Trend Toward Broader Communication Continues as Congress Codifies Life Sciences Companies' Ability To Share Product Information With Payors Prior to FDA Approval

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Embedded in the thousands of pages of the Consolidated Appropriations Act of 2023 (the omnibus legislation) that President Joe Biden signed into law on December 29, 2022, is a section that amends the Food, Drug and Cosmetic Act (FDCA) to permit both drug and medical device companies to communicate various types of product information to payors, formularies and other third parties prior to receiving Food and Drug Administration (FDA) approval or clearance for the relevant product or indication.

The legislation largely codifies the 2018 FDA guidance (2018 Guidance) on this topic,[1] providing certainty to drug and device manufacturers about ways they can responsibly structure such communications. The legislation also addresses a previous anomaly in the statute that permitted drug, but not medical device, manufacturers to share health care economic information (HCEI) about approved or cleared products with payors.

Key Takeaways

- Under Section 114 of the Food and Drug Administration Modernization Act of 1997 (FDAMA), Congress authorized drug companies, subject to certain limitations, to disseminate HCEI about approved products to formulary committees and other similar entities. The omnibus legislation amends the FDCA to expressly extend the same safe harbor to medical device manufacturers.
- The omnibus legislation further amends the FDCA to enable manufacturers of investigational drugs and medical devices to engage in preapproval communications with payors, formularies and health plans. The statute requires that those preapproval communications include certain disclaimers and contextual information, which substantially mirrors the 2018 Guidance.
- The amendment also requires manufacturers to update previously communicated information if such information "becomes materially outdated" as a result of unspecified "significant changes" or due to "new information regarding the product or its review status."
- By providing statutory protection for preapproval/pre-clearance communications, Congress has recognized the importance of providing clarity regarding the manner in which manufacturers can communicate about their products, while also recognizing the importance of the exchange of particular types of information between manufacturers and certain third parties prior to product approval.

Section 3630 of the omnibus legislation codifies the ability of manufacturers to share product information with formularies and other decision-makers by making two key changes to the FDCA, described below.

HCEI Definition Expressly Includes Device Manufacturers

The omnibus legislation builds on protections that were initially included for drug manufacturers in Section 114 of FDAMA, as amended by the 21st Century Cures Act, by expressly including medical devices within its protections. Specifically, the omnibus legislation adds the following bolded and italicized language to the definition of HCEI, found in Section 502(a)(2) of the FDCA:

[1] See U.S. Food & Drug Admin., Drug and Device Manufacturer Communications With Payors, Formulary Committees, and Similar Entities – Questions and Answers: Guidance for Industry and Review Staff (2018).

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> "[A]ny analysis (including the clinical data, inputs, clinical or other assumptions, methods, results, and other components underlying or comprising the analysis) that identifies, measures, or describes the economic consequences, which may be based on the separate or aggregated clinical consequences of the represented health outcomes, of the use of a drug ***or device***. Such analysis may be comparative to the use of another drug ***or device***, to another health care intervention, or to no intervention. … [HCEI] does not include any analysis that relates only to an indication that is not approved under section 505, ***510(k)***, ***513(f)(2)***, ***or 515*** of [the FDCA] or section 351 of the Public Health Service Act" (*emphasis added*).[2]

The amended HCEI definition is consistent with the 2018 Guidance, which interpreted drug-specific requirements in Section 502(a) to be generally applicable to devices.[3] The definition of HCEI remains narrow, however, and includes only communications that relate to approved or cleared uses.

Section 502(a) sets forth the circumstances in which HCEI communicated to payors, formulary committees or other similar entities would not be considered false and misleading, and expressly anticipates that comparative information may be provided for approved or cleared products.

Protection for the Dissemination of Information Regarding Investigational Products and/or Uses

The omnibus legislation also permits manufacturers to provide certain information to payors about unapproved products by adding Section 502(gg) to the FDCA, which authorizes particular preapproval communications to formularies, payors and similar entities. Unlike Section 502(a), which expressly excludes information regarding unapproved uses from the definition of HCEI, Section 502(gg) directly addresses the dissemination of information regarding an investigational product as well as an investigational use of an approved or cleared product.

Section 502(gg) states that, notwithstanding Section 502(f)'s requirement that labeling bear adequate directions for use, "no drug or device shall be deemed to be misbranded under [Section 502(f)] through the provision of truthful and not misleading product information to a payor, formulary committee, or other similar entity with knowledge and expertise in the area of health care economic analysis carrying out its responsibilities for the selection of drugs or devices for coverage or reimbursement if the product information relates to an investigational drug or device or investigational use of a drug or device that is approved, cleared, granted marketing authorization, or licensed under section 505, 510(k), 513(f)(2), or 515 of this Act or section 351 of the Public Health Service Act (as applicable)," and certain conditions are met.

For the purposes of Section 502(gg), "product information" that can be shared includes:[4]

- information describing the product (*e.g.*, drug class, device description, features);
- information about the indication(s) being investigated;
- the anticipated timeline for possible approval, clearance, marketing authorization or licensure of the investigational product or investigational use;
- product pricing information;
- patient utilization projections;
- product-related programs or services; and
- factual presentations of study results that neither characterize nor make conclusions regarding safety or efficacy of the investigational product or investigational use.

In addition to requiring that information be truthful and nonmisleading, product information provided to payors, formulary committees or other similar entities regarding an investigational product or investigational use must meet the following criteria set forth in Section 502(gg)(1):[5]

- Include "a clear statement that the investigational drug or device or investigational use of a drug or device has ***not*** been approved, cleared, granted marketing authorization, or licensed" and that "safety and effectiveness of such drug or device for such use has ***not*** been established" (*emphasis added*);
- Include information relating to the stage of development of the drug or device, such as "the status of any study or studies in which the investigational drug or device or investigational use is being investigated," "how the study or studies relate to the overall plan for the development of the drug or device" and "whether an application, premarket notification, or request for classification for the investigational drug or device or investigational use has been submitted to the Secretary and when such a submission is planned";

[2] The additional statutory references included in the amended Section 502 relate to premarket notification (Section 510(k)), *de novo* classification (Section 513(f)(2)) and premarket approval (Section 515).

[3] *See* 2018 Guidance at 17-18 (Q&A B.1).

[4] These categories of information are consistent with those outlined in the 2018 Guidance as the types of information that may be communicated regarding unapproved products or unapproved uses of approved or cleared products. *See* 2018 Guidance at 18-20 (Q&A C.1).

[5] These criteria correspond to the requirements set forth in the 2018 Guidance governing information that should be communicated regarding unapproved products and unapproved uses of approved or cleared products. *See* 2018 Guidance at 20-21 (Q&A C.2 and C.3).

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- Where factual presentations of study results are shared, describe "all material aspects of study design, methodology, and results," including relevant "material limitations," and do not selectively present results;
- Where applicable, include "a prominent statement disclosing the indication or indications for which the Secretary has approved, granted marketing authorization, cleared, or licensed the product" as well as a copy of the "most current required labeling";
- Include "updated information, if previously communicated information becomes materially outdated as a result of significant changes or as a result of new information regarding the product or its review status"; and
- Do not represent that an investigational drug or device or investigational use of a drug or device has been approved, cleared, granted marketing authorization or licensed, or has otherwise been determined to be safe and effective for the purpose or use for which the product is being studied.

Conclusion

Although the amendments are consistent with FDA's 2018 Guidance regarding payor and formulary communications, Congress' statutory enactment of these principles provides clarity for drug and device companies about the rules of engagement with payors and other population-level decision-makers. Congressional recognition of the importance of enabling open communication between manufacturers and those making payment decisions is consistent with developments in First Amendment jurisprudence relating to the constitutional protections afforded to truthful, nonmisleading commercial speech, as well as congressional efforts over the last decade to encourage comparative effectiveness research and new data mining. The new statutory provisions do not, however, represent a meaningful change to the status quo, including FDA's general position that companies should not engage in promotional activity relating to their products prior to approval or clearance.

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