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**SUSTAINABLE Rx PRICING**  
Transparency. Competition. Value.

**Testimony Submitted for the Record**

**U.S. House Energy and Commerce Committee  
Subcommittee on Health**

**Hearing on “Examining Medical Product Manufacturer Communications”**

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Chairman Burgess, Ranking Member Green, and members of the House Energy and Commerce Subcommittee on Health, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on medical product manufacturer communications.

CSRxP is a project of the National Coalition on Health Care Action Fund. We are a [broad-based coalition of leaders](#) – physicians, nurses, hospitals, consumers, health plans, PBMs, pharmacists, and businesses – promoting bipartisan, market-based solutions to lower drug prices in America. It is a fact: prescription drug prices are out of control. The consequences of this crisis hurt everyone, from patients and consumers to doctors, hospitals, and hardworking taxpayers. That’s why it is critical to solve this crisis now with smart, effective solutions that work.

CSRxP believes that permitting more open medical product manufacturer communications will provide increased certainty and clarity to payers as they predict and prepare for future spending on emerging therapies, thus allowing them to set more stable premium and out-of-pocket spending levels for consumers over time. Such communications should have appropriate parameters, however, so that manufacturers maintain incentives to undergo the FDA approval process, thereby giving U.S. patients, their families, and their healthcare providers peace of mind that the products they use are safe and effective.

H.R. 2026, the Pharmaceutical Information Exchange Act would facilitate more open, pre-decisional communication – communication about an emerging therapy prior to FDA approval or clearance – between manufacturers and payers while at the same time preserving appropriate incentives for manufacturers to seek FDA approval for their products. With respect to H.R. 1703, the Medical Product Communications Act of 2017, CSRxP believes Congressional action may be premature and warrant further consideration of the issues as presented in the legislation.

**I. Pre-decisional manufacturer communications can help payers establish more predictable rates for patients and consumers over time, as well as enable more use of value-based payment arrangements.**

Healthcare stakeholders try to forecast costs of healthcare spending several years into the future to keep rates and premiums as predictable as possible for patients and their families. Predictability results in more stable rates and fewer unexpected spikes in year-over-year out-of-pocket costs and premiums – a particularly meaningful benefit to U.S. consumers as they consider their healthcare needs.

Accurate rate development relies on detailed assumptions about the anticipated utilization of health care services, including prescription drugs and medical devices. Without accurate, reliable, and more transparent clinical and pharmacoeconomic information about new products or expanded indications of existing products, payers cannot appropriately account for emerging therapies when budgeting for the future – whether it be for a hospital system or for a health plan setting premiums. The concern is becoming more acute as medical products are moving more quickly and efficiently through the FDA approval process.

Moreover, more open and transparent pre-decisional communications may better position payers to conduct their own population-based value assessments of therapies and related benefit designs to broaden use of value-based healthcare payment strategies. For example, such information could support development of outcome-based contracts and indications-based pricing arrangements.

**II. Drug makers should be able to engage in more transparent pre-decisional communications about their products only if they also are required to be more transparent in their drug pricing strategies prior to FDA approval.**

More open communications should be considered just the first step in the broader goal of creating more transparency into how pharmaceutical companies determine how they are going to price their products. Without requiring the pharmaceutical industry to be more transparent on drug pricing and price growth, American patients and their families will continue to face unsustainable and needless increases in prescription drug costs.

Consequently, CSRxP strongly urges that any legislation which permits drug makers to conduct more open and transparent pre-decisional communications about their products also must require them to be more transparent about product pricing prior to FDA approval. Such information should include the maximum unit price the drug maker intends to charge for the product; the cost of a course of treatment; the label under discussion with the FDA that indicates the target population with other important clinical details; and a projection of federal spending on the product.

More transparent pre-decisional drug pricing also could help payers expand use of value-based healthcare payment strategies, which potentially can lower costs, increase access and improve health outcomes for patients taking these medications. In other words, pre-approval drug pricing transparency is a critical strategy in making prescription drugs more affordable for all Americans, while at the same time, maintaining and potentially expanding access to treatments that can improve patient health and quality of life.

**III. Communications should follow a regulatory framework that enables manufacturers to convey pre-decisional information about their products while at the same time ensuring that incentives remain to have the products go through the FDA approval process.**

Knowing that medical products are safe and effective for use is critical for both patients and the prescribing physicians. Hence, any pre-decisional manufacturer communications should maintain appropriate safeguards to incentivize manufacturers to go through the FDA approval process, which deems their products safe and effective for patient use. Such safeguards should include the following:

- Pre-decisional communications only should reflect scientifically-sound, competent and reliable evidence that is truthful, non-misleading, and unbiased. The communications should include information such as risk/benefit and quality data, as well as appropriate disclaimers on the limitations of the data presented.
- Existing FDA policies should not be modified in any way that would extend increased flexibility to manufacturers to promote off-label uses of their products directly to consumers. Rather, pre-decisional communications only should occur between entities with both financial and clinical interests in avoiding the unintended consequence of affecting prescribing practices by physicians directly treating patients. For example, any communications between manufacturers and medical service providers should adhere to specific criteria to ensure the information is relevant, scientifically sound and responsibly presented. They should be limited to appropriate proactive requests to manufacturers or to certain venues that meet widely accepted and recognized standards for communications about scientific and clinical data such as scientific journals, clinical practice guidelines, and compendia, but not to lay media, letters to the editor, or proactive and reactive communications.
- Manufacturers only should discuss information related to medical product indications undergoing FDA review.
- The pre-decisional communications only should occur within a certain timeframe of the expected FDA approval date.

- Given the many emerging technologies and evolving organizations and relationships into which manufacturers enter, the FDA should have latitude to periodically revisit and reassess the definitions of entities covered by the pre-decisional communications safeguards.

The FDA currently is reviewing the extent to which appropriate safeguards, such as those outlined above, may allow for additional communications from manufacturers about their products. As noted above, with respect to H.R. 1703, CSRxP believes the FDA should complete its review prior to any Congressional action to expand the definition of scientific exchange between manufacturers and health care professionals so that any expanded communications strictly include information that is truthful, non-misleading, unbiased, supported by competent and reliable evidence, relevant, and responsibly presented.

#### **IV. Conclusion**

CSRxP appreciates the Subcommittee's leadership and, again, thanks the Subcommittee for the opportunity to submit testimony for the record on medical product manufacturer communications. We look forward to collaboration in the future on developing market-based policies that promote competition, transparency, and value to make prescription drugs more affordable for all American patients and their families while at the same time maintaining access to the treatments that can improve health outcomes and save lives.