Feb. 4, 2014

Susan DeSanti – Morning Roadmap

Good morning. I'm Susan DeSanti, formerly Director of the Office of Policy Planning and now an attorney with the FTC's office in San Francisco.

Today we're here to discuss policy issues involving biologic medicines and their potential substitutes. Biologics comprise the fastest-growing sector within pharmaceuticals; they target a variety of serious diseases, such as cancer, diabetes, and multiple sclerosis; and they are generally very expensive, with the cost of one year of treatment typically ranging from $50,000 to $250,000.

Health care purchasers and consumers, not surprisingly, are interested in whether and, if so, when FDA-approved biosimilars or interchangeables could be automatically substituted for biologics, just as generic drugs can be automatically substituted for brand-name drugs in certain circumstances, saving literally billions of dollars for U.S. purchasers and consumers over the thirty years since the Hatch-Waxman Act was passed. Although the market dynamics for biologics, biosimilars, and interchangeables is likely to differ from that for generics and brand-name drugs, with lower discounts than for generic drugs, it appears that significant savings from competition could still be achieved.

As Chairwoman Ramirez pointed out, Congress passed legislation that permits certain FDA-approved biosimilars – those that the FDA finds to be "interchangeable" with a given biologic -- to be substituted without any intervention by a physician – that is to say, "automatically substituted."

This type of "automatic substitution" happens thousands of times every day with FDA-approved generic drugs, **but that is in part because state laws permit automatic substitution of FDA-approved therapeutically equivalent generics,** unless a physician writes the brand name on a prescription and specifies "dispense as written."

Our first topic involves whether state substitution laws for biologics should operate in a similar manner. First, we need to note that federal law describes two types of "follow-on biologics."

One is biosimilars. By statute, FDA must determine that biosimilars are "highly similar" to the original biologic. Nonetheless, biosimilars require a separate prescription; they cannot be automatically substituted for a biologic.

Second, there are interchangeables, which **can** be automatically substituted for a biologic. Federal law has more stringent requirements for a medicine to be approved as interchangeable.

Currently, in the United States, the FDA has not yet approved either a biosimilar or an interchangeable, and indeed has so far provided draft guidelines only for biosimilars. Nonetheless, some states have started developing laws that will apply to the substitution of both biosimilars and interchangeables for reference biologics.

This morning, we will discuss whether it makes sense to develop those laws now and, if so, what, if anything, they should say to maximize competition and protect patient safety.

Now let me move to some introductions. As Chairwoman Ramirez said, we are grateful to our accomplished speakers for their time and effort in preparing for and attending this workshop. I encourage all of you to read their very impressive bios, which we have distributed.

Because we have a jam-packed schedule, we decided to do all of the introductions of our panelists at the beginning of the morning and the beginning of the afternoon, so that we reduce the time in transition from one speaker to the next. We ask that, when one speaker finishes, the next speaker should simply come up to the podium.

As I give very brief introductions for our morning presenters and panelists, you can follow along on the agenda to see the topics they will address. I ask the speakers' forgiveness, because I am planning to omit their many advanced degrees and focus on their current jobs.

Aaron Kesselheim will help us understand the statutory and scientific framework for the evaluation of follow-on biologics as compared to generic drugs. Aaron is an Assistant Professor of Medicine at Harvard Medical School, a faculty member in the Department of Medicine in Brigham and Women's Hospital in Boston, and a primary care physician at that hospital.

Then **Emily Shacter** will speak about FDA practice related to biosimilars. Emily regulated therapeutic proteins at the FDA for 18 years, serving most recently as the Chief of the Laboratory of Biochemistry in CDER's Division of Therapeutic Proteins in the Office of Biotechnology Products. She now works as an independent consultant.

Next, **Leigh Purvis** will bring a consumer perspective to the issues around biosimilars. Leigh is Senior Strategic Policy Advisor with AARP's Public Policy Institute, where her work focuses on prescription drug pricing, biologic medicines, and prescription drug coverage under Medicare.

Following Leigh, we will hear about the current marketing of follow-on biologics in the U.S. and Europe from **Ronny Gal**. Ronny is the Senior Research Analyst covering the specialty pharmaceutical industry at Sanford C. Bernstein, which provides research for institutional clients.

We will then have a 10-minute break. And perhaps I should emphasize that we will start precisely at the end of each break, so that we don't get behind on our schedule.

After the break, **Jessica Mazer** will provide us with an introduction to state laws related to biosimilar substitution. Jessica is the Assistant Vice President of State Affairs for the Pharmaceutical Care Management Association, which represents prescription benefit managers, known as PBMs.

Following Jessica, **Geoffrey Eich** will give the perspective of a reference biologics manufacturer on state substitution laws. Geoff is the Executive Director of R &D Policy at Amgen.

Next, **Steven Miller** will speak from the perspective of a PBM that administers prescription drug benefits. Steve is Senior Vice President and Chief Medical Officer for Express Scripts.

Bruce Leicher will then provide the perspective of a biotech company, Momenta Pharmaceuticals, Inc., which seeks to develop interchangeable biologics, among other things. Bruce is Senior Vice President and General Counsel at Momenta.

We will then have another 10-minute break.

Following the break, we will have **a one-hour moderated, panel discussion of state substitution laws.** All of our morning speakers will join us on that panel, as well as some other representatives, who I will now introduce, some of whom will also speak in the afternoon.

Bruce Lott is Vice President of State Government Relations for Mylan, a leading generic and specialty pharmaceutical company.

Mark McCamish is the Global Head of Biopharmaceutical Development for Sandoz International, a Division of Novartis.

Sumant Ramachandra is Senior Vice President and Chief Scientific Officer of Hospira, Inc.

Marissa Schlaifer joined CVS Caremark as Head of Policy in April 2013. She is a pharmacist with experience in both the managed care and community pharmacy segments, as well as leadership positions in other organizations.

Krystalyn Weaver is a pharmacist and serves as Director of Policy and State Relations at the National Alliance of State Pharmacy Associations.

After that panel, we have **one hour for lunch**, and you are on your own for that. There are a variety of sandwich shops and delis nearby, and FTC staff will be happy to point you in the right

direction to find a quick lunch. You should feel free to bring your lunch back here and eat in this room.

I will introduce our first speaker after lunch, **Elizabeth Jex,** so she does not have to introduce herself. She will give you a brief introduction to the naming topics that are the focus of the afternoon. **Elizabeth** has more than 20 years of experience investigating pharmaceutical, biotech, and medical device mergers, acquisitions, and intellectual property licensing arrangements. Her work on the FTC's 2009 *Follow-On Biologic Drug Report* won her one of the agency's top awards.

Now, please welcome our first speaker, Aaron Kesselheim.