SUPREME COURT OF KENTUCKY
No. 2019-SC-641

UNIVERSITY MEDICAL CENTER, INC.
D/B/A JAMES GRAHAM BROWN CANCER CENTER;
AND UNIVERSITY MEDICAL CENTER, INC.
D/B/A/ UNIVERSITY OF LOUISVILLE HOSPITAL;
ROGER H. HERZIG, M.D.; AND
CRAIG L. SILVERMAN, M.D.

APPELLANTS

v.

ON DISCRETIONARY REVIEW FROM THE COURT OF APPEALS
No. 18-CA-001188

REAGAN BROOKE SHWAB;
HUGH MCNEILLY SHWAB; AND
KADIYALA V. RAVINDRA, M.D.

APPELLEES

BRIEF OF *AMICI CURIAE* AMERICAN MEDICAL ASSOCIATION AND KENTUCKY MEDICAL ASSOCIATION IN SUPPORT OF DEFENDANTS/APPELLANTS

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Certificate of Service

I hereby certify that on August 5, 2020, a copy of this brief was sent via U.S. Mail to Rebecca Combs Lyon, Clerk of the Kentucky Court of Appeals, 360 Democratic Drive, Frankfort, Kentucky 40601; David B. Gray, GRAY LAW PLLC, 10200 Forest Green Boulevard, Suite 112, Louisville, Kentucky 40223; Beth H. McMasters, Whitney Graham, MCMASTERS KEITH BUTLER, INC., 730 West Main Street, Suite 500, Louisville, Kentucky 40202; Allison O. Wildman, Joseph A. Wright, THOMPSON MILLER & SIMPSON PLC, 734 West Main Street, Suite 400, Louisville, Kentucky 40202.

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INTRODUCTION

This is an appeal from the Court of Appeal's reversal of summary judgment in favor of Defendants where plaintiff Brooke Shwab agreed to participate in a Phase I clinical trial and signed the disclosure and consent form, which raised various risks known to be associated with the trial including the potential for unspecified cancers. After she allegedly contracted a type of cancer from the trial that had not been observed before and, therefore, was not specifically identified in the consent form, the trial court properly granted summary judgment pursuant to the objective standards set forth in state and federal informed consent laws, KRS 304.40-320 and 21 C.F.R. § 50.25.

STATEMENT OF POINTS AND AUTHORITIES

PURPOSE AND INTEREST OF *AMICI CURIAE*

The application of the doctrine of informed consent, which assigns rights and responsibilities of patients and physicians in determining treatment and participation in clinical trials, is of utmost importance to the American Medical Association (AMA) and Kentucky Medical Association (KMA). 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, substantially all United States physicians, residents and medical students are represented in the AMA's policymaking process. The AMA, founded in 1847, promotes 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 Kentucky, and in every medical specialty.

The KMA is the professional organization for physicians throughout the Commonwealth. Established in 1851, the KMA works on behalf of physicians and the patients they serve to ensure the delivery of quality, affordable healthcare. It is the only state association representing every specialty and type of medical practice in Kentucky. The KMA has participated as *amicus curiae* in cases of importance to physicians and the greater medical community.

The AMA and KMA appear on their own behalf 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.

STATEMENT OF THE FACTS

This case involves a 32-year old woman, Brooke Shwab, whose kidney failed and needed to undergo a kidney transplant. Studies have shown that 17 percent of kidney transplants fail by the end of the third year and almost half after ten years.[1] The reason for this failure rate is that recipients' bodies react to the new kidneys as foreign cells, fighting the transplant much as they would viruses. To aid the opportunity for success, recipients must take a strict daily regimen of immunosuppressant drugs for the remainder of their lives. This regimen includes dozens of drugs, each with its own significant side effects, from serious infection to gastrointestinal issues to high blood pressure and more.

When Ms. Shwab needed her transplant, Defendants were part of a team conducting a Phase I clinical trial of a new treatment that might allow a recipient's body to develop a tolerance to the transplanted kidney and avoid this immunosuppressant regimen. As Defendants explain, this approach used a combination of stem cell and kidney transplantation from the same donor, along with sequential chemotherapy and total body irradiation. According to the record, Plaintiffs heard about this study, asked their physician about it, and met with the studies' personnel to discuss participation. Deposition testimony reveals the Shwabs were provided the consent form reviewed by the FDA for this Phase I clinical trial, took the form to review, engaged in further discussions about the clinical trial, agreed to participate, and signed the consent form.

The record shows that Plaintiffs were cautioned several times that participating in this Phase I clinical trial could lead to various types of cancer. For example, Dr. Silverman testified he discussed a "long list of potential second cancers" with the

[1] https://www.kidney.org/transplantation/transaction/TC/summer09/TCsm09_TransplantFails

Shwabs, including "blood cancers, leukemia, lymphomas . . . [and] bone cancers," and he included those "second cancers" in the consent form. The consent form also included the potential for "delayed effects [that] may include certain types of cancer" and that the study's drugs "can also cause high blood pressure, kidney damage, and possibly cancer." In this case, Plaintiffs allege that Ms. Shwab developed a type of cancer or leukemia, myelodysplastic syndrome (MDS), not specifically identified in the consent form and, therefore, they were not adequately informed of the risks of participating in the trial.

Finding the disclosures were adequate based on objective metrics provided by state and federal law, the trial court granted summary judgment for Defendants. The Court of Appeals overturned the trial court based on Plaintiffs' assertion that they should have been warned about this specific cancer. Defendants appeal the case because the Court of Appeals improperly applied the doctrine of informed consent. To the extent needed, *amici* adopt and incorporate Appellants'/Defendants' Statement of the Facts.

ARGUMENT

Physicians in Kentucky and other states cannot be guarantors of positive outcomes. As this Court has long held, a physician's responsibility to a patient is to inform a patient of the medical risks the physician knows about or should have known about with respect to a certain procedure or treatment regimen. *See Holton v. Pfingst*, 534 S.W.2d 786 (Ky. 1975); KRS 304.40-320. It is the right of the patient, with this information, to decide for himself or herself whether to submit to a particular treatment option. The patient controls her own body and her own choices. The issue for the courts is whether the disclosures were truthful and sufficient for a reasonable person to understand those attendant risks to make an informed decision—not whether the path chosen led to a desirable outcome. There are many situations, including with Ms. Shwab

here, when the path a plaintiff chooses does not work out. These are difficult and emotional situations. The trial court here properly ensured that hindsight did not improperly give rise to liability for lack of informed consent.

In this case, the trial court had a significant advantage over most situations in assessing whether there were triable issues on informed consent: this case involves a Phase I clinical trial, and the FDA had reviewed a 16-page document for this trial that discussed the risks of participating in it. The consent form, which is included as an Appendix to Defendants' brief, specifically raised the potential that the treatment being studied could lead to "certain types of cancer" and "possibly cancer." In addition, deposition testimony showed the physicians raised with the Shwabs the potential for cancer, including forms of leukemia. The record shows that, as required, Plaintiffs were given the consent form to bring home, where they could study it and seek alternative opinions. In signing the consent form, Plaintiffs acknowledged they reviewed and understood this document and the risks. The trial court, after assessing these materials and accounting for Plaintiffs' allegations and their expert's assertions, found that Ms. Shwab was sufficiently warned about the potential that she could develop cancer from the clinical trial and still chose to participate. The trial court further held the consent form satisfied objective Kentucky statutory authority and FDA requirements and properly granted summary judgment for Defendants.

The Court of Appeals should not have reversed this ruling. It acknowledged the "consent form indicated that the methods used in the study had been untested in humans and that there were extreme risks involved. Some risks included cancer, loss of fertility and death." Yet, it reversed the ruling based solely on the existence of subjective counter testimony the trial court considered and rejected. Kentucky's doctrine of informed

consent cannot be so fragile. *Amici* respectfully urge the Court to overturn the ruling below; patients and physicians must be able to rely on Kentucky courts to follow sound law and produce just outcomes, even in difficult situations. It is inappropriate to subject Defendants to liability when the record clearly shows they properly informed Ms. Shwab of the risks, including the risk of cancer, in participating in this clinical trial.

I. Phase I Clinical Trials Are Critical to the Development of Medical Science; They Help Identify Risks of a Proposed Drug or Treatment

The Court of Appeals ruling to allow this case to go to trial undermines the way new drugs and treatments are developed. Specifically, Phase I clinical trials are conducted to determine the risks of a particular drug or treatment regimen. *See* Iver P. Cooper, 1 Biotechnology and the Law § 4:21.50 (2020 Update) ("Phase I clinical trials . . . are designed to determine safety, not efficacy."). Although a treatment may have been tested in lab and animal studies, side effects in people cannot always be predicted. Phase I trials exist to discover these unknown risks. *See* Step 3: Clinical Research, Food & Drug Admin.[2] Here, Defendants knew the treatment could cause certain types of cancer, including leukemia, and warned Plaintiff accordingly, but they did not caution specifically against MDS because no other person who participated in the trial had developed MDS. It is that level of specificity that Phase I clinical trials are intended to uncover.

Clinical trials in humans have developed over the past century to become the centerpiece of the FDA New Drug Application approval process and must not be undermined through improper liability for practicing physicians who participate in them. Each prescription drug application is subjected to rigorous formal rule-making so that the

[2]https://www.fda.gov/patients/drug-development-process/step-3-clinical-research

FDA can carefully assess the risks and benefits of each proposed drug and treatment, understand the risks, determine whether to approve it and, if so, how to craft warnings that are safe and effective for a class of patients. *See generally* 21 C.F.R. pt. 314 (2004). Under this regulatory regime, investigating a new drug or treatment starts with discovery, development and preclinical research in a laboratory. The goal of these early phases is to identify potentially beneficial treatments, determine if they warrant study, and anticipate how they would be absorbed in humans and what side effects they may have.

Only drugs that meet the FDA's extensive requirements are approved for trial in humans; the FDA must determine that the benefits could outweigh the risks for practicing physicians and patients to participate in them. Phase I clinical trials are "the initial introduction of an investigational new drug into humans." 21 C.F.R. § 312.21(a). Their principal purpose is to evaluate the risks identified in the preclinical studies and identify unforeseen risks by determining "the metabolism and pharmacologic actions of the drug in humans [and] the side effects associated with increasing doses." *Id.* As the American Cancer Society explains, "Phase I trials are the ones with the most potential risk." What Are the Phases of Clinical Trials?, Am. Cancer Soc'y.[3] Their purpose is to look "at what the drug does to the body and what the body does with the drug," and because these studies are limited, "rare side effects may not be seen." *Id.*; *see also* NIH Clinical Research Trials and You, Nat'l Institutes of Health (explaining researchers are testing the drug in people "for the first time . . . to learn about safety and identify side effects").[4]

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[3]https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials/what-you-need-to-know/phases-of-clinical-trials.html
[4]https://www.nih.gov/health-information/nih-clinical-research-trials-you/basics

About 30 percent of the drugs and treatments studied in Phase I clinical trials are deemed not sufficiently safe and do not advance to Phase II. *See* Step 3: Clinical Research, Food & Drug Admin., *supra.* In Phase II, practicing physicians work with patients to start "evaluate[ing] the effectiveness of the drug." 21 C.F.R. § 312.21(b). In Phase II studies, the physicians administer the drug to a group of patients with the disease or condition for which the drug is being developed to collect additional safety data. They use these findings to refine their research questions, develop their methodology, and design their Phase III research protocols. "Approximately 33% of drugs" move on to Phase III. Step 3: Clinical Research, Food & Drug. Admin., *supra.* Phase III clinical trials then "gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labeling." 21 C.F.R. § 312.21(c). These trials are "substantially longer than the Phase I or II trials." W. Kip Viscusi et. al, *Deterring Inefficient Pharmaceutical Litigation: An Economic Rationale for the FDA Regulatory Compliance Defense*, 24 Seton Hall L. Rev. 1437, 1443 (1994) (stating that the entire FDA approval "process is a lengthy one, typically taking between five and seven years to complete").

This reliance on clinical trial data for the advancement of medical treatment has long relied on practicing physicians and their patients to be willing to participate in the trials—particularly as here when the risks are not fully developed. *See* Suzanne White Junod, Ph.D., *FDA and Clinical Drug Trials: A Short History*, Food & Drug Admin.[5] More than a century ago, before the development of federal clinical trial rules and

[5]https://www.fda.gov/media/110437/download. Originally published as "FDA and Clinical Drug Trials: A Short History," in A Quick Guide to Clinical Trials, Madhu Davies and Faiz Kerimani, eds. (Washington: Bioplan, Inc.: 2008), pp. 25-55.

regulations, it was actually the American Medical Association and physicians, operating under the AMA codes and structures, that were the primary actors ensuring pharmaceutical companies did not widely market unsafe drugs, but tested their drugs in controlled environments. *See id.* In 1935, the Michigan Supreme Court became the first state high court to recognize that physician involvement was needed to facilitate this experimentation and help medical progress. *See Fortner v. Koch*, 261 N.W. 762 (Mich. 1935). The court explained that practicing physicians must be protected from excessive liability when a patient experiences an injury from a trial drug in order to encourage them to participate in these efforts. *See id.* at 765. Since then, Congress has enacted an array of statutes setting forth rules and regulations that pharmaceutical manufacturers and physicians must follow to facilitate the public's participation in clinical trials, ultimately creating the current structure discussed above. Under this regime, practicing physicians remain the bridge between pharmaceutical companies and patients.

Today, the AMA continues to encourage physicians to participate in clinical trials when appropriate to their practice and patients; it is well recognized that clinical trials are essential to the advancement of medical science. *See* Physician Involvement in Research, Code of Medical Ethics Opinion 7.1.1, Am. Med. Ass'n ("Biomedical and health research is intended to contribute to the advancement of knowledge and the welfare of society and future patients.").[6] Just as in the 1930s, maintaining an appropriate liability structure is critical for practicing physician participation, particularly as trials involve personalized medicine where the risks are less subject to what other participants may

[6]https://www.ama-assn.org/delivering-care/ethics/physician-involvement-research

have experienced. *See* Junod, *supra*. It is critical that physicians be judged on only objective standards—not subjective assertions based on hindsight when injury occurs.

Here, the trial court looked to such objective sources—Kentucky and federal laws and rules for conducting Phase I clinical trials and factors for providing informed consent—and determined the physicians complied with those standards. *See* KRS 304.40-320; 21 C.F.R. § 50.25. The Court of Appeals did not disturb these findings. It found, however, Plaintiffs could "potentially convince a jury" to award damages based on their subjective testimony and that of their expert. This subjective approach to liability would be unprincipled, chill participation in clinical trials, and harm medical advancement.

II. Defendants Properly Informed Plaintiffs of the Risks of This Phase I Trial and Honored Plaintiffs' Decision to Participate in It

The trial court's granting of summary judgment on the issue of informed consent is aided by the fact that this case involves a clinical trial; Defendants provided Plaintiffs with a written consent form reviewed by FDA explaining the risks of participating in this trial. Those risks unequivocally included "certain types of cancer" and "possibly cancer," which is what Plaintiffs allege Ms. Shwab contracted. Plaintiffs were given the consent form to review, had the opportunity to read it in detail, consult with other physicians, and determine whether participating in the clinical trial was right for them. Ms. Shwab signed the consent form under her own volition, and it is "settled law in Kentucky that one who signs a contract is presumed to know its contents." *Hathaway v. Eckerle*, 336 S.W.3d 83, 89 (Ky. 2011) (quoting *Clark v. Brewer*, 329 S.W.2d 384, 387 (Ky. 1959)). Reliance on such objective indicia of informed consent, whether provided in written form and signed as here or as part of a verbal agreement in a physician's office, is fundamental to medical

treatment. *See generally* Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* (8th ed. Oxford Univ. Press 2019).

As in regular treatment, the doctrine of informed consent for participation in clinical trials "arises out of respect for persons and a desire to respect the autonomy of the individual deciding whether to volunteer to participate in biomedical or health research." *See* Informed Consent in Research, Code of Medical Ethics Opinion 7.1.2, Am. Med. Ass'n.[7] Before Kentucky and 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).

An early pronouncement of informed consent 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 battery. Courts then began to differentiate between this concept of "basic consent," and "informed consent," which gave patients the right to decide which

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

medically sound treatment to undergo, if at all.[8] This Court adopted the doctrine in 1975 in *Holton v. Pfingst*, 534 S.W.2d 786 (Ky. 1975). The Kentucky General Assembly codified these principles, ensuring the physicians are to be subject to liability only when there is objective evidence that the physician failed to adhere to accepted medical standards or failed to explain the risks in ways that a reasonable individual would not understand the procedure and the substantial risk and hazards inherent in the treatment. *See* KRS 304.40-320(1)-(2).

This shift to ensuring patients have autonomy over their medical decisions, including when they decide to participate in medical research, is 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.[9]

> 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 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

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[8]*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); *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).

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

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.[10] This ethics opinion states 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.*

The record demonstrates that Plaintiffs were provided the opportunity to review the informed consent forms, ask questions of the physicians and make a decision that participation in this Phase I clinical trial for recipients of kidney transplants was the proper decision for them. Once Ms. Shwab signed the consent form, the physicians took her at her word. The Court of Appeals adoption of this subjective, hindsight-based challenge to the informed consent here contravenes this century-long development of medical ethics.

III. Lowering the Standards for Challenging Informed Consent Will Hinder Medical Advancement and Patient Care in Kentucky

The Court of Appeals should have given deference to the trial court's assessment of Plaintiffs' allegations, including by their expert. In today's litigation, "[i]nstances when an attorney cannot find anyone to testify as an expert are rare, because it is often possible for an attorney to find someone who may qualify as an expert witness to testify to the opinion needed by the attorney." Stephen D. Easton, *Ammunition for the Shoot-Out*

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

With the Hired Gun's Hired Gun: A Proposal for Full Expert Witness Disclosure, 32 Ariz. St. L.J. 465, 506 n.134 (2000); *see also* L. Timothy Perrin, *Expert Witness Testimony: Back to the Future*, 29 U. Rich. L. Rev. 1389, 1389 (1995) (calling such experts "mercenaries"). Allowing this case to go to trial based on the availability of such expert testimony runs counter to longstanding efforts of the General Assembly and this Court to maintain rational liability rules and a stable medical environment in Kentucky.[11]

The General Assembly has a long history of "promot[ing] the health and general welfare of the inhabitants of the Commonwealth through the adoption of reforms in health care malpractice claims." KRS 304.40-250 (stating the legislative purpose of Medical Malpractice Insurance and Claims Act). The codification of informed consent was part of a series of reforms responding to the fact that in the 1970s, "the cost and availability of malpractice liability coverage in Kentucky reached a situation of crisis proportion." R. David Clark, *Medical Malpractice*, 65 Ky. L.J. 337, 338 (1976). The General Assembly has also enacted numerous other laws to safeguard physicians from unprincipled, speculative liability. *See, e.g.,* KRS 411.167 (providing a certificate of merit requirement for medical malpractice actions against long-term-care facility); KRS 413.140 (setting a one-year statute of limitations for medical malpractice actions).

In addition, this Court has rejected many attempts to expand liability related to the provision of medical care. *See Lake Cumberland Reg'l Hosp., LLC v. Adams*, 536 S.W.3d 683, 689 (Ky. 2017) (rejecting "stand-alone tort of negligent credentialing" based in part on the proposed "tort's far-reaching implications" and unknown impact on rural hospitals and communities); *Kemper v. Gordon*, 272 S.W.3d 146, 148 (Ky. 2008) (rejecting "'lost

[11] *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).

or diminished chance' doctrine of recovery"); *Grubbs v. Barbourville Fam. Health Ctr., P.S.C.*, 120 S.W.3d 682, 891 (Ky. 2003) (rejecting claims for wrongful birth and wrongful life). In *Gordon*, the Court cautioned that "our society is wallowing near the water line with the burdensome and astronomical economic costs of universal healthcare and medical services." 272 S.W.3d at 152. "Rising malpractice insurance premiums for physicians are undoubtedly a part of that financial burden." *Id.*

Some of these efforts have helped mitigate medical liability crises when they occur. *See AMA: 21 States 'in Crisis' from Closing Practices*, Relias Media, Apr. 1, 2006 (including Kentucky).[12] For example, in the early 2000s liability concerns led to an increase in the number of physicians leaving the state or retiring early. Nearly two-thirds of Kentucky counties were deemed "medically underserved" due to the critical shortage of physicians by the U.S. Department of Health and Human Services. *See* Laura Ungar, *Kentucky's Health: Critical Condition*, Courier-Journal (Louisville), Dec. 5, 2005. The state had lost 36 percent of its practicing neurosurgeons, 29 percent of its general surgeons, and 25 percent of its obstetricians. *See Leaders Say Senate Democrats Might Thwart Medical Malpractice Legislation,* Assoc. Press, Jan. 13, 2004. These conditions also remain a serious concern today. *See* Medically Underserved Areas, Health Resources & Services Admin.[13] The reality is that rising medical malpractice premiums have repeatedly jeopardized patient care, and rulings like the one here create such uncertainty.

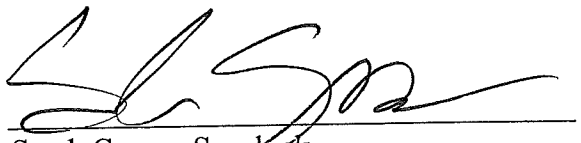
As this Court has appreciated, ensuring access to quality and affordable care requires that courts impose liability on medical providers only when patients have been

[12]https://www.reliasmedia.com/articles/128664-ama-21-states-8216-in-crisis-8217-from-closing-practices
[13]https://data.hrsa.gov/tools/shortage-area/

wrongfully injured and only for damages grounded in the facts. Adopting strained theories of liability, as here, threatens to turn the courts into mechanisms for transferring money to people with negative health outcomes irrespective of fault or the facts.

CONCLUSION

For these reasons, the American Medical Association and Kentucky Medical Association respectfully request that this Court reverse the Court of Appeals and reinstate the trial court's issuance of summary judgment.



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