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Gorsuch's Antipathy to Agency Rules May Boggle Health Industry

President Donald Trump's nomination of Neil M. Gorsuch to the Supreme Court could have important ramifications for health law, as he has shown he's no fan of deferring to administrative agencies such as the HHS and the CMS, has spoken in favor of religious rights and brings a deep knowledge of antitrust law to the bench.

If he is confirmed, Gorsuch's presence on the high court could affect how health-care regulations are interpreted, and possibly affect reproductive rights and other women's health issues. His biggest influence, however, would be on administrative law issues, according to attorneys familiar with his work. And, because health care is a heavily regulated industry, his actions as a Supreme Court justice likely would be felt strongly when it comes to determining what the Department of Health and Human Services and the Centers for Medicare & Medicaid Services can do.

At 49 years old, Gorsuch has the potential to be one of the longest-serving and most influential justices of this century. But his reticence to defer to executive agencies may put him at odds with current and future administrations.

'Reliable Conservative.' Gorsuch is a ''reliable conservative,'' Robert A. Sedler, who teaches constitutional law at Wayne State University Law School in Detroit, told Bloomberg BNA. The nominee is a ''politically smart choice,'' Sedler said, because he isn't ''a flamethrower.''

That is, Gorsuch's confirmation process isn't likely to be tripped up by controversial stances that have derailed some nominees. Gorsuch probably will tell Democrats during the confirmation process that he strongly supports the stare decisis doctrine, which holds that courts are bound by decisions in previous cases.

Sedler predicted Gorsuch will be confirmed in a fairly standard way, despite reports of Democratic opposition. The judge isn't ''an extremist,'' Sedler said.

Sedler doesn't foresee Gorsuch breaking new ground on the court. Instead, he will take the court back to where it was when the late Justice Antonin Scalia sat on the bench. Gorsuch often is compared to Scalia and is said to share the late jurist's legal philosophy.

Anti-Deference Stance. The biggest area in which Gorsuch may influence health law is in his attitude toward executive agencies. Gorsuch isn't a fan of agency deference. In fact, some court-watchers have predicted he could help bury the *Chevron* doctrine, under which courts defer to agencies' reasonable statutory interpretations in rules they issue.

Most recently, Gorsuch, who sits on the U.S. Court of Appeals for the Tenth Circuit, excoriated the CMS in a decision striking the agency's attempt to collect Medicare overpayments from a home health provider. The CMS ''seems unable to keep pace with its own frenetic lawmaking,'' he said, criticizing the agency for the sheer volume of its regulatory guidance. This position, interestingly, may put Gorsuch at odds with the Trump administration as it begins enforcing its own regulations and guidance in the health field.

Gorsuch's opinion in *Caring Hearts Personal Home Services v. Burwell*, 824 F.3d 968, 2016 BL 171256 (10th Cir. 2016), ''says a great deal about how he may view challenges to health care and other regulations,'' Jesse Witten, a partner with Drinker Biddle & Reath LLP, Washington, told Bloomberg BNA.

In that opinion, ''Gorsuch ripped CMS for misunderstanding its own regulations and applying them retroactively to demand recoupment of $800,000 in Medicare reimbursement from a home health agency,'' Witten said. ''Gorsuch faulted CMS for insisting that the home health agency 'knew or should've known its conduct was unlawful only in light of regulations that were then but figments of the rulemakers' imagination, still years away from adoption.' ''

''Fitting the case into a broader judicial philosophy, Gorsuch quoted James Madison's warning about an out-of-control government that enacts laws 'so voluminous they cannot be read,' '' Witten said. ''Gorsuch seems to fear that we have reached this point with the Medicare program, as he pointedly observed that 'about 37,000 separate guidance documents can be found on CMS's website—and even that doesn't purport to be a complete inventory.' ''

Health-care providers challenging regulatory agency actions ''may find a receptive audience in Justice Gorsuch,'' Witten said.

Influencing Others. Gorsuch could pick up Justices Clarence Thomas and Samuel A. Alito Jr. in cases challenging agency rulemaking or guidance, Stuart Gerson told Bloomberg BNA. Gerson served as acting U.S. attorney general under President Bill Clinton. He also served in the George H.W. Bush administration as as-

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sistant attorney general for the Department of Justice's Civil Division.

Now a member of Epstein Becker Green's health law practice in Washington, Gerson sees potential conflict between Gorsuch and the Trump administration's HHS with respect to CMS and Food and Drug Administration payment rules on which constituents are likely to request guidance. Gorsuch might not agree with the HHS's interpretations.

Gorsuch is a ''literalist,'' Gerson said. That is, he interprets statutes according to the plain language, without looking at the statutory history or agency interpretation. Gorsuch will try to discern the statute's ''original meaning,'' Gerson said.

Reading a law literally could make a difference in a case like *King v. Burwell*, 135 S. Ct. 2480, 2015 BL 202885 (U.S. 2015), in which the court broadly construed the Affordable Care Act to make subsidies available to all health-insurance purchasers, regardless of whether they bought insurance on an exchange created by a state or on an exchange operated by the federal government in a state that had opted not to do so.

The law was silent as to whether subsidies were available for state-exchange buyers, but the Internal Revenue Service interpreted it as making subsidies available to all. The challengers argued the ACA's plain language precluded the IRS's interpretation.

The majority, led by Chief Justice John G. Roberts Jr., said the challengers' interpretation made no sense in light of the ACA's ''context and structure.'' Scalia, writing in dissent, called the court's decision ''quite absurd.'' Joined by Thomas and Alito, Scalia wrote that when the ACA ''says 'Exchange established by the State,' it means 'Exchange established by the State,' '' not an exchange established by the federal government.

Gorsuch's judicial philosophy generally is believed to be akin to Scalia's view, so he likely would have joined the late justice in his dissent.

Labor Rulings, Security Rules. The union-heavy health industry also may be interested in Gorsuch's criticism of the National Labor Relations Board. The majority of Gorsuch's opinions in labor cases don't support the board, Gerson said. Gorsuch ''hasn't been impressed'' by the NLRB's positions, he said.

Gorsuch isn't likely to approve the Labor Department's persuader rule, for example, Gerson said. This rule requires employers to disclose their involvement in documents and actions meant to influence workers during union organizing campaigns. The U.S. District Court for the Northern District of Texas issued a nationwide permanent injunction against the persuader rule on Nov. 16, 2016 (*Nat'l Fed'n of Indep. Bus. v. Perez*, N.D. Tex., No. 16-66). The Labor Department appealed the ruling Jan. 12, so the case potentially could reach the Supreme Court.

The Supreme Court also may be asked to weigh in on the Federal Trade Commission's authority to oversee electronic data privacy and security issues, another area of import to the health industry, W. Reece Hirsch, of Morgan Lewis in Los Angeles, told Bloomberg BNA. Health-care stakeholders must comply with these rules under the Health Insurance Portability and Accountability Act (HIPAA).

A potential circuit split is brewing between the U.S. appeals courts for the Third and Eleventh circuits over the FTC's authority to enforce regulations in this area, he said. The Eleventh Circuit, in November 2016, temporarily blocked an FTC data security enforcement order against LabMD Inc. (*LabMD, Inc. v. FTC*, 11th Cir., No. 16-16270, stay granted 11/10/16).

The court stayed enforcement until it could determine whether the FTC acted reasonably in interpreting a section of the FTC Act that applies to unfair or deceptive acts or practices that affect interstate commerce. In granting LabMD's stay request, the appeals court said there are ''compelling reasons'' why the commission's interpretation applying Section 5 to data security breaches may not be reasonable.

The Third Circuit, in *FTC v. Wyndham Worldwide Corp.*, 799 F.3d 236, 2015 BL 271793 (3d Cir. 2015), affirmed the commission's authority under the FTC Act to challenge data security failures. Up until recently, the FTC and the HHS Office for Civil Rights acted together to enforce privacy and security rules, but as these cases show, the FTC is now asserting it has unilateral authority to do so, Hirsch said.

Gorsuch's opposition to agency deference could lead to a court decision scaling back the FTC's authority to bring a security rule enforcement action against a health-care provider, Hirsch said.

Religious Liberty. Gorsuch was a ''great pick'' from the viewpoint of religious liberty advocates, Hannah Smith, senior counsel at the Becket Fund for Religious Liberty in Washington, told Bloomberg BNA.

As a member of the Tenth Circuit, he voted to allow secular for-profit corporations to claim an exemption from an ACA regulation requiring employers to provide employee health plans that cover birth control and related services at no cost to employees, a decision later upheld by the Supreme Court (*Hobby Lobby Stores, Inc. v. Sebelius*, 723 F.3d 1114, 2013 BL 172106 (10th Cir. 2013).

Gorsuch also dissented from a denial of rehearing by the full Tenth Circuit in *Little Sisters of Poor Home for Aged v. Burwell*, 799 F.3d 1315, 2015 BL 289684 (10th Cir. 2015). A three-judge panel had rejected the nuns' challenge to the procedure the HHS required them to follow to obtain an religious-based opt-out from the contraceptive mandate.

The Supreme Court sent the case back to the Tenth Circuit with instructions to the parties to work out a compromise that would allow the nuns the exemption while assuring their employees had access to cost-free contraceptives. Smith said Becket, which represented the Little Sisters, is hopeful an administrative fix is in the offing. She doesn't foresee the case going back to the Supreme Court, and noted that Gorsuch probably would recuse himself if it did.

Alliance Defending Freedom, which also represents religious liberty interests, praised Gorsuch. ''The president promised to appoint justices committed to interpreting the Constitution of the United States as the Founders intended, and Judge Gorsuch's extensive record reflects that commitment,'' CEO and General Counsel Michael Farris said in a press release.

''While ADF does not take a position on the merits of Supreme Court nominees, we are hopeful that Judge Gorsuch will continue to interpret the Constitution faithfully and according to the intent of the Founders,'' Farris said. ''That is essential to protect our first freedom—the right to peacefully live and work consistently with one's religious beliefs.''

Reproductive, End-of-Life Rights. Abortion rights advocacy groups, however, are firmly opposing the Gorsuch nomination. Cecile Richards, president of Planned Parenthood of America, had ''a message for members of the Senate on Judge Gorsuch: opposing Roe v Wade is a disqualifier.''

Gorsuch ''has an alarming history of interfering with reproductive rights and health,'' Richards said. ''The right to safe and legal abortion has been the law of the land for more than 40 years, and is a part of the fabric of this country.'' Supreme Court nominees, like Gorsuch, ''must make clear that they will protect our fundamental rights—including the right of a woman to control her body,'' she said.

NARAL Pro-Choice America called Gorsuch an ''existential threat to legal abortion in the United States.''

''With a clear track record of supporting an agenda that undermines abortion access and endangers women, there is no doubt that Gorsuch is a direct threat to *Roe v. Wade* and the promise it holds for women's equality,'' Ilyse Hogue, the group's president, said in a press release. ''The fact that the court has repeatedly reaffirmed *Roe* over the past four decades would no longer matter.''

Sedler, on the other hand, predicted Gorsuch wouldn't vote to overturn *Roe v. Wade*, 410 U.S. 113 (1973), given his stated commitment to stare decisis.

Moreover, Sedler doesn't see a case testing reproductive rights coming to the court anytime soon. The court's June 2016 decision in *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2016 BL 205262 (U.S. 2016), expanded the substantial burden test adopted by the court in *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992), he said. Lower courts are bound to apply that decision in cases challenging state abortion laws and regulations, he said.

End-of-life choice advocacy groups also are rallying against Gorsuch. Compassion & Choices, for example, said the Senate's confirmation of Gorsuch ''could seriously weaken the right of individuals to make their own personal healthcare decisions.''

''A judge who is willing to allow others, including corporations, to impose their religious beliefs on individuals making personal healthcare decisions at the end of life would be a dangerous addition to the nation's highest court,'' Kevin Diaz, the organization's national director for legal advocacy, said in a press release.

Antitrust. Gorsuch, however, ''is an excellent pick for antitrust buffs,'' according to Douglas Ross, an antitrust attorney with Davis Wright Tremaine LLP in Seattle. Supreme Court justices don't typically have deep antitrust backgrounds: The only one currently is Justice Stephen G. Breyer, he said.

''Gorsuch teaches antitrust at the University of Colorado law school, handled antitrust cases while in private practice (among many others), and has written several significant antitrust opinions,'' Ross said.

For example, in *Four Corners Nephrology Assocs., P.C. v. Mercy Med. Ctr. of Durango*, 582 F.3d 1216, 2009 BL 207942 (10th Cir 2009), Gorsuch wrote the opinion holding a Colorado hospital didn't violate federal or state antitrust law in refusing to grant a nephrologist staff privileges after it recruited another physician to join its staff as the exclusive provider of inpatient nephrology services.

Ross doesn't see Gorsuch bringing any bias to the bench in antitrust matters. He isn't likely to favor plaintiffs or the government, Ross said. With Gorsuch's knowledge of antitrust law, Ross is confident he will understand even the most complicated antitrust arguments.

Gorsuch's antipathy toward agency regulation probably won't affect his rulings on antitrust matters, Ross told Bloomberg BNA.

The antitrust agencies, the FTC and the Department of Justice's Antitrust Division, don't issue regulations. They see themselves as law enforcement, not regulatory, agencies, he said. The agencies issue guidelines and statements regarding the enforcement priorities, but those aren't the same as regulations, Ross said. He also doesn't see Gorsuch's skepticism toward agency regulation as affecting his view of FTC cases.

There are several high-profile hospital and insurance company merger cases pending in the courts. It will be interesting to see how Gorsuch would view these cases should any make their way to the Supreme Court.

Life Sciences. Gorsuch has written only a few opinions on life sciences and medical research litigation. But in these and other written opinions, he indicated familiarity with the legal precedents in these areas, as well as with the core statutes and regulations.

In a medical device case, *Russo v. Ballard Med. Prods.*, 550 F.3d 1004, 2008 BL 280126 (10th Cir. 2008), Gorsuch wrote that patent law didn't preempt the plaintiff's trade secret misappropriation claim. ''Were the law otherwise, it would be incongruous indeed,'' Gorsuch wrote. ''Any defendant could (and would have a significant incentive to) insulate itself from a trade secret misappropriation claim simply by patenting the stolen idea.''

The potential future justice similarly discussed the preemption provisions of the Medical Device Amendments (MDA) in a personal injury case against a medical device manufacturer in *Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 2015 BL 112893 (10th Cir. 2015). There, he discussed the balancing act Congress set up between the MDA and the Federal Food, Drug and Cosmetic Act.

In addition, in *Surefoot LC v. Sure Foot Corp.*, 531 F.3d 1236, 2008 BL 143872 (10th Cir. 2008), Gorsuch discussed the dispute standard set up by the Supreme Court in the biopharma litigation *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 75 U.S.L.W. 4034 (2007).

BY MARY ANNE PAZANOWSKI

—With assistance from John T. Aquino.

To contact the reporter on this story: Mary Anne Pazanowski in Washington at mpazanowski@bna.com

To contact the editor responsible for this story: Peyton M. Sturges at PSturges@bna.com

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