STATEMENT FOR THE RECORD

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Chairman Graham, Ranking Member Feinstein, and members of the Committee, thank you for the opportunity to be here and represent the great State of South Carolina. I am Joshua Baker, Director of the South Carolina Department of Health and Human Services, the state's agency responsible for administering the Medicaid program. We finance health care coverage for over a quarter of South Carolina's citizens at a cost of nearly $8 billion annually. Our mission as a health policy and financing organization mandates that our decisions balance health outcomes for beneficiaries against fiscal stewardship of limited public funds. One of our greatest tools for improving health outcomes – prescription drugs – is also one of our most significant cost drivers, second only to population growth itself.

While most of my testimony today will focus on the challenges health payers face given current market incentives, we should acknowledge the positive effects of intellectual property protections. Some market protections for companies that take significant financial risk in developing new technologies for our citizens should exist. In many cases they have led to life-saving and disease-curing innovations that may not exist otherwise. However, the current path of prescription drug prices generally, and specifically the escalation of costs for low marginal

value drugs, is both unsustainable and incompatible with the long-term viability of a publicly-funded, open-ended health entitlement program.

For my agency, this phenomenon resulted in an increase to per-capita prescription drug spending of 58% over the last half decade, adding an average of $50 million per year to the plan. This means a quarter of a billion dollars more spent on prescription drugs in 2018 than in 2014. In contrast, natural growth in pharmacy spending due to increases in program participants contributed about $35 million to the program budget.

In its simplest form, there are two competing interests health payers must contend with as it applies to drug development – innovation and competition. As I mentioned, there are many examples of IP protections yielding life-saving innovations in the marketplace. We also know that competition in the prescription drug market, as in most markets, is an effective guard against high prices. The introduction of competing products into the market routinely results in declining drug prices and the presence of generic manufacturers for a medication drives greater discounts relative to brand-name equivalents. Accordingly, the withdrawal of generic products from the US market in recent years has been followed by sharp trends in drug price increases. Maintaining a healthy and efficient balance of these competing interests – innovation and competition – should be the goal of the intellectual property and other protections available to pharmaceutical manufacturers. In achieving this balance, the role of patents, as administrated by the United States Patent and Trademark Office, market exclusivity, as granted by the US Food and Drug Administration, and payer mandates, such as those imposed by section 1927 of the Social Security Act, cannot be examined independently of one another.

Patents and market exclusivity can be blunt policy instruments. As applied to the pharmaceutical market in their current form, they do not adequately consider the underlying value of a product being protected, nor do they capture the true novelty of a product. Consequently, a medication that combines an over-the-counter pain reliever with an over-the-counter antacid is permitted to pursue market exclusivity and come to market with a price tag of several thousand dollars per month. In another instance, an over-the-counter antihistamine was combined with a vitamin to create a treatment for nausea in pregnant women. The price tag for this medication is $600 per month. These examples demonstrate the ability of medications that offer relatively low marginal benefits to come to market with the same protections as the next potential cancer cure. This dynamic is magnified when one considers the coverage mandates that exist in the US health care payer system, effectively requiring that public and private payers cover these medications.

An additional consideration is that intellectual property protections are meant to be time-limited. In some instances, manufacturers have found ways to lengthen their monopolistic period beyond what was intended by these protections. For example, “pay-for-delay” arrangements, in which brand manufacturers pay generic manufacturers not to bring products to market, artificially depress the supply of a drug, therefore increasing market prices. Another example is orphan drugs which are given market exclusivity for reasons other than the drug’s primary use.

Finally, I want to briefly discuss the indirect effect patent protections and market exclusivity have on public health payers. When the FDA approves a medication, Medicaid is statutorily bound to provide coverage for that medication, outside narrow exceptions. Also,

pharmacy reimbursement provisions require Medicaid to pay for medications based on a price the manufacturer sets. Unlike other monopolies, where the market power of a single supplier is balanced against consumer willingness and ability to pay, brand medications in the US market enjoy both a lack of competition and a requirement that health care payers provide coverage for their medications. While this dynamic is obvious in Medicaid, it is certainly not unique. Recent debate surrounding Medicare Part D's six protected drug classes highlight this same issue.

In closing, I would like to leave you with a few thoughts. First, along with the obvious benefits of intellectual property protections, there are nonetheless inefficiencies in the prescription drug market that result from the inability of intellectual property and market exclusivity provisions to differentiate between high and low value drugs. Second, the impacts of market exclusivity and patents should be considered together. And finally, the health care payer space – where buyers exist for nearly any product that passes through the approval process – magnifies the financial impact of these inefficiencies to taxpayers and health care consumers.

On behalf of the South Carolina Department of Health and Human Services, and the citizens of South Carolina, my sincere thanks for your time and attention today.