



Agenda Item 5d

April 16, 2013

ITEM NAME: Senate Bill 598 (Hill) – Prescription Drugs: Biosimilar Products

As Introduced February 22, 2013

Sponsor: Author

PROGRAM: Legislation

ITEM TYPE: Action

RECOMMENDATION

Adopt an **Oppose** position on Senate Bill (SB) 598 because it would impose unnecessary, burdensome, and potentially costly requirements on pharmacists when dispensing biosimilar drugs already approved as interchangeable with biologic drugs by the federal Food and Drug Administration (FDA). Any costs associated with these requirements would likely be passed onto consumers, e.g., California Public Employees' Retirement System (CalPERS) members and employers. In addition, SB 598 would impede access to biosimilars that cost less than their reference products, which would likewise potentially increase health care costs for CalPERS members and employers.

EXECUTIVE SUMMARY

SB 598 would allow a pharmacist filling a prescription order for a prescribed biological product to select a biosimilar only if the following recordkeeping and verification requirements are met: 1) the biosimilar is determined interchangeable by the FDA with the prescribed biologic product; 2) the prescriber does not personally indicate, either orally or in his or her own handwriting, "Do not substitute"; 3) the pharmacist notifies the prescriber or enters the appropriate information in a patient record system shared by the prescriber within five business days of the selection; and, 4) the pharmacy retains a written record of the biosimilar selection for at least three years.

CalPERS Federal Health Care Policy Initiatives related to prescription drugs include advocating for the development of a clear, efficient and timely regulatory pathway to bring generic biologics to market, including specialty drugs, and remove arbitrary access barriers for patients. While this bill would add biologics to other categories of generic drugs allowed to be substituted for brand name drugs under State law, it imposes additional recordkeeping and verification requirements on dispensing pharmacists that could serve to limit access. In addition, it could create doubt in the minds of the consumers before the FDA has promulgated its regulations.

STRATEGIC PLAN

This item is not a specific product of the Annual or Strategic Plans, but is a part of the regular and ongoing workload of the Office of Governmental Affairs.

BACKGROUND

1. Biologic Drugs, Biosimilar Drugs, and Interchangeability

Biological products are used to prevent, treat, or cure diseases and can include vaccines, blood and blood components, gene therapy, tissues, and proteins. Unlike most traditional, small-molecule prescription drugs that are made through chemical processes, biological products are generally made from human and/or animal materials. Biosimilars are biological products that are highly similar to a United States (U.S.)-licensed reference biological product, notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency. Interchangeability means that the biologic product is biosimilar to the U.S.-licensed reference biological product and is expected to produce the same clinical result as the reference product in any given patient.

2. CalPERS Drug Costs

In 2011, CalPERS spent more than \$6.67 billion to purchase health benefits for 1.3 million active and retired State and local government public employees and their families. Prescription drugs accounted for about 22 percent—or more than \$1.5 billion—of that amount. Specialty drugs, including biologics, make up a significant portion of CalPERS drug spending, as described below:

- The number of participants using specialty medication has increased by 33 percent between 2004 and 2011, to almost 30,000 participants.
- Both specialty and traditional drug utilization increased between 2007 and 2011, with specialty drug utilization increasing at a slightly lower rate than traditional drugs (10 percent v. 13 percent); however, the cost for specialty drugs increased at a significantly higher rate than traditional drugs (43 percent v. 28 percent).
- Total spending for specialty drugs exceeded \$250 million in 2011, a 43 percent increase since 2007, and a 120 percent increase since 2004.
- Specialty drugs comprised 1.2 percent of total drugs dispensed in 2011, but represented 17 percent of CalPERS total drug cost.
- Of the approximately \$250 million spent on specialty drugs, biologics comprised approximately \$236 million, or 94 percent, of this cost.

3. Existing Law Related To The Substitution Of Generic Drugs

Current State law allows the substitution of generic drugs for brand name drugs; however, the substitution of biological products is currently not addressed under California law. Current law specifically:

- Prohibits selection of a generic drug if the prescriber personally indicates, either orally or in his or her own handwriting, “Do not substitute” and specify that nothing prohibits a prescriber from checking a box on a prescription marked “Do not substitute” if the prescriber personally initials the box or checkmark.
- Prohibits a pharmacist from substituting a generic product unless it costs less than the brand product, including any professional fee that may be charged by the pharmacist.
- States that the selection of a generic drug is within the discretion of the pharmacist, unless the provider specifies “Do not substitute.” Requires the pharmacist dispensing a generic drug to assume the same responsibility for substituting the dispensed drug as would be incurred in filling a prescription for a generic drug using the prescribed form of medication.
- Holds prescribers harmless for an act or omission by a pharmacist in selecting, preparing, or dispensing a generic drug.
- Requires the substitution of a generic drug be communicated to the patient and the full name and manufacturer of the dispensed drug be indicated on the prescription label, unless the prescriber orders otherwise.

4. Recent Federal Actions and Pending State Legislation Related to Biologics and Biosimilars

The Affordable Care Act (ACA), signed into law by President Obama in March 2010, contained a provision establishing an abbreviated pathway for biological products that are demonstrated to be “biosimilar” to, or “interchangeable” with, an FDA-licensed biological product. To date, the FDA has not approved a biosimilar product nor have they determined a biosimilar to be interchangeable with a U.S.-licensed reference biological product. The FDA is currently establishing standards for the licensing of these products.

Similar legislation to place additional barriers on the ability of pharmacists to substitute a biosimilar for a reference biological product have been proposed in 17 states: Arizona, Arkansas, California, Colorado, Florida, Illinois, Indiana, Maryland, Massachusetts, Mississippi, North Dakota, Oregon, Pennsylvania, Texas, Utah, Virginia, and Washington.

Recently, Virginia Governor Bob McDonnell signed into law the nation’s first biosimilar substitution law. While the Virginia law is similar to what is being proposed in SB 598, the law includes a two-year sunset clause which will expire in 2015, likely before an interchangeable biologic is approved by the FDA and available in the U.S.

ANALYSIS

1. Proposed Changes

Specifically, SB 598 would:

- Apply the existing generic drug substitution requirements on biosimilars.
- Allow a pharmacist filling an order for a biological product to select a biosimilar only if the:
 - Biosimilar is determined interchangeable by the FDA with the prescribed biologic product
 - Prescriber does not personally indicate, either orally or in his or her own handwriting, "Do not substitute"
 - Pharmacist notifies the prescriber or enters the appropriate information in a patient record system shared by the prescriber within five business days of the selection
 - Pharmacy retains a written record of the biosimilar selection for at least three years
- Require the Board of Pharmacy to maintain a link on its public website to the current list, if available, of biosimilar products determined by the FDA to be interchangeable.
- Define biological product, biosimilar, interchangeable, prescription, and the term "351(k) pathway."
- Specify that nothing in the section prohibits the administration of immunization.

2. Potential Impacts to the Future Use of Biosimilars

SB 598 would impose additional requirements on pharmacists when dispensing an FDA-approved interchangeable biosimilar beyond what is currently required for generic drugs. The author claims his bill is necessary to update State law so that when the FDA approves interchangeable biosimilars, pharmacists can substitute for these potentially lower cost drugs. He states that biosimilar drugs are not identical to reference drugs, as is the case with generics, and that while the use of biologics is safe, a risk of an immune response from a biologic drug is much more significant than with generic pills.

Many generic drug companies and insurers characterize legislative efforts by the biotechnology industry, such as SB 598, as an attempt to deter the use of biosimilars by undermining confidence in their safety, even before these products get to market. They believe these efforts attempt to thwart competition as lucrative biologics lose patent protection.

Since passage of the ACA, the FDA has been establishing standards for licensure to ensure the safety and effectiveness of biosimilars when they go to market. However, by imposing additional requirements on pharmacists when they dispense a biosimilar product that has been certified by the FDA as interchangeable, this bill could undermine patients' and health care providers'

trust in these products. Suggesting biosimilars are inferior to the reference biologics and not safe may deter patients from using these lower-cost treatments.

In addition, the physician notification requirement in this bill could create potential liabilities for providers and impede access to biosimilars. SB 598 requires the pharmacist notify the prescribing physician within five days of the switch, but it is unclear if the notification transfers the liability for dispensing an interchangeable biosimilar to the physician. To avoid potential liability, providers may choose the biological product over the less expensive biosimilar.

3. Potential Impact to CalPERS

The existing generic drug substitution law should be sufficient for pharmacists to dispense biosimilars approved by the FDA in the same manner as generic drugs, without the additional notice and recordkeeping requirements proposed by this measure. Without the ability to access safe, effective, and less expensive biosimilar products, CalPERS may ultimately be forced to raise prescription drug co-payments or raise health care premiums, shifting the costs onto employers, members, and their families.

4. Costs

Benefit Costs

Unknown, but potentially large health benefit costs – Many in the health care industry estimate that, overall, the cost of biosimilars could be 20 to 30 percent less than their reference products. Increasing restrictions on dispensing interchangeable biosimilar products could prevent CalPERS from realizing significant health care cost savings, especially as the use of biologic drugs increases.

While the first biologic products are only now beginning to lose their patent protection, the development and manufacture of biosimilars is in its infancy and may not produce an interchangeable substitute for all biologic products manufactured. If even a fraction of CalPERS current annual \$236 million spending on biologic products were reduced in the future by the substitution of biosimilars, the tens of millions of dollars in associated savings could potentially lower the rate of increases to member premium costs and drug co-pays.

Administrative Costs

None.

BENEFITS/RISKS

1. Benefits of Bill Becoming Law

- According to the Alliance for Safe Biologic Medicines, these “measures are necessary to protect patient safety because biosimilars are not identical to the originals.”

2. Risks of Bill Becoming Law

- According to CVS Caremark, this bill is “both premature and unnecessarily burdensome to pharmacies and will likely result in a chilling effect to patient and prescriber adoption and acceptance of these promising drugs even before the FDA has issued guidance for approval of biosimilars or a single manufacturer had brought a biosimilar drug to market in California.”

ATTACHMENTS

Attachment 1 – Legislative History

Attachment 2 – List of Support and Opposition

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