FDA Finalizes Drug Communication Guidance

P&T Committees Can Receive Data Beyond the Drug Label

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The FDA has just made it easier for pharmacy and therapeutics (P&T) committees to make formulary coverage decisions by expanding the health care economics information (HCEI) that drug manufacturers can supply to them. Final guidance in the form of a "Questions & Answers" format from the FDA opens the door more widely to information about a drug's "economic consequences," meaning its cost versus its benefits.

One clarification the FDA provides is that only physicians, pharmacists, and health care professionals who sit on P&T committees can receive HCEI; other health care professionals cannot. Availability of broader information about a drug is important, according to Jennifer Graff, PharmD, Vice President of Comparative Effectiveness Research, National Pharmaceutical Council (NPC). NPC members are drug manufacturers. "In a 2017 survey NPC conducted with Xcenda/Amerisource-Bergen, payers cited at least six aspects of a drug that are very/extremely important to understand as part of making medical policy and coverage decisions, but only three of these aspects are typically available in a product's FDA-approved label," she explains. "Payers said more information would help them improve their ability to individualize treatment for patients, improve the quality of care for patients, be more efficient searching for appropriate information to inform decisions, and increase their ability to do value-based contracting."

The FDA's final guidance issued in June covers communications that drug manufacturers can have with regard to existing products as well as investigational products and new, unapproved uses for existing products. In the latter case, that was an expansion from the draft guidance issued in January, 2017.There was no mention of communication of information about unapproved drugs. Graff calls that a large and important change. Companies often test new drugs for multiple indications simultaneously and submit a new drug application for each indication in staggered fashion, as results dictate. "In recent years, the number of approvals for supplemental new indications was nearly equal to the number of new product approvals," explains Graff. "Because product utilization and medication costs for supplemental indications may exceed those of the initial approval, plans needed information at the indication- rather than the product-level."

Insurers and manufacturers have pushed the FDA to expand the information flow as they have warmed up to the notion of value-based drug contracting, which is still in its infancy, and impeded by a number of factors beyond communication limitations. For example, if the contract was based on hospital readmissions, but readmissions were not part of the label, there were often concerns, according to Graff. The final guidance clarifies that the guidance is not intended to address the terms of contracts between industry and payers and value-based contracts are not subject to FDA reporting requirements. The guidance also puts in play another hot topic related to drug evaluation by noting that HCEI can be based not just on clinical trials but also on real-world drug utilization data from a health plan database or the electronic health records of a hospital system.

The NPC and the Academy of Managed Care Pharmacy have been among those lobbying for the FDA to allow more HCEI to flow. In part, their arguments have been based on a contention that FDA limits on drug communication are a violation of their First Amendment speech rights. The FDA, on the other hand, has been worried about sanctioning what might be described as "loose talk" by drug manufacturers who might be tempted to skew clinical trials data or epidemiological post-marketing data in a way that makes a drug's cost benefit argument more persuasive than it really is.

One of the key standards in the final guidance—and it was not changed significantly from the draft guidance—is that HCEI must be based on *competent and reliable scientific evidence* (CARSE). The FDA considers HCEI to be based on CARSE if the HCEI has been developed using generally accepted scientific standards, appropriate for the information being conveyed, that yield accurate and reliable results. There is considerable wiggle room as to the type of information that must be conveyed, though it should include study design and methodology, generalizability, limitations, sensitivity analyses, and information that provides a balanced and complete presentation.

The "balanced and complete" requirement is important. It is an allusion to providing context, such as noting where data from well-controlled studies are omitted. In that event, the HCEI must include an explanation of how that omission "may change or affect the conclusion."

The FDA's leeway on HCEI transmittal for investigational drugs and off-label usage is much the same as for approved uses, although it is couched a little differently. There, HCEI must be "unbiased, factual, accurate, and non-misleading." The FDA here is trying to split the difference between allowing information based on early clinical trials to flow, allowing an insurer to plan for and make coverage and reimbursement decisions for medical products that may become available in the future, and stifling incentives for a company to continue escalating clinical trials all the way to an application for a new drug.

An expanded flow of information from drug companies to insurers and their P&T committees makes a lot of sense as long as this higher-flowing river includes useful facts and not marketing muck. ■