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Clash Of Titans over Biosimilars at FTC Workshop

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On Tuesday, February 4, the Federal Trade Commission (FTC) conducted an all-day public workshop at its headquarters in Washington, D.C. on competition issues involving biologics and biosimilars.[1] During highly informative presentations and roundtable discussions, the FTC and various stakeholders, including top-level representatives from originators of biologics (Pfizer and Amgen), biosimilars developers (Sandoz, Momenta and Hospira), payors (Aetna), prescribers (CVS and Express Scripts) and academia (Harvard Medical School), analyzed the likely impact of recent state substitution laws and naming conventions on biosimilars.

No one denied nor debated that the future of the drug industry lies in the robust and dynamic area of biologics. In 2010, 4 of the top 10 drugs were biologics and it is anticipated that in 2016 biologics will account for 7 of the top 10 drugs worldwide.[2] At the same time, all panelists were concerned that the costs associated with biologics are rising at a staggering rate and are therefore not sustainable for patients nor payors, and that many patients will be unable to afford biologics if competition is not introduced.

According to Harry Travis, Vice President at Aetna, patients currently spend about $1 a day on non-specialty medication (traditional drugs) whereas they spend roughly $100 a day for specialty medication (biologics).[3] He stated that only 1% of Aetna's customers use specialty products, which account for 50% of Aetna's total drug spending. This trend was confirmed by Steve Miller, Chief Medical Officer at Express Scripts, who underlined that specialty products (biologics) currently account for 30% of total drug spending, but this number will rise to 50% in 5 years.

It is thus not surprising that all participants urged for FDA-approved biosimilars in order to improve access to biologics while at the same time protecting public health and safety. Participants were also virtually unanimous in their recommendations that fostering public confidence in biosimilars will be crucial to their success and that unnecessary obstacles to substitution may restrict competition.[4]

The following points were discussed, relying on a large amount of data and comparative studies between countries:

- **Competition between originators of biologics and biosimilars developers**: Panelists agreed that competition is not expected to have the same effects on the biologics industry as it has had in the small-molecule drugs space when generics penetrated the latter. Because

the dynamics are completely different, the entry of biosimilars is unlikely to result in either steep price discounting or rapid acquisition of market share by manufacturers of biosimilars.[5]

- **Premature state biosimilar substitution laws**: 18 states have already decided to introduce bills to regulate biosimilars, and 4 of them have enacted laws, all of which may seem slightly premature given that the FDA has yet to approve a biosimilar. Certain provisions of these substitution laws appear controversial as they place onerous requirements on the substitution of biosimilars for branded biologics. Of particular concern are certain substitutions laws requiring pharmacists to promptly notify patients and/or prescribers when dispensing a biosimilar, and to keep special records. These state-level restrictions not only deter substitution by imposing on pharmacists burdensome recordkeeping and additional communications with the physician, they also contradict federal law, namely the Biologics Price Competition and Innovation Act (BPCIA), which expressly provides for substitution.[6] These state laws are arguably inconsistent with the BPCIA and could undermine the attractiveness and access to more affordable biologics.

- **Impact of naming on biosimilars**: There was debate as to whether biosimilars should bear different non-proprietary names and whether such a requirement would have anticompetitive effects. Some argued that requiring distinct non-proprietary names is simply an effort to cause doubt and distrust among physicians and patients by making biosimilars appear different from biologics. As noted by Bruce Leicher, General Counsel at Momenta, the Biotechnology Industry Organization opposes GMO labelling on genetically modified foods precisely for the same reason – requiring a different name for biosimilars would communicate a different (and perhaps suspicious) product and would therefore grant a competitive advantage to branded biologics. Other panelists argued that names and other types of identifiers were justified by the need for an effective pharmacovigilance system, while some speakers expressed the need for distinguishable naming or other identifiers for purposes of linking a responsible product to a specific adverse event in the event of product liability.

The FTC did not express its own views on the effect of state-level restrictions and naming conventions on competition in the biosimilars market, but did note that securing more prescribing physicians on the panel might have added to the debate.

We will continue to monitor federal and state activities in the regulation of biosimilars.

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[1] The Food and Drug Administration defines biologics as medical products made from a variety of natural sources (human, animal or microorganism). Moreover, a biological product may be demonstrated to be "biosimilar" if data show that, among other things, the product is "highly similar" to an already-approved biological product.

[2] As presented by Steve Miller, Senior Vice President and Chief Medical Officer at Express Scripts.

[3] More alarming to Mr. Travis is that the cost of biologics increased by approximately 15% annually, as compared to the approximately 5% increase in the cost of small molecule drugs.

[4] Substitution, by allowing the pharmacist to automatically substitute an interchangeable biosimilar for the branded biologic without the intervention of the physician, provides a strong incentive to use biosimilars.

[5] According to Dr. Sumant Ramachandra, Hospira's Senior Vice President and Chief Scientific Officer, it takes approximately $5 million and 2-3 years for a generic manufacturer to bring a small molecule drug to market, whereas it takes over $100 million and 8-10 years for a biosimilar manufacturer to bring a biosimilar to market.

[6] The BPCI provides that "the [interchangeable] biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product."