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patient safety for the decrease in the cost of care, because in the long run, the cost of care will actually be increased if we make the wrong decision."

Added Rep. Michael C. Burgess (R-Tex.), a physician and also the chairman of the congressional Health Care Caucus, at the July press conference: "Can you really go through an abbreviated process with a drug that is just simply similar to the complex biologic that has already been introduced?"

"My concern as a physician, first, always comes back to safety," he said.

The Next Steps

To resolve these terms, and to figure out a pathway for biogeneric approval, the FDA has formed the Biosimilar Implementation Committee and placed at its head Dr. Janet Woodcock, who is also director of the Center for Drug Evaluation and Research. The new center will hold public meetings to solicit comment from stakeholders, experts, innovators, patients, and the public on some of the concerns surrounding biosimilar approval, according to Dr. Woodcock in a recent press release.

Mr. Johnston said that he expects a meeting to be held sometime by the end of 2010. However, the details remain vague. FDA spokesperson Karen Mahoney could not confirm that any meeting had been scheduled, and would not give any information on when physicians and patients could expect to see the first approvals of generic biologics.

"There are so many factors that will impact when biosimilar products will enter the market," added Ms. Mahoney. "Therefore, it is not reasonable to speculate."

Added Rep. Burgess: "This is a difficult concept, and it does involve a lot of moving parts, and a lot of different contingencies. "For your average member of Congress—or even for your member of Congress with some background in health—it does become difficult to think about these things," he added.

Dr. Kolba, meanwhile, offered some ideas about how to move forward—without generics.

"If the companies currently manufacturing biologic drugs and selling them at huge profits (having made back their research and development costs years ago) are truly concerned about the potential harm of generic biologics [to their market share,] they can simply decrease their prices to costs plus 10%. This would decrease the overall cost of the drugs by about 65%," she said.

"At the new prices, generic drug makers will no longer be willing to enter the market, there will be no expensive lawsuits or advertising to pay for, and the 1% of the population with rheumatoid arthritis and other TNF [tumor necrosis factor]-driven diseases will be assured of safe and effective drugs."

Dr. Kolba disclosed being a past consultant or speaker for the pharmaceutical companies Abbott, Amgen, Bristol-Myers Squibb, Genentech, and UCB. She is currently a principal investigator in clinical trials sponsored by Abbott, Amgen, Lilly, Pfizer, Sanofi-Aventis, and UCB. Dr. Craig Kessler has also disclosed consulting for and receiving research support from pharmaceutical companies including Amgen, Eisai, GlaxoSmithKline, and Sanofi-Aventis. ■

To view an online version of the July 19 press conference featuring Dr. Kessler, Dr. Matthews, and Congressman Burgess, visit http://health.burgess.house.gov/Blog/?postid=198224.

To view the entire text of the Biologics Price Competition and Innovation Act of 2009, visit www.fda.gov/downloads/ Drugs/Guidance ComplianceRegulatoryInformation/UCM216146.pdf.

Hybrid Foot Plating Works for Arthrodesis

FROM THE ANNUAL MEETING OF THE AMERICAN ORTHOPAEDIC FOOT AND ANKLE SOCIETY

NATIONAL HARBOR, MD. — Hybrid plating for midfoot arthrodesis offers a high union rate, according to a review.

About three-fourths of patients (76%) had radiographic union by 9 weeks. An additional 15% had union by 12 weeks, and 4% had union by 16 weeks. Only four patients did not achieve union, Dr. Jorge Filippi Nussbaum reported. Most patients (82%) had no complications. In all, 5% of patients had wound dehiscence, 5% had neuropraxia, 2.5% had hardware irritation, 4% had screw breakage, and 2.5% had tendon adhesion, said Dr. Nussbaum.

The researchers conducted a retrospective, multicenter study of patients who had undergone multijoint tarsometatarsal fusion. This technique was used in 78 patients: 60% with primary osteoarthritis, 21% with posttraumatic osteoarthritis, and the remainder with instability and OA, nonunion, Paget's disease, or metatarsus adductus. A plate—flat or curved, depending on the dorsal surface—was aligned, and locking and compression screws were placed, said Dr. Nussbaum, an orthopedic surgeon at Pontifical Catholic University of Chile in Santiago. ■

—**Kerri Wachter**

Disclosures: *Dr. Nussbaum reported that he has no relevant financial relationships.*