America's Health Insurance Plans
601 Pennsylvania Avenue, NW
South Building, Suite Five Hundred
Washington, DC 20004

March 10, 2021

Senator Michelle R. Benson
Chair, Health and Human Services Finance and Policy Committee
3109 Minnesota Senate Bldg.
St. Paul, MN 55155

Senator Rich Draheim
Vice Chair, Health and Human Services Finance and Policy Committee
3227 Minnesota Senate Bldg.
St. Paul, MN 55155

Dear Senator Benson and Senator Draheim,

RE: S.F. 990 – Alternative Biological Products – Oppose

I am writing on behalf of America's Health Insurance Plans (AHIP)[1] to oppose S.F. 990. While we strongly support fostering greater competition among drug manufacturers—and policy efforts that encourage growth of the alternative biological product (biosimilars) market—this legislation will have the opposite effect. S.F. 990 will undermine health care affordability by mandating equal coverage, without regard to cost or clinical effectiveness, for all alternatives of a reference biological product that are competitively chosen for inclusion within a health plan's and pharmacy benefits manager's (PBM) formulary.

Health plans and PBMs use medical management tools – such as formularies – to ensure patient access to safe, effective, evidence-based care at affordable costs. Just as **medical management tools are vital to ensure the safe prescribing of biological product treatments** in the first place, these tools play an important role in ensuring biosimilars are administered in a manner that is safe, effective, and appropriate for the needs of that patient.

Medical management is also critically important for cost management of biosimilars, which are federally approved as having no clinically meaningful differences from their reference biological products in terms of safety, purity, or potency, much like with brand-name and generic drugs[2]. The primary difference between the two treatments is that reference biological products' list prices are generally far more expensive.

S.F. 990 is a flawed attempt to reign in the high costs of biological products

[1] America's Health Insurance Plans (AHIP) is the national association whose members provide insurance coverage for health care and related services. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.
[2] https://www.fda.gov/drugs/biosimilars/biosimilar-and-interchangeable-products#:~:text=A%20biosimilar%20is%20a%20biological,existing%20FDA%2Dapproved%20reference%20product.

The critical flaw in S.F. 990 is the presumption that biosimilars will cost patients and payers less because their list prices are lower than the reference biological product; this confuses list vs. net prices. While biosimilar list prices are, in fact, typically lower (often ranging between 10 percent and sometimes more than 25 percent) than the reference biological product's, the reality is that the *net* prices for some reference biological products may end up being lower due to negotiated discounts with health plans and PBMs.

This market phenomenon occurs because reference biological product manufacturers enjoy a lengthy patent exclusivity period that allows for recoupment of R&D and manufacturing costs and substantial profits to be earned. By the time a biosimilar is approved for marketing the reference biological product manufacturer can choose to reduce their profit margin in exchange for retaining market share against new competitors. This is done through negotiating discounts with purchasers (i.e. plan sponsors/PBMs) that lower the net prices paid for these drugs.

In contrast, while a biosimilar may have a lower list price than the reference biological product's, there is almost no margin for additional discounts because biosimilar makers have yet to recover their R&D costs. These expenses are substantial, especially when compared to developing generic drugs. For example, Pfizer noted: "Biosimilar development may take five to nine years and cost more than $100 million, not including regulatory fees. A generic, however, costs $1-2 million and takes approximately two years to develop.[3]"

Because of the presence of biosimilars, reference biological product manufacturers are incented to offer a greater discount to net price to compete. These market dynamics are good for patients and payers because they **pay a lower net price** while making **all biological drugs more accessible and affordable**. Despite the attempt for biosimilars to have a similar impact on reference biologic drug prices as generics have had on brand drugs, their effect on this market—for now—is more akin to having another "brand" biologic drug enter the same therapeutic class as the reference biologic manufacturer.

S.F. 990's pharmacy and provider choice provisions will blatantly remove any incentives reference biologic product manufacturers have to offer lower net prices to health plans and PBMs. This legislation will obstruct the current competitive market dynamics and cripple health plans' and pharmacy benefit managers' ability to promote safety, effectiveness, and affordability through proven medical management tools. If you have any questions, please do not hesitate to contact me at jkeepes@ahip.org or (202) 400-0928.

Sincerely,

Joshua D Keepes, J.D.

[3] https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2018/our-innovation/progressing-our-science/biosimilars-vs-generics/index.html