Dan Casserly
Vice President, and Head
Federal Government Affairs

Novartis Services, Inc.
701 Pennsylvania Ave., NW
Washington, DC 20004
Tel (202) 662-4361
Fax (202) 628-4764
E-Mail: dan.casserly@novartis.com
www.novartis.com

November 13, 2017

Lieutenant Governor Nancy Wyman
Chair, Governor's Health Care Cabinet
State of Connecticut
Office of the Lieutenant Governor
210 Capitol Avenue Room 304
Hartford, Connecticut 06106

Dear Lt. Governor Wyman:

On behalf of Novartis Services, Inc. thank you for the opportunity to comment on the draft proposals for possible 2018 legislation developed by the Health Care Cabinet's subcommittee on drug pricing. This letter is submitted on behalf of Novartis Pharmaceuticals Corporation ("NPC"), Sandoz, Inc. ("Sandoz"), and Alcon Laboratories, Inc. ("Alcon"). We refer collectively herein to NPC, Sandoz, Alcon and Novartis Services Inc. as "Novartis."

NPC researches, develops, manufactures, and markets innovative medicines aimed at improving patients' lives. We offer a broad range of medicines for cancer, cardiovascular diseases, inflammatory disease, infectious disease, neurological disease, eye disease, organ transplantation, respiratory disease, and skin conditions. Sandoz is a leader in generic pharmaceuticals and biosimilars, providing access to a broad portfolio of high quality, affordable medicines. Sandoz launched the first biosimilar approved under the new Biologics Price Competition and Innovation Act (BPCIA) pathway in the United States. Alcon is a leader in research, development, manufacturing, and marketing of eye care products, including surgical devices and vision care products.

Our mission is to discover new ways to improve and extend people's lives. We use science-based innovation to address some of society's most challenging healthcare issues. We discover and develop breakthrough treatments and find new ways to deliver them to as many people as possible.

At Novartis, we believe that all individuals deserve access to affordable quality healthcare, including prescription medicines, health education about their disease or condition, and information on the medicines they take. We support patients, caregivers, and physicians throughout the patient journey with a suite of services, including reimbursement support, patient education, and adherence programs. We provide medicines at no cost to eligible patients experiencing financial hardship who have limited or no prescription drug coverage, and for eligible commercially insured patients we offer copay assistance programs for the vast majority of our branded and biosimilar products. Novartis would like to express its concerns with some of the Subcommittee proposals.

Pharmaceutical pricing is complicated, and the publicly available wholesale acquisition cost or average wholesale price is not what purchasers actually pay.

Novartis is committed to managing price adjustments responsibly for all of our innovative and generic medicines. We apply U.S.-specific cost-effectiveness modeling to inform U.S. prices for new drugs. Over the past few years, our annual price adjustments have gradually decreased. In 2016, the gross price increase across our portfolio was 6.2%. However, our net price over the same period decreased by 2.0%. Net price reflects the final amount received by the company. The difference between gross and net price is the result of many negotiations that take place between the pharmaceutical manufacturer and other stakeholders in the supply chain, including government payers, commercial insurers, pharmacy benefit managers, wholesalers, retailers, providers, and hospitals. These negotiations result in rebates and discounts to the gross price that vary between entities.

Pharmaceutical manufacturers, like other companies that research, develop and market products, must be allowed to evaluate the marketplace and determine the need for price changes. State legislation, like that enacted in Maryland that seeks to impose price controls or restrictions on price increases, impairs interstate commerce by affecting the prescription drug price on sales outside the State and may violate the Commerce Clause of the U.S. Constitution. Additionally, the lack of clear standards of what constitutes price gouging in such legislation is unconstitutionally vague.

Copay cards are important for patients who may have high out of pocket prescription costs and/or other medical expenses.

Novartis is opposed to prohibitions on the appropriate, compliant use of patient assistance programs aimed at ensuring that commercially insured patients can afford the out of pocket cost sharing required by their health insurer. For U.S. patients with commercial insurance, Novartis provides copay assistance programs that result in eligible patients paying no more than $30 per 30-day supply, retail or mail order, for the vast majority of our branded and biosimilar products. This assistance not only allows patients to afford to fill their prescriptions and be adherent to prescribed therapies, but also frees up money for patients to use for other healthcare needs. It is not uncommon for health plans that require high deductibles and coinsurance to have a negative impact on patients who need high cost specialty products, since the patient can move through many levels of the benefit with the first prescription. Benefit designs with high deductibles can require patient payments of thousands of dollars at the start of therapy. Without copay cards or other financial assistance, many of these patients may never begin therapy. According to a Kaiser Family Foundation survey; one in five individuals with health insurance reports having trouble paying their medical bills.

Although FDA-approved generics may have the same active ingredients; strength and dosage form as the original brand name drug, some patients may not respond appropriately to a generic, either because of differences in patient metabolism or disease, or because the non-active ingredients in the generic may result in adverse reactions. Banning the use of copay cards when a generic is available, despite a prescriber's request for the patient to remain on the branded product, may leave the patient with no affordable option available to them. Improved adherence has been shown to lead to better health outcomes and reductions in spending on overall health care costs. Many studies have shown that high cost-sharing results in more patients skipping doses or not even picking up their prescription at the pharmacy -- even for drugs that treat life threatening diseases like cancer. Therefore, patients who cannot

pay their out of pocket costs without assistance could go without medication, take less than the dose prescribed, or skip doses.

Drug importation places U.S. citizens at risk, and ignores the fact that the FDA sets the international gold standard for drug approval agencies.

Novartis is opposed to state legislation that would allow the importation of prescription drugs into the U.S. market that have not been approved by the FDA. Importation places the health and well-being of U.S. patients in jeopardy due to the risks of adulterated or unsafe product being imported, and risks the health and well-being of patients in other countries due to the potential for drug shortages caused by the exporting of prescription drugs to the U.S.

Further, drug importation is pre-empted by the U.S. Food Drug and Cosmetic Act, and not within the jurisdiction of states. In 2015, a U.S. District Court held that a Maine law allowing importation from select countries was pre-empted by federal law. The Medicare Modernization Act of 2003 allows for the importation of drugs from Canada provided that the Secretary of HHS certifies that it is safe and cost effective, however no HHS Secretary has agreed to such certification to date. The US Food and Drug Administration (FDA) has asserted that states and/or other entities that encourage, act, or even cause illegal importation will run afoul of the Federal Food, Drug, and Cosmetic Act.

Novartis shares the goals of improving patient outcomes, increasing access to medicines, promoting innovation, and creating a more affordable and sustainable healthcare system. We are interested in learning more about the Subcommittee's proposal to "add adherence assistance, monitoring to care coordination contracts, and performance measures for value-based payments." We are committed to leading efforts that assist in transforming the healthcare system from the current "pay-for-service" approach to one that ties payment to outcomes delivered. We believe a value-based healthcare system can help reduce some of the unnecessary spending and focus everyone on what matters most – better outcomes for patients. In the pharmaceutical sector, Novartis is pioneering the shift to value-based pricing. We aim to focus our pricing approach on the value our medicines deliver with respect to clinical, patient, health system, and societal outcomes.

Thank you for your consideration. We look forward to working with you and the members of the Health Care Cabinet on proposals to increase patient access to high quality and affordable healthcare.

Sincerely,

Daniel P. Cassarly

Cc: Patricia Baker, President and CEO Connecticut Health Foundation
Cc: Victoria Veltri, JD, LLM, Office of the Lieutenant Governor