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Outline of Senate HELP Committee Presentation: Making Medicines Affordable

1. Thank the National Academy of Sciences for their contribution to this important policy debate. Let me make a few general remarks and then I will be happy to respond to questions about the specifics.

2. To begin, there is not single drug market and there is not a general problem. There are some specific markets that are generating the attention at the moment – sole-source generics and specialty drugs (especially oncology). The rest are working fine.

3. In thinking about drug prices, it is important to be very clear about two distinct issues:
   - Lowering the cost of bringing drugs to market, and the prices generated by market competition
   - Shifting the overall cost among stakeholders so as to make drugs more "affordable" to a target group – but not everybody simultaneously

4. Addressing the overall cost issue is inevitably a matter of fostering competition and getting more than on drug on the market. The NAS report as a number of suggestions in this area; for example I like some of the ideas in: "Accelerate market entry and use of safe and effective generics as well as biosimilars; foster competition to ensure the continued affordability and availability of these products."

5. Cost-shifting is pervasive in pharmaceuticals; indeed, it is important to keep in mind that insurance is basically a financial product for cost-shifting. The issue is whether the cost-shifting is deliberate or unanticipated, and furthers a policy goal.

   - For example, Medicaid best price undercuts vigorous competition in the private market; effectively shifting costs from Medicaid to private payers
   - Proposals to focus on net prices (e.g., "DIR") would shift costs away from beneficiaries. Who would pick up the tab?
   - In this regard, let me say a few words about "government negotiations"
     - I have been quite vocal about the non-interference clause in Part D and the absence of any real savings from allowing the Secretary to negotiate. This would not change if Part D were aggregated with Medicaid, or the VA or other programs.

- What does matter is allowing the programs to institute a formulary and deny manufacturers access to the beneficiary population. It is precisely this ability to impose tiered pricing that has made private competition in Part D so successful. It has nothing to do with the government *per se*.
- Doing this on a large scale runs the risk of permitting the government to negotiate "good prices", while private sector payer get stuck with higher prices to make up the shortfall. This would be a large cost-shift and not a genuine improvement in drug pricing.

6. Finally, if one has a public policy problem, first stop making it worse. Well-intentioned programs that have grown to be poorly-targeted and inefficient – 340B and the Orphan Drug program come to mind – should be reformed.