SOUTH CAROLINA DEPARTMENT OF HEALTH AND HUMAN SERVICES
Healthy Connections
MEDICAID

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The Honorable Lindsey O. Graham
Chairman, United States Senate Committee on the Judiciary
Washington, DC 20510-6275

Dear Chairman Graham,

Thank you for the invitation and opportunity to testify before the United States Senate Committee on the Judiciary on May 8, 2019. It is an honor to represent our state and a privilege to speak before of the Committee about the rising costs of prescription drugs. Enclosed you will find responses to questions for the record posed by Senators Grassley and Booker.

Please contact me at joshua.baker@scdhhs.gov or 803.898.2504 if I may be of assistance with this or any other issue. Thank you for your efforts on behalf of the citizens of South Carolina.

Sincerely,

Joshua D. Baker

Enclosures:
1. Responses for Senator Grassley
2. Responses for Senator Booker

Enclosure 1: Joshua Baker response for Senator Grassley

Question: USPTO Director Iancu says that the U.S. Patent Office does not grant patents for "tweaks" or minor improvements to inventions. Do you agree? Please explain. If you believe that this is an issue, what action would you recommend Congress take to ensure that follow on patents for drug improvements are only granted for true innovations?

Response:

While I believe that the U.S. Patent Office has set a threshold for issuance that it believes to be material, that level of materiality does not necessarily coincide with true clinical value or an actual change to the clinical pathways used to deliver a therapy. For example, there are instances in which a new pharmaceutical delivery system represents a clear distinction in the release of a medication, once taken, than current products. In a case such as slow release insulin or an opiate with crush-resistant properties, the delivery mechanism is the novel item, as opposed to the underlying therapy. Whether that modified release profile represents a meaningful clinical advantage compared to the original product, however, is less clear.

Further, the implications of patenting must be considered in concert with the market exclusivity parameters offered by USFDA approval. Any attempt to address the intersection of drug pricing and intellectual property should include both patent and exclusivity parameters.

As Congress considers action on this issue, I would ask continued consideration on the downstream implications of patent and exclusivity determinations. With each new introduction and FDA approval, Medicaid is required to provide coverage without regard for the price of the medication or the value that it brings to the market. As I mentioned in my testimony, unlike other monopolies created through the patent system, where the market power of a single market supplier is still balanced against consumer willingness and ability to pay, brand medications in the US market enjoy both a lack of competition and a requirement that healthcare payers provide coverage for their medications.

Enclosure 2: Joshua Baker response for Senator Booker

You noted in your written testimony that South Carolina's Medicaid program spent a quarter of a billion dollars more on prescription drugs in 2018 than in 2014. This represents an increase in per capita prescription drug spending of 58 percent. There is a similar trend in Medicaid programs nationwide. According to a July 2018 investigation by the Center for Public Integrity (CPI) and National Public Radio (NPR), Medicaid drug costs grew almost 50 percent per patient between 2008 and 2016. This doubled the program's drug spending to $31 billion. These figures detail a clear need to address prescription drug costs, both for patients and for coverage programs like Medicaid.

As you mentioned, state Medicaid programs are required to cover most FDA-approved medications. However, states can utilize tools to control spending, like preferred drug lists, which are shaped in part by states' Medicaid drug use review boards. Despite these tools, the CPI/NPR investigation found that Medicaid programs may still spend more money than necessary on medications on account of tactics drug companies use to influence Medicaid programs' drug coverage decisions. These tactics can include providing free meals, paid travel, and other compensation and perks to individuals who serve on these state boards.

a. Have you found this to be an issue in your state? Please provide any relevant details about your state's experience.

Response:

To ensure that aggressive or unethical lobbying and marketing tactics do not influence South Carolina Medicaid coverage decisions, the South Carolina Department of Health and Human Services requires the following:

- Members of South Carolina's Pharmacy and Therapeutics (P&T) Committee are required to disclose contractual relationships, ownership interest, or other potential conflicts of interest with pharmaceutical manufacturers.
- P&T Committee recommendations are advisory to the Department, and final decisional authority regarding formulary coverage rests with the SCDHHS Director who is subject to a broad range of state-directed ethics rules and financial disclosure requirements.
- Other SCDHHS employees involved in drug coverage decisions are also subject to state ethics rules that govern the acceptance of any items of value from third parties.

While these practices outlined above are concerning and should be addressed, a broad approach to expanding the policy levers available to states to curtail increases in prescription drug prices is necessary. While preferred lists are an effective measure in therapeutic classes where competition is robust, they do not allow states the latitude to limit coverage for first-in-class drugs that are inherently low value. Eliminating the undue influence of pharmaceutical manufacturers, while important, would be much more effective if combined with additional levers to allow more flexibility for drug coverage.

b. Would transparency tools, like the ones outlined in the Medicaid Drug Decisions Transparency Act, help your state? Specifically, would it be helpful to (1) expand the payment reporting requirements established by the Physician Payments Sunshine Act to include individuals who serve on a state drug use review board, and to (2) have a summary of that information reported annually to states?

Response:

Yes. Transparency tools, such as those mentioned, are useful and will curtail the influence of drug manufacturers in state decision making. Although current requirements of South Carolina ethics law, as well as the SCDHHS P&T bylaws, provide similar transparency requirements today, a consistent and portable source of data would reduce reporting variability and allow national comparison of the financial influence manufacturers have over prescribers.