Actavis

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Honorable Patricia H. Vance
Chair, Public Health & Welfare Committee
Senate of Pennsylvania
173 Capitol Building
Harrisburg, PA 17120

The Honorable Shirley M. Kitchen
Minority Chair, Public Health & Welfare Committee
Senate of Pennsylvania
463 Capitol Building
Harrisburg, PA 17120

The Honorable Matthew E. Baker
Chair, Committee on Health
Pennsylvania House of Representatives
108 Ryan Office Building
Harrisburg, PA 17120

The Honorable Florindo J. Fabrizio
Minority Chair, Committee on Health
Pennsylvania House of Representatives
200 Irvis Office Building
Harrisburg, PA 17120

RE: SB 405 and HB 746 — Patient Access to Biosimilar Medicines

Dear Chairwoman Vance, Chairwoman Kitchen, Chairman Baker and Chairman Fabrizio:

I am writing today to add our voice in support of SB 405 and HB 746. 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 supplier of affordable medicines to patients in Pennsylvania.

Actavis joins many others in supporting the proposed changes within SB 405 and HB 746 to Pennsylvania 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 405 and HB 746 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 405 and HB 746, 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. While characterized by opponents as restricting access and diminishing the potential savings biosimilars can provide, SB 405 and HB 746 do 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. Many in the industry expect the first products to be available to

consumers with the next year. Therefore, there are a number of benefits 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.

While opponents of SB 405 and HB 746 have falsely portrayed the FDA as standing in opposition to the legislation, in reality, the FDA has stated that the agency "does not have a position on any particular state legislation."

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.

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. Ensuring this record exists will significantly enhance this response, and will be a crucial component in establishing patient, physician and health care payer confidence in the safety and efficacy of biosimilars which, particularly in the initial years of usage, will be critical to their adoption and usage and to maximizing the cost savings that will result.

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 405 and HB 746 are 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 405 and HB 746 do 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 three days of the substitution occurring.

The value of SB 405 and HB 746 have been recognized by lawmakers in numerous states through the passage of similar legislation, most recently by an overwhelming majority of the California legislature, and remains pending in others, including Illinois.

As a longtime leader in medical innovation who has consistently been on the leading edge of pharmacy regulation in the United States, Actavis encourages you to continue that legacy for

Pennsylvania, ensure positive patient outcomes and position the Commonwealth as a leader in the acceptance of biosimilars by approving SB 405 and HB 746.

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

Regards,

Paul M. Bisaro
President & CEO
Actavis, Inc.

Cc: Members of the Pennsylvania House Health Committee
Members of the Pennsylvania Senate Public Health & Welfare Committee