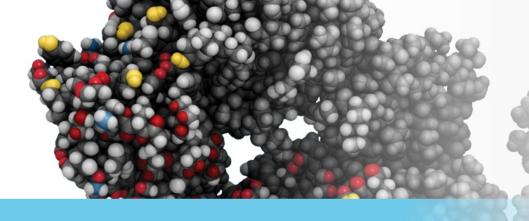
## Morgan Lewis



### **BLOCKBUSTER BIOLOGICS REVIEW ISSUE 14**

# **Legislative Updates**



### **Legislative Updates**

#### > On September 20, 2021, FDA issued two guidance documents:

- > Questions and Answers on Biosimilar Development and the BPCI Act
- > New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 3)
  - > In both documents, FDA states that each provides "answers to common questions from prospective applicants and other interested parties" regarding the BPCIA

Morgan Lewis

### **Legislative Updates**

- > On July 29, 2021, the Senate Judiciary Committee's antitrust panel advanced a biosimilar-related bill
  - > Bill seeks to prohibit biological product manufacturers from compensating biosimilar companies in exchange for the biosimilar company delaying entry into the market

#### **Contacts**



Christopher J. Betti, Ph.D. Chicago T: +1.312.324.1449 christopher.betti@morganlewis.com



Maria E. Doukas Chicago T: +1.312.324.1454 maria.doukas@morganlewis.com



**Kelly A. Plummer, Ph.D.**Chicago
T: +1.312.324.1490
kelly.plummer@morganlewis.com

Morgan Lewis