

**Testimony in Support of MD SB622 (Middleton)  
Health Insurance – Step Therapy or Fail-First Protocol  
Senate Finance Committee – February 19, 2014**

Chairman Middleton and Members of the Committee:

On behalf of the Leukemia & Lymphoma Society and the thousands of blood cancer patients we serve throughout the state of Maryland, we thank you for the opportunity to comment on Senate Bill 622.

Step therapy, also known as “fail first,” is a widely-used technique that insurers use to control drug costs. Step therapy requires patients to first try and fail on medications selected by their insurer—based on cost—before a patient is granted coverage for the medication that had been initially prescribed by the patient’s healthcare provider.

In 2010, almost 60% of commercial insurers were utilizing step therapy.<sup>i</sup> The practice is applied to drugs used to treat a wide range of diseases and conditions, including cardiovascular disease, cancer, diabetes, HIV/AIDS, mental health, hemophilia and other rare diseases. In fact, we are joined today by local organizations representing patients in many of these communities, along with the Maryland Medical Society (Medchi) and other healthcare providers.

When used in tandem with appropriate patient protections, step therapy can indeed function as an effective and safe strategy for controlling healthcare costs. When these protections are in place, the need for effective cost containment is balanced with the recognition that a healthcare professional—rather than an insurer—should ultimately determine what treatment a patient is on and for how long.

Unfortunately, these protections are not in place in much of the country, including Maryland. This has led to patient harm due to serious side effects from inadequate medications and to disease progression due to delays in appropriate treatment. Also concerning are the studies showing that a significant number of patients—when faced with a step therapy program—end up receiving no medication at all. According to a recent study, a total of 67% of patients whose specialty drugs were rejected under step therapy did not receive an alternate drug within a 30 day window.<sup>ii</sup> These situations could result in costly episodes of care that might have been avoided, if not for misuse of the step therapy technique.

For many patients—including those with cancer—every day is a battle. From the moment of diagnosis, patients rightfully want to know that they will have access to the treatment plan determined by their medical team to offer the greatest clinical benefit. Many of them who are forced to abide by step therapy programs will suffer for long periods of time on older, less effective, more toxic forms of treatment.

We’d like to share with you Dorothy Sprigg’s story. Dorothy lives in Baltimore County and in 2000, she received her diagnosis with Chronic Myelogenous Leukemia (CML). Dorothy was forced onto Interferon, a chemotherapy, for 9 ½ months, because her insurer would not allow her to take Gleevec, a new, less toxic, more effective drug on the market. Unfortunately, Dorothy’s doctor was subject to the insurance company’s mandate that Dorothy fail traditional chemotherapy first. Interferon showed very little positive change in her disease, and had terrible side effects. After a very long 9 ½ months, Dorothy was finally able to make the case that she should be on Gleevec. After a short time, this drug helped to show a marked improvement in her disease, and has helped her maintain a good quality of life. Dorothy remains healthy and on Gleevec to this day.

Data from 2012 shows that an increasing percentage of plans are applying step therapy programs specifically to oncology products: 54% of plans, up from only 36% the year before.<sup>iii</sup> This trend is deeply worrying to the cancer community, given that recent treatment breakthroughs are driven by the principles of “precision medicine”: today, oncologists have access to more diagnostic information than ever before, allowing them to make treatment decisions based on a patient’s specific profile.

Fundamentally, an insurer using a step therapy approach is not taking into account unique patient responses to different forms of treatment. That’s because step therapy relies upon information that makes generalizations about large patient populations.

Fortunately, Chairman Middleton’s bill offers some common-sense, balanced solutions that enable insurers to realize their goals of cost-savings through step therapy while also ensuring that treatment decisions are left to the patient and his/her medical team. The bill does so by establishing a standardized process for a provider to request an override of the payor’s step therapy protocols, when medically necessary.

In cases where step therapy is appropriate for use, the bill would also limit the amount of time a patient could be subjected to step therapy so that patients cannot be obligated for an indefinite period of time to risk treatment delays or adverse reactions.

Legislatures around the country are taking steps to address this issue, having recognized the importance of establishing step therapy protocols<sup>iv</sup>. Fortunately these simple protections do not lead to increases in cost for insurers.

In closing, we hope that as you consider this bill, you will remember Dorothy’s story. While this story has a happy ending, Dorothy went through 9 ½ months of ineffective treatment with toxic side effects. We urge you to support this legislation so that treatment decisions are driven by clinical considerations and medical expertise, which in the long-run will most effectively promote cost-savings.

With questions, please contact:

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<sup>i</sup> Motheral, Brenda. *Journal of Managed Care Pharmacy*. Vol. 17, No. 2. March 2011.

<sup>ii</sup> Belazi, Dea. *The American Journal of Managed Care*. Vol. 19, Special Issue 4. May/June 2013.

<sup>iii</sup> Report from Health Strategies Group, published by *Managed Care Oncology* during the 4<sup>th</sup> quarter of 2012.

<sup>iv</sup> In 2013 alone, four states passed legislation related to step therapy: CT, LA, NM, and VT.