



STATEMENT FOR THE RECORD

**Submitted to the
House Energy and Commerce Committee
Subcommittee on Health**

Examining Medical Product Manufacturer Communications

July 12, 2017

America's Health Insurance Plans
601 Pennsylvania Avenue, NW
Suite 500, South Building
Washington, D.C. 20004

America's Health Insurance Plans (AHIP) is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access and well-being for consumers.

We appreciate this opportunity to offer our comments on two draft bills addressing pharmaceutical manufacturer communications on medical products: the "Medical Product Communications Act" and the "Pharmaceutical Information Exchange Act." Proposed changes to the rules surrounding these communications could have far-reaching implications for the decisions made by health care providers, in consultation with their patients, about which medications and other medical products are safe, effective, and appropriate for treating their patients. We believe it is critically important for Congress to fully consider the potential impact of these proposed changes on patient safety, health outcomes, and our shared goal of promoting high quality, affordable health care for all Americans.

"Medical Product Communications Act" (H.R. 1703)

Patients deserve to have more information about their medical care – from the cost of their care, to the quality of their providers, to the efficacy of their treatments. With more information, more consumers can make better-informed decisions. However, it is critical to understand that better decisions are based on *accurate, evidence-based* information – not just *more* information. Information that is inaccurate, incomplete, or inconclusive helps no one.

Health insurance providers are committed to helping every patient access high-quality care that gets them well when they're sick and keeps them well when they're healthy. That means finding the safest, most effective treatments that best meet the individual needs of individual patients. That may include the innovative use of prescription drugs for conditions that are not specifically approved by the Food and Drug Administration (FDA) and not included or indicated on the product label. This "off-label" use has helped many patients get well and stay healthy. When there is strong evidence to support off-label use of prescriptions drugs, health plans often provide coverage for such usage. For example, in the Medicare prescription drug program, Part D plans

cover drugs prescribed for off-label use if the drugs are identified as safe and effective for that use in certain officially recognized drug compendia.¹

The “Medical Product Communications Act” would not provide or ensure that patients and care providers have access to better research and evidence. Rather, it would allow drug manufacturers to communicate information about prescription drugs that has not been approved by the FDA. The lack of approval may be due to contradictory evidence – or the lack of any evidence at all – or the need for additional research.

The FDA’s current requirements for meeting high standards of evidence for safety and efficacy help ensure that robust evidence exists to support approval of drugs, biologics, and devices for specific uses and indications. To truly help patients get the most effective treatments, it is essential to maintain the highest standards of safety, research and evidence. These rules – and the incentives for manufacturers to comply with proper FDA processes – should be preserved.

Because we want to ensure that patients and care providers have access to accurate information based on the best possible research and the strongest possible evidence, AHIP does not support this legislation. We have serious concerns that it could undermine the FDA’s efforts to ensure that providers and patients receive information that is truthful, is supported by rigorous scientific evidence, and is not misleading or biased. Specifically, we are concerned that allowing drug manufacturers to communicate about unapproved uses of their products reduces the incentive for them to go through the FDA’s supplemental application approval process. The draft legislation proposes removing the scientific exchange of off-label uses from the definition of “intended use” of the drug or device, preventing the FDA from any oversight of the scientific exchange of information about off-label uses of drugs and devices. This, in turn, reduces the incentive for manufacturers to conduct large, well-controlled, randomized clinical trials that would prove a product is both safe and effective for a particular indicated use.

Ultimately, this result would weaken the FDA’s role to ensure patient safety and public health, introducing far more safety risks into the health care system than potential rewards.

Additionally, at a time when policymakers are working on ways to increase value and decrease

¹ Social Security Act §1860D-2(e)(4)(A). Also of note, drugs indicated to treat sexual or erectile dysfunction are not covered in Medicare Part D, and coverage of any off-label uses of such indicated drugs are also prohibited under Social Security Act §1860D-2(e)(2)(A).

costs across the health care system, we must consider that this has the potential to dramatically increase costs by utilizing potentially expensive therapies, without substantial evidence of better care, better quality, or better outcomes.

We also want to emphasize that – even without the proposed legislation – health care service providers already have access to scientific information about unapproved uses of medical products, and physicians currently are free to use drugs for “off-label” indications. This information is widely available through public sources such as scientific journals, clinical practice guidelines, and compendia.

While these existing sources of information provide evidence-based information with respect to the safety and efficacy of medical products, a recent *Journal of the American Medical Association* (JAMA) study tracking off-label use in 45,000 adults through electronic health records (EHRs) over 2005-2009 found that, of the off-label prescriptions studied, 80 percent lacked scientific evidence and had a higher occurrence of adverse drug events (ADEs). The study concluded that off-label use is associated with a higher occurrence of ADEs, and recommended that EHRs “be designed to enable postmarketing surveillance of treatment indications and treatment outcomes to monitor the safety of on- and off-label uses of drugs.”²

We appreciate that the parameters around the scientific exchange of off-label uses have been strengthened in the draft legislation, preventing the communications from promotional use and requiring competent and reliable scientific evidence and appropriate contextual information regarding any limitations of evidence. However, we believe these communications would be inherently promotional and less likely to reflect the rigorous scientific analysis that providers need to serve the best interests of their patients while preventing adverse events.

The FDA currently is reviewing its policies to determine the extent to which additional communications from manufacturers can provide access to information on off-label uses that is relevant, scientifically sound, and responsibly presented. We believe this process offers promise for developing a common sense policy. AHIP has submitted comments to the FDA, urging the agency to consider defining allowable parameters for these communications, such as limiting

² Tewodros Equale, et al., “Association of Off-label Drug Use and Adverse Drug Events in an Adult Population,” *Journal of the American Medical Association Internal Medicine* 176, no. 1 (2016): 55-63, doi:10.1001/jamainternmed.2015.6058.

them to indications undergoing FDA review and occurring within a certain timeframe of the expected FDA approval date. We also recommend that the communications include risk-benefit and quality data, appropriate disclaimers (including the limitations of such evidence), and other relevant information.³

We appreciate the committee's interest in examining the rules that apply to manufacturer communications on "off-label" uses, as many of these issues have been the subject of legal disputes. However, we urge you to proceed cautiously when considering the pending draft legislation and take into consideration the long-term patient safety implications, the potential increase in health care costs associated with investigational drug use, and the FDA's deliberations on this issue.

"Pharmaceutical Information Exchange Act" (H.R. 2026)

The "Pharmaceutical Information Exchange Act" would expand the ability of drug and device manufacturers to share health care economic information (HCEI) and scientific information with payors, formulary and technology review committees, and similar entities for investigational use drugs and devices before they are approved by the FDA.

We addressed these issues in a comment letter we recently submitted to the FDA.⁴ Our letter highlighted our members' priorities in three areas:

- The importance of holding communications between manufacturers and payers, formulary committees, and similar entities to strong evidentiary standards;
- The value of a regulatory framework that enables manufacturers to communicate HCEI or real world evidence (RWE) related to an FDA-approved indication to payers, formulary committees, and similar entities; and,

³ AHIP [letter](#) to Food and Drug Administration, responding to request for comments on "Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products." April 18, 2017.

⁴ AHIP [letter](#) to Food and Drug Administration, providing comments on draft guidance on "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities -- Questions and Answers." April 18, 2017.

- The need for timely and appropriate communications based on strong evidentiary standards between manufacturers and payers, formulary committees, and similar entities about products that are investigational or under review by the FDA.

AHIP supports the goals of this draft legislation. The current uncertainty over what communications are permitted often makes it difficult for health plans to obtain reliable HCEI related to an FDA-approved indication and therefore complicates their efforts to make accurate assessments regarding value, pricing, and utilization. Health plans need sound information based on strong evidentiary standards to inform estimates of anticipated costs for up to several years into the future when making business decisions involving pricing and contracts.

In addition, because this information is not permitted for products that are labeled investigational or under FDA review, it is currently difficult for plans to obtain information about manufacturer pipelines (including both new products and additional indications for existing FDA-approved products), which is also essential to their ability to make accurate assessments about value, pricing, and utilization in the longer term. A regulatory framework that enables manufacturers to communicate with payers regarding products that are investigational and under review by the FDA will allow payers to take that information into consideration as they plan for and make coverage and reimbursement policies far in advance of the effective date of the decisions. Additionally, early and appropriate communication of this type of information can enable manufacturers and payers to develop alternative, value-based payment arrangements, such as outcome-based contracts and indication-specific pricing.

While we support the goals of this draft legislation, we would like to reemphasize the importance of ensuring these communications promote patient safety and public health. Safeguards must be in place so that information communicated regarding HCEI for products that are investigational or under review be held to strong evidentiary standards. We appreciate that the draft legislation requires these communications to be based on “competent and reliable scientific evidence” (CARSE), and support the FDA’s intent to consider HCEI to be based on CARSE if “the HCEI has been developed using generally-accepted scientific standards, appropriate for the information being conveyed, that yield accurate and reliable results.”

Additionally, we believe the FDA should periodically revisit and reassess the definitions and entities covered. Over time, emerging technology, evolving organizations and relationships,

along with other changes in health care may create some ambiguity in the intended audience for these communications. It will be important to ensure that the information sharing occurs between sophisticated entities with both a financial and clinical interest to avoid the unintended consequence of affecting prescribing practices by physicians who are directly treating patients.

Thank you for considering our views on these draft bills. We stand ready to work with you on medical product manufacturer communications. We also look forward to working with you on broader issues surrounding the high cost of prescription drugs and the need for market-based solutions to ensure that consumers have access to affordable medications.