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CLIENT ALERT

Finally—A Regulatory Pathway for Biosimilars in the United States

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Lost in much of the political fanfare surrounding healthcare reform is that, for the first time, a regulatory pathway for the approval of biosimilar medicines was created when President Obama signed healthcare reform legislation into law. While the European Union has had a regulatory pathway for biosimilars since 2006, the United States, which is by far the world's largest potential market for biosimilars, has not--until now.

The Senate Healthcare Reform Bill that was signed by the President this week will be unchanged by any pending House of Representative amendments. The biosimilar regulatory pathway is now law.The biosimilar regulatory pathway is based on the innovator's or "reference product's" prior FDA approval and determination of safety, purity and potency. Biosimilar applications will be reviewed by the same FDA division as the reference product. To be approved, the application must satisfy two standards:

- *Biosimilar*-requires analytics demonstrating that product is "highly similar", preclinical, clinical (including immunogenicity, pharmacokinetics and pharmacodynamics) studies, any of which may be waived by the FDA; and
- *Interchangeability*--meeting above biosimilar requirement *and* (a)"expected to produce same clinical result …in any given patient"; and (b) risk of "safety or diminished efficacy of alternating or switching between use of the [biosimilar] and reference product is not greater than the risk of using the reference product" alone.

Other key features of the new law are

- No biosimilar applicant can file sooner than 4 years after the reference product is first licensed (4.5 if pediatric request);
- 12 years of exclusivity for reference products from "first licensure";
- 1 year of exclusivity after first commercial marketing for first biosimilar applicant;
- Confidential document exchange and good faith negotiation between applicant and reference product patent owners before patent litigation;
- 180 day "Notice of Commercial Marketing" by biosimilar applicant to reference product owner prior to marketing;
- But unlike small molecule generics, there will be no "Orange Book" Listing

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

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