Hogan Lovells

FDA guidances promote greater communication to payors about medical product value, clarify CFL communications

June 14, 2018

On June 12 the U.S. Food and Drug Administration (FDA or the agency) finalized two guidance documents regarding the types of information that drug and device manufacturers may communicate to payors and what the agency regards as "consistent with" FDA-required labeling. FDA Commissioner Scott Gottlieb, M.D., said these guidances aim "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."

The guidance titled "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities" (the Payor Guidance) covers the communication of health care economic information (HCEI) regarding both prescription drugs and medical devices, and finalizes draft guidance from January 2017. The guidance titled "Medical Product Communications That Are Consistent With the FDA-Required Labeling" (the CFL Guidance) covers the communication of information not contained in the FDA-required labeling for a product but that may be consistent with that labeling; it also finalizes draft guidance from January 2017, which we summarized here.

The most significant departures from the 2017 draft guidances are in the Payor Guidance. In this guidance, FDA expanded the scope of permissible preapproval communications to include manufacturer statements about unapproved uses of approved products, in addition to statements about unapproved products. In this respect, FDA appears to modify its 2017 position paper regarding information about unapproved uses of approved products at least insofar as those communications are directed at payors. However, FDA maintains its prior positions by not permitting such statements to prescribers and consumers in both the Payor Guidance and the CFL Guidance. Also of note in the Payor Guidance, FDA expanded the applicability of the HCEI policies to medical device firms, affording them greater certainty that such communications to payors, if compliant with the recommendations, will not be considered false or misleading, or evidence of a new intended use.

Key Changes in the Final Guidances:

1. **FDA permits discussions with payors about unapproved uses**

   Section III.C of the Payor Guidance says communication by firms to payors of information about unapproved products and about unapproved uses of approved/cleared medical products would not be objectionable under the IND/IDE regulations (21 CFR 312.7(a) or 21 CFR 812.7(a)), which prohibit preapproval promotion of investigational drugs and devices, respectively. FDA offers examples of the types of information that may be shared about an unapproved product/use, including:

   – Product information and product pricing information

   – Information about the indication(s) sought

   – Anticipated timeline for possible approval

   – Patient utilization projections

   – Product-related programs or services

   – Results of studies

However, in communicating to payors about unapproved products/uses, FDA cautions firms to consider whether this information could impact

– the development of robust scientific data on safety and efficacy;

– the premarket review process for safety and efficacy of each intended use in order to prevent harm and to protect against fraud, misrepresentation, and bias;

– the integrity and reliability of promotional information regarding medical product uses; and,

– the diversion of health care resources toward ineffective treatments.

The expansion of the scope of permissible preapproval communications to include manufacturer statements about unapproved uses of approved products, in addition to statements about unapproved products, is a major shift in thinking, and particularly important for medical device firms' communications with technology assessment committees (TACs) – the organizations within health care entities that are charged with evaluating biomedical device technologies, including for example capital equipment, implants, and disposable medical devices, and in many cases make acquisition decisions or recommendations. Device firms may now share with TACs, without concern for FDA repercussions (provided they stay within the bounds of the guidance), the types of information noted above. The ability to share such information with TACs prior to clearance or approval will alleviate the typical conundrum capital equipment manufacturers face, which is that health care facilities set their budget for major capital expenditures a year in advance, and having to wait until clearance or approval is obtained to provide information about their device that will require a major capital expenditure often results in missing out on a full year of the purchasing cycle.

FDA seems concerned about assuring that payors receive non-misleading information about unapproved products and unapproved uses of approved medical products. FDA also emphasizes

that the information should be conveyed in a neutral and non-promotional manner to assure that it is not misleading.

2. **FDA clarifies what types of information are "related" to an approved indication**

   Section 502(a) of the Food, Drug, and Cosmetic Act (FD&CA) provides that HCEI shall not be considered false or misleading if, among other things, it "relates to an [approved] indication." Answer A.4 of the Payor Guidance clarifies that in order to be considered related to an approved indication, "HCEI analyses should relate to the disease or condition, the manifestation of the disease or condition, or symptoms associated with the disease or condition in the patient population for which the drug is indicated in the FDA-approved labeling."

   Notably, FDA clarified in a footnote that "if an analysis is based on data that includes both patients who are within the indicated patient population and patients who are outside of the indicated patient population . . . FDA would also consider that to be within the scope of HCEI as defined in section 502(a)." The draft guidance was not clear on this point, and numerous comments sought clarification on it.

3. **Application of HCEI communication policies to approved/cleared medical devices**

   As noted above, one of the more significant changes between the draft and final versions of the Payor Guidance is the addition of a new section addressing the applicability of the HCEI communication policies to medical device firms. Specifically, Section 114 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), as amended by the 21st Century Cures Act, applies solely to drugs. However, the final Payor Guidance notes that, while the statutory provisions are specific to drugs, the recommendations provided in the Payor Guidance are generally applicable to firms' communications to payors of HCEI about approved/cleared medical devices as well. FDA bases its decision to extend the applicability of its recommendations to medical devices on the fact that the general requirement that labeling not be false or misleading is equally applicable to medical devices, and application of the guidance's principles to medical devices will help to ensure that device firms' communications of HCEI are not false or misleading.

   In light of this explicit acknowledgement of the application of the HCEI communication policies to medical devices, medical device firms can proceed with greater certainty that such communications with payors, which includes TACs, will not be considered false or misleading, or evidence of a new intended use if such communications comply with the recommendations set forth in the guidance.

4. **Limitation of parts of CFL Guidance to approved medical devices**

   The additions and changes in the final CFL Guidance are primarily aimed at providing greater clarity to the process for analyzing whether a product communication is consistent with FDA-required labeling (CFL). The final CFL Guidance relies on the same three factors previously included in the draft to determine whether the representations or suggestions in a product communication are consistent with the product's FDA-required labeling, all three of which must be satisfied to be considered consistent with the FDA-required labeling.

Of note for medical device firms, as compared to the draft guidance, the final CFL guidance limits the applicability of certain aspects of the guidance to approved medical devices only. Specifically, while the analysis factors listed in the final CFL guidance are to be utilized to determine whether or not a communication is consistent with the labeling for PMA-approved medical devices, the agency is now directing firms to use existing frameworks for assessing labeling modifications for 510(k)-cleared and 510(k)-exempt devices in lieu of the factors sets forth in the CFL guidance. Thus, for 510(k)-cleared devices, the communications would be assessed in accordance with the risk-based assessment approach set forth in 21 CFR § 807.81(a)(3) and FDA's previously issued guidance titled, "Deciding When to Submit a 510(k) for a Change to an Existing Device." Similarly, for 510(k)-exempt devices, the communication should be assessed per the limitations on the exemptions as set forth in the "XXX.9" provision of the applicable classification regulation. If the contemplated communication would trigger the need for a new filing, that communication would be considered inconsistent with FDA-required labeling. FDA indicated that it does not intend to rely on communications that meet the criteria for consistency with FDA-required labeling as evidence that a manufacturer is promoting its device for a new intended use, although such communications may be part of the overall material evaluated in assessing a firm's conduct.

Other Notable Modifications:

In response to the comments provided to the draft guidance on the application of the factors FDA considers in determining whether a product communication is CFL, FDA clarifies that it is not sufficient to merely determine whether the product communication conflicts with FDA-required labeling. Rather, if a product communication does not conflict with FDA-required labeling, but increases the potential for harm (Factor 2) or does not provide information needed to safely or effectively use the product (Factor 3), then such communication would not be viewed as consistent with FDA-required labeling. The final guidance provides further clarification, through examples, of how Factors 2 and 3 may be applied in an analysis of whether a product communication is CFL.

The CFL Guidance also confirms that the "scientifically appropriate and statistically sound" (SASS) evidentiary standard for CFL communications is a lower standard than "substantial evidence." In the discussion of SASS evidence, FDA stated that: "For example, evidence other than that which meets the new drug approval standard of 'substantial evidence' of effectiveness could be used to support certain representations or suggestions about a prescription drug in a CFL promotional communication." In a footnote, FDA also acknowledges that "under such circumstances" the agency would not interpret its regulations that require substantial evidence to support certain types of claims. At the same time, the agency notes that certain types of evidence may be inherently insufficient to support proposed communications that are CFL, explaining that "if a CFL promotional communication relies on a study that is inadequate to support the representations or suggestions it presents, disclosure of the material limitations of that study does not correct the misleading message conveyed by the communication."

As in the draft guidance, FDA clarified that even though it does not intend to rely on a firm's product communications that are CFL to establish a new intended use, it would still consider such information if there is other evidence of a new intended use for the product. Thus, the agency will continue to evaluate companies' actions based on a number of factors, and drug and medical device manufacturers should examine each of their promotional activities to ensure compliance with FDA communications rules.

Contacts

Meredith Manning
Partner, Washington, D.C., Denver
T +1 202 637 6585
meredith.manning@hoganlovells.com

Susan Lee
Partner, Washington, D.C.
T +1 202 637 5561
susan.lee@hoganlovells.com

Heidi Gertner
Partner, Washington, D.C.
T +1 202 637 5676
heidi.gertner@hoganlovells.com

Jennifer Henderson
Partner, Washington, D.C.
T +1 202 637 5783
jennifer.henderson@hoganlovells.com

Jodi Scott
Partner, Denver
T +1 303 454 2463
jodi.scott@hoganlovells.com

Arthur Kim
Senior Associate, Washington, D.C.
T +1 202 637 4648
arthur.kim@hoganlovells.com

Suzanne Levy Friedman
Associate, Washington, D.C.
T +1 202 637 5532
suzanne.frieman@hoganlovells.com

Danielle Humphrey
Counsel, Washington, D.C.
T +1 202 637 8853
danielle.humphrey@hoganlovells.com

Jane Kalinina
Associate, Washington, D.C.
T +1 202 637 5461
jane.kalinina@hoganlovells.com

Yetunde Oni
Associate, Washington, D.C.
T +1 202 637 5516
yetunde.oni@hoganlovells.com

www.hoganlovells.com

"Hogan Lovells" or the "firm" is an international legal practice that includes Hogan Lovells International LLP, Hogan Lovells US LLP and their affiliated businesses.
The word "partner" is used to describe a partner or member of Hogan Lovells International LLP, Hogan Lovells US LLP or any of their affiliated entities or any employee or consultant with equivalent standing. Certain individuals, who are designated as partners, but who are not members of Hogan Lovells International LLP, do not hold qualifications equivalent to members.
For more information about Hogan Lovells, the partners and their qualifications, see www. hoganlovells.com.
Where case studies are included, results achieved do not guarantee similar outcomes for other clients. Attorney advertising. Images of people may feature current or former lawyers and employees at Hogan Lovells or models not connected with the firm.
© Hogan Lovells 2018. All rights reserved.