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FDA Issues Guidance on Drug and Device Manufacturer Communications: Part I – Health Care Economic Information and Unapproved Products/Use Communications with Payors

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On June 12, the FDA issued guidance that clarifies its recommendations for certain medical product communications. The guidance, "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities - Questions and Answers" (the "Guidance"), provides answers to common questions about the communications between medical product manufactures, packers, and distributors ("firms"), and insurance companies, formulary committees and similar entities ("payors"). In particular, it addresses communications by firms to payors regarding approved or cleared products as well as unapproved products and unapproved uses of approved or cleared products.

In a statement, FDA Commissioner Scott Gottlieb acknowledged the sophistication of payors as an audience and recognized their need for access to a range of information on the effectiveness, safety, and cost-effectiveness of approved/cleared products. The Guidance is therefore designed to enable truthful, non-misleading and appropriate company communications to promote public health benefits such as increased cost savings from informed and appropriate coverage and reimbursement decisions. The FDA similarly seeks to give companies clear guidelines for providing payors with truthful and non-misleading information about unapproved products and unapproved uses of approved/cleared products. Through the Guidance, the FDA aims to help facilitate communications that can allow payors to provide coverage for these new products and new uses more quickly after FDA approval or clearance as well as help companies and payors to establish pricing structures that benefit patients as well as health plans.

First, the Guidance addresses the communication of health care economic information ("HCEI") regarding both approved drugs and approved/cleared devices. HCEI is defined

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in section 502(a) of the Food, Drug, and Cosmetics Act ("Section 502(a)") as "analysis… that identifies, measures, or describes the economic consequences… of the use of a drug." As noted in the Guidance, HCEI generally pertains to economic consequences related to the clinical outcomes of treating, preventing, or diagnosing a disease.

The Guidance clarifies Section 502(a), which provides that the FDA will not consider dissemination of HCEI to an appropriate audience to be false or misleading if the HCEI relates to an approved indication and is based on competent and reliable scientific evidence (the "CARSE" standard). Specifically, the Guidance expounds on the FDA's thinking as to what it means to "relate to an [approved] indication," the type of evidentiary support needed for HCEI, and the components of HCEI to which the CARSE standard applies, among other topics. Notably, although the language in Section 502(a) addressing HCEI applies to drugs, not devices, the FDA states that its recommendations are also applicable to firms' communications of HCEI regarding approved/cleared devices.

The Guidance also describes information that should be included when disseminating HCEI. While recognizing not all categories of information will be applicable to particular HCEI presentations, the Guidance provides that, when relevant, the HCEI presentation should also clearly and prominently include appropriate background and contextual information, including study design and methodology, generalizability, limitations, sensitivity analysis, and additional information for a balanced and complete presentation. The disclosure of this information may be concise, so long as all material information is provided.

In response to indications from payors that they need to plan for and make coverage and reimbursement decisions far in advance of the effective date of such decisions, the Guidance also discusses types of information about unapproved products or unapproved uses of approved/cleared/licensed products that a firm may communicate to a payor. Provided that the information is "unbiased, factual, accurate, and non-misleading," communications may include product information, information about the indication sought, anticipated timeline for possible FDA approval/clearance/licensure of the product or new use, product pricing information, patient utilization projections, product-related programs or services, and factual presentations of results from studies including clinical studies of drugs or devices or bench tests that describe device performance. Additionally, the communication must be accompanied by additional information, including a clear statement that the product or use is not approved/cleared/licensed, and that the safety or effectiveness of the product or use has not been established.

In the same statement introducing the Guidance, Commissioner Gottlieb also introduced accompanying guidance, "Medical Product Communications That Are Consistent With the FDA-Required Labeling - Questions and Answers," which we will cover in more detail in Part II of this post.

Authors' Note: Summer Associate Margaret Fitzpatrick provided substantial assistance with the drafting of this blog post.