Payers And The Era Of Data-Driven Medicine Renews Interest In FDAMA 114

By Ilyssa Levins, president and founder, Center for Communication Compliance (CCC)

The presentation on payers during the annual Advertising and Promotion Conference sponsored by the Food and Drug Law Institute (FDLI) was informative, engaging and thought provoking. The speakers addressed enforcement activities from the FDA, Department of Justice (DOJ), and others involved in the regulation and oversight of communications regarding formularies. The main question is: What should industry understand regarding the rules and practices that govern the communication of drug information to payers and formulary committees in light of evolving FDA policies on scientific exchange, First Amendment case law, and proposed legislative changes to FDAMA 114?

Era of Data-Driven Medicine

Healthcare economic information (HCEI) about drugs has long been in demand by managed care organizations and other payers, such as pharmacy benefits managers, to aid in drug formulary decision making. “We are in the era of data driven medicine where healthcare professionals and payers seek more, not less, information about the safety, effectiveness and value of treatments,” explained Jeff Francer, VP and senior counsel at PhRMA. “Patients expect their physicians and payers to receive accurate, data-driven information about medicines.”

Francer continued: “Today the wealth of information about medicines is more comprehensive and complex than ever before. In addition to information in the approved labeling, companies continually generate and collect important data and analyses that can benefit patient care and enhance the efficiency of our healthcare system. “

HCEI is needed by managed care experts and other healthcare providers responsible for evaluating the benefits, other consequences, and costs of competing therapies. This fact has long been acknowledged by the U.S. Congress, which recognized that, “Biopharmaceutical companies typically have the best and most comprehensive information about the cost, effectiveness, and safety of their products.”

Specifically, Section 114 of the Food and Drug Administration Modernization Act (FDAMA) of 1997 allows biopharmaceutical companies under certain conditions, to provide healthcare economic information not in labeling to formulary committees and similar entities. The Act defines healthcare economic information as, “An analysis that identifies measures or compares the economic consequences of the use of the drug to the use of another drug, another healthcare intervention, or no intervention.”

The Act states that HCEI will not be considered “false or misleading” if it is based on “competent and reliable scientific evidence,” which is a standard followed by the Federal Trade Commission. This is a different standard than the more stringent “substantial evidence,” which generally means two adequate and well-controlled clinical trials required by the FDA.

Squeeze Play of Regulations

Michael Labson, a partner at Covington and Burling, stated that given the growing focus on value-based medicine, the current standards must be modernized to conform to the First Amendment. “Policy must consider what’s in the best interest of public health and efficiency of our healthcare system,” explained Labson. “Companies typically have vast clinical and economic information about their drugs, and the law provides greater flexibility to communications with payers because of the special expertise payers have to review such information. Yet, while there are special rules for payer communications, these are limited and there are many key terms that are ambiguous.”

Labson said there are barriers to: 1) pre-approval communications (promotion of investigational drug), 2) providing information on unapproved new uses of approved drugs and 3) communicating comparative information without head-to-head studies. “We need to provide information that supports a drug’s value, but we’re squeezed because the package insert is the only document that companies may use as the basis for their communications according to the regulations.”

Change in the Air

There is change in the air with the FDA’s Guidance Agenda for calendar Year 2016 where the Center for Drug Evaluation and Research (CDER) has included this topic. There is also an FDA notice in the September 1 Federal Register regarding a public hearing and request for comments on Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products.

Within the 21st Century Cures Act, changes were made to reflect new thinking as well.
**Responsible Sharing of Information**

How does the industry communicate information that is truthful and nonmisleading to inform HCPs and payers about the safe and effective use of medicines? Three key principles were presented by Francer:

1. Communicate accurate, science-based non-misleading communication
2. Provide appropriate context about data
3. Tailor communications to the intended audience

Francer then reviewed the PhRMA-Bio Principles for Responsible Information Sharing (click here). He stated that the FDA could manage regulatory change in a stepwise approach, beginning with company communications with payers and population health decision-makers, extremely sophisticated consumers of medical information. The FDA could then address communications about real-world evidence and other information that is consistent with approved labeling, and then medically accepted, reimbursed alternative uses of medicines.

**AMCP Addresses Renewed Interest in FDAMA 114**

Soumi Saha, PharmD, JD, assistant director, pharmacy & regulatory affairs, Academy of Managed Care Pharmacy (AMCP), summarized the renewed interest regarding this important topic and AMCP’s responsive action. Saha pointed to the passage of the Affordable Care Act and its formation of the Patient Centered Outcomes Research Institute (PCORI), with its focus on comparative effectiveness research (CER), more “Big Data” driving more observational studies, sophisticated economic models, a shift from quantity/process to quality/outcomes and commercial-free speech as catalysts for renewed discussions about FDAMA Section 114.

In response, AMCP convened a Partnership Forum, **FDAMA 114: Improving the Exchange of Pharmacoeconomic Data**, where a diverse group of healthcare stakeholders representing pharmaceutical companies, managed care organizations, academia, healthcare providers and patient advocacy groups gathered to develop consensus on a wide range of recommendations to make it easier for pharmaceutical companies to share pharmacoeconomic information with healthcare organizations that make coverage decisions. Click here for the proceedings.

Forum participants agreed to include the following recommendations to the FDA for inclusion in guidance on FDAMA Section 114 that is expected later this year:

- Dissemination of information under Section 114 should be expanded to healthcare decision makers beyond health plan formulary committees, including those making coverage decisions in accountable care organizations (ACOs) and integrated delivery networks, as well as organizations that evaluate pharmacoeconomic information or develop value frameworks and compendia.
- HCEI must be truthful and non-misleading, and be based on the expertise of professionals in the relevant area. The HCEI also must be derived and disclosed in a transparent, reproducible and accurate manner. This recommendation stems from a Section 114 requirement that a company support HCEI with “competent and reliable scientific evidence,” not the stricter “substantial evidence” standard required for drug approval. The lower standard has never been fully defined.

Participants also discussed the types of information, format and processes by which managed care pharmacy and other healthcare decision-makers seek to receive pharmacoeconomic information from manufacturers.