

# 3<sup>rd</sup> International Conference and Exhibition on **Biowaivers, Biologics & Biosimilars**

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## Biosimilars in the United States - Update on FDA implementation and other current issues

James C Shehan

Hyman, Phelps & McNamara, USA

Legislation enacted in 2010 as part of the Affordable Care Act established for the first time in the United States a mechanism for approval of biosimilars. But FDA has not approved any biosimilars under the Biologics Price Competition and Innovation Act (BPCIA) in the four years since it was enacted and many policy and procedural issues remain open. This session will explore the current status of biosimilars at FDA and some of the most significant open issues. Included will be what is currently known about FDA standards on biosimilar approval, the heightened standards for interchangeability, the BPCIA's complex patent litigation process, including recent cases such as Sandoz v. Amgen, the provisions regarding exclusivity for reference products, the ongoing debate regarding how biosimilar products should be named, the state of laws and proposed laws in various US states that limit the ability of pharmacists to substitute biosimilars for reference product, and the transitional provisions that take products such as insulin and human growth hormone that are currently regulated as drugs and make them biologics.

### Biography

James C Shehan advises healthcare clients on issues such as product development, manufacturing, and promotion, and compliance matters such as internal investigations, government investigations and establishing compliance programs. In the pharmaceutical area, he has particular expertise in product lifecycle strategy, including Hatch-Waxman litigation; the emerging field of biosimilar regulation and policy; and orphan drug regulation and exclusivity. He was Novo Nordisk Inc.'s General Counsel and Corporate Vice President of Legal, Government and Quality for 19 years and has also worked at Pfizer and the US FDA. He has an undergraduate degree from Columbia University and a law degree from Georgetown University Law School.

[JShehan@hpm.com](mailto:JShehan@hpm.com)