FDA Says Sharing Medical Product Information is Caring, to an Extent

Alan G. Minsk and Kalie E. Richardson

FDA recently issued a draft guidance, "Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities—Questions and Answers", which is intended to bring clarity to a specific provision in the Federal Food, Drug, and Cosmetic Act (FDC Act).[1] FDA has requested that any comments on this draft guidance be submitted within 60 days of the Federal Register notice, dated January 19, 2017, announcing the document's availability. The Food and Drug Administration Modernization Act of 1997 and the recently enacted 21st Century Cures Act both reference how manufacturers may communicate healthcare economic information (HCEI) to payors and other related parties.[2] This draft guidance aims to describe FDA's current thinking on the permissible content of those communications. The draft guidance and this Bulletin are split into two parts: communications of HCEI about approved drugs and communications about investigational drug and medical device products.

This guidance is part of a series of newly-issued statements from FDA about product discussions. We have prepared summaries of those other FDA communications in separate Bulletins.[3]

Communication of HCEI on Approved Drugs

- Drug sponsors may communicate HCEI to payors and formulary committees about their products in certain situations without misbranding the drug. HCEI is a defined term in the FDC Act that encompasses competent and reliable scientific evidence (CARSE) related to the economic consequences of the clinical outcomes of a disease. Only HCEI that meets the CARSE standard is considered not false and misleading and the standard applies to all elements of the HCEI. HCEI also includes comparative analyses of the use of one drug versus another or no therapy at all. This part of the draft guidance only applies to drugs and does not cover communication of HCEI to payors about medical devices.

- Payors and other related parties often request HCEI when making their coverage and reimbursement decisions.

    - drug manufacturers are allowed to communicate HCEI to payors, so long as it is truthful, complete, and non-misleading
    - comprehensive study design and methodology information must also be included

- The draft guidance provides several key clarifications about HCEI communications:

    - HCEI cannot be communicated to practitioners making prescribing decisions for an individual patient, or to the public at large
    - if the HCEI differs from the FDA-approved labelling for the drug, the manufacturer must include a prominent disclaimer explaining the material differences
    - communication of HCEI should also include the current FDA-approved labeling

1 http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM537347.pdf; *see also* 21 U.S.C. 352(a)

2 *See*, section 114, Public Law 105-115 and section 3037, Public Law 114-255

3 http://www.agg.com/publications/?mega=false&service=5f9f443b-1037-4f12-a34c-f331f0484fa9&PublicationTypes=de9bb700-7f55-47a6-9c91-b2b87dbf8321

- HCEI is considered "promotion" under the FDC Act and must meet the requirements for promotional materials
- only HCEI related to FDA-approved indications can be shared; for unapproved indications, FDA refers to the 2011 draft guidance on "Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices"[4]

- The guidance also provides several examples of what kind of information is considered "related to" an FDA-approved indication.
- Information that is not explicitly included in the FDA-approved product labeling, but that FDA will nevertheless consider "related to" the approved labeling, is permissible.
- The agency offers the following categories of HCEI as examples permissibly related to an approved indication:
  - duration of treatment
  - practice setting
  - burden of illness
  - dosing
  - patient subgroups
  - length of hospital stay
  - validated surrogate endpoints
  - clinical outcome assessments or other health outcome measures (must include information on the validity and reliability of the assessment)
  - persistence
  - comparisons
- However, HCEI from patient populations outside the indicated population are not considered related to the approved indication.
- HCEI covering disease course modification for a drug that is only indicated to treat the symptoms, rather than the disease itself, would also not be considered related to the approved indication.

Communication About Unapproved Products

- The second section of the draft guidance covers communication of information related to unapproved medical products--both drug and medical devices.
- FDA recognizes that payors often request information on investigational products in order to plan for future coverage and reimbursement scenarios.
- FDA only permits the following unbiased and non-misleading dissemination of limited types of information related to unapproved products:
  - general product information
  - information about the requested indication
  - factual results of clinical or preclinical studies (cannot extrapolate study results to the safety or effectiveness of the product)
  - possible timeline to FDA approval or clearance
  - pricing
  - marketing strategies
  - product-related programs

4 AGG's Bulletin on this guidance can be found at: http://www.agg.com/files/Publication/25e251ad-39a8-41c1-b181-81611942d5e0/Presentation/PublicationAttachment/81801f2f-7f3c-4849-a587-0882821f1115/Minsk-Cohen-Asked-Answered-Now-Move-On%5b1%5d.pdf

- When the product sponsor shares any permissible information, it must make clear that the product is still under investigation and is not yet approved; FDA recommends that sponsors note the product development stage and follow up with the payor if any of the information changes.

AGG Observations

- The agency continues to evaluate how to balance lawful dissemination of product information versus unlawful pre-approval or off-label promotion.
- With the implementation of the 21st Century Cures Act, which emphasizes data access, it is possible this trend of FDA guidance about product communications will continue.
- The guidance provides useful explanations and limitations, and it offers a glimpse into FDA's current and ever-evolving thinking on the highly-visible issue of product information dissemination.

Authors and Contributors

Alan G. Minsk
Partner, Atlanta Office
404.873.8690
alan.minsk@agg.com

Kalie E. Richardson
Associate, Atlanta Office
404.873.8622
kalie.richardson@agg.com

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Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

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