OREGON DOCTORS AND PATIENT SUPPORT FOR PRESCRIBER COMMUNICATION

"Patients on biological products (whether brand or a biosimilar) are typically being treated for chronic illnesses that require active and ongoing care management. Knowing exactly what product they are on is essential to providing high quality, cost effective care both in the short and long term. We believe the burden to notify providers to be manageable for pharmacists. Only a small number of biological products are expected to be approved in the next few years that will require notification, and for the most part, these products are dispensed by pharmacists in places that have the capability and/or resources to easily provide this communication back to the treating provider."

"Physicians and patients should be notified in any case when a biologic medication is replaced by a biosimilar treatment. This is important for a number of reasons. First, this gives a physician the opportunity to review the change and approve or deny the decision. Secondly, swiftly notifying patients whose medication is being substituted places them in a safer circumstance. This is not an unreasonable request and it presents an opportunity for providers and distributors to work together for the good of their patients. Health care decisions are extremely important and notification of treatment changes needs to occur in the quickest possible manner. Our main goal as medical professionals should be to ensure that a patient remains safe and informed. This is a logical extension of other efforts to maintain a clear and comprehensive medical record for those undergoing treatment to guarantee they receive high quality care."

"SB 147 will help promote patient safety by simply requiring pharmacists to notify a patient's physician if a biosimiliar is used to fill a prescription for an 'innovator' biologic. Physician notification is crucial when dealing with biosimilars as patients on this type of medication are often being treated for chronic illness. The physician is going to have a deeper understanding of the patient's medical history and can determine if a biosimilar is the best choice for their patient, or if the original prescription should be filled."

Oregon
Rheumatology
Alliance

"[Biosimilars] are intended to work as well as their biologic counterparts. However, they are not carbon copies and if a prescription is switched from a biologic to a biosimilar, a patient has a right to know. The FDA has only recently begun approving biosimilar medications, and we need to make sure that a patient's physician knows when a pharmacist alters their prescription during the dispensing process."

ODS
Oregon Dermatology Society

"Amending the legislation to require pharmacists to notify a physician by the time of dispensing ensures that a physician's medical judgment is involved in the patient's care. The prescribing physician who has a thorough knowledge of the patient's medical history could identify potential adverse outcomes among multiple biosimilar medications before the medication is dispensed to the patient. Further, concerns raised that notification by the time of dispensing would impede access or increase the administrative burden on the pharmacy are not justified, as most biologics are delivered via shipping to patients through specialty pharmacies and are not picked up at the pharmacy in the same way as more traditional medications."

BASIC RIGHTS OREGON

"Biologics are different than conventional medications. Because they are made from living cells, it is impossible to create an exact duplicate of any individual biologic drug. In short, biosimilars are not a generic version of the original treatment and as such, a patient may react differently to a biosimilar than a biologic. Sometimes those reactions may be adverse, and that is why it is critical that a physician know exactly what drug their patient has been given. This is sound healthcare practice and SB 147 simply ensures that this practice will continue."

SHOCK
SHERIE HILDRETH OVARIAN CANCER FOUNDATION

"In the event that a patient's prescription is switched to a biosimilar medication, that patient has the right to know of this change. Moreover, this information should be provided quickly and before the patient begins taking the biosimilar treatment. This notification system will provide a smooth process that guarantees that distributors and providers are working together for the patient's health and well being. It is important to emphasize that changes in a patient's treatment need to be clearly relayed to the patient to support safety and awareness when making decisions about healthcare. When a change is made, it should be required that the patient is informed in an immediate and timely manner. This way, in the off chance that a patient has a bad reaction, knowing this information could make a serious difference."

"With SB 147, Oregon has a unique opportunity to set a safe standard and promote medical transparency and patient consideration. Innovations with biological medicines known as biologics have revolutionized treatments of many diseases such as cancer, arthritis, MS, colitis and much more. Additionally, these medications have the potential to treat HIV/AIDS in an unprecedented manner. The advent of biosimilars will enhance the accessibility of these drugs for millions of patients. But the distinctions between biologics and biosimilars are notable, and such distinctions need to be reflected in the way these different drugs are dispensed."

"These medications have the potential to treat HIV/AIDS in an unprecedented manner, not to mention countless other diseases for which these medicines hold promise. However, a new version of these medications is becoming available, known as biosimilars and while these variations are intended to have interchangeable treatment outcomes, they are not exact replicas of biologics and should not be treated as such."

Oregon AIDS Memorial

"Biosimilar treatments are pharmaceuticals formulated to achieve the same goals as their biologic counterparts. However, they are not direct replicas. While we are excited that biologics have been heralded as the next generation of tools to fight HIV/AIDS, the differences between biologics and biosimilars must be acknowledged. We are hopeful regarding biosimilars, but believe that physicians must be informed when a patient's prescription is changed from a biologic to a biosimilar. This is common sense and it is smart policy to keep patients informed to avoid confusion and keep patients safe in the event of a bad reaction."

"If biosimilar substitution occurs, patients want their physicians guiding the process. It's possible that a biosimilar will have zero side effects and work extremely well. However, in the event that a negative reaction occurs, it is common sense for physicians to be aware that a change was made in the pharmacy. Above all, Senate Bill 147 is an opportunity to promote patient safety and policies to ensure that comprehensive medical records are up to date. Given the complexity of these new medications, we need reasonable laws to keep patients and physicians aware of the entire health care process. I hope you will support Senate Bill 147, as all Oregonians will benefit from legislation that upholds transparency and communication in medical practice."

William D. Noonan, M.D.
Partner, Klarquist Sparkman

"As a medical doctor, I also know how important communication is to patient safety. Although affordable medical treatment is an important goal, it must always be coupled with efforts to maintain the safety of patients. Clinical caution is particularly important when working with relatively new technologies, such as biologic treatments. Consequently, I support Senate Bill 147 to ensure that biosimilar treatments that have been approved by the FDA should not be substituted without physician notification."

Dr. Tanja Pejovic
Gynecologic Oncologist, Oregon Health and Science University

"Physicians should be notified in a prompt manner if a pharmacist wishes to substitute a biosimilar when a biologic has been used in previous circumstances. SB 147 will make this a legal requirement and will promote clear and considerate communication between patients, pharmacists, and physicians. This type of cohesive treatment is necessary for effective health care and it can be upheld through wise legislation."

Diane F. Whitney, M.D.
Retired Psychiatrist

"I have always believed that physicians and pharmacists must work together to determine the best treatment available for patients. Moreover, I believe this type of collaboration is particularly important when prescribing new medicines, such as biosimilar medicines. These treatments hold great promise in the fight against diseases such as Multiple Sclerosis and this is tremendously important to me, as I have had a number of patients with MS, as well as a family member. However, biosimilars and biologics are not precisely the same in their composition and we must make sure that physicians are aware of any changes in a prescription. Biosimilar medicines have been developed to replicate the positive aspects and effects of the biologic medications they are fashioned after. However, they are not precise duplicates and a pharmacist should be required to notify a physician if they decide to substitute a biosimilar for a biologic. Senate Bill 147 would require this notification process when a substitution occurs, providing clear, honest communication through all stages of the medical treatment process."

Raymond Johnson
Cancer Support Group Facilitator

"I run a Caregiver Support Group for Men in Eugene and I must frequently witness the pain a person experiences as a result of their sickness, not to mention the additional burden of unintended side effects. Having seen how badly some patients react to treatments, I believe a patient must always be aware of what he or she is being treated with. The FDA has just begun approving biosimilar medicines, which are meant to have the same effect as biologic innovator drugs, but are not exact carbon copies. Thus, it is important that we preserve clarity and make sure that patients know when they are prescribed these medications in place of biologic drugs."

Elizabeth Cochran
Colitis Patient

"When I was in the hospital this past summer, my doctors knew exactly the drugs that I was on and therefore were able to consider that drug's role in my health crisis. SB 147 will help ensure that all physicians have that type of information for their patients who are on biologics. Biosimilars are not generic versions of the original biologic and therefore have the potential to impact a patient like myself in different ways. With the passage of SB 147, we can be assured that the medical team has the right information on patient treatments so that they can make the best health decisions for that patient."

David Paul
Dermatitis Patient

"Biologics are complex, new treatments that have proven incredibly effective in tackling other diseases including many diseases of the skin. I can speak for myself and others I know with this disease, that the availability of new, more impactful treatments would be a welcome development. I am also aware that biologic drugs and biosimilars sometimes have severe consequences for patients. SB 147 is an important bill for exactly this reason. These types of drugs impact individuals differently and it is important to remember that biosimilars are not identical 'generic' copies of the original biologic drug, and while they may be interchangeable treatments, they may also have different effects for each patient. It is scary to imagine a situation where a physician is left unaware regarding patient treatment. If a patient were to experience harmful side-effects it could be incredibly difficult to determine the cause and for this reason I believe we need to require physicians to be informed of any alteration in a prescription as a result of a biosimilar swap out."

Lina Bjerke
Pharmacist

"I am the lead pharmacist at a Walgreens. Every day, I work with patients and their health care teams to dispense prescriptions and engage with physicians and patients alike on treatment options. I understand the importance of everyone involved in patient care being on the same page, and I cannot emphasize enough the need for communication and coordination. Pharmacists, just like physicians, all have the same goal: to provide the best and safest quality care for their patients. I often contact doctors' offices to ensure that patients are getting the right treatment option, and as access to biologics and biosimilars expands, I fully expect that this part of my job will continue. At this juncture, biologics dispensed at the pharmacy level are limited, and it will not be a burden for me or for the other pharmacists at my Walgreens to communicate with prescribers when a substitution is made.

Pharmacists are trained to recognize the subtle differences between types of drugs that are used to treat the same diseases or illnesses, and biologics and biosimilars will not be any different in that respect. Biologics and biosimilars are highly similar, but they are not identical. We know these differences can cause patients to react differently; therefore, communication between our pharmacists and our patients' doctors is even more critical."

Alyce Jantzen
Coordinate of the Rheumatoid Arthritis Support Group of Central Oregon

"As a longtime advocate of innovative treatments, I believe we must do everything in our power to promote new medicines in Oregon, but it must be done through a safe and considerate approach. In regards to biosimilars, we have an excellent opportunity before us to support a sensible framework for handling these new treatments by passing Senate Bill 147. This legislation is a logical extension of how good medicine is practiced and simply requires pharmacists to inform patients if they switch their generic biologic treatment to a biosimilar treatment."

"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."

"Because biologics are manufactured in living organisms, biosimilars are not exact replications of their reference biologic products. 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. The treating physician must know of a biosimilar substitution in order to appropriately assess the patient's experience and further treatment options. For these reasons, patient substitution decisions for biosimilars should be carefully considered and should include a physician's medical judgment."

"Since 2012, different versions of substitution legislation have dropped in numerous states. Late last year, GPhA agreed to support compompromise automatic substitution legislation put forth by several GPhA members because it reflects our core principles by upholding the current pharmacy practice of automatic substitution; insisting on the science-based FDA determination of interchangeability; and the most important part of the legislation, treating interchangeables and their corresponding brand biologics the same during dispensing. SB 147 contains these principles."

"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."

"As medical innovation continues to evolve, policies at the state level must be reevaluated to ensure that patient safety is prioritized. Furthermore, as legislative proposals and rules on biosimilars advance throughout the U.S., we encourage state legislators and regulators to incorporate strong language requiring active pharmacist-prescriber communication…However, the therapeutic results and side effects of biologics vary based on genetics within and across ethnic groups. Therefore, it is critical for prescribing physicians to know which biologic has been dispensed to support patient care. This is especially relevant to retail-dispensed biological products, where a pharmacist and physician may not normally communicate about a patient's medical history. Communication supports prescriber knowledge of the dispensed biologic: be it the innovator, biosimilar or an interchangeable biological product…[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."

"As you can imagine, patients undergoing treatment to fight cancer can be on a variety of both biologic products as well as pharmacological products. In today's health care delivery system patients need to be more actively engaged in their treatments, but can only be as effective as the information provided to them by the providers who are caring for them…Dispensing a biosimilar without the knowledge of the prescriber and patient could jeopardize patient safety. In addition, we are very concerned that allowing that action to occur without notification implies that the risks associated with biosimilars are minor, when they are not…Given the complexity of treatments for cancer patients, these minor differences could result in significant complications that would not be readily understood if both the patient and the prescriber are left uninformed of the biosimilar substitution."

"Importantly, SB 147 addresses key policy issues to ensure patient safety is preserved, including physician authority to prevent substitutions and ensuring that once biosimilars come to market the treating physician is notified if another version of the biologic medicine is substituted for the version prescribed by the doctor."

The Alliance of Specialty Medicine (Alliance) is a coalition of national medical specialty societies representing more than 100,000 physicians and surgeons which include: ***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 communication 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. "

"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."

"According to the legislation, Oregon pharmacists will be required to communicate—to a patient's prescribing physician—any and all dispensations of a substitute biosimilar for a biologic drug. NKF supports the expanded access that biosimilars will offer for patients, and as biosimilars enter the market, the substitution of a biosimilar must include communication between the pharmacist and the prescriber to ensure patient safety."

"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."

"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."

"Autoimmune patients by nature of their disease have a higher level of immune response than normal, which puts them at a higher risk for reacting to any change. For these reasons, patient substitution decisions for biosimilars should be carefully considered and should include their physician's medical judgment.

A proposal that requires physician communication of the substitution at the time of dispensing will ensure patient safety. Further, communication will ensure that both patients and prescribers know exactly what was dispensed to their patient. Having precise and adequate information on what medicines are dispensed is essential for patient safety."

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"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."

"Let me make it clear that HealthHIV welcomes the emergence of biosimilars. Biologic therapies have brought tremendous, life-strengthening benefits to the HIV/AIDS community, and biosimilars offer the promise of greater affordability. Substituting a biosimilar for a biologic, though, is substantially different than substituting a generic drug for the original chemical compound. Chemicals can be reproduced with exactness. Biologic material cannot, and those differences can have a significant impact on a patient's health."

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. This is a best practice and not much different than the process pharmacists practice today to ensure that patients are receiving the medicines that will serve them most effectively when they fill their prescriptions…Ultimately, open communication will serve to increase confidence in interchangeable biologicals among patients, physicians and pharmacists and enhance the acceptance of these important medicines."

GLOBAL HEALTHY LIVING FOUNDATION
YOUR HEALTH. YOUR HAPPINESS.

"If it is determined by the doctor and patient that an interchangeable biosimilar can be substituted for a biologic, or is the preferred treatment, it is obvious to healthcare providers, patients and, we think, the majority of legislators, that proper record keeping be in place in order to track any adverse events that may occur. As patient advocates, it is our duty to ensure that physicians are in charge of the drugs prescribed and that are both aware of what drugs they are taking. Patients and physicians are the primary individuals who report any adverse events that occur while on therapy. Adverse events can only be reported accurately if patients and physicians have received proper communication from a pharmacist about what medication has been dispensed. Patient safety is the top priority in the health care process and medical decisions must remain between a doctor and patient."

THE cholangiocarcinoma FOUNDATION

"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."

SafeBiologics
ALLIANCE for SAFE BIOLOGIC MEDICINES

"Communication between pharmacists and physicians enhances the safety and efficacy of biologic products while also advancing more treatment options to patients."

Alliance for Safe Biologic Medicines is an organization of patients, physicians, pharmacists, biotechnology companies that develop innovative and biosimilar medicines and others, who are working together to ensure patient safety is at the forefront of the biosimilars policy discussion.

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.

"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. This is a best practice and not much different than the process pharmacists practice today to ensure that patients are receiving the medicines that will serve them most effectively when they fill their prescriptions."

"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."

"[W]e strongly support [legislation] which includes language to ensure prescribers are notified when a biosimilar drug is substituted… Among all patients and especially those with chronic diseases, the patient-physician relationship as well as the communication among the patients' health care team is crucial to the treatment process."

"Others have weighed in on why biosimilars are unique and the science behind this groundbreaking medicine. Because the medicine and its structure are complicated, from the perspective of the older Americans, it seems such a common sense requirement that the patient's physician be notified if a biosimilar is substituted by the pharmacist. A recent survey that we sent out nationwide on this issue received over 1,400 replies. Over 90% of those respondents thought that the communication between the doctor, the patient and the pharmacist should be open and required when a substitution is made concerning biologics, biosimilars and interchangeable biologics."

“Oregon must prioritize patient safety as its chief concern, and recognize that a clear line of communication is the best way to achieve trust in biosimilars and safeguard patient safety. This applies to caretakers as much as patients. We are concerned about the possibility of biologic substitution without prescriber-pharmacist communication and how that will affect caretakers as well.

With biologics, we know that individual patients can respond differently to even seemingly insignificant changes in the manufacturing process, packaging, storage, or handling, which could cause unintended adverse effects. Treatment requires a great deal of clinical judgment from the prescribing physician, who carefully weigh the expected benefits and risks. The women of WAPC know first-hand the importance of having trust in their loved one’s medical team. They oversee medical appointments, manage treatment options and navigate the health care system. They trust that the medications prescribed by physicians are being dispensed at the pharmacy setting and that any deviation would be communicated back to the prescribing physician. If a substitution was made by a pharmacist without the physician or the caretaker’s knowledge, it could undermine the established relationship that is crucial to a patient’s care.”

AfPA Alliance for Patient Access | National Physicians Biologics Working Group

“The physician communication provision is critical as it will help ensure a complete medical record and help assure the best medical response to a patient adverse event by making it clear exactly what medicine a patient is taking…AfPA supports making less costly medicines available to patients and physicians but all efforts must be made to create policies that balance access, safety and cost.”

Bio Biotechnology Industry Organization

“[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."