effect,” which can be nightmarish for the unprepared mother and, yet, at the very same moment, extremely lucrative to the hospital and obstetrician.²³⁷

Recall the twenty-four hour rule, which authorizes obstetricians to administer induction drugs if the expectant mother has experienced a measured, but only slight amount of dilation in the twenty-four hour period since her water spontaneously broke or since her amniotomy.²³⁸ The rule seems almost certain to be implicated because the EFM confines a woman to a horizontal position not conducive to facilitating delivery, particularly if she has an internal EFM.²³⁹

Once the twenty-four hour rule is met, the obstetrician will likely sound the fetal distress “alarm,” and the mother will be told that she is not progressing fast enough.²⁴⁰ Under the guise of emergency authorization, the obstetrician may then require that she receive Pitocin (synthetic oxytocin) to stimulate the cervix and induce the labor fully.²⁴¹ Because Pitocin also stimulates nerve endings, the mother’s level of pain will increase dramatically, so much so that the epidural begins to sound like a good idea.²⁴² Unfortunately for the mother, the Marcaine (Bupivacaine) epidural injection will reduce the pain,²⁴³ but will also

231. GOER, *supra* note 10, at 88–89.

232. *Id.* at 89.

233. *Id.* at 93.

234. *Id.* at 91.

235. *Id.* at 91–93.

236. *Id.* at 105.

237. GOER, *supra* note 10, at 205 (internal quotation marks omitted).

238. *Id.* at 52–53.

239. *Id.* at 205.

240. *Id.* at 52.

241. *Id.* at 205.

242. *Id.*

243. GOER, *supra* note 10, at 205.

offset the Pitocin, as well as her natural oxytocin, and may slow down labor.²⁴⁴ Depending on how slow the mother progresses, the use of the epidural could result “in a [C]esarean section for poor progress or fetal distress.”²⁴⁵

Recall that many obstetricians will not perform a normal, vaginal birth after a Cesarean section because many insurers view it as a dangerous risk and will only cover the birth if it is performed by cesarean.²⁴⁶ Consequently, the cascading ends with a mother who is effectively uninsurable for natural, vaginal birth and thus may at best be forever plagued to have Cesareans.²⁴⁷

There is no doubt that the law requires a physician to have the patient’s informed consent prior to the administration of a drug or procedure, subject to only a couple of well-established exceptions. This means “material risks,” risks likely to affect a mother’s decision to obtain or forego a treatment or procedure, must be disclosed. Without these effects and consequences being sufficiently explained to expectant mothers, how can consent to these procedures possibly be informed? There is no doubt that expectant parents should hear about these practices, which are standard in virtually every hospital.

CONCLUSION

The obvious and recurring question is why. Why are such seemingly material risks of drugs and procedures unconscionably being withheld from expectant mothers by obstetricians? Without a doubt, every mother would expect to be told the preceding information, yet so few actually receive it. Supplementing the explanations above, the answer yields from diverse roots.

At the most basic level, obstetricians fail to inform because the law allows them to. Indeed, courts have expressed that only material risks need be disclosed and this necessarily implies that a whole category of risks need not be disclosed. Perhaps the informational truth is unknown to some incompetent practitioners and, as such, they lack the ability to valuably inform patients on the risks. It is unlikely, however, that physicians are indifferent to the duty to inform. After all, they do not get paid for the procedure if the mother says “no.”

Logic demands that few physicians will employ the dictates of the duty to inform beyond what the law requires because doing so exponentially increases the likelihood that their patients, both mother and

244. *Id.*

245. *Id.*

246. *Id.* at 162–63.

247. *Id.*

baby, will elect not to have a particular drug or procedure. The economic engine driving hospitals and doctors to administer drugs and perform procedures is therefore threatened by the doctrine of informed consent. It appears that a substantial reason our expectant couple failed to receive the whole truth is because the industry profits greatly when the parents-to-be are in the dark.

Although economically self-serving hospital policies are a clear culprit for a weak duty to inform in obstetrical practices, equally as significant is the fact that many of the risks to mother and child associated with common obstetrical drugs and procedures are both horrific and unknown. Quite simply, it appears that practitioners do not want expectant parents to know how much doctors themselves do not understand about the very drugs and procedures they administer to patients. Without a doubt, the duty to inform in obstetrical practices is in peril. With practitioners reluctant to disclose off-label uses and areas of uncertainty associated with drugs and procedures, expectant parents are merely getting the tip of the informational iceberg. It is imperative, therefore, that the duty to inform in obstetrics be strengthened through our legislatures and courts to safeguard the lives of mother and child.

ANDREW IVERSON ALMAND*

* This Note is dedicated to Doris and John Haire and their family, the true inspirations for this Note and tireless advocates of improving the standards for informed consent in obstetrical practices. Mrs. Haire, with her husband's support, stands as a beacon to expectant mothers going through the trials and triumphs of pregnancy and delivery. Thank you for making this cause your life's work and for your great contributions to this Note, this cause, and our society as a whole. Andrew Almand is a Virginia attorney and graduate of the Marshall-Wythe School of Law at the College of William & Mary in Williamsburg, Virginia. Mr. Almand is currently serving as a law clerk to Senior District Judge Claude M. Hilton of the United States District Court for the Eastern District of Virginia.