United States Senate

WASHINGTON, DC 20510

November 16, 2018

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20201

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
200 Independence Ave, SW
Washington, DC 20201

Re: CMS-4187-P

Dear Secretary Azar and Administrator Verma:

We write to voice our strong support for the proposed regulation to require drug pricing transparency (CMS-4187-P) issued by the Centers for Medicare and Medicaid Services (CMS) on October 18, 2018. We are committed to helping reduce prescription drug prices by requiring price disclosure in direct-to-consumer (DTC) pharmaceutical advertisements as well as other measures. We commend the Department of Health and Human Services (HHS) for advancing regulations that build upon similar bipartisan legislation passed by the Senate to put American patients first. We strongly encourage this policy be effectuated by the end of 2018.

Each year the pharmaceutical industry spends more than $6 billion in drug advertising. The motivation is clear—studies show that DTC drug advertising correlates with increased sales of high-cost, brand-name medications. According to the American Medical Association, "DTC advertising inflates demand for new and more expensive drugs, even when these drugs may not be appropriate." The average American views nine prescription drug ads *every day*. Those ads provide information regarding the indication for the drug, the side effects of the drug, and even information about where to go when the drug is too expensive to obtain. Adding the list price of the drug will provide patients and their doctors with a necessary data point to make the best health care decision.

The skyrocketing cost of prescription drugs and biologics is squeezing American families with both high out-of-pocket and insurance premium costs. Taxpayers feel the effect of high drug costs because of increased Medicare and Medicaid spending on expensive brand-name pharmaceuticals. Transparency is a cornerstone of efficient market competition, and today's drug pricing market is woefully opaque for consumers. When choosing to advertise prescription drugs directly to American patients, the least the pharmaceutical industry can do is to tell the whole story about the costs of prescription drugs. Any proposal to only mention an industry-backed website is, very clearly, inadequate and a half-hearted attempt to be transparent—such voluntary action is no substitute for price disclosure in ads.

As part of the Fiscal Year 2019 Defense/Labor, Health and Human Services (HHS), Education, and Related Agencies appropriations bill, the United States Senate on August 23, 2018, unanimously passed our bipartisan amendment that would promote transparency and empower consumers by appropriating $1 million to HHS to issue regulations under existing statutory authority, requiring appropriate price disclosure in prescription drug and biologic advertising. We were pleased to have the support for this policy of your Administration, the AARP, American Medical Association, American Hospital Association, America's Health Insurance Plans, BlueCross BlueShield Association, the Federation of American Hospitals, and 76 percent of Americans.

We strongly support CMS' proposed regulation to require DTC prescription drug and biologic ads to disclose the Wholesale Acquisition Cost for a 30-day supply or typical treatment course of advertised medications that cost more than $35. The pharmaceutical industry claims this may cause confusion for patients. We have more faith in American patients and the health care providers who care for them.

We also believe it is important to remember several key points. First, manufacturers voluntarily choose to promote their drugs to patients over the airwaves, they are not required to do so—but if they elect to advertise, they should be required to disclose the price tag. Second, there needs to be a common understanding of price to ground comparisons between products, and the Wholesale Acquisition Cost is a sensible price point given that it is defined in statute, is an objective and well-understood point within the supply chain, and is at the sole discretion of manufacturers to set and adjust. It is also the starting point for negotiations with third parties. Third, it is important to keep in mind that list prices do directly impact the amount paid by many beneficiaries, such as those in high-deductible health plans or if a drug is not on a formulary. But even if a patient does not pay a full list price, someone within the supply chain bears the higher cost—whether that be the negotiated rate paid by insurers or, more deceptively, patients through higher insurance premiums due to ever-increasing drug prices.

It is also clear—and unanimous Senate passage of the Durbin/Grassley DTC amendment underscores this point—that CMS and HHS are acting within existing statutory authority under Sections 1102 and 1871 of the Social Security Act to issue this regulation. These two authorities provide broad latitude to the HHS Secretary to issue regulations that advance the efficient administration of the Medicare and Medicaid programs, and are routinely cited as the statutory authority for a wide-ranging array of several hundred existing HHS regulations. Pharmaceutical companies are also already required to report specific price metrics to the federal government, in part as a means of reducing unreasonable or unnecessary federal expenditures. And in the case of DTC advertising, the rationale is evident—such advertising has an inflationary impact on spending in both the Medicare and Medicaid programs on prescription drugs that may not be necessary, cost-effective, or clinically appropriate. In fact, the top 20 most advertised drugs on television today cost Medicare and Medicaid a combined $22 billion in 2016. One 2009 study found that DTC advertising was associated with an additional $207 million in Medicaid spending for a single drug, and a 2014 study found that for every dollar spent on DTC advertising, the average return for a pharmaceutical company in sales was $9. To further examine how DTC prescription drug advertising inflates Medicare and Medicaid spending on pharmaceuticals, we are requesting that the Government Accountability Office (GAO) study this topic.

As CMS finalizes this regulation, we support the contextualization and formatting for the stated disclosure of list prices as proposed, and further encourage CMS to do the following: (1) require a modified form of a verbal/audible statement regarding the list price of a medication that is reasonably achievable for manufacturers within a broadcast advertisement; (2) add more specificity to strengthen the prominence, duration, and conspicuousness of the disclosure statement so that the list price is clearly legible and digestible; (3) require brief, explicit language to express an expiration date of the current listed price, to clarify for consumers the frequently fluctuating nature of prices over time; and (4) broaden the disclosure requirement to radio, print, social media, and Internet advertisements.

Requiring price disclosure when pharmaceutical companies choose to advertise their medications directly to consumers is a bipartisan, common-sense strategy to boost competition and help Americans struggling with outrageously high and skyrocketing drug costs. We strongly support the proposed regulation to bring transparency to DTC prescription drug advertising as one of many necessary strategies to lower prescription drug costs. It is well-past time for drug manufacturers to level with the American public, and we applaud CMS and HHS for capitalizing upon our legislative efforts to implement this policy.

Sincerely,

Richard J. Durbin
United States Senator

Chuck Grassley
United States Senator