Client Alert.

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Pathway for Follow-on Biologics Survives the Supreme Court

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The Supreme Court of the United States delivered its much-anticipated and historic ruling in *National Federation of Independent Business v. Sebelius* today, holding the major provisions of the Patient Protection and Affordable Care Act (Affordable Care Act) to be constitutional. While much of the public debate and commentary focused on the validity of the individual health insurance mandate, the Affordable Care Act also contains important provisions for the development and regulatory approval of biosimilars. Although these provisions were not challenged, questions of severability placed them in jeopardy along with the whole of the Act. Today's 5-4 Supreme Court decision leaves the Affordable Care Act, including the biosimilars provisions, largely unchanged.

BACKGROUND

Part of the Affordable Care Act—the Biologics Price Competition and Innovation Act (BPCIA)—created a Food and Drug Administration (FDA) approval pathway for "biosimilars," follow-on versions of biopharmaceutical products such as therapeutic proteins and antibodies. The BPCIA permits manufacturers of these follow-on versions to rely on previously disclosed pre-clinical and clinical trial data for the safety and efficacy of the biologic products, so long as the sponsor demonstrates that it (i) is "biosimilar" to a reference product (a different standard than the "bioequivalence" requirement for generic drugs), (ii) uses the same mechanism of action as the reference product, and (iii) is being proposed for previously approved condition(s) of use. In some cases, the FDA may deem a biosimilar product "interchangeable" with the reference product, providing other advantages. The BPCIA also provides a complex framework for resolving patent disputes between sponsors of a biosimilar product and the reference biologic product and resolved long-running disputes by specifying exclusivity periods for reference and certain follow-on biologics.

The main focus of the Affordable Care Act, however, was to change the way Americans purchase private health insurance, access public and private providers, and receive coverage for preexisting conditions, seeking to extend private health care access to 30 million previously uninsured Americans. To this end, the so-called "individual mandate" requires that most Americans maintain minimal essential health insurance coverage or pay a penalty, while the "Medicaid expansion" provision expands the scope of the Medicaid program. Twenty-six states and other parties challenged the constitutionality of these two provisions. The Supreme Court granted certiorari on appeal from an Eleventh Circuit decision, which found the individual mandate unconstitutional.

HOLDING

In a 5-4 decision, the Supreme Court upheld the individual mandate under Congress's power to tax, and placed limits on the Medicaid expansion. Other than limiting the Medicaid expansion, today's decision leaves the Affordable Care Act, including the BPCIA, unchanged.

OUTLOOK FOR BIOSIMILARS

While today's decision leaves the BPCIA intact, uncertainty remains regarding the criteria for biosimilar approval, interchangeability standards, and procedures for patent litigation relating to biosimilars. In February 2012, the FDA issued

three draft guidance documents on biosimilar product development, focusing on scientific and quality considerations in demonstrating biosimilarity of a proposed product and not addressing product interchangeability or litigation particulars. A more complete summary of these documents is in our February 13, 2012 client alert, available here.

The FDA solicited public comments on the draft guidances, receiving greater than 100 written comments and several presentations made during a May 11, 2012 hearing. Among the commenters were major brand and generic drug-makers, universities, members of Congress, foreign governments, and various organizations and advocacy groups. Concerns included the definition of "protein" under the Public Health Services Act, biosimilar naming and labeling requirements, interchangeability standards, trade secret protection, and the ability to rely on data from non-U.S. approved drugs.

The guidance documents remain in draft form and are unaffected by today's decision. Some expect the next direction from the FDA to be in the form of class-specific guidances, with details relevant to approval of particular types of biosimilars, such as therapeutic antibodies.

Meanwhile, in April 2012, Abbott Laboratories filed a citizen petition, requesting that biologics applications submitted to the FDA before enactment of the BPCIA be exempt from the BPCIA, asserting that the FDA's use of information in those biologics applications would constitute a taking of trade secrets and a violation of the Fifth Amendment. (Docket No. FDA-2012-P-0317-0001/CP.) The FDA has not issued a substantive response to Abbott Labs's citizen petition.

While the Court's ruling in *National Federation of Independent Business* leaves the BPCIA unchanged and available as a potential pathway for the approval of follow-on biologics, industry players await further clarity on navigating its various provisions in light of these continued uncertainties.

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