Draft questions biosimilars hearing 2.4.16

- Provider Education: One of the keys to the adoption of biosimilars is ensuring that providers are adequately educated about the rigorous approval process they face. FDA regularly engages in provider education regarding its stringent product approval standards. Have you begun any of this education on biosimilars? Providers are a key component of ensuring patient access to these more affordable treatments; and therefore, they will be critical in establishing the public's confidence in the burgeoning biosimilars market in the United States.

- Public Education: Generic utilization in the United States has reached 88% since the enactment of the Hatch-Waxman Act in 1984, but it took many years for utilization to reach that level. One of the keys in increasing generic utilization was ensuring that the public, as well as healthcare providers, had confidence in the safety and efficacy of FDA-approved generic drugs. To ensure the widespread use of biosimilars in the United States, it will be vital that healthcare providers and patients have that same confidence in the safety and efficacy of FDA-approved biosimilars. Can you discuss the types of public education efforts that the FDA has and will engage in regarding biosimilars?

- Coordination with CMS: As you mentioned, last fall FDA released its proposed guidance on the non-proprietary naming of biosimilars. In it you specifically noted that you were not addressing future interchangeable biosimilars at this time, and asked for feedback on how to approach those products. Just a few months earlier in July, however, CMS proposed reimbursement policies for biosimilars entering the market without making such a distinction about interchangeable biosimilars, though it did ultimately discuss interchangeables in its final rule. Is FDA communicating with CMS on where the regulatory pathway is on interchangeables? Do you think CMS should be addressing reimbursement for interchangeable products before your agency has developed the approval pathway?

- Coordination with CMS: In addition to the regulatory approval requirements necessary for manufacturers to invest in the development of biosimilars, the other major variable is government reimbursement for biosimilars. In its final 2016 Physician Fee Schedule, addressing biosimilars reimbursement, CMS left a number of questions unanswered, questions which are closely linked to the progress FDA is making on a number of its guidances. Is FDA communicating with CMS on these issues?

- Naming: Dr. Woodcock, biologic medicines are the fastest growing segment of prescription drug spending in the United States. According to projections, this year eight

of the top 10 drugs on the market will be biologics. The average cost of a biologic product is approximately 22 times greater than a traditional drug. I am pleased that the FDA approved the first biosimilar product in the United States just last year. The agency recently released a draft guidance regarding naming that requires a unique name for biosimilars, but does not yet address naming for interchangeable biosimilars. I am concerned that a unique naming requirement for biosimilars will hurt patient access to biosimilars, and in particular would have a detrimental effect on substitution for interchangeable biosimilars. When can we expect a draft guidance from the agency regarding naming for interchangeable biosimilars?

- Naming: Dr. Woodcock, the agency recently released a draft guidance regarding naming that requires a unique name for biosimilars, but does not yet address naming for interchangeable biosimilars. I am concerned that a unique naming requirement for biosimilars will hurt patient access to biosimilars, and in particular would have a detrimental effect on substitution for interchangeable biosimilars. This draft guidance on naming is a departure from what the regulatory authorities in other highly regulated markets have established. It is also counter to what WHO, the establisher of INNs and USP, one of the three establishers of USAN advocates – non-unique naming. Can you explain why you have taken this course given WHO's and USP's positions and the robust track and trace system that the agency is currently implementing under the Drug Quality and Security Act?

- Interchangeability: A great savings potential to patients and payors is when a biosimilar has been designated "interchangeable" with the originator biologic. FDA has yet to release guidance on what evidence companies will be required to present to the Agency to prove they have met the requirements to receive an interchangeable designation for biosimilars. At the same time, companies are making significant advancements in how to analyze biologics with increasing precision, potentially reducing the necessity for expensive clinical trials. As the agency develops that guidance, will you leave room for future advancements in analytical technologies so that these products can be brought to market faster without overly burdensome regulatory requirement? Ensuring that manufacturers have the flexibility to provide the best, most relevant data without unnecessary hurdles is critical to bringing these lower cost products to patients as quickly as possible.

- Labeling: The agency has announced that it expects to release a draft guidance on the framework for labeling biosimilars in 2016. For both biologics and biosimilars, healthcare professionals need access to reliable information in a succinct manner that they can use for every product. That is the basis of current labeling requirements, to provide the information directly relevant to prescribing decisions. As part of the FDA's review process for biosimilars, the agency will determine that the biosimilar has no

clinically meaningful differences in terms of safety and effectiveness from the reference product. If additional labeling were required of the biosimilars, beyond that of the reference protein product, it could lend itself to conclusions that the biosimilars do not possess the same safety and efficacy profiles as their reference protein products. Can you discuss how you plan to approach the labeling guidance?

- Additional Guidances: Dr. Woodcock, recently the agency indicated that you were anticipating several draft guidances to be released this year related to biosimilars, notably on interchangeability, extrapolation, and labeling. Now that the draft guidance on naming has been released, can you tell us when we can expect the additional guidances on interchangeability, extrapolation, and labeling to be released?

- Reimbursement: Deputy Director Cavanaugh, this past fall finalized a payment methodology for biosimilars in Part B that, as I understand it, has been widely criticized by various elements of the healthcare sector as disincentivizing biosimilar development. As finalized, all biosimilars are being grouped into one payment calculation separate from the reference product. Isn't this just protecting the brand from price competition while forcing the biosimilars to cannibalize one another?

- Litigation: Dr. Woodcock, it is our understanding that the courts have been interpreting the notification provisions in the BPCIA to effectively extend brand exclusivity by 6 months. When we wrote the BPCIA we intended brand products to receive 12 years of exclusivity, and not this artificial 12.5 years. Is there anything your agency can do to ensure that we have biosimilars available on the first legally eligible day after exclusivity expires, perhaps tentative approvals as seen with generics?