

Put It on the Board, 3/16

[Case raises uncertainty on autopsy's legal status](#)

[ConfirmMDx added to NCCN guidelines](#)

[Higher-throughput FilmArray system cleared](#)

[CE for BD blood separation technology](#)

[Most DTC genetic results not shared with doctors](#)

[Blue Cross covers Sequenom tests in California](#)

Case raises uncertainty on autopsy's legal status

Should a hospital-provided autopsy be considered health care? It's a question the Supreme Court of Texas will decide this spring, and its answer to that question will make a big difference—in the millions of dollars—to the claimants, *Christus Health Gulf Coast v. Carswell*. It could also have an impact on the medical liability coverage available to pathologists who perform autopsies in the Lone Star State.

The legal battle began with the 2004 death of Linda Carswell's husband, Jerry, who was admitted to Christus St. Catherine Hospital in Katy, Tex., for kidney stones but died days later as an inpatient. In a bid to find out what caused her husband's death, Carswell requested an autopsy. She alleged that hospital employees steered her toward having an autopsy performed by a contracted pathology firm, instead of one performed by the county medical examiner's office that would have included toxicology testing.

Carswell sued the pathologist who performed the autopsy, the pathology group, and Christus Health. The jury failed to find medical negligence against the defendants, but Carswell prevailed in her civil claim that Christus Health defrauded her by denying the "complete autopsy" she had requested. She was awarded \$1 million for mental anguish, and \$1 million in punitive damages.

But Christus Health's attorneys argue the case should fall under the purview of the Texas Medical Liability Act, which not only limits noneconomic damages but also presents procedural hurdles that plaintiffs must meet before proceeding to court. One of those is to get an independent expert to agree the plaintiff has a valid case within 120 days of filing a suit. But Carswell's legal team pursued fraud claims they believed fell outside the state's medical liability law and so didn't require that outside expert report.

That's where the worm turns. Is autopsy covered by the state's medical liability law? The state's appeals court ruled that in this case it is not, because the central issue is the alleged fraud that occurred after Jerry Carswell died, when he was no longer a hospital patient.

In its brief to the state Supreme Court, Christus Health's attorneys note the statute defines "health care" as "any act or treatment performed or furnished, or that should have been performed or furnished, by any health care provider for, to, or on behalf of a patient during the patient's medical care, treatment, or confinement." And "medical care," they note, is defined as "any act defined as practicing medicine...performed or furnished, or which should have been performed, by one licensed to practice medicine in this state for, to, or on behalf of a patient during the patient's care, treatment, or confinement."

Christus Health's attorneys argue that while autopsy is not performed during the patient's care or treatment, in this case it did occur during the patient's "confinement," because the contracted pathologist performed the autopsy in the dissection room at a Christus hospital in Houston. The autopsy was part of "the patient's medical

care,” they add, because it was ordered to help determine the cause of his death while he was an inpatient.



McCabe

In their brief, Linda Carswell’s attorneys, led by Neil McCabe, argue that “a corpse is not a patient” and cite a previous state court decision to the effect that “the idea that a cadaver can be a patient is, on its face, illogical.” They also cited several other Texas cases, as well as cases from other jurisdictions, to support their arguments.

In a CAP TODAY interview, McCabe says his team’s legal argument is not intended to cast aspersions on pathologists or deride their essential role within the medical system.

“The statute does not support the position that it [autopsy] falls under the health care liability act,” he says. “It’s not a reflection on pathologists. You have to follow the law.”

McCabe says that if the court rules in his client’s favor (he expects a decision by June) and decides that autopsy is not “health care” for purposes of the state’s medical liability law, Texas pathologists have another court of redress: the Republican-dominated capital.

“If they are not covered by the statutes, just go to the legislature. The legislature is giving people what they want in this area,” he says. “It’s the legislature that decides to make that the law. The court takes the position on the law as is, rather than trying to rewrite the law.”

Houston medical liability attorney Tom Sartwelle defended the pathologist and pathology group initially sued in the case and has followed the matter closely ever since.

“Is doing an autopsy the practice of medicine? Absolutely,” he says. “If you look at the state statute, I think the court of appeals got it dead wrong.”

If the Texas Supreme Court disagrees, pathologists may feel the effects, says Sartwelle, who practices with the law firm of Beirne, Maynard and Parsons.

“First of all would be insurance,” he says. “Insurance is normally issued to cover a physician who, in the practice of medicine, causes injury to a patient. That’s generally the language. If the court in this case holds that a dead person’s not a patient, then absolutely there’s no insurance coverage for a pathologist who may make a mistake and gets sued—or may not make a mistake and gets sued. They would have no insurance and would have to pay a lawyer like me to defend them out of pocket.”

Moreover, he adds, the Texas Medical Liability Act’s \$250,000 limit on noneconomic damages for physician defendants would not apply in autopsy cases. Sartwelle acknowledges that such cases are “fairly rare” but not out of the realm of possibility.



Dr. Wheeler

Thomas Wheeler, MD, testified in defense of the pathologist whom Carswell sued initially. Dr. Wheeler, chair of the Department of Pathology and Immunology at Baylor College of Medicine, is more sanguine about the case's potential consequences.

"I don't think it will have any significant impact for pathologists," he says. "It may have some [impact] for health care entities that are brought into a case and are attempting to be shielded by the tort reform law. But for pathologists, I think the precedents are there that the performance of autopsy is the practice of medicine."

The Texas Society of Pathologists is "watching the case closely," society president Kevin Homer, MD, tells CAP TODAY. "Texas pathologists...understand well that the performance of an autopsy is the practice of medicine. It requires a Texas medical license and years of postgraduate training in pathology. The Texas Supreme Court's determination as to whether it meets the legal standard of 'health care' will likely turn on the court's analysis of several factors, including Texas citizens' strong desire to limit lawsuits and attract more physicians to the state."

—Kevin B. O'Reilly

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ConfirmMDx added to NCCN guidelines

MDxHealth SA announced that its ConfirmMDx for Prostate Cancer test has been included in the 2016 National Comprehensive Cancer Network Guidelines.

"Inclusion in the guidelines establishes ConfirmMDx as a 'standard of care' for the management of men at risk for undetected prostate cancer," MDxHealth CEO Jan Groen, PhD, said in a statement. "This is the second MDxHealth test to be included in the NCCN guidelines, with PredictMDx for Glioblastoma added in 2013, and illustrates our commitment to delivering clinically valuable solutions to improve patient outcomes."

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Higher-throughput FilmArray system cleared

The FDA has given 510(k) clearance to BioFire Diagnostics' new FilmArray platform, which has a smaller footprint and provides six times more sample throughput compared with the existing system. The new system, called FilmArray Torch, has been cleared for use with the FilmArray Respiratory Panel. BioFire has submitted 510(k) applications for Torch to be cleared for use with its gastrointestinal, meningitis/encephalitis, and blood culture identification panels.

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CE for BD blood separation technology

Becton, Dickinson has obtained the CE mark for a next-generation blood separation technology that is designed to enhance sample quality, improve laboratory efficiency, and reduce laboratory turnaround time.

The BD Vacutainer Barricor tube is a single-use, plastic evacuated tube used to collect, separate, transport, and process venous blood specimens to obtain high-quality plasma for in vitro diagnostic use. The tubes are optimized to deliver a high-quality plasma sample by reducing cellular content (versus plasma gel tubes), as a result of the mechanical separator remaining open throughout the centrifugation cycle. It is designed to eliminate gel artifacts that can lead to instrument downtime. With no clotting time required, the BD tube can cut centrifugation time by up to seven minutes and reduce overall turnaround time by as much as 37 minutes, BD said.

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Most DTC genetic results not shared with doctors

Direct-to-consumer genetic testing may create unrealistic expectations for patients and a conundrum for physicians who largely feel unprepared to discuss test results, says a recent study. Using data from the Impact of Personal Genomics Study, a large, longitudinal study of actual users of 23andMe and Pathway Genomics DTC genetic tests, researchers described the characteristics and perceptions of consumers who shared their results with their doctor or another health professional (van der Wouden CH, et al. *Ann Intern Med*. Published online ahead of print March 1, 2016. doi:10.7326/M15-0995).

The researchers found that 27 percent of consumers shared their genetic test results with their primary care physician, and most of those who did were satisfied with the discussion of results. For the minority who were unsatisfied with the physician encounter, the physician's inability to adequately answer the patients' questions and concerns could be to blame. The authors suggest that patient perceptions and expectations may influence their attitudes. They say that given the increasing importance of genetic concerns in primary care, physicians should be trained to at least engage in a discussion about these tests.

The authors of an accompanying editorial suggest that deceptive marketing messages create unrealistic expectations about the health benefits of at-home genetic tests (Burke W, et al. *Ann Intern Med*. Published online ahead of print March 1, 2016. doi:10.7326/M16-0257). They call upon the health system to counter unrealistic marketing messages with real advice for consumers.

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Blue Cross covers Sequenom tests in California

Sequenom has completed an agreement with Anthem Blue Cross that provides in-network coverage to Anthem's California customers for Sequenom's noninvasive prenatal tests in both high- and average-risk pregnancies, effective March 1.

"Our contract with Anthem is another important step in our strategy to be an in-network provider and to bring the benefits of noninvasive prenatal testing to as many patients as possible, including women with average-risk pregnancies," Sequenom CEO Dirk van den Boom, PhD, said in a statement.