

# Newly Full SCOTUS Will Have Its Say in Healthcare

Cases involving biosimilars, gene patents in the hopper

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WASHINGTON -- Now that [Neil Gorsuch](#) has been sworn in as an associate justice on the Supreme Court, the speculation begins over which healthcare cases the court will be hearing soon and how the newly reconstituted court will decide them.

## Contraceptive Coverage Cases

The Affordable Care Act's (ACA) rule requiring insurers to cover contraceptives free of charge is one issue that could re-appear at the court, according to Miles Zaremski, JD, a healthcare attorney in Northbrook, Ill. In the [Burwell v. Hobby Lobby Stores](#) case, *Hobby Lobby*, a large chain of craft stores whose owners objected on religious grounds to providing contraceptive coverage to their employees, argued that the ACA's requirement violated the Religious Freedom Restoration Act; in 2014, the Supreme Court ruled 5-4 in *Hobby Lobby*'s favor.

As a lower-court judge, Gorsuch ruled on two ACA contraceptive coverage cases, including the *Hobby Lobby* case; both times he ruled in favor of the employer. "If that issue comes back to the Supreme Court in some fashion, given what Gorsuch did in those cases ... chances are he'd find against anybody who would argue that the contraceptive coverage rule should still apply," Zaremski, who is also a past president of the American College of Legal Medicine, said in a phone interview.

The current cases of interest in this area don't involve for-profit companies, but instead revolve around non-profit religiously affiliated employers. One such case is [\*Zubik v. Burwell\*](#), which is actually a combination of seven different cases involving nonprofit religious employers who objected to having to provide their employees with coverage for contraception.

The Supreme Court looked at the case and remanded it back to the lower courts involved so that the parties involved could be given a chance to work out their disagreements. "[Justice Anthony] Kennedy is the decisive vote in those cases, but I think we could safely assume Gorsuch would be in the conservative camp" on these issues, said Stuart Gerson, JD, a former acting attorney general under the Clinton administration who is now with the law firm of Epstein Becker Green here.

In addition to contraception cases, "there are always abortion cases bubbling up as well" that could come before the court, said Timothy Jost, emeritus professor of law at Washington and Lee University in Lexington, Va., in an email.

#### **Gorsuch and "Chevron Deference"**

On the employer side, the court will be hearing a trio of important cases, which are likely to be decided 5-4 in employers' favor with Gorsuch on the court, according to Mary-Christine "M.C." Sungaila, JD, of the Haynes Boone law firm in Costa Mesa, Calif. The cases are known as [\*Epic Systems Corp. v. Lewis\*](#), [\*Ernst & Young LLP v. Morris\*](#), and [\*NLRB v. Murphy Oil USA Inc.\*](#)

The issue in these cases, which would affect the healthcare industry along with other employers, is "whether the National Labor Relations Board is correct in its position that federal labor law bars employment arbitration agreements that contain class action waivers, because the National Labor Relations Act (NLRA) requires employees to be able to act in concert and bring employment related grievances collectively," Sungaila, who filed "friend of the court" briefs in two of the cases, explained in an email. She noted that "Justice Gorsuch has famously been critical of the Chevron doctrine, under

which courts defer to agency interpretations of their rules, and this is likely to factor into these cases."

Gorsuch "has an engaging, approachable, narrative writing style, which will go a long way toward the public directly understanding the decisions of the court and their practical impact," Sungaila continued. She cited as an example a dissent he wrote involving a decision made by the Tenth Circuit Court of Appeals:

"If a seventh grader starts trading fake burps for laughs in gym class, what's a teacher to do? Order extra laps? Detention? A trip to the principal's office? Maybe. But then again, maybe that's too old school. Maybe today you call a police officer. And maybe today the officer decides that, instead of just escorting the now compliant 13-year-old to the principal's office, an arrest would be a better idea. So out come the handcuffs and off goes the child to juvenile detention. My colleagues suggest the law permits exactly this option and they offer 94 pages explaining why they think that's so. Respectfully, I remain unpersuaded."

Gorsuch's reservations about the Chevron doctrine may come into play if the Supreme Court hears cases dealing with administrative law, said Gerson.

"That's an area of great interest for Gorsuch with regard to the FDA and approval of biosimilars and devices." The court will hear arguments April 26th on one such case, [Sandoz v. Amgen](#), which involves the question of whether a biosimilar applicant must wait until after FDA approval before notifying the brand-name drugmaker that it plans to put a generic on the market.

"What's significant about Gorsuch, besides the fact that he can wade into these problems, is that he is technically very sound," Gerson said. "I think he'll impose tougher burdens on agencies in these cases, and he may be of influence in getting [other justices] to come along with him."

#### **The House's Case Against the ACA**

There are at least two healthcare cases currently before the court that Gorsuch would likely not be involved with because the oral arguments have already taken place, said Zaremski. One case -- *Life Technologist v. Promega* --

involves whether a biotechnology company infringed on a patent related to genetic testing kits.

The second case, a trio of cases collectively known as *Advocate Health Care Network v. Stapleton*, has to do with whether pensions maintained by religious nonprofit organizations qualify for a religious exemption under the Employee Retirement Income Security Act (ERISA) -- a ruling that could affect religiously affiliated healthcare organizations, he noted.

The court may also eventually take up *House v. Price* (formerly known as *House v. Burwell*), a case brought by the Republican-led House of Representatives, which argued that the Obama administration was out of bounds when it appropriated money under the ACA to reduce the cost-sharing burden for low-income enrollees in the act's health insurance exchanges, without the approval of Congress.

"That could affect the ACA, because insurers wouldn't receive reimbursement" for cutting enrollees' out-of-pocket expenses if the suit was decided in favor of the House, Zaremski said. A district court ruled in favor of the House; the Obama administration appealed the ruling, but the appeal was stayed due to the election. If the Trump administration decides to drop the appeal -- which it could do -- the district court ruling would stand, the issue would not go up to the Supreme Court, and the cost-sharing subsidies would disappear, which could negatively affect the insurance exchanges.