OREGON DOCTORS AND PATIENT RATIONALE AND SUPPORT FOR PRESCRIBER COMMUNICATION

"[Urologists] often prescribe biological products. Knowing exactly what product our patients are taking – especially with biologics which are much more susceptible to varying degrees of success depending on the individual patient (this is not as true for generic drugs) – ***is essential to providing high quality, cost effective care both in the short and long-term***."

AMERICAN COLLEGE OF RHEUMATOLOGY
EDUCATION • TREATMENT • RESEARCH

"Like with innovative biologic products, predicting how a patient will respond to a biosimilar or interchangeable biologic may be challenging. Safety is a critical concern with any of these products that directly impact the immune response in a patient. It is possible that small variations from the original biologic may result in an immune response or other potentially serious side effect, which could result in emergency room visits or hospitalizations."

American Association of Clinical Endocrinologists
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"Given the importance of the specific needs of each individual patient and the distinct differences between biologics and biosimilars, we believe that communication between pharmacists and physicians is crucial to ensure that patients are receiving the best treatment as prescribed by their physician."

American Academy of Dermatology
Excellence in Dermatology™

"Due to this variability, a patient's response to a biosimilar may not always mirror the response to the reference drug. Even minor changes in the manufacturing process can significantly affect the efficacy of the biosimilar. For these reasons, patient substitution decisions for biosimilars should be carefully considered and should include a physician's medical judgment. "

"[The] complexity and variability of treatment paradigms using biologics will be of continuing concern to prescribers serving American Indian and Alaska Native, African American, Asian American, Pacific Islanders and Hispanic patients. * * * It is to this end, that both physicians and patients must be aware of which complex biological product has been dispensed."

"[Patient] safety and transparency on information on variations or changes made in treatment plans far outweigh the concerns that may exist about timing and opportunity for proper notification."

"Notification and record keeping will be very important once biosimilars are available because it will ensure accurate patient records are maintained and allow for accurate attribution of any adverse events that may occur." ***American Academy of Facial Plastic & Reconstructive Surgery; American Association of Neurological Surgeons; American College of Mohs Surgery; American Gastroenterological Association; American Society of Cataract and Refractive Surgery; American Society of Echocardiography; American Society of Plastic Surgeons; American Urological Association; Coalition of State Rheumatology Organizations; Congress of Neurological Surgeons; North American Spine Society; Society for Cardiovascular Angiography and Interventions; Society for Excellence in Eyecare***

"[W]e must insist that patient safety remain the most important concern and request all legislation on biosimilars allow physicians to quickly know what medicine their patient receives and if a patient's biologic medicine is substituted."

“Given the importance of the specific needs of each individual patient and the distinct differences between biologics and biosimilars, we believe that communications between pharmacists and physicians is crucial to patient care to ensure that patients are receiving the best care as prescribed by their physicians.”

“[It] is essential that both the prescribing physician and patient know what is dispensed, ideally at the time of dispensing. This will ensure patient safety and the ability of the prescribing physician to manage any possible reaction. “

”Prescribers should feel confident that if the pharmacist substitutes the biologic for an interchangeable product that they will be notified and able to record the substitution in the patient’s medical record. Prescriber notification paired with pharmacy record keeping is important to patient safety and tracking of adverse events. A patient experiencing an adverse reaction may not realize it is their medication that caused their symptoms and is more likely to contact their practitioner with concerns than their pharmacist. A practitioner should have at his or her fingertips a list of medications prescribed to the patient in order to more quickly diagnose, treat, and report the event.”

“Substitution without the knowledge of the health care provider would . . . weaken the tracking, reporting, and surveillance system for adverse events for both biologics and biosimilars.”

“We need our pharmacists and physicians to work collaboratively in order to ensure that patients are receiving the medicines intended, and more importantly, to help quickly pinpoint potential causes of adverse events if they occur when there has been a substitution. Our doctors must be able to follow our situations and be able to chart out whether our health is either improving or declining health based on any particular drug we are receiving.”

CROHN'S & COLITIS FOUNDATION OF AMERICA

“Failure to incorporate proper prescriber communication when biologics are substituted for biosimilars, may increase the likelihood for medication errors and compromise patient safety through adverse drug events.

American Autoimmune Related Diseases Association, Inc.

“[The] concern that notification would impede a patient’s access to medication is not justified as most biologics are delivered via shipping to patients through specialty pharmacies as opposed to traditional medications that are purchased at a patient’s local pharmacy.”

COLON CANCER ALLIANCE

“Regulation has to ensure appropriate communication between pharmacists and physicians so a “shared awareness for the exact medicine being taken exists, a practice that is especially important when it involves biologics. “

Kidney Cancer Association
www.KidneyCancer.org

“Regulation has to ensure appropriate communication between pharmacists and physicians so a shared awareness for the exact medicine being taken exists, a practice that is especially important when it involves biologics.”

Immune Deficiency Foundation

“Patients should not be changed to a biosimilar immunoglobulin product, which they may not tolerate as well as the product on which they are already stabilized, without consultation from their provider.”

International Myeloma Foundation

“Even though interchangeable biologics may produce the same clinical result, there is still a risk that the patient could have a negative reaction to the change and having the primary provider in the loop from the start, will help to ensure quick and appropriate treatment to unintended consequences.”

“Substituting a biosimilar for a biologic, though, is substantially different than substituting a generic drug for the original chemical compound.”

“Inclusion of a mechanism for communication between physicians and pharmacists would help ensure positive patient outcomes and accelerate the savings that interchangeable biological products will produce.”

“The only way to make sure that this new era of biosimilars is safe for patients is to make sure that pharmacists keep doctors in the loop on what they have actually given to a patient.”

"The National Patient Advocate Foundation believes that patients should have appropriate access to innovative medications and therapies, including biosimilar medications that have been approved by the U.S. Food and Drug Administration. In order for those mechanisms to work, however, patients and their providers need to know exactly how a given treatment is conducted and managed."

"Communication between pharmacists and physicians enhance the safety and efficacy of biologic products, while also advancing more treatment options to patients." ***American Academy of Dermatology, American Autoimmune Related Diseases Association (AARDA), Association of Clinical Research Organizations, Colon Cancer Alliance, Global Colon Cancer Association, Global Healthy Living Foundation, Health HIV, International Cancer Advocacy Network, Kidney Cancer Association, National Hispanic Medical Association, National Psoriasis Foundation, ZeroCancer.***

"[It] it is in the interest of public health to be advised of which biologic is being administered as it will facilitate attribution to the proper product for adverse event reporting."

"[The communication] requirement will facilitate treating patients, tracking of adverse events, and the accurate keeping of patient medical records. PhRMA believes that this provision places patient safety first, affirms the decision-making authority of prescribers, and requires that proper safeguards are in place for future reference to the patient's medical record."