February 4, 2014

Elizabeth Jex – Afternoon Roadmap

Good afternoon, I am Elizabeth Jex, an Attorney Advisor with the FTC's Office of Policy Planning.

Thank you for staying for our afternoon presentations and panel discussion focused on naming and pharmacovigilance.

Policy makers in the U.S. and internationally are debating whether the existing paradigm for naming medicines should be used for biologics and follow-on biologics, or should be changed. Currently, reference biologic medicines in the United States have at least two names: a proprietary branded trade name, and a non-proprietary name that reflects certain scientific characteristics of the product. Some parties argue that patient safety can best be protected if biosimilars and interchangeables have unique or distinguishable non-proprietary names that differentiate them from the reference biologic's non-proprietary name.

Others contend that unique or distinguishable names could diminish the viability of competition from biosimilars and interchangeables and thereby deter companies from investing in the development of such drugs. They further argue that different types of patient confusion, resulting in possible patient harm, could result from the use of unique or distinguishable names.

These issues intersect with the current pharmacovigilance system in the United States. This system aims to keep track of what medicine a patient receives, so that it can be identified if it has

caused a problem. The choice of what to do about non-proprietary names for biosimilars and interchangeables could affect how incidents involving biosimilars or interchangeables would be reported.

By way of background, the term "pharmacovigilance" is derived from the Greek word "pharmakon," which means drug, and the Latin word "vigilare," which means to keep watch.

Doctors and their patients, pharmacists, and manufacturers keep watch over pharmaceuticals in the U.S. through a voluntary drug safety program overseen by the U.S. FDA. FDA receives some adverse event and medication error reports directly from healthcare professionals (such as physicians, pharmacists, nurses and others) and consumers (such as patients, family members, lawyers and others).

Healthcare professionals and consumers may also report adverse events and/or medication errors to the products' manufacturers. If a manufacturer receives an adverse event report, it is required to send the report to FDA as specified by regulations. The FDA' s Adverse Event Reporting System then collects these reports in a database.

Our speakers this afternoon will describe how non-proprietary names have been used to date for generic drugs and their views on whether unique or distinguishable non-proprietary names should be used for biosimilars and interchangeables. We are looking forward to a lively debate.

Now let me now introduce the speakers who will educate us this afternoon.

To begin, we will hear from **Angela Long** and **Tina Morris,** who will provide further background information on drug naming issues. Angela is Senior Vice President, Global Alliances and Organizational Affairs and Executive Secretariat, Council of Experts for the United States Pharmacopeia. Tina Morris is Vice President, Biologics and Biotechnology in the Global Science and Standards Division at U.S. Pharmacopeia, which she joined in 2003.

Next, **Mark McCamish**, Global Head of Biopharmaceutical Development for Sandoz International, a Division of Novartis, will discuss his company's experience with biosimilars and how naming affects market penetration and customer acceptance in European markets.

Gustavo Grampp will then provide the perspective of a leading reference biologics manufacturer, Amgen, on naming issues. Gustavo is a Director of R&D Policy at Amgen.

Next, **Sumant Ramachandra**, Senior Vice President and Chief Scientific Officer for Hospira, will discuss naming issues and the worldwide development of the biosimilar market. Hospira is a leading provider of injectable drugs and infusion technologies.

Helen Hartman will follow with a case study of adverse event reporting. Helen is Director, Worldwide Regulatory Strategy, at Pfizer.

Next, **Emily Alexander** will discuss the views of Abbvie, a reference biologic producer formed in 2013 after its spin-off from Abbott. Emily is the Director of U.S. Regulatory Affairs in the Biologics Strategic Development Group at AbbVie.

We will then hear from **Alan Lotvin**, who is Executive Vice President of Specialty Pharmacy for CVS Caremark. Alan will discuss whether the pharmacovigilance system, rather than the naming system, needs to be modernized and strengthened to protect consumers.

Finally, **Harry Travis** will offer the perspective of a private insurer on the growth of specialty pharmaceuticals and naming issues. Harry is Vice President and General Manager for Aetna Specialty and Home Delivery Pharmacy.

We will then have a 10-minute break, which will be followed by **a one-hour moderated, panel discussion of naming issues and pharmacovigilance.** To introduce that panel, we will have a brief presentation by **Neal Hannan**, who recently joined the FTC's Office of Policy Planning from the law firm of Boies, Schiller & Flexner, where he was an intellectual property litigator.

Following that panel, the Director of the Office of Policy Planning, **Andy Gavil** will share concluding remarks. Andy is on leave from his position on the faculty of Howard Law School. He is a leading scholar in antitrust who has written and spoken extensively in the U.S. and abroad on antitrust law and policy.