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Assembly Member Richard Gordon
Chair
Business, Professions and Consumer Protection Committee
Legislative Office Building, Room 383
Sacramento, CA 95814

RE: SB 598 Patient Access to Biosimilar Medicines

Dear Chairman Gordon:

I am writing today to add our voice in support of SB 598. Actavis (formerly Watson Pharmaceuticals, Inc.) is the world's third largest generic pharmaceutical company, the third largest U.S. generic pharmaceutical company, a developer of biosimilar pharmaceutical products and a long-time California employer, with facilities in Corona that employ approximately 800 people.

Actavis joins BayBio, the California Healthcare Institute, BIOCOM and many others in supporting the proposed changes within SB 598 to California Pharmacy Law that will ensure patient access to more affordable biosimilar versions of originator biologic products when those products enter the marketplace over the next several years. In addition to ensuring patient access to these critical medicines, SB 598 will also establish a mechanism for notifying physicians about which specific biosimilar product is used in patient treatment, enhancing the physician/patient partnership to ensure the highest level of care.

The most vocal opponents to SB 598, and to similar legislation in other states, claim that the bill's notification provisions represent a barrier to patient access. This position is inaccurate, and represents a fundamental misunderstanding of the proposed legislation.

As a veteran of the generic pharmaceutical industry for more than two decades, I personally have spent many years opposing ill-conceived legislation that would raise barriers to FDA-approved, interchangeable traditional small molecule pharmaceuticals. The opposition to SB 598 is rooted within its proponents' experience solely in this small molecule traditional pharmaceutical environment, and is based on erroneous assumptions from a dated model that simply does not apply to biosimilars. While characterized by opponents as restricting access and diminishing the potential savings biosimilars can provide, SB 598 does neither.

In fact, Actavis believes that the legislation will ultimately serve to increase confidence in biosimilar products among patients, physicians and pharmacists and, as a result, enhance the acceptance of these critical products and accelerate the savings they will produce.

Opponents also characterize this legislation as being introduced "too early" in this process. They are mistaken. Now is the time to act to ensure an orderly, codified, well-understood system that enhances patient access to biosimilars. There are a number of benefits to the notification provisions included in SB 598, and to enacting this legislation now, rather than after biosimilars enter the marketplace in the near future.

As a leading participant in the development and commercialization of biosimilars, with a portfolio of five products currently in various stages of clinical development, Actavis fully supports the unrestricted substitution of biosimilars judged by FDA to be interchangeable. We strongly believe that no restrictions to substitution should be erected in any regulatory or state forum once the determination of interchangeability has been made by FDA.

Rather, establishing patient, physician and health care payer confidence in the safety and efficacy of biosimilars, particularly in the initial years of usage, will be critical to their adoption and usage, and to maximizing the cost savings that will result. SB 598 will be a crucial component in ensuring that confidence. By creating a mechanism to record which specific biosimilar is used in patient treatment, and ensuring that the prescribing physician has this information, the bill will help to create a process that can confirm the clinical effectiveness and safety of biosimilars in ongoing patient usage, and ensure that clinicians and physicians can respond rapidly and efficiently if the use of any specific biosimilar product results in adverse reactions.

Unlike small molecule traditional pharmaceuticals, which are derived from chemicals, the active drug products used to produce biologics are derived from living cells. Because biologics are complex and work in the body in ways that are different from small molecule traditional drugs, physicians and healthcare providers must partner with patients to monitor for adverse reactions, which, in some cases, can occur many months into a treatment regime.

Ensuring a reliable record of which biosimilar product is being used will make this process more efficient and better serve patients and clinicians. If an adverse reaction occurs, it is critical that the healthcare provider, manufacturer and other authorities have a clear record of which products are being used, in order to respond appropriately. Notification of which biosimilar is used in each treatment session will significantly enhance this response.

In addition, while many biosimilars will be administered in physician or clinical settings, some will be self-administered by patients, and purchased through pharmacies. It is this population where notification will provide the largest benefits. Patients can, and do, use multiple pharmacies over the course of their treatment and identifying which drug was administered after the fact may be extremely challenging if there is no mechanism in place for determining which specific drug has been used. The rightful place for this information should be in the office of the prescribing clinician.

It is important to note that the proposed procedure of notifying physicians following dispensing does not place an unreasonable burden on retail pharmacists, and any minimal burden is far outweighed by the assurance of enhanced patient care by the physician. SB 598 is estimated to require a mere two additional faxes per pharmacy, per month. With pharmacies already sending millions of faxes to doctors' offices across the state each month, it is a small price to pay for ensuring patient safety.

It is also important to note that SB 598 does not require a pharmacist to get approval from the physician to substitute a biosimilar product. The physician notification provision in the bill ONLY requires that the prescribing physician be notified within five days of the substitution occurring.

California has always been on the forefront in the development of our nation's significant public health policy. Actavis, with operations in California, can speak as a native son in encouraging you to continue that legacy, ensure positive patient outcomes and position California as a leader in the acceptance of biosimilars by approving SB 598.

I would be happy to provide any additional information as you consider this proposal.

Regards,

Paul M. Bisaro
President & CEO
Actavis, Inc.

Cc: Assembly Member Brian W. Jones, Vice Chair
Senator Jerry Hill
Sarah Huchel, Consultant
Ted Blanchard, Consultant
Members of the Business, Professions and Consumer Protection Committee