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Testimony of the
Biotechnology Innovation Organization (BIO)

Hearing of the House Committee on Healthcare
March 31, 2016

VT H.866, An act relating to prescription drug manufacturer cost transparency

I submit this testimony in opposition to House Bill 866 on behalf of the Biotechnology Innovation Organization (BIO) – a Washington, DC-based trade group representing more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations that are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. Vermont's biotechnology industry is comprised of 234 entities, employing nearly 2,600 people, with an average annual salary of $72,436. The Green Mountain State has an above-average concentration of bioscience academic R&D as well as NIH funding on a per capita basis.

BIO respectfully urges Chairman Lippert, Vice Chairman Pearson, and Members of the House Committee on Health Care to reject H. 866

While BIO shares the Legislature's concerns about affordability of health care for Vermont patients, H. 866 is not the answer. Specifically, we are concerned that H. 866 seeks to require manufacturers to publicly report data points on the total costs for the production of a drug without regard to the relevance and context for the data nor the ability for a company to actually generate the detailed data required.

I. The Proposed Transparency Requirements Place an Undue Burden on Small, Pre-Commercial Biotechnology Researchers Across the World

The transparency requirements proposed by H. 866 are unduly burdensome, especially on the engine of biotech innovation. Small, emerging companies with only a few or no 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. By requiring a series of data points retrospectively, this bill will have the unintended consequence of changing how research is conducted, and will divert scarce resources to accounting activities for research that may never become marketable.

A significant portion of research and development is done by individual scientists; small, venture backed companies; and academic researchers. In the most nascent stages of research, scientists research for breakthrough therapies by investigating broad categories of molecules, painstakingly separating those which may be fruitful to research further from the vast majority that will not. Should this legislation pass, researchers not only in Vermont but across the world will have to incorporate burdensome accounting measures into their laboratory practices.

Instead of focusing on science, we will have thousands of highly trained scientists setting aside their work on treatments for Alzheimer's, HIV/AIDS, cancer, and other unmet medical needs to parse out how much of their overhead (the electric bill, as an example) is attributable to their research on Molecule A versus Molecule B, and so on. The worst part of this ill-conceived idea is that the vast majority of those molecules will never become marketable drugs. The majority of pre-clinical research never goes to clinical trial, and 7 in 8 drugs that go into clinical trials never make it to the market[1]. However transparency guidelines are drafted, a large compliance burden would inherently fall on the small companies conducting very early stage research for new cures.

Finally, some of the data points required in the bill are proprietary and would put biotech companies' research, innovation, and ability to raise capital at risk. For companies that already have products to market and have not tracked some of the data points required in the bill, there may be no plausible means to gather the data after the fact.

II. H. 866 Proposed Transparency Requirements Will Interfere with the Market-Based Ecosystem for the U.S. Healthcare Sector That Works.

The requirements proposed in H.866 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 that assess the value of the product vis-à-vis its utility to reduce overall downstream healthcare costs. Moreover, these proposed "transparency" requirements cannot capture fully, and may even interfere with, the market-based environment in which pricing decisions are made. This includes negotiations between manufacturers and payers that impact how a therapy is covered and reimbursed by public health programs and insurance plans.

It is this same market-based system that, while not perfect, underlies the successful Medicare Part D program. Part D 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.[2] In fact, 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 "[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."[3] Moreover, the Congressional Budget Office (CBO) accounts or

[1] J. DiMasi. H. Grabowski. R. Hansen. "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs." "http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf

[2] *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: Eight Year Update." September 2013. Available at: http://www.medicaretoday.org/MT2013/KRC%20Survey%20of%20Seniors%20for%20Medicare%20Today%20%20FINAL.pdf*

[3] 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.

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.[4]

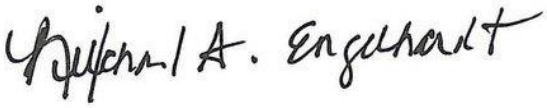
III. H.866 Proposed Transparency Requirements Ignore the Value and Benefits of Timely Access for Patients to Life-Saving Innovation

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. Nor does it consider 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. 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.[5] This result has generated more than $140B in societal benefits since 2001, of which more than 90 percent is retained by patients and society.[6] 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.[7]

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.

For the reasons stated above, BIO must respectfully oppose H.866 and ask that you oppose this bill when it is heard in the House Health Care866 Committee.

Respectfully submitted,



Ritchard Engelhardt, *Biotechnology Innovation Organization (BIO)*

BIO is a national trade organization, based in Washington, DC, representing more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial and environmental biotechnology products. Biotechnology researchers expand the boundaries of science to benefit mankind by providing better healthcare, enhanced agriculture, and a cleaner and safer environment. ***www.bio.org***

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[4] 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

[5] 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.

[6] *Id.*

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