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ELECTRONIC DRUG LABELING

No Consensus on the Advantages and Disadvantages of Its Exclusive Use

GAO Highlights

Highlights of GAO-13-592, a report to congressional committees

Why GAO Did This Study

Public health experts note the importance of providing physicians, pharmacists, and consumers with the most current prescription drug information to help inform their respective decisions on which drugs to prescribe, how best to counsel patients, and how to use drugs safely. FDA reviews manufacturer-developed drug labeling, which is generally available in paper form. However, prescription drug labeling is also publicly available in electronic form on government-operated websites.

Drug manufacturers have supported eliminating paper labeling, thus relying on electronic drug labeling as a complete substitute for paper labeling. However, others, such as drug labeling manufacturers and patient advocates, disagree, suggesting that it could adversely affect public health.

GAO was mandated to examine the benefits and efficiencies of electronic labeling as a partial or complete substitute and its impact on public health. Because drug labeling is already available in electronic form, representing a partial substitute, this report focuses on (1) the advantages and disadvantages of relying on electronic labeling as a complete substitute for paper labeling and (2) the barriers associated with relying on electronic labeling as a complete substitute for paper labeling.

GAO interviewed federal officials, including those from FDA, and stakeholders representing physicians, pharmacies, patients, drug manufacturers, and drug labeling manufacturers. GAO also reviewed relevant FDA guidance documents and regulations.

View GAO-13-592. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

GAO found no consensus among stakeholders on the advantages and disadvantages of eliminating paper labeling and relying instead on electronic labeling as a complete substitute for the three types of drug labeling discussed in this report and approved by the Food and Drug Administration (FDA)—an agency within the Department of Health and Human Services (HHS). This report focuses on three types of prescription drug labeling: the prescribing information intended for health care practitioners, Medication Guides intended to inform patients about drugs FDA has determined pose a serious and significant public health concern, and patient package inserts (PPI) required for oral contraceptives and estrogens. Stakeholders said an advantage of such a change would be that it could provide physicians, pharmacists, and patients with the most current drug information in a more user-friendly format, which would positively impact public health. For example, drug labeling could be made interactive to include hyperlinks to definitions of key terms or to additional information, enhancing patients' knowledge about the drugs they are using. However, stakeholders noted disadvantages that could offset any advantages gained from such a change. Relying on electronic labeling as a complete substitute for paper labeling could adversely impact public health by limiting the availability of drug labeling for some physicians, pharmacists, and patients by requiring them to access drug labeling through a medium with which they might be uncomfortable, that they might find inconvenient, or that might be unavailable. In addition, for electronic drug labeling to be successful, stakeholders said it is important to have a single data source that is reliable and unbiased for physicians, pharmacists, and patients to use, particularly given that there are multiple websites these groups can use to access information about prescription drugs. However, these websites that currently provide electronic labeling have limitations. For example, nongovernmental websites are not standardized, and one website can include information on a particular drug not included on another website.

Relying on electronic drug labeling as a complete substitute for paper drug labeling would require amending or reviewing relevant federal regulations and shift some responsibilities from drug manufacturers to pharmacies. According to FDA officials, changing to an exclusively electronic version would require the agency to amend or review regulations for two of the three types of FDA-approved drug labeling that are the focus of this report. Additionally, drug manufacturers currently provide pharmacies with a supply of paper labeling for patients. However, stakeholders said that if patients want to continue receiving drug labeling in paper form and pharmacies are expected to print drug labeling for distribution, it would shift the costs of printing to the pharmacies. In 2011, retail pharmacies filled approximately 3.8 billion prescriptions for drugs.

HHS provided technical comments, which are incorporated as appropriate.