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U.S. Supreme Court Upholds Patient Protection and Affordable Care Act Under Taxation Clause in *Nat'l. Fed'n. of Independent Business v. Sebelius*

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In a history-making decision, the Supreme Court today ruled that the Patient Protection and Affordable Care Act (PPACA) is constitutional under the taxation clause of the Constitution. The most controversial provision was the individual mandate or "minimum essential" coverage provision that establishes the requirement that nearly all Americans secure health insurance (26 U.S.C. §5000A).

In an extremely fractured opinion, authored by Chief Justice John G. Roberts Jr., the Court upheld this central component of the PPACA, finding that that a penalty for refusing to buy health insurance amounts to a tax and is therefore within Congressional power to impose. The Court also noted that another key provision of the law, involving existing Medicaid funding from the Federal government to the states, cannot be implemented by withdrawing this funding entirely from states that decide not to participate in a broad expansion of Medicaid eligibility. The ruling comes as a bit of a surprise for many who have been tracking the progression of the case. Following oral arguments on March 26-28, the general feeling was that the PPACA would be substantially modified by the Supreme Court, and since the PPACA lacks a severability clause, the bill in its entirety was at risk of being struck down.

Justice Ruth Bader Ginsburg concurred in part, and was joined by Justice Sonia Sotomayor, and partly joined by Stephen G. Breyer and Elena Kagan. Justice Anthony M. Kennedy dissented, and was joined by Justices Antonin Scalia, Clarence Thomas and Samuel A. Alito Jr.

Receiving far less mainstream news coverage is the ruling's effect on the Biologics Price Competition and Innovation Act (BPCIA), a part of the PPACA which created a new approval pathway in the U.S. for biosimilar products. As a less controversial provision, the BPCIA was

barely acknowledged during oral argument, and none of the Justices today expressed any opinions regarding biologic drugs. Nonetheless, if the Supreme Court would have overturned the entire PPACA, the biosimilars legislation would have gone with it. Biosimilar producers can now move forward with their products without fear of legislative overhaul and disruption of their approval progress. The survival of the BPCIA is welcome news for biologics consumers as well, who hope to see lower prices in the near future on these important drugs.

The opinions in *Nat'l. Fed'n. of Indep. Bus., et al. v. Sebelius, et al.* can be found on the Supreme Court's website (<http://www.supremecourt.gov/opinions/11pdf/11-393c3a2.pdf>).

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