Written Statement of G. Caleb Alexander, MD, MS
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Good afternoon.

My name is Caleb Alexander. I am a practicing internist and prescription drug researcher at Johns Hopkins, where I co-direct the Center for Drug Safety and Effectiveness. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University. Thank you for inviting me.

Policy makers and the public have been concerned about the high prices for prescription drugs in the U.S. for years. We consistently spend more per capita on drugs than other countries; we typically pay the highest prices; outpatient spending on pharmaceuticals is approaching $400 billion; and rates of growth of drug prices in the U.S. have returned to double-digit levels. These prices are impeding access for millions of Americans, including many Maryland residents.

Much of the concern has focused on specialty drugs like new treatments for high cholesterol, cancer and Hepatitis C. These cost of these drugs may exceed $100,000 a year, and although they account for less than 1% of drugs dispensed, they are responsible for 30% of drug spending. (Separate issues have been raised about generic drug costs. I'm sure you remember the case of Daraprim, for example, and the outrage that ensued when Martin Shkreli justified its 5000% price increase. I'm not going to focus on high cost generics here, though my colleague Jeremy Greene will do so later this afternoon).

Concerns regarding soaring drug prices are not lost on the public, and surveys suggest a majority of consumers feel drug costs are unreasonable and drug companies prioritize profits over people. These sentiments have contributed to a surge of interest in the issues by policymakers and those in political office, including our new President.

One thing that complicates efforts to address drug prices is that fundamental questions about the costs of drug development remain debated. It's clear that drugs are expensive to develop, most tested products never reach market and that some products bring enormous value. But determining the precise cost of developing a new drug has been difficult because companies have resisted calls to improve transparency regarding these data.

In addition, the relationship between revenue and R&D is unclear. While the best estimates are that the large drug companies spend about 17% of their revenues on R&D, the degree to which additional revenue will necessarily result in greater drug development is unclear. Also, while some drugs bring enormous value, many others do not.

A final question open for debate is whether the private market can generate a reasonable price. Here, there are many reasons to be skeptical. Drug prices don't follow usual economic models, they're not transparent to consumers and they don't correspond with common sense measures to determine reasonable prices such as the value to the patient, the cost of production or the "sunk" costs of conducting R&D.

These aren't just theoretical concerns. As a practicing internist, it's not unusual for me to encounter a patient who, after some probing, admits to skipping or stretching a medicine due to costs – and nationally, we know that about one in four people report difficulty affording their medicines. As the late Surgeon General C. Everett Koop reminded us, "medicines don't work in patients who don't take them".

Through support from the Arnold Foundation, Gerry Anderson, Josh Sharfstein and other colleagues and I at Johns Hopkins are working on more than a dozen projects to develop policy options to reduce pharmaceutical costs.

Let me begin with a few that are especially relevant.

First, drug coupons. Drug manufacturers can offer coupons that offset patients' out-of-pocket costs. These coupons undercut the ability of insurers to use economic incentives to encourage patients and providers to choose cost-effective treatments. They also reduce the leverage of insurers and pharmacy benefits managers when negotiating with drug companies. It's estimated that coupons will increase drug spending by $32 billion in the next decade. These coupons are not permitted for patients enrolled in Medicare and Medicaid, but they're prevalent in the private sector. There are many options that states can pursue to limit coupons, from banning them outright to limiting them to settings where there is no generic alternative, and thus less potential to introduce large market distortions.

Second, physician dispensing. In most cases, pharmacies fill prescriptions for self-administered drugs. However, increasingly physicians are dispensing these drugs in their own offices. This creates incentives to prescribe drugs that are more lucrative, but may not be in patients' best clinical or financial interests. Some of the most egregious examples of this have occurred in the setting of worker's compensation, such as the dispensing of prescription opioids and other drugs highly prone to non-medical use. But physician dispensing is also common for oral cancer drugs, for example. States vary a great deal in how they regulate this practice, and policy options include limiting profits or premiums from dispensing, requiring that dispensing regulations for physicians maintain parity with regulations for pharmacies, restricting dispensing to exceptional circumstances such as emergencies or prohibiting it altogether.

Third, mandatory reporting of price information. I've already noted that the rationale for the prices of drugs is opaque. In general, the actual prices that are paid are also opaque, given the many different kinds of rebates that exist. Proposals to improve the reporting of drug pricing are intended to force greater transparency and accountability on the part of manufacturers. The details of these proposals vary with respect to when and what types of disclosures are required. For example, with respect to what is to be disclosed, recommendations include: reporting of drug development costs, requiring justification for price increases, and providing public [or confidential] disclosure of price discounts and rebates. Few would argue that disclosure alone will be a panacea, but arguments in support of such transparency include that it may temper how frequently and dramatic price increases are when they occur.

A fourth area of increasing interest is in price gouging legislation. Since these are generally focused on essential generic drugs, I'll let my colleague Jeremy Greene say more about our work in this space.

We are also working on many other areas of pricing policy, though many are more relevant at a federal than state level. These include:

First, revising the patent system, such as increasing generic competition through revisions that prevent "ever-greening" and "pay-for-delay", or allowing for re-importation or compounding in settings where there is little to no competition.

Second, decreasing the use of limited supply chains that permit only one wholesaler to sell a drug, since companies use these to decrease competition by controlling product access.

Third, altering pharmaceutical regulation, such as developing policy options to prevent drug companies from taking advantage of FDA orphan designation when drug sales exceed a certain threshold.

Fourth, instituting a federal formulary that would increase efficiencies across federal programs such as Medicare, the Department of Defense, Veterans Affairs and the Indian Health Service, each of which has its own formulary.

Fifth, supporting the federal government's use use of patents under Section 1498 in specific circumstances as part of essential public health initiatives. This strategy was discussed for the purchase of ciprofloxacin following 9/11.

Sixth, clearing the FDA backlog for generic drugs, since this has been growing and it makes it more expensive for drug companies to enter certain markets.

Seventh, developing innovative pricing strategies like bundled payments, which include the costs of drugs within bundles such as those used by CMS to reimburse hospitals for hip and knee replacements.

Eighth, modifying cost-sharing arrangements in the catastrophic portion of Part D, since spending is increasing three times faster in catastrophic part of Part D because of high priced specialty drugs, yet Medicare currently covers 80% of these costs.

And last, instituting a single price that the government pays for prescription drugs, since currently the federal government pays very different prices for drugs and uses a variety of mechanisms to establish the price, yet loses substantial bargaining power in the process.

Let me close by asking you a rhetorical question, “Why do drug companies charge so much for their products?” There are a lot of ways to answer this, of course, but one reasonable answer is “Because they can!” No one would argue that companies don’t deserve a good return on investment, but there is increasing consensus that they have been getting far more than this, and that the status quo is untenable.

The problem of drug costs is complex and multi-faceted, and there is no single magic answer. States have a major responsibility for both the health of their citizens and the expenditures of taxpayers. As a result, states cannot and should not sit on the sidelines on this important issue.

Thank you for the opportunity to testify today. I look forward to your questions.