New Efforts to Advance Medical Product Communications

Prices should be able to adjust to reflect the value in how medicines are prescribed and the outcomes they deliver.

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Statement from FDA Commissioner Scott Gottlieb, M.D., on new efforts to advance medical product communications to support drug competition and value-based health care

We're living in a time of unparalleled scientific advancement. Innovative medical treatments continue to be developed at an astonishing pace and are delivering increasingly targeted and meaningful benefits. More patients have more opportunities to benefit their health. But to realize the potential of these scientific advances, American patients must be able to gain access to these innovations. That means they must be able to afford the resulting medicines. And the rising list prices of drugs can create an obstacle to access. This is especially true for patients who find themselves underinsured or uninsured for medicines.

Last month, Secretary of Health and Human Services Alex Azar set forth a sweeping blueprint to address this pressing challenge. Among the new steps, HHS highlighted the importance of linking payments for drugs to their value and committed to removing regulatory obstacles to value-based purchasing by payors.

This call to action is taking place against the backdrop of an information transformation. In the era of "big data," scientists, drug makers, regulators, payors and others have unprecedented access to new sources of information. Already, the ability to harness this information and use it to help establish the value of medicines is providing the foundation for a shift toward innovative, value-based payment arrangements.

The Food and Drug Administration, working with our sister agencies in the Department of Health and Human Services, can help nurture this change by providing clear guidance to pharmaceutical companies about open, responsible communication with payors, formulary committees and others. To advance these goals, the FDA is issuing updated, final guidance documents that provide greater clarity about our thinking and recommendations for certain medical product communications. In particular, this guidance will inform market participants developing contracts that include value-based arrangements how to communicate information about how a drug might impact outcomes that are important to purchasers like a health plan or hospital, but is not an endpoint that is expressly described in the drug's approved labeling.

The blueprint put forward by HHS advances an important principle around these relationships: that prices should be able to adjust to reflect the value in how medicines are prescribed and the outcomes they deliver, to control rising spending and reduce the burden of drug costs for consumers. To achieve these goals, selling models should be able to tie the price of drugs more closely to the usefulness of the clinical setting in which they are prescribed. We want to encourage competitive contracting based on measures of value that matter most to purchasers and patients, not get in the way of these competitive negotiations.

The first guidance, "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities—Questions and Answers," answers common questions about companies' communications to payors, including insurance companies, formulary committees and similar entities. It recognizes that payors seek a range of information on the effectiveness, safety and cost-effectiveness of approved/cleared medical products, including information from pharmaceutical manufacturers, to help support product selection, formulary management and/or coverage and reimbursement decisions. This information may overlap with, but differ from, the information that the FDA reviews in making regulatory decisions. We have heard from some manufacturers that in the absence of clear guidance from the agency, they were inhibited from sharing certain economic and other information and, potentially, even from generating additional rigorous data for payors to evaluate in determining the value of a product to their health plans and their beneficiaries, and then to tie value-based contracts to these measures.

Taking into consideration the many thoughtful comments from stakeholders on our draft guidance, our final guidance now includes recommendations that are designed to enable truthful, non-misleading and appropriate company communications with insurers across a product's lifecycle. The goal is to advance public health benefits such as increased cost savings from informed and appropriate coverage and reimbursement decisions. In this way, we can help ensure patients have more timely access to cutting-edge medical technologies. We can facilitate access by helping to reduce the overall cost of providing these benefits to patients. And in promoting access, we will advance important public health goals.

The payors who receive this information, and evaluate it for purposes of developing value-based contracts, are sophisticated parties who have access to a lot of expertise in evaluating this data. But we know that coverage and reimbursement decisions by payors impact many patients. The FDA believes it's critical that information provided by manufacturers to payors about their medical products be truthful and non-misleading and that appropriate background and contextual information be provided to enable payors to make informed decisions. This guidance provides important recommendations from the FDA to help firms meet these important standards so that patients benefit from such decisions.

Additionally, it's our belief that giving companies clear guidelines for providing payors with truthful and non-misleading information about unapproved products and unapproved uses of approved or cleared products will help facilitate communications that can allow payors to provide coverage for these new products and new uses more quickly after FDA approval or clearance. And our hope is that these communications can also help companies and payors establish pricing structures that

benefit patients as well as health plans.

The second guidance, "Medical Product Communications That Are Consistent With the FDA-Required Labeling," provides the FDA's views on manufacturers' communication of information that is not contained in the FDA-required labeling for their products, but that is consistent with that labeling.

The FDA-required labeling is the primary tool that communicates the essential information needed for the safe and effective use of a medical product. Therefore, the labeling is subject to content requirements and limitations to help ensure that it effectively communicates information. It's not intended to exhaustively address all that's known about a product for its approved or cleared uses. Consequently, there are types of information that are not in the labeling, but that are consistent with the labeling, which medical product companies also may want to share. This information, such as data from post-market studies and surveillance of a product's approved uses, or additional information from the pre-market studies that were used to support approval of the product, may help inform decision-making regarding patient care.

Sometimes payors also want this information to inform purchase decisions, or to serve as the basis for value-based contracts where reimbursement may hinge on measures of benefit that aren't expressly described in the drug's label. This might include, for example, information about the time of onset of action of a product, or about patient compliance or adherence.

We received a number of questions from medical product companies about this topic. In response to these questions to our docket, we're issuing this final guidance to provide greater clarity around questions such as: What types of information are considered consistent with FDA-required labeling? How does the FDA recommend companies communicate this information in a truthful and non-misleading way? The final guidance explains the FDA's current thinking on these and other questions. The guidance also explains that the FDA does not intend to rely on communications that are consistent with the FDA-required labeling to establish a new intended use.

Together, we believe these two guidances will provide clarity to companies as they develop communications about their medical products and help ensure that patients, providers and insurers have access to a range of relevant, truthful and non-misleading information from companies about medical products. The aim of our policy is to help facilitate contracting for new medical products that are based on the value that these products are delivering to health systems, providers and especially patients. However, these guidances are not intended to address how firms currently provide information to doctors and patients about unapproved products or unapproved uses of approved products.

The ultimate goal is to help facilitate a market that is more competitive, based on the outcomes that matter most –the benefit to patients. Helping facilitate appropriate company communications with these audiences may help foster these outcomes, and enable better access to medical products and possibly more affordable options for Americans.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public

health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation’s food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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