March 16, 2015

The Honorable Mitch Greenlick, Chair
House Committee on Healthcare
900 Court Street NE
Salem, OR 97301

Transmitted Via Email

Dear Chairman Greenlick,

On behalf of the Biotechnology Industry Organization (BIO), I would like to express our strong opposition to HB 3486, which would require reporting to the Oregon Health Authority for costs associated with prescription drugs. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. Our members are committed to advancing science and improving the health and well-being of our planet through the use of biotechnology. We also work closely with the Oregon Bioscience Association, which is a state affiliate of BIO.

While BIO shares the Oregon legislature's concerns about affordability of health care for Oregon patients, HB 3486 is not the answer. Specifically, we are concerned that HB 3486 seeks to require manufacturers to publicly report data points on the cost to develop and market a therapy in the name of "transparency" without regard to the need for context, the perspective of individual patients, and the undue burden such reporting requirements would impose on manufacturers.

I. The Proposed "Transparency" Requirements Disregard, and May Even Interfere with, the Market-Based Ecosystem of the U.S. Healthcare Sector.

The requirements proposed in HB 3486 call for manufacturers to publicly report a compilation of individual data points on the costs to develop and market an innovative therapy. However, such an approach does not provide adequate context for the complex issue of pricing, which is based not just on manufacturers' costs, but also on market forces and an assessment of value that cannot simply be reduced to a line on a balance sheet. Moreover, these proposed "transparency" requirements cannot capture fully, and may even interfere with, the market-based environment in which pricing decisions are made, including negotiations between manufacturers and payers that impact how a therapy is covered and reimbursed by a given insurance plan.

It is this same market-based system that, while not perfect, underlies the successful Medicare Part D program, which has expanded access to prescription drugs for Medicare beneficiaries, with a satisfaction rate of 90 percent, and done so at a cost almost 50 percent below initial estimates.[1] In fact, by some estimates, the Part D program has helped to decrease overall expenditures: a 2011 study published by the Journal of the American Medical Association (JAMA) noted that

[1] CBO. July 2014. *Competition and the Cost of Medicare's Prescription Drug Program*. Available at: http://www.cbo.gov/sites/default/files/45552-PartD.pdf; KRC Survey for Medicare Today. "Seniors' Opinions About Medicare Rx: Eigth Year Update." September 2013. Available at: http://www.medicaretoday.org/MT2013/KRC%20Survey%20of%20Seniors%20for%20Medicare%20Today%20%20FINAL.pdf.

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"[i]mplementation of Part D was associated with a $1200 decrease in annual non-drug medical spending among enrollees with prior limited or no drug coverage."[2] Moreover, the Congressional Budget Office (CBO) includes lower non-drug related spending due to prescription drugs in Medicare: for every dollar spent on innovative medicines, total healthcare spending is reduced by $7.20.[3]

II. The Proposed "Transparency" Requirements Ignore the Important Issues of Identifying the Value of, and Ensuring Timely Access to, Innovative Therapies for Individual Patients.

The information identified by the proposed requirements does not address the value that an innovative therapy can have to an individual patient—especially one who may have no other recourse—or the societal impact innovative technologies can have—including increased productivity and decreased overall healthcare costs (e.g., due to fewer hospitalizations, surgical interventions, and physicians' office visits). As just one example, since 1980, the life expectancy for cancer patients has increased significantly, and over 80 percent of those gains are attributable to new treatments, including medicines. For example in the case of chronic myeloid leukemia (CML), the ten-year survival rate has increased from less than 20 percent to more than 80 percent as a result of treatment advances.[4] This result has generated more than $140B in societal benefits since 2001, of which more than 90 percent is retained by patients and society.[5] Studies have also shown that gains in cancer survival more broadly are worth nearly $2 trillion to our society, with more than 80 percent, possibly up to 95 percent, of that going to patients, family, and our economy as a whole.[6]

Moreover, this information does not address the larger societal aim of ensuring that patients get timely access to the innovative therapies most appropriate for them. For instance, this proposed approach ignores the impact of out-of-pocket costs on patients' access to innovative therapies, which is dictated not by manufacturers but by the specific benefit structure offered by an individual patient's insurance plan.

III. The Proposed "Transparency" Requirements Place an Undue Burden on Manufacturers.

The transparency requirements proposed by HB 3486 are also unduly burdensome, especially on the engine of biotech innovation: small, emerging companies with only one or two products on the market that must use their limited resources as efficiently as possible to continue to supply the therapies patients need and to invest in future innovation.

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[2] J.M. McWilliams, A.M. Zaslavsky, and H.A. Huskamp, *Implementation of Medicare Part D and Nondrug Medical Spending for Elderly Adults With Limited Prior Drug Coverage*, Journal of the American Medical Association 306, no. 4 (2011): 402–409.

[3] CBO. July 2014. *Competition and the Cost of Medicare's Prescription Drug Program*. Available at: http://www.cbo.gov/sites/default/files/45552-PartD.pdf

[4] W. Yin, J.R. Penrod, J.R. Maclean, D.N. Lakdawalla; and T. Philipson, *Value of survival gains in Chronic Myeloid Leukemia*, American Journal of Managed Care (2012), http://www.ajmc.com/publications/supplement/2012/A386_12nov_Oncology/A386_12nov_Onclogy_Yin_S257to64#sthash.sPsCayRI.dpuf.

[5] *Id.*

[6] Lakdawala DN, et al. *An economic evaluation of the war on cancer*. Journal of Health Economics. May 2010. 29(3):333-346.

IV. Conclusion

In light of the foregoing, BIO respectfully requests a "no" vote on HB 3486. The bill seeks to require manufacturers to publicly report data points on the cost to develop and market a therapy in the name of "transparency" without regard to the need for context, the perspective of individual patients, and the undue burden such reporting requirements would impose on manufacturers – all with no benefit to Oregon patients.

Regards,

Patrick J. Plues
Senior Director, State Government Affairs

CC: House Committee on Healthcare