In The

Court of Special Appeals of Maryland

No. 1585
September Term, 2019

CSA-REG-1585-2019

JOHNS HOPKINS BAYVIEW MEDICAL CENTER, INC.,

Appellant,

v.

ZUBIDA BYROM, *et al.*,

Appellees.

Appeal from the Circuit Court for Baltimore City, Maryland
(The Honorable Audrey J.S. Carrion)

BRIEF OF *AMICI CURIAE*
AMERICAN MEDICAL ASSOCIATION,
MEDCHI, THE MARYLAND STATE MEDICAL SOCIETY, AND
AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

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QUESTION PRESENTED ADDRESSED BY THIS *AMICI* BRIEF

Maryland's informed-consent doctrine protects patients' autonomy over medical treatment decisions. Here the record reflects that the physicians disclosed the relevant treatment risks and alternatives and repeatedly recommended the best option, but Plaintiff withheld consent for that option. Did the court err when denying JNOV on the informed-consent claim?

INTEREST OF *AMICI CURIAE*

The application of the doctrine of informed consent, which assigns rights and responsibilities of patients and physicians in determining treatment, is of utmost importance to the American Medical Association (AMA), Maryland State Medical Society (MedChi), and American College of Obstetricians and Gynecologists (ACOG). The AMA is the largest professional association of physicians, residents, and medical students in the United States. Through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents and medical students are represented in the AMA's policymaking process. The AMA was founded in 1847 to promote the science and art of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every state, including Maryland, and in every medical specialty.

MedChi is a statewide, non-profit association of Maryland physicians. It is the largest physician organization in Maryland. MedChi, formally known as The Medical and Chirurgical Faculty of Maryland, was founded in 1799 by an act of the Maryland General

Assembly. Today, MedChi's mission is to serve as Maryland's foremost advocate and resource for physicians, their patients, and the public health.

The AMA and MedChi appear on their own behalves and as representatives of the AMA Litigation Center. The Litigation Center is a coalition among the AMA and the medical societies of every state. The Litigation Center is the voice of America's medical profession in legal proceedings across the country. The mission of the Litigation Center is to represent the interests of the medical profession in the courts. It brings lawsuits, files *amicus* briefs, and otherwise provides support or becomes actively involved in litigation of general importance to physicians.

ACOG is the nation's leading group of physicians providing health care for women. With more than 60,000 members, it represents obstetricians-gynecologists in the United States, including in the State of Maryland. ACOG advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care. ACOG has previously appeared as *amicus curiae* in various courts throughout the country. ACOG's briefs and guidelines have been cited by numerous courts seeking authoritative medical data regarding childbirth. The parties have consented to the filing of this brief.

STATEMENT OF THE FACTS AND CASE

This appeal arises out of a medical negligence claim by Ms. Erica Byrom, a 16-year old pregnant woman who decided to induce her baby at about 26 weeks gestation because she had severe preeclampsia, a pregnancy-induced hypertension that can have

serious fetal and maternal risks. When she presented at Johns Hopkins Bayview Medical Center, a medical examination showed fetal complications, including low-level amniotic fluid, intrauterine growth restriction, poor umbilical-artery circulation, and excess fluid around the fetal heart. (E.694-95)

The record shows the physicians told Ms. Byrom there was a substantial risk the fetus would not survive or would be born with severe neurological and other disabilities. It also shows they informed Ms. Byrom of her options and material risks of each option: delivering the baby through a cesarean section, which they strongly preferred; inducing labor—with or without cesarean intervention for fetal indications—which they warned against; and terminating the pregnancy, which was ruled out based on gestational age and Ms. Byrom's lack of interest. (E.1285-86, 749)

The record also shows the physicians repeatedly encouraged Ms. Byrom to choose a cesarean section for fetal indications and explained the fetal risks of declining a cesarean section. (E.1316, 747, 1273, 1318-1319) Ms. Byrom refused and consistently told the physicians she wanted labor to be induced. (E. 1316) In consultation with physicians and family, she signed a consent to induction of labor detailing substantial risks to the fetus. (E.1332) The physicians honored Ms. Byrom's choice and induced labor. The baby survived delivery, but unfortunately, developed significant disabilities.

Ms. Byrom now seeks to place responsibility for the decision to induce labor on the physicians. Among other things, her experts and counsel argued the physicians should not have presented inducing labor as an option, even though the physicians could not have performed a cesarean section without Ms. Byrom's consent and not taking action

could have led to worse risks. (E.738-39) They also suggested the same risks should have been presented with a more optimistic view of the baby's prognosis to convince her to choose the cesarean section. (E.75) The jury awarded Ms. Byrom $203 million. The hospital is appealing the case on several grounds, including on the improper application of the legal doctrine of informed consent.

SUMMARY OF THE ARGUMENT

This case turns the fundamentals of the informed consent doctrine on its head. As the Court of Appeals has long held, the "fountainhead of the doctrine of informed consent is the patient's right to exercise control over his [or her] own body . . . by deciding for himself [or herself] whether or not to submit to the particular" treatment option. *Sard v. Hardy*, 281 Md. 432, 439 (1997). The responsibility of the physician is to provide a patient with the available medical options and "any material risks or dangers inherent" to each option "so as to enable the patient to make an intelligent and informed choice" as to which treatment to choose. *Id.* The record shows the physicians repeatedly and properly fulfilled this obligation. As a result, Ms. Byrom is seeking to create liability *because* they provided her with this information. The trial court allowed her to argue that the physicians should not have provided her with her medical options or, at least, shaded the material risk information to force her into the specific treatment they thought best.

This inverted view of informed consent can be explained only by the trial court's understandable sympathy toward Ms. Byrom. She is a young person who presented at the hospital with severe preeclampsia, which elevated her blood pressure in ways that created substantial risks to her fetus and, without treatment, to her own health as well. There were

no easy solutions. She, along with her adoptive mother, made the difficult choice to refuse a cesarean section for fetal indications, leading to the induced labor and disabilities to the child. As much as Ms. Byrom and her family may justifiably wish they made a different decision, the Court cannot create a legal fiction that a cesarean section was their only medical option. The desire to provide her with compensation does not justify bending Maryland's longstanding rules on informed consent.

Amici respectfully urge the Court to overturn the ruling below; patients and physicians must be able to rely on Maryland courts to follow sound law and produce just outcomes, even in difficult situations. It is inappropriate to subject Appellant to liability when the record shows that its physicians properly informed Ms. Byrom of her treatment options and material risks of each option. Even though they disagreed with her decision, the physicians followed her clear, informed and repeatedly asserted decision. It would have been unethical for them not to do so, to coerce Ms. Byrom into a cesarean section, or to withhold a treatment option that was medically available.

ARGUMENT

I. THE RECORD REFLECTS THAT THE HOPKINS PHYSICIANS FOLLOWED LONGSTANDING MARYLAND LAW ON THE DOCTRINE OF INFORMED CONSENT

Since the Maryland Court of Appeals formally recognized the doctrine of informed consent in *Sard v. Hardy*, 281 Md. 432 (1977), a physician can face liability in the State for failing to inform a patient of the available medical options and the material risks that a reasonable patient would want to know to make a competent treatment decision. The Court explained that the doctrine "follows logically from the universally

recognized rule that a physician, treating a mentally competent adult under non-emergency circumstances, cannot properly undertake to perform surgery or administer other therapy without the prior consent of his [or her] patient." *Id.* at 438-39. The purpose of this rule is to "enable the patient to make an informed choice about a particular therapy or procedure so that healthcare providers [do] not substitute their own judgment for that of the patient's." *McQuitty v. Spangler*, 410 Md. 1, 20 (2009). "[P]ersonal autonomy and personal choice [are] the primary foundations of the informed consent doctrine." *Id*.

Maryland courts have been clear as to what the legal obligations to provide informed consent entail. Physicians must "reveal to his [or her] patient the nature of the ailment, the nature of the proposed treatment, the probability of success of the contemplated therapy and its alternatives, and the risk of unfortunate consequences associated with such treatment." *Sard*, 281 Md. at 440 (citations omitted). The record reflects that the Hopkins physicians unequivocally fulfilled these obligations. They clearly and repeatedly explained that if they induced labor, "the fetus could die in utero prior to delivery" (E.1273), the infant could be "severely compromised" (E.1318), or the "additional stress to the fetus" could result in "permanent disability." (E.1321) As Ms. Byrom's experts testified, "many times [the] doctors tried to talk her into having a C-section." (E.747) The physicians provided her with her options, informed her of material risks, and repeatedly offered their judgment of which option they believed was best.

Contrary to the liability theory in this case, the Hopkins physicians could not impose their preferred treatment option on Ms. Byrom. They also would not have been permitted to present the material risk information in a way intended to force or trick Ms.

Byrom into a cesarean section. "[T]he appropriate test is not what the physician in the exercise of his medical judgment thinks a patient should know before acquiescing in a proposed course of treatment; rather, the focus is on what data the patient requires in order to make an intelligent decision." *Sard*, 281 Md. at 442.

The issue for the Court is whether the disclosures were truthful and sufficient for the patient to make her own decision. Typically, informed consent claims "involve allegations that the physician failed to make adequate disclosure of a material risk or collateral effect of the contemplated procedure or of an available alternative not carrying that risk or effect." *Dingle v. Belin*, 358 Md. 354, 370 (2000). Thus, to succeed here, Ms. Byrom would have had to have put forward expert testimony to establish that there were other, nondisclosed "material risks and other pertinent information regarding" induced labor. *Univ. of Maryland Med. Sys. Corp. v. Waldt*, 411 Md. 207, 232 (2009). No such allegations were made here. To the contrary, the record show the Hopkins physicians provided Ms. Byrom with the material risk information "significant to a reasonable person in [her] position in deciding whether or not to submit to" induced labor. *Sard*, 281 Md. at 444. The physicians properly fulfilled their informed consent obligations.

At that point, it became Ms. Byrom's "exclusive right to weigh these risks together with [her] individual subjective fears and hopes and to determine whether or not to place [her] body in the hands of the surgeon or physician." *Id.* at 443. "Under the law of informed consent, an adult has the right to refuse treatment, even if the refusal has a detrimental effect, so long as the individual is competent." *Baer v. Baer*, 128 Md.App. 469, 481 (1999); *see also Sard*, 281 Md. at 443 (explaining "the patient must suffer the

consequences" of the decision). Patients have the right to be wrong. As Appellant points out, there have been many examples where patient choices have led to adverse outcomes, including when physicians agreed with the choice. Such outcomes, as difficult as they are, do not give rise to liability for lack of informed consent.

Maryland physicians cannot be guarantors of positive outcomes. They also cannot allow the prospect of tort liability to distort the information they provide to patients. Such a rule could be abused, including to deny patients treatment options consistent with their personal beliefs. For example, some patients may have personal objections to a surgery, including a cesarean section, and others may not. Here, the Hopkins physicians met their obligation to inform Ms. Byrom of her medical options and material risks. They respected her free will to make her decision, even though they vehemently disagreed with it. Allowing the trial court to nevertheless leave intact the jury's liability finding violates informed consent law and would undermine patient autonomy.

II. THE RECORD REFLECTS THAT THE HOPKINS PHYSICIANS FOLLOWED THEIR MEDICAL ETHICS OBLIGATIONS TO RESPECT MS. BYROM'S AUTONOMY AND ALLOW HER TO MAKE HER OWN DECISIONS

The liability ruling in this case also violates the principles of medical ethics the Hopkins physicians, as well as all other physicians, have been sworn to uphold. *See* Tom L. Beauchamp and James F. Childress, *Principles of Biomedical Ethics 4th Edition* (Oxford Univ. Press 1994), at 120, 181. The AMA's Code of Medical Ethics provides that "[i]nformed consent to medical treatment is fundamental in both ethics and law."

Informed Consent, Code of Medical Ethics Opinion 2.1.1, Am. Med. Ass'n.[1] All fifty states now require informed consent. *See* Evelyn M. Tenenbaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 Okla. L. Rev. 697 (2012).

Before Maryland and the other states adopted informed consent, there had been a paternalistic view of the physician. The physician was "recognized and accepted as the guardian who use[d] his specialized knowledge and training to benefit patients, including deciding unilaterality what constitutes a benefit." J.J. Chin, *Doctor-patient Relationship: From Medical Paternalism to Enhanced Autonomy*, 43(3) Singapore Med. J. 152, 152 (2002). This notion stemmed from Hippocrates, who cautioned physicians to perform treatment "calmly and adroitly, concealing most things from the patient while you are attending to him." Hippocrates, Decorum, in 2 Hippocrates 279, 297 (W.H.S. Jones Trans., G.P. Putnam Sons 1923).

The legal concept of informed consent developed in the twentieth century. An early pronouncement of this principle came from Justice Cardozo, who recognized that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body." *Schloendorff v. Society of New York Hosp.*, 211 N.Y. 125, 129 (1914). Justice Cardozo found that a physician who does not secure consent from a patient to undergo a medical procedure could be subject to liability for committing a

[1] https://www.ama-assn.org/delivering-care/ethics/informed-consent.

battery. Courts then began to differentiate between this concept of "basic consent,"[2] and "informed consent," which gave patients the right to decide which medically sound treatment to undergo, if at all.[3] The Court of Appeals recognized this shift, explaining the "obligation to obtain consent evolved over the course of the twentieth century into an obligation to obtain 'informed' consent, primarily to enable the patient to make an informed choice about a particular therapy or procedure so that healthcare providers did not substitute their own judgment for that of the patient's." *McQuitty*, 410 Md. at 20.

This progression is well-illustrated by The Belmont Report, published in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *See* The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, U.S. Dep't of Health & Human Services.[4] Among other things, it addressed medical ethical principles, including that individuals should be treated as autonomous agents: "To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. . . . To show lack of respect for an autonomous agent is to repudiate that person's considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information

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[2] *See, e.g.*, *Pratt v. Davis*, 79 N.E. 562 (Ill. 1906); *Perry v. Hodgson*, 148 S.E. 659 (Ga. 1929); *Pizzalotto v. Wilson*, 437 So. 2d 859 (La. 1983).

[3] *See, e.g.*, *Corn v. French*, 289 P.2d 173 (Nev. 1955); *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 317 P.2d 170 (Cal Ct. App. 1957).

[4] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html

necessary to make a considered judgment, when there are no compelling reasons to do so." *Id.* at Part B: Basic Ethical Principles, 1. Respect for Persons.

"Today, the principles of patient autonomy and self-determination have emerged as the dominant ethos in health care" and "paternalism is almost always perceived in a negative light." Chin, *supra*, at 152. The AMA Code of Medical Ethics also includes autonomy and informed consent in its section on patient rights. *See* Patient Rights, Code of Medical Ethics Opinion 1.1.3, Am. Med. Ass'n.[5] This ethics opinion states that patients have the right to: "receive information from their physicians and to have opportunity to discuss the benefits, risks, and costs of appropriate treatment alternatives, including the risks, benefits and costs of forgoing treatment"; the right to "ask questions about their health status or recommended treatment when they do not fully understand what has been described and to have their questions answered"; and the right to "make decisions about the care the physician recommends and to have those decisions respected." *Id.* Such "[t]ruthful and open communication between physician and patient is essential for trust in the relationship and for respect for autonomy." Transcript of AMA House of Delegates Proceedings, Annual Meeting (1991), at 234.

The professional ethical duty of informed consent is now fully ensconced in American and international law. In 2017, the Declaration of Geneva, which was initially enacted to guard against the medical ethical atrocities in World War II, was amended to include provision requiring a physician to respect "the autonomy and dignity of [the] patient." The Declaration of Geneva, Adopted by the General Assembly of The World

[5] https://www.ama-assn.org/delivering-care/ethics/patient-rights.

Medical Association at Geneva, Switzerland, Sept. 1948 as Amended by the 68th WMA General Assembly, Chicago, United States, Oct. 2017.

The informed consent theory adopted by the trial court contravenes this century-long, global development of medical ethics. As the AMA has explained: "Withholding pertinent medical information from patients in the belief that disclosure is medically contraindicated creates a conflict between the physician's obligations to promote patient welfare and to respect patient autonomy." Transcript of AMA House of Delegates Proceedings, Annual Meeting (1991), at 234. The court's ruling would require physicians to breach these important, patient-centric ethical and professional duties.

III. A RETURN TO LIABILITY AWARDS NOT GROUNDED IN THE LAW AND FACTS WILL HINDER PATIENT CARE IN MARYLAND

Appellate review is particularly important in cases like here where physicians provided proper medical care, but are found liable so a patient will have funds to care for an injury. *See generally* Victor E. Schwartz, Phil Goldberg & Christopher E. Appel, *Deep Pocket Jurisprudence: Where Tort Law Should Draw the Line*, 70 Okla. L. Rev. 359 (2018). There is no doubt Ms. Byrom's baby will need life-long care. But, the desire to provide her with funding—here nearly five times the $42 million even her own experts estimated for future medical bills—should not come at the expense of the law and need for liability to be based on sound legal principles and credible medical evidence. When physicians and hospitals, along with their insurers, must spend enormous sums of money when the liability finding is not appropriate, the result can negatively impact patient care.

Maryland, like many states, experienced these impacts in the 1970s. Expansive

liability rulings caused insurance rates for medical malpractice coverage to spike. The state's largest insurer, facing a $10 million deficit and continuing to lose money, planned to stop offering insurance coverage to Maryland physicians. *See St. Paul Fire & Marine Ins. Co. v. Ins. Comm'r*, 275 Md. 130, 133-39 (1975). No other insurer offered to provide coverage to the 3,600 Maryland physicians it insured. *See id*. at 138-41. To avert a crisis, the General Assembly enacted the Health Care Malpractice Claims Act ("the Act") in 1976. The next year, the Court of Appeals adopted the doctrine of informed consent.

Maryland's medical malpractice insurance market has since stabilized.[6] Data indicates that the number of medical malpractice payments and the amounts of those payments has been stable in Maryland for at least a decade. *See* Nat'l Practitioner Data Bank, NPDB Research Statistics (providing medical malpractice payment data reported by Maryland medical practitioners between 1990 and 2019).[7] The rates paid by Maryland physicians for malpractice insurance have also held steady or decreased in the past decade. *See* 2019 Report on the Availability & Affordability of Health Care Medical Professional Liability Insurance, Md. Ins. Admin. (Sept. 2019), at Exh. A5.[8]

Obstetrician-gynecologists are among the most expensive specialties to insure, as they regularly engage in "high risk" procedures such as the one at bar and are commonly sued over negative outcomes, sometimes regardless of fault. *See* Anupam B. Jena et al.,

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[6] *See also* H.B. 2 (Md. 2005) (limiting noneconomic damages); S.B. 558 (Md. 1986) (limiting on noneconomic damage to all personal injury cases).

[7] https://www.npdb.hrsa.gov/analysistool/.

[8] https://insurance.maryland.gov/Consumer/Appeals%20and%20Grievances%20Reports/2019-Availability-Affordability-of-Health-Care-Professional-Liability-Insurance-MSAR2976.pdf.

Malpractice Risk According to Physician Specialty, 365 (7) New Eng. J. Med. 629 (2011). They also face among the greatest rate of payments on claims per year compared to other physicians, and the proportion of claims in which payments exceed $1 million is increasing.[9] These dynamics have contributed to a concerning shortage of obstetrician-gynecologists nationally. *See* Mattie Quinn, *Brace Yourself for an Ob/Gyn Shortage by 2020*, SELF, Sept. 8, 2017 (anticipating a shortage of 8,000 Ob/Gyns based on information from ACOG and the U.S. Bureau of Labor Statistics).[10]

Because of the laws Maryland has enacted, obstetrician-gynecologists here are now faring somewhat better than in other states. There has developed a "wide geographic variation" in premiums for obstetrician-gynecologists. Jose R. Guardado, *Medical Professional Liability Insurance Premiums: An Overview of the Market from 2008 to 2017*, Am. Med. Ass'n (Jan. 2018) (reporting in 2017 Ob/Gyns faced annual premiums that ranged from a low of $49,804 in some areas of California to a high of $214,999 in areas of New York).[11] In Maryland, obstetrician-gynecologists frequently pay premiums in excess of $100,000 per year. *See* Maryland Medical Malpractice Insurance,

[9] *See* Robert L. Barbieri, *Good News for ObGyns: Medical Liability Claims Resulting in Payment Are Decreasing!*, OBG Management, Vol. 31, No. 5 (May 2019) at https://mdedge-files-live.s3.us-east-2.amazonaws.com/files/s3fs-public/issues/articles/obgm03105010_editorial.pdf.

[10] https://www.self.com/story/brace-yourself-for-an-obgyn-shortage-by-2020.

[11] https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/government/advocacy/policy-research-perspective-liability-insurance-premiums.pdf.

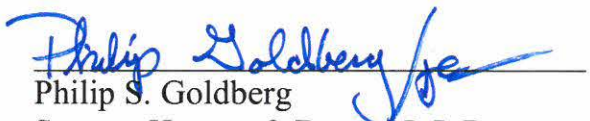
Cunningham Group.[12] That progress can be lost with verdicts, such as the case at bar, where liability is unprincipled and the award is excessive.

Ensuring access to quality and affordable care requires that Maryland courts impose liability on medical providers only when patients have been wrongfully injured and only for damages grounded in the facts. Adopting strained theories of liability or awarding multiples of damages sought threatens to turn the courts into mechanisms for transferring money to people with negative health outcomes irrespective of fault or the facts. It also threatens bedrock principles of patient autonomy and medical ethics. For the benefit of patients throughout Maryland, medical liability, including under the doctrine of informed consent, must remain based on sound principles of law, science, and medical ethics. Further, the damage award, if allowed, should be reduced in accordance with the facts, which do not exceed $42 million in future medical costs.

CONCLUSION

For these reasons, this Court should grant Appellant's requested relief.

Respectfully submitted,



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[12] https://www.cunninghamgroupins.com/historic-medical-malpractice-insurance-rates/maryland/.

CERTIFICATE OF WORD COUNT AND COMPLIANCE WITH RULE 8-504

1. This brief contains 3898 words, excluding the parts of the brief exempted from the word count by Rule 8-503.

2. This brief complies with the font, spacing, and type size requirements stated in Rule 8-112.

Philip S. Goldberg

CERTIFICATE OF SERVICE

Court of Special Appeals

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February 21, 2020

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