House Committee on Health Policy
October 20, 2015

Testimony of Michigan Association of Health Plans in support of HB 4437

Good morning Chairman Callton and members of the committee, my name is Christine Shearer, Deputy Director, of Legislation and Advocacy for the Michigan Association of Health Plans. Our association represents 17 health plans serving over 2.5 million Michigan citizens in Medicaid, Medicare and Commercial products and 55 business and limited members. With me today is Karen Jonas, Pharmacist Consultant with MAHP and Doctor Marguerite Shearer, MD, Emeritus.

MAHP supports HB 4437 as before you today. Development of biosimilars is expected to be less risky, less costly, and take less time; therefore, FDA approved biosimilars are expected to be less expensive than the reference product.

MAHP would caution against any amendment which would restrict insurers' ability to provide affordable options. For example, notification language found in HB 4812, while seemly harmless would actually restrict insurers from covering biosimilar products once approved by the FDA, which are highly similar to existing licensed biological products in place of the substantially more expensive branded counterparts. The primary difference between the two treatments is that brand-name biological products are dramatically more expensive and increase the cost of coverage.

MAHP opposes notification language for the following reasons:

1) Notification requirements creates an disingenuous scare that an interchangeable biologic is not safe and requires additional prescriber notice upon dispensing and undercuts the FDAs approval that such drugs are interchangeable due to sound clinical science, and

2) Notification requirements are often proposed by the pharmaceutical industry which are intended to impede the ability for biosimilars and interchangeable biologics to be dispensed, delaying cost-savings that could be achievable with the wide-spread use of such interchangeable medications. It is estimated "that biosimilar competition for the 11 most-popular biologics would save the US $250 billion on health care over the next decade if 11 of the biologic products whose

patents expired or are about to expire come to the market as biosimilars."[1]

3) Notification requirements create an unnecessary burden on the pharmacists and prescribers.

I will now turn it over to Karen Jonas.

- The European Medicines Agency (EMA) as well as the World Health Organization (WHO) adopted guidelines for approval of biosimilars in 2005.
- A Rand study found biosimilars marketed in Europe cost up to 35% less than reference biological products and have been used for the past 8 years with no known safety-related issues.
- Competition from follow-on biological products, both biosimilars and interchangeable biosimilars, entering the US market will help to lower drug prices
- Many state legislatures have passed laws limiting the ability for substitution of biosimilar and interchangeable biosimilar medications which has raised the concern of the Federal Trade Commission.
- The FTC was so concerned about state legislatures limiting substitution of biosimilars that it convened a meeting in February 2014 which included consumer groups, pharmaceutical manufacturers, pharmacy and pharmacy benefits manager companies and other stakeholders addressing that anti-substitution legislation as "anti-competitive" or "deceptive."
- The FTC's played a key role fighting against state anti-substitution laws in the 1970's when generics were first introduced which resulted in increased generic completion and reducing costs to consumers.
- The FTC will advocate for greater transparency in the biosimilar market to ensure competition to deliver the benefits of biologics at affordable prices for consumers.

[1] The Washington Post, January 16, 2015, "The coming revolution in much cheaper life-saving drugs" by Jason Millman, accessible at http://www.washingtonpost.com/blogs/wonkblog/wp/2015/01/16/the-coming-revolution-in-much-cheaper-life-saving-drugs/.

mahp
Michigan Association of Health Plans

I will not turn it over to Doctor Shearer to provide a physician's point of view.

- History of Brand name verse generic in the 70's
- Does the information really get into the patients chart?
- As a Medical Director for a health plan, the physician groups who refused to prescribe generics

The FDA is the only U.S. regulatory body with the scientific expertise to determine when and how biosimilars may be substituted for branded biologics, the FDA should be permitted to fully investigate these drugs before states react prematurely and remove the possibility of patients having access to clinically cost treatment options. Federal regulators have assured the public that any standards established for biosimilars will be based on rigorous efforts to determine their safety.

I'll turn it back to Christine for conclusion.

We believe competition is essential in Michigan to drive down costs so that when interchangeable biologics are approved by the FDA they are readily available to patients. Notification language and other unnecessary administrative requirements are in direct conflict with that goal. Other states have shared our concerns. Legislation which included notification language, was vetoed in California after the California Public Employees Retirement System predicted that the "*unnecessary physician notification requirements . . . could potentially reduce the number of prescriptions substituted with biosimilars" and that they could "ultimately be forced to raise prescription drug co-payments or premiums, shifting the increasingly unaffordable health care costs onto our employers, members, and their families.*[2]"

MAHP members believe controlling medical costs is a key to expanding coverage and access to care. For these reasons, we fully support HB 4437 and feel HB 4812 is counterproductive to existing cost-effective quality care efforts that would benefit all Michiganders.

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[2] Letter, Anne Stausboll, CEO CalPERS to Gov. Edmund G. Brown, Jr., Sept 12, 2013.