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*The mission of the American College  
of Cardiology and the American  
College of Cardiology Foundation  
is to transform cardiovascular care  
and improve heart health.*

July 16, 2018

Alex M. Azar II  
Secretary  
Department of Health and Human Services  
200 Independence Avenue SW  
Washington, DC 20201

**RE: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs; Policy Statement; Request for Information [RIN 0991-ZA49]**

Dear Secretary Azar:

The American College of Cardiology (ACC) is pleased to submit comments to the Department of Health and Human Services (HHS) regarding its request for information on its Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs as published in the *Federal Register* on May 16, 2018. The ACC is a 52,000-member medical society that is the professional home for the entire cardiovascular care team. The College's mission is to transform cardiovascular care and improve heart health. The ACC leads in health policy formation, standards and guidelines. The College operates national registries to measure and improve care, provides professional medical education, promotes cardiovascular research and bestows credentials on cardiovascular specialists who meet stringent qualifications.

The twenty-first century has ushered in a new era of innovation, leading to novel therapies and cures for diseases and conditions that were not thought possible previously. However, it has also brought with it unsustainable spending on drugs. Far too many seniors and individuals living at or close to the poverty line are forced to choose between critical medications and other necessities. The College's mission to transform cardiovascular care and improve heart health will not be achieved without successful efforts to significantly reduce the cost of drugs – both brand name and generic.

### Drug pricing

Much of the focus on drug spending has been on novel therapies. Particularly, biologics can cost upwards of \$10,000. For example, PCSK9 inhibitors, first approved in 2015 to treat high cholesterol, cost approximately \$14,000 per year of treatment. However, novel therapies are not alone in their exorbitant pricing. In recent years, manufacturers have increased the prices for generic medications, as well. For instance, Valeant Pharmaceuticals increased the price of two generic cardiovascular medications significantly from 2012 to 2015. The price of nitroprusside, a medication aimed at

rapidly reducing dangerously high blood pressure increased by over 3,000 percent, while the price of isoproterenol, aimed at addressing abnormally slow heart rates, increased by over 6,500 percent during this time. This has occurred in a number of situations, but those of particular note are situations where manufacturers have opted to maximize profit over public welfare, such as in the case of a generic orphan drug. It is essential that manufacturers recognize the effects of such activities and balance their need to generate profit with the essential nature of their product.

### Access

The College has long advocated that access to healthcare is not merely about availability; instead, cost plays a significant role in access and must be treated as such. This applies to drug pricing, as well. **To that end, the ACC supports affordable access for all patients, regardless of insurance coverage or lack thereof, to all approved prescription drugs with scientific evidence of net clinical benefit or as articulated in clinical practice guidelines.** Additionally, excessive out-of-pocket expense represents an insurmountable hurdle for many patients. **It is essential to diminish any financial barriers including co-pays, co-insurance and deductibles. The College calls for a close examination of the role played by such barriers in the ability of patients to access crucial medications.**

### Transparency in pricing

What has become clear during the discussion of drug pricing is that the supply chain is quite complex, and there is not necessarily one single cause of high drug pricing. **To that end, the ACC urges pricing transparency throughout the distribution chain.** Accurate information on drug prices, plan benefits, formulary changes, and discounts must be readily available to enable clinicians and patients to be better informed about expected cost-sharing when discussing treatment plans. **The College further believes that pricing decisions should be made with an emphasis on value, as assessed through scientific evidence and analysis of both comparative effectiveness and cost-effectiveness.** Any movement toward value-based pricing must prioritize the impact on patient outcomes and not consider cost as the sole criteria.

### Administrative burden

**Additionally, the College urges the Administration to consider relevant administrative burdens in the conversation regarding drug pricing.** While prior authorization and other such processes are not factored into the cost of drugs themselves, they do add to the costs contributed by drugs to healthcare spending in this country. Processes that hamper patient access to evidence-based, approved therapies and serve little to no benefit must be eliminated.

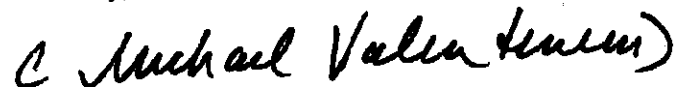
### Regulatory review

The College supports transparency throughout the process the Administration is undertaking to examine and analyze the problem of exorbitant drug pricing in this country. As such, it is essential that the Administration issue proposals to address these concerns through established formal rulemaking processes, including observing required notice and comment periods.

## Conclusion

The ACC appreciates the opportunity to provide these comments on Administration's plan to reduce drug pricing and would welcome an occasion to provide further input as needed. The College looks forward to working with HHS on this and other important issues. Please direct any questions or concerns to Lisa P. Goldstein, Director, Research and Innovation Policy, at (202) 375-6527 or [lgoldstein@acc.org](mailto:lgoldstein@acc.org).

Sincerely,

A handwritten signature in black ink that reads "C. Michael Valentine, MD, FACC". The signature is written in a cursive style.

C. Michael Valentine, MD, FACC  
President