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Health System Reform

High Court Upholds Health Reform Law, Biosimilars Pathway Remains Operative

Health reform law provisions that affect life sciences companies, such as the abbreviated biosimilars pathway, will now move forward after the U.S. Supreme Court June 28 upheld the law (*National Federation of Independent Business v. Sebelius*, U.S., No. 11-393, 6/28/12).

In a 5-4 decision, the U.S. Supreme Court upheld the insurance mandate that is the centerpiece of the Patient Protection and Affordable Care Act (PPACA). Chief Justice John G. Roberts Jr. cast the deciding vote to uphold the constitutionality of PPACA's individual mandate.

But the ruling utilized unexpected grounds. The majority held that neither the commerce clause nor the necessary and proper clause gave Congress the authority to enact the requirement that citizens who do not acquire health insurance must pay a penalty. But Roberts wrote that the individual mandate may be characterized as a tax and that Congress has power under the Constitution's taxing and spending clause to order individuals to pay money to the federal government.

The court limited the Medicaid expansion provision in PPACA, saying that it violates the Constitution by threatening states with the loss of existing funding if they decline to comply with the expansion. Congress had the power to condition receiving new Medicaid funds on the states' compliance with the expansion but cannot threaten to take away all Medicaid funds, the court said.

Medical device companies said after the ruling that they will continue to fight the excise tax on devices that is part of the law, and the Biotechnology Industry Organization promised to continue to support efforts to repeal the law's Independent Payment Advisory Board.

Almost Where We Were Before. Wendy Krasner of Manatt Phelps & Phillips LLP, Washington, told BNA June 28, ''I think people are pretty happy about the ruling. Uncertainty leaves a lot of things open, and we feel the decision brings some clarity to the health care system.''

Krasner noted the court's ruling on the Medicaid expansion raises some questions.

''Does it mean that some states may not go along with the Medicaid expansion, which would defeat the whole purpose of the PPACA, which is providing health care to people who do not have it? But our Medicaid experts believe that most states will go along with the Medicaid expansion.''

Krasner said it also will be important to see how the states react to expediting PPACA's health insurance exchanges and to watch whether health delivery transformations are accelerated.

Bernadette Broccolo of McDermott Will & Emery LLP, Chicago, said June 28, ''The ruling means we're going forward with the PPACA, except for the Medicaid expansion portion, which has now been limited. So we're basically back to where we were when the PPACA became law.

''Biosimilars remains intact, along with all of the things life sciences companies have found negative about the law's comparative effectiveness provisions,'' she said. Those provisions establish a nonprofit Patient-Centered Outcomes Research Institute to undertake comparative effectiveness research that examines the relative health outcomes, clinical effectiveness, and appropriateness of different medical treatments by evaluating existing studies and conducting its own.

''But the continued movement for providers to analyze data to meet the demands of health reform will continue as well, and this sophisticated data analysis may be of interest to life sciences companies. I think we'll be seeing more collaborations formed around these data,'' Broccolo said.

Ruling's Approach 'Surprising.' J. Mark Waxman of Foley & Lardner, Boston, said June 28, ''At the end of the day, of course, the individual mandate and the core of the law survive. Thus, all the programs with respect to accountable care organizations and the like move forward, as well as the Disproportionate Share and other Medicare provisions.

''The one real ringer is the Medicaid ruling. It raises significant new issues with respect to federal spending programs in ways that previously were not really imagined. How it will affect federal spending programs, including Medicaid, is uncertain. And whether there is any potential application beyond Medicaid is something that will be analyzed over time,'' he said.

Howard Bremer of the Wisconsin Alumni Research Foundation, Madison, Wis., said he was surprised at the way the majority arrived at its ruling.

''But it was clear from the arguments that they weren't going to pick the law apart,'' he told BNA June 28. ''After all, Justice [Antonin] Scalia said during the oral arguments that the court couldn't be expected to go through the 2,700 pages of legislation and evaluate each provision individually to determine whether it could operate independently of the mandate. He even invoked the Eighth Amendment barring cruel and unusual punishment.''

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John C. Lechleiter, president and chief executive officer of Eli Lilly and Co., June 28 said his company ''will continue to work toward full implementation of the health care law.

''Even with today's decision, we expect that the debate about health care and health coverage will continue, and that further reforms and changes are likely in the years ahead. As we have in the past, Lilly will continue to engage actively in this process,'' Lechleiter said. ''In doing so, we will be guided by a core set of principles. We will advocate for health care reforms that enhance patient access to good health care and medicines; provide consumer choice through market-based competition; promote prevention and evidence-based disease management; maintain high standards of quality and safety; and foster future medical innovation.''

Biosimilars Approval Pathway Moves Forward. D'vorah Graeser, founder and chief executive officer of the intellectual property firm Graeser Associates International Inc., June 28 told BNA that because the Biologics Price Competition and Innovation Act of 2009 (BPCI Act), part of the health reform law, was upheld, biosimilars now will be available and the Food and Drug Administration will move forward with its biosimilar guidelines. The BPCI Act established an abbreviated approval pathway for biologic products demonstrated to be biosimilar to, or interchangeable with (a higher standard than biosimilar to), the reference biologic drug.

Graeser said brand biologic companies now will take the fight to keep biosimilars off the market to FDA. For instance, she said Abbott Laboratories has filed a citizen petition with FDA asking the agency not to approve biosimilar versions of Humira (adalimumab) (6 LSLR 486, 5/4/12). Humira is a monoclonal antibody treatment for rheumatoid arthritis.

Graeser said brand companies also will try to fight biosimilars in court.

Richard Dolinar, chairman of the Alliance for Safe Biologic Medicines (ASBM), said in a statement that ''patient safety must be the top priority while the FDA creates a pathway for their approval.''

''Because biosimilars are similar to, but not exact copies of the biologic medicines they aim to replicate, it is imperative that patient safety is the cornerstone of the approval process,'' Dolinar said. ''Unlike traditional pharmaceutical drugs that are made from chemicals, biologics are developed from living cells, large and complex molecular mixtures that are not easily replicated. The smallest differences in the structure or manufacturing process could have serious implications for patients.''

ASBM has ''supported the initial steps the FDA has taken to create this framework and will continue to encourage the incorporation of a patient-centered, science-based approach, similar to those taken in the European Union and in Canada'' and ''we are looking forward to additional opportunities to weigh in with the FDA as it formalizes the biosimilar pathway,'' Dolinar said.

Uncertainty Over FDA Guidelines Remains. Deborah L. Lu of Vedder Price PC, New York, told BNA June 28 it is significant that the ruling does not change the provisions in PPACA for the abbreviated pathway for approval of biosimilars. ''There still remains, however, some uncertainty about biosimilars as a result of the Food and Drug Administration guidelines that came out Feb. 12, 2012, and that created more questions than they have answers.''

William J. Simmons of Sughrue Mion PLLC, Washington, said June 28 that there was a twist in the Supreme Court's ruling that was potentially troubling.

''The abbreviated approval pathway is an important component of the PPACA, and there was a concern that the justices would concern themselves with portions of the law that were not before them. Now, the ruling doesn't mention biosimilars, but the justices in dissent made it clear that they felt the mandate portion made the entire statute defective and that it should, as a result, have been struck down. So, we really dodged a bullet,'' Simmons said.

Simmons cited a portion of the dissent:

> The Act before us here exceeds federal power both in mandating the purchase of health insurance and in denying nonconsenting States all Medicaid funding. These parts of the Act are central to its design and operation, and all the Act's other provisions would not have been enacted without them. In our view it must follow that the entire statute is inoperative.

The dissenting justices go on to state, ''For all these reasons, to say that the Individual Mandate merely imposes a tax is not to interpret the statute but to rewrite it.''

Simmons said that these statements reveal the true feelings about PPACA of not just one but four Supreme Court justices. ''I think this poses some room for concern for companies who are interested in exploiting the abbreviated pathway approval for biosimilars. What if other portions of the law are challenged? Will companies who have opposed the PPACA use the dissent? Here you have multiple justices saying that the core of the law is defective and therefore the law should fall. That's a pretty bold statement,'' Simmons said.

''But as of today, the abbreviated pathway for biosimilars is operative,'' Simmons said.

BIO Will Still Work to Repeal IPAB. The Biotechnology Industry Organization (BIO) ''will continue to work with relevant federal and state agencies to ensure implementation of the [health care reform] law in a manner that helps enable the U.S. biotech community's continued development of lifesaving cures and other medical breakthroughs while expanding patient access to these critical cures, medicines and innovations,'' BIO president and CEO Jim Greenwood said June 28 in a statement.

''We will work to ensure that biotech researchers can continue to address the diseases of today while conducting the research and investment required to develop the advanced medicines and cures of tomorrow,'' Greenwood said. ''We also will continue our work with [FDA] to implement the bipartisan-backed biosimilars pathway that was enacted under the law.''

For the biosimilars pathway, Greenwood said, BIO ''will advocate for implementation approaches that ensure patient safety, expand patient access and competition, and provide necessary and fair incentives that will help spur continued biomedical breakthroughs.

''FDA regulations and guidance must help today's patients while enabling the biotech community to move into tomorrow with cures and continued breakthroughs so our children and grandchildren won't have to live with the same diseases we have faced and, perhaps, one

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day, any diseases at all,'' Greenwood said. ''In addition, BIO will continue to support efforts to repeal the Independent Payment Advisory Board (IPAB), which threatens patient access to needed cures and medical breakthroughs.''

IPAB, created under the health reform law, is to begin operating in 2014. In years when Medicare's costs grow faster than target rates, the board's 15 members—appointed by the president and subject to Senate confirmation—are to set program reimbursement policy that would become law unless Congress intervenes. In March, the House approved a repeal of IPAB.

AdvaMed Still Opposes Device Tax. The Advanced Medical Technology Association (AdvaMed) ''supported goals of health care reform consistent with our long-held principles,'' AdvaMed President and CEO Stephen J. Ubl said June 28 in a statement.

Ubl said AdvaMed has ''consistently opposed the $29 billion medical device tax [in the health care law] because of its damaging effects on economic competitiveness, jobs and the research and development needed to find tomorrow's treatments and cures.''

''The House has already voted to repeal the device tax, and we are heartened by the number of senators who have said they oppose the tax,'' Ubl said. ''We will continue to work with policymakers on both sides of the aisle to achieve this goal.''

On June 7, the House voted 270-146 to pass a bill that repeals the 2.3 percent excise tax on medical devices, which was created by the health reform law (6 LSLR 661, 6/15/12). The bill faces an uphill climb toward enactment, with Senate consideration not expected and President Obama standing by the 2010 overhaul of the nation's health care system.

Mark Leahey, president and CEO of the Medical Device Manufacturers Association (MDMA), said the Supreme Court's decision ''adds new urgency to repealing the medical device tax so that patients and providers can continue to expect innovative devices and technologies.''

''While MDMA and our members still have seen no evidence or reports showing any 'windfall' for medical device companies as a result of the PPACA, it is clear that this misguided policy has already led to job losses and cuts to research and development,'' Leahey said. ''If the true goal of health care reform is to reduce costs and to improve patient care, then Congress and the President need to repeal the device tax so America's medical technology innovators can continue to develop cutting edge products. Doing so will be a win-win for patients and jobs.''

BY JOHN T. AQUINO AND BRONWYN MIXTER

The Supreme Court's opinion is at http://www.supremecourt.gov/opinions/11pdf/11-393c3a2.pdf.