



July 2013

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.

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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.

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Abbreviations

CMI	consumer medication information
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
PDR	Physicians' Desk Reference
PMI	patient medication information
PPI	patient package insert

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July 8, 2013

The Honorable Tom Harkin
Chairman
The Honorable Lamar Alexander
Ranking Member
Committee on Health, Education, Labor, & Pensions
United States Senate

The Honorable Fred Upton
Chairman
The Honorable Henry A. Waxman
Ranking Member
Committee on Energy & Commerce
House of Representatives

Public health experts have long agreed on the importance of providing health care practitioners—such as physicians and pharmacists—and patients with the most current and accurate prescription drug information. This information helps health care practitioners to make informed decisions on which drugs to prescribe and to determine how best to counsel patients; it also helps patients to be informed about how to use drugs safely and effectively. For example, in 2007, the Institute of Medicine issued a report noting that the way in which drug information is communicated to physicians can directly affect their knowledge of how the drugs they are prescribing will work in patients, particularly in specific populations, such as children and the elderly.¹ This report also noted that drug information communicated to pharmacists is critical to helping them appropriately fill prescriptions and to check for potential safety concerns for a specific patient. Additionally, information provided to patients can directly affect how they use prescription drugs. The importance of prescription drug information to public health is further highlighted by the frequency with which these drugs are used as a form of therapy. For

¹Institute of Medicine, Committee on Identifying and Preventing Medication Errors, *Preventing Medication Errors* (Washington, D.C.: 2007).

example, approximately 75 percent of physician's office visits in 2010 involved drug therapy, according to the most recent data available.²

Drug manufacturers provide prescription drug information, such as information on any known contraindications, by means of prescription drug labeling to health care practitioners (e.g., physicians and pharmacists) and patients.³ This report focuses on three types of prescription drug labeling approved by the Food and Drug Administration (FDA), which provide information to health care practitioners and patients: the prescribing information intended for health care practitioners, Medication Guides intended to provide patients with information about the drug's safety and effectiveness, and patient package inserts (PPI) required for oral contraceptives and estrogens.^{4,5} Currently, prescription drug labeling is provided in paper form, but is also publicly available electronically on government websites, such as DailyMed, which is

²Centers for Disease Control and Prevention, *National Ambulatory Medical Care Survey: 2010 Summary Tables* (Atlanta, Ga.: 2013).

³Contraindications describe situations in which the drug should not be used because the risks of the drug clearly outweigh any possible benefit, such as use with other drugs because of life-threatening drug interactions. 21 C.F.R. § 201.80(d).

⁴The Federal Food, Drug, and Cosmetic Act defines "labeling" as all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article. 21 U.S.C. § 321(m). Although the term "labeling," as defined in the Act includes more than just these three types of labeling, we use the terms "prescription drug labeling" and "drug labeling" in this report interchangeably and to mean only these three types of labeling. We do not use these terms to describe the drug label that the pharmacist attaches to the drug container, which includes specific patient information and dosage instructions when using these terms. FDA's labeling regulations, as relevant to this report, are found at 21 C.F.R. Part 201 (general labeling provisions), 21 C.F.R. Part 208 (Medication Guides), and 21 C.F.R. §§ 310.501 and 310.515 (oral contraceptives and estrogens). Different types of drug labeling are intended for different audiences, such as physicians or patients.

⁵Patients may also receive written drug information, generally called consumer medication information (CMI), which is produced by third parties (i.e., organizations or individuals other than the drug's manufacturer) and distributed in the pharmacy when prescription drugs are dispensed. Because CMI is not approved by FDA, we do not include CMI in our analysis.

maintained by the National Library of Medicine, and Drugs@FDA, maintained by FDA.⁶

Drug manufacturers have supported eliminating paper drug labeling and instead making this information exclusively available in electronic form. Others, such as drug labeling manufacturers and patient advocates, disagree, suggesting that making drug labeling exclusively electronic could adversely affect public health. The Food and Drug Administration Safety and Innovation Act mandated GAO to examine the benefits and efficiencies of electronic drug labeling as a complete or partial substitute for paper labeling, the barriers to utilizing electronic labeling, and the impact on public health.⁷ Labeling approved by FDA—an agency within the Department of Health and Human Services (HHS)—is currently available in paper and electronic form, which we considered to represent a partial substitute of paper labeling with an electronic version. Because a partial substitute currently exists, we focused our work on (1) the advantages and disadvantages of relying on electronic drug labeling as a complete substitute for paper labeling, and (2) the barriers associated with relying on electronic drug labeling as a complete substitute for paper labeling.

To identify the advantages and disadvantages of relying on electronic drug labeling as a complete substitute for paper labeling and the barriers associated with relying on electronic drug labeling as a complete substitute for paper labeling, we interviewed officials from FDA, the National Library of Medicine, and the Agency for Healthcare Research and Quality, all of which are part of HHS. We also interviewed officials from stakeholder organizations—such as those representing drug manufacturers, printed literature manufacturers, health care practitioners with prescribing authority, pharmacists and pharmacies, patient advocates, and academic researchers. (See app. I for a complete list of the entities we interviewed.) We also reviewed peer-reviewed literature,

⁶Part of the National Institutes of Health, the National Library of Medicine is the world's largest biomedical library. It produces electronic information resources on a wide range of health-related topics, used by people around the globe. It also supports and conducts research, development, and training in biomedical information and health information technology.

⁷Pub. L. No. 112-144, § 1140, 126 Stat. 993, 1126 (2012). For the purposes of this report, we define the “impact on public health” as the impact of electronic labeling on the availability of the most current drug labeling.

relevant FDA guidance documents, regulations related to prescription drug labeling, and transcripts of FDA public meetings on drug labeling. We did not evaluate costs associated with the exclusive use of electronic labeling—such as how much it would cost to implement or how much it might save the health care industry—because we were unable to obtain reliable cost data. We also did not evaluate stakeholders’ assertions about the consequences of changing to exclusively electronic drug labeling because they were unable to provide us with objective data on the implications of such a change.

We conducted our work from October 2012 to June 2013 in accordance with all sections of GAO’s Quality Assurance Framework that are relevant to our objectives. The framework requires that we plan and perform the engagement to obtain sufficient and appropriate evidence to meet our stated objectives and to discuss any limitations in our work. We believe that the information and data obtained, and the analysis conducted, provide a reasonable basis for our findings.

Background

FDA is responsible for protecting the public health by, among other things, assuring the general safety, effectiveness, and security of prescription drugs sold in the United States. Part of its responsibility includes reviewing the proposed prescription drug labeling included in a new drug application as well as any proposed changes to the labeling made after the application has been approved. In certain circumstances, the agency can require drug manufacturers to make safety-related changes to their drug labeling, or drug manufacturers can also voluntarily submit changes to the agency. Drug manufacturers make these changes as they learn new information about a particular drug, such as a change

to the warnings and precautions section, or the addition of a new indication for use.⁸

Types of FDA-Approved Prescription Drug Labeling

FDA approves the three types of prescription drug labeling that are the focus of this report—prescribing information, Medication Guides, and PPIs required for oral contraceptives and estrogens—which manufacturers provide. Although these three types of drug labeling are generally available in paper form, they are also available in electronic form. For example, Medication Guides are available to patients on some manufacturers' websites. All three of these drug labeling types are also available on government-operated websites, such as the DailyMed website and Drugs@FDA.⁹ (See table 1 for a summary of these three types of labeling.)

⁸Changes to drug labeling are classified into one of three categories—major, moderate, or minor. For major changes, FDA requires that drug manufacturers submit a supplement to the original application for approval. This supplement must be approved before these manufacturers distribute the drug with the revised labeling. Major changes include all changes except those identified as moderate or minor. According to FDA guidance, an example of a major change includes changes made on the basis of results of studies conducted after the drug has been approved for marketing, including, but not limited to, labeling changes associated with new indications and usage. FDA regulations and guidance also describe moderate labeling changes, such as the addition of a contraindication or an adverse reaction based on newly acquired information. Manufacturers may begin to distribute the drug with such moderate labeling changes when FDA receives the supplement proposing the changes. For minor changes to drug labeling, drug manufacturers may distribute the drug with the revised labeling and notify FDA by noting changes to the drug labeling in their annual reports to FDA. Examples of minor changes include editorial revisions. With regard to changes to drug labeling for generic drug manufacturers, these manufacturers can only make changes to the generic-drug labeling after the brand-name manufacturer has made an FDA-approved change to the brand-drug labeling. FDA, *Guidance for Industry: Changes to an Approved NDA or ANDA* (Rockville, Md.: April 2004). Also see 21 C.F.R. § 314.70. Regulations require the approved labeling for a generic drug to be the same as the approved labeling for the corresponding brand-name drug with certain exceptions.

⁹See <http://dailymed.nlm.nih.gov/dailymed/about.cfm> for the DailyMed website and <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/> for the Drugs@FDA website.

Table 1: Three Types of FDA-Approved Labeling for Prescription Drugs Developed by Drug Manufacturers

Type of labeling	Intended audience	Description	General methods for accessing
Prescribing information ^a	Health care practitioners (e.g., physicians, pharmacists)	<ul style="list-style-type: none"> Required for prescription drugs. Included on or within prescription drug packaging. Includes the essential information necessary for the safe and effective use of the drug. Includes technical and clinical information, such as the molecular structure of the drug and results of clinical trials. Typically the focus of electronic labeling efforts. 	<ul style="list-style-type: none"> Physicians access this labeling using various methods, such as paper compilations, like the Physicians' Desk Reference (PDR), or in electronic form. Pharmacists may also access this labeling using paper compilations, like the PDR, or when it arrives with the packaging. Patients access this labeling as part of the packaging, by requesting a copy from the pharmacist, or via the Internet.
Medication Guides ^b	Patients	<ul style="list-style-type: none"> Required to be provided by pharmacists directly to patients for 383 brand-name prescription drugs, as well as any generic drug products that reference those brand-name products. Typically provided in an outpatient setting, such as a retail pharmacy.^c Includes information on serious side effects, including those that might require emergency medical care or involve life-threatening conditions. 	<ul style="list-style-type: none"> Physicians access this labeling using various methods, such as paper compilations, like the PDR, or in electronic form. Pharmacists may access this labeling using paper compilations, like the PDR. They also receive copies of this labeling or the means to produce copies from the drug manufacturer. Patients receive copies of this labeling from the pharmacist or via the Internet.
Patient package inserts (PPI) ^d	Patients	<ul style="list-style-type: none"> Required for oral contraceptives or estrogen-containing drugs. Includes information on how to take the drug and, when applicable, the effectiveness of oral contraceptives. Included in or with prescription drug packaging. 	<ul style="list-style-type: none"> Physicians access this labeling using various methods, such as paper compilations, like the PDR, or in electronic form. Pharmacists access this labeling when it arrives with the packaging. Patients access this labeling as part of the packaging, by requesting a copy from the pharmacist, or via the Internet.

Source: GAO analysis of FDA information and interviews with FDA officials, pharmacists, physicians, and patient advocacy groups.

^aPrescribing information is commonly called other names, such as professional labeling, package insert, direction circular, and package circular.

^bA Medication Guide will be required if FDA determines that one or more of the following circumstances exists: (1) the drug is one for which labeling could help prevent serious adverse effects; (2) the drug is one that has serious risk(s) (relative to benefits) of which patients should be made aware because information concerning the risks could affect patients' decision to use or continue to use the product; and (3) the drug is important to health and patient adherence to directions for use is crucial to the drug's effectiveness. 21 C.F.R. § 208.1(c).

^cThe number of brand-name prescription drugs requiring a Medication Guide is as of May 2013.

^dFor the purposes of this report, we use PPI to refer to the drug labeling described in 21 C.F.R. §§ 310.501 and 310.515 for oral contraceptives and estrogens.

Other Patient Drug Information

Patients can receive written drug information provided along with their prescription drugs in the form of CMI. Unlike prescribing information, Medication Guides, and PPIs, CMI is not approved by FDA, and drug manufacturers do not produce this type of drug labeling. Instead, it is produced by third parties and distributed to patients at the pharmacy when their drugs are dispensed.¹⁰ CMI can include information from the prescribing information and can also include additional information not contained in FDA-approved labeling, such as off-label uses of certain drugs.¹¹ According to officials from third parties that produce CMI, they also use other sources, such as peer-reviewed literature, to develop the information for their CMI. FDA has not asserted the authority to require third parties to submit CMI for review by the agency before CMI is distributed, according to agency officials. However, FDA has issued a guidance document used by third parties, which includes recommendations to help ensure that CMI is useful to patients.¹²

For more than a decade, patient advocates and others have expressed concerns about the quality and consistency of patient drug information. (See app. II for a timeline of key events related to these concerns.) Additionally, two FDA-funded studies evaluating CMI found that, while CMI was widely distributed to patients, the quality of the content of CMI provided at the pharmacy did not meet certain statutory goals related to the distribution of useful written information.¹³ For example, these studies

¹⁰CMI may also be distributed to patients that receive their drugs through the mail.

¹¹Off-label use refers to the use of drugs for a condition or patient population for which the drug has not been approved or in a manner that is inconsistent with information found in the drug's labeling that has been approved by FDA. Off-label use of prescription drugs often occurs. According to FDA, if a drug manufacturer promotes a drug for off-label uses, such promotion may constitute evidence to support a violation of the Federal Food, Drug, and Cosmetic Act. FDA recognizes that in certain situations, a health care provider might use a lawfully marked drug in the course of medical practice for an indication or in a population not included in the approved labeling.

¹²For example, this guidance document recommends that CMI includes information on precautions and warnings, such as drugs or foods to avoid because of potential interactions. FDA, *Guidance: Useful Written Consumer Medication Information (CMI)* (Rockville, Md.: July 2006).

¹³Bonnie L. Svarstad and Jeanine K. Mount, *Evaluation of Written Prescription Information Provided in Community Pharmacies*, a final report prepared at the request of FDA (Madison, Wisc.: December 2001) and Carole L. Kimberlin and Almut G. Winterstein, *Expert and Consumer Evaluation of Consumer Medication Information*, a final report prepared at the request of FDA (Gainesville, Fla.: November 2008). See Pub. L. No. 104-180, § 601, 110 Stat. 1569, 1593 (1996).

found that the information given to patients varied greatly from pharmacy to pharmacy.¹⁴

In response to these concerns, FDA is currently considering how to help ensure that patients receive essential information about prescription drugs, including considering the development of a new form of patient information that the agency refers to as patient medication information (PMI). FDA's effort is intended to provide patients with prescription drug information in a single document based on the approved labeling for the product, and could incorporate relevant information currently communicated in two types of FDA-approved labeling—Medication Guides and PPIs—with information communicated in CMI, as appropriate.¹⁵

No Consensus Exists among Stakeholders on the Advantages and Disadvantages of Relying on Electronic Drug Labeling as a Complete Substitute for Paper Labeling

We found no consensus among stakeholders on the advantages and disadvantages of relying on electronic drug labeling as a complete substitute for paper labeling. While stakeholders described a variety of advantages of electronic drug labeling that could improve public health, they also noted disadvantages that could offset advantages gained.

¹⁴Specifically, one of these studies found that although the CMI for a particular drug was created by the same third party, the CMI provided to patients varied in length. One version of the CMI had 760 words, while the other included 2,457 words. According to this study, the CMI content is determined by a small number of private vendors who sell drug information to pharmacy outlets through their pharmacy software vendors. The formatting of the CMI is then determined by the pharmacies. The format can also be determined by the pharmacies and their software vendors. Kimberlin and Winterstein, *Expert and Consumer Evaluation of Consumer Medication Information*.

¹⁵According to FDA officials, it has held a series of public workshops soliciting input on the optimal content and format for PMI as well as its distribution. As of May 2013, FDA was analyzing data from a study on possible formats for presenting drug information, and officials said results from a study on the distribution of drug information were forthcoming. It is also unclear who will produce PMI (e.g., drug manufacturers or third parties) and whether FDA will review it.

Relying on Electronic Drug Labeling Could Provide the Most Current Drug Labeling in a User-Friendly Format, According to Stakeholders

Stakeholders we spoke with said that relying on electronic drug labeling as a complete substitute for paper labeling could help ensure that physicians, pharmacists, and patients have the most current labeling in a more user-friendly format, thereby improving public health. Revisions can often be made to drug labeling as more data about the drug become available from its wider use by patients, according to FDA officials. In calendar year 2010, FDA reported 747 changes to drug labeling; this number increased to 975 in calendar year 2011 and to 1,357 in calendar year 2012. Because it takes time to print new labeling and incorporate it into new drug packaging, some drugs that have already been shipped to their distribution points might be on the market with labeling that is out-of-date.¹⁶ Additionally, physicians said that the paper compilations can also take time to update. For example, physicians receive monthly supplements of changes to the PDR. Having the most current drug labeling available could improve public health by helping to inform physicians' decisions on which drugs to prescribe. It could also help pharmacists when counseling patients on prescription-drug use and could help patients better understand the drugs they are taking.

Relying on electronic drug labeling as a complete substitute for paper labeling could also positively impact public health by allowing prescription drug labeling to be presented in a more user-friendly format for physicians, pharmacists, and patients, according to stakeholders. For example, electronic versions of drug labeling have a search function, which facilitates physicians' and pharmacists' access to important safety information, such as potential warnings and drug interactions. Stakeholders representing pharmacists and pharmacies said an electronic format allows pharmacists to access certain sections when counseling patients. For example, an electronic version could allow pharmacists to provide patients with information from the most useful sections of the prescribing information, such as on possible side-effects, and not the less useful sections, such as the molecular structure of the drug. Stakeholders we spoke with said electronic drug labeling could also enhance patients' knowledge about the drugs they are using. For example, patients can enlarge the font size, making the labeling easier to read. Drug labeling could also be made interactive to include hyperlinks to

¹⁶According to stakeholders we spoke with, although the paper labeling might not be as current as an electronic version, it does not mean the drugs are unsafe, and most drug labeling changes are largely minor and do not require removing the drug from circulation in order to replace the labeling.

definitions of key terms or to additional information. Additionally, it might be easier to translate drug labeling into different languages.

However, some stakeholders suggested that the advantages of making the most current drug labeling available in a more user-friendly format could be achieved without eliminating paper labeling. Stakeholders representing drug labeling manufacturers said it takes little time to print revised drug labeling. For example, officials from one drug labeling manufacturer told us that they can provide revised labeling for distribution within 24 hours, depending on the revision. They also noted that there might be less out-of-date drug labeling in circulation than in the past, in part because there are likely fewer drugs kept in stock at any point in time as businesses operate in a more just-in-time economy. With fewer drugs in stock, it is possible that there are fewer drugs with out-of-date labeling in circulation, according to these officials. Stakeholders also noted that improving the content and format of paper labeling could make it more user-friendly. In 2006, FDA finalized its efforts to reformat prescribing information for physicians to make it more useful by, for example, requiring new drug labeling to include a highlights section and a table of contents.¹⁷ According to FDA, its PMI initiative is also intended to improve communication with patients about prescription drugs. Stakeholders we spoke with suggested that having drug labeling available in both paper and electronic form would best serve patients because it would allow them to take advantage of both options.

Stakeholders Noted That Relying on Electronic Labeling Could Limit the Availability of Drug Information for Some Physicians, Pharmacists, and Patients

Some stakeholders we spoke with noted disadvantages that could offset any advantages gained from relying on electronic drug labeling as a complete substitute for paper labeling. Specifically, relying on electronic 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, they might find inconvenient, or that might be unavailable. For example, stakeholders representing physicians and patients said that some patients, such as seniors, will simply not access drug labeling electronically because they are not comfortable doing so or because it is

¹⁷See 71 Fed. Reg. 3922 (Jan. 24, 2006).

not convenient for them.¹⁸ Similarly, stakeholders also noted that in certain situations, the availability of technology is limited. For example, patient advocates noted that some patients live in areas with limited Internet access, such as certain rural areas. According to recent data published by the Federal Communications Commission, approximately 14 million Americans have inadequate access or no access to adequate broadband capabilities. This broadband gap is greatest in areas with low population density.¹⁹ Additionally, some patients may not have access to a computer or a smart phone. There are also times when such technology is simply not available, due to temporary power outages or during the aftermath of natural disasters, such as Hurricanes Sandy and Katrina, according to one stakeholder group representing drug labeling manufacturers.²⁰ Another stakeholder group representing drug labeling manufacturers also noted that in some situations it might be faster to review a paper form of the drug labeling than accessing it electronically, such as when health care personnel are responding to an emergency.

In addition, for electronic labeling to be successful, stakeholders with whom we spoke 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, websites that currently provide electronic labeling have limitations. For example, although some stakeholders suggested using DailyMed for electronic

¹⁸However, stakeholders also told us that as health care practitioners and patients begin to utilize the Internet more often, exclusively electronic labeling could become more feasible to implement. The number of seniors that use the Internet has been increasing. For example, according to the Pew Research Center, 53 percent of Americans aged 65 and older now use the Internet or e-mail, as of April 2012. This percentage is up from 2008, when only 38 percent of this same age group reported Internet use. The study also reported that this is the first time that more than half of seniors 65 years and older reported using the Internet. Pew Research Center's Internet & American Life Project, *Older Adults and Internet Use* (Washington, D.C.: June 2012).

¹⁹According to the Federal Communications Commission adequate broadband capabilities include ensuring that every household and business in the United States has access to a basic set of applications, including sending and receiving e-mail and downloading information from websites. See Federal Communications Commission, *Connecting America: The National Broadband Plan* (Washington, D.C.: 2010).

²⁰However, according to one stakeholder official representing pharmacies, pharmacies often have contingency plans in place for how such services will be provided during events such as power disruptions and natural disasters. For example, some pharmacies may rely on back-up generators or refer patients to another nearby pharmacy.

labeling, others described it as not being user-friendly and noted that users must search through multiple versions of labeling for the same drug to determine which is the most current. However, in its comments on a draft of this report, HHS noted that the National Library of Medicine recently incorporated additional search capabilities to DailyMed, adding that DailyMed is designed for medical professionals and not for patients. Although FDA's website, Drugs@FDA, is organized to identify the most current version of the FDA-approved drug labeling, one stakeholder group said that this website is also not user-friendly. Nongovernment websites also have weaknesses, in part, because such websites are not standardized. For example, one website we reviewed listed a potential side effect not included on another website for a particular drug.

One stakeholder group representing physicians noted that if they had to rely exclusively on electronic drug labeling, physicians might require additional training on where and how to access prescribing information electronically. Studies have shown that some physicians might not access the most reliable resources on the Internet in order to find the information they need. For example, in one study of family physicians' favorite medical websites, researchers found that, in some cases, physicians based clinical decisions on websites that ranked lower than other sources in measures such as reliability and relevance.²¹ Another study found that the websites used by emergency room staff, residents, and medical students to obtain clinical information were not the highest quality in terms of evidence-based medicine.²² Similarly, studies have shown that patients might not access the most reliable websites, in part because of limited skills in conducting searches. For example, one study concluded that patients vary in their ability to conduct searches, affecting the type of drug information they retrieve.²³

²¹Julie G. Kosteniuk, Debra G. Morgan, and Carl K. D'Arcy, "Use and Perceptions of Information among Family Physicians: Sources Considered Accessible, Relevant, and Reliable," *Journal of the Medical Library Association*, vol. 101, no. 1 (2013).

²²Robin Chisholm and John T. Finnell, "Emergency Department Physician Internet Use during Clinical Encounters," *American Medical Informatics Association Annual Symposium Proceedings* (November 2012).

²³Geraldine Peterson, Parisa Aslani, and Kylie A. Williams, "How Do Consumers Search for and Appraise Information on Medicines on the Internet? A Qualitative Study Using Focus Groups," *Journal of Medical Internet Research*, vol. 5, no. 4 (2003).

Additionally, one stakeholder group said that the best method of ensuring that patients receive and understand drug labeling is to hand it directly to them, accompanied with oral counseling. Another stakeholder representing pharmacists said pharmacists are familiar with using paper labeling. Some pharmacists could find it easier, when counseling patients, to take the paper version of the labeling directly from the drug packaging and show it to the patient at the counter rather than searching for the labeling on a computer and then showing the patient the computer monitor or printing the labeling. If pharmacists' workflow is disrupted because they need to print drug labeling for patients, it could reduce the time available for patient consultations.²⁴ Interruptions to pharmacists' workflow have been shown to increase the risk for errors made when dispensing a drug.²⁵

²⁴Charles Ruchalski, "The Paperless Labeling Initiative: A Proof-of-Concept Study," *The Annals of Pharmacotherapy*, vol. 38 (2004).

²⁵Institute of Medicine, *Preventing Medication Errors*.

Relying on Electronic Drug Labeling as a Complete Substitute for Paper Labeling Would Require Amending or Reviewing Certain Regulations and Place Additional Responsibilities on Pharmacies, According to Officials and Stakeholders

FDA officials and other stakeholders told us that relying on electronic labeling as a complete substitute for paper labeling would require amending or reviewing certain federal regulations and would place additional responsibilities on pharmacies. According to FDA officials, eliminating the paper version of prescribing information and instead relying exclusively on an electronic version would not satisfy the current regulation. Specifically, FDA would need to amend the language that currently requires prescribing information to be “on or within” the drug packaging.²⁶ In addition, the regulations requiring the distribution of PPIs for oral contraceptives and estrogens require that the PPIs be provided “in or with” the drug packaging.²⁷ FDA officials stated that they have not yet considered whether the PPI regulations would need to be amended to permit drug manufacturers to provide this type of labeling in electronic form as a complete substitute for paper. However, FDA officials said that the regulations for Medication Guides currently allow for their electronic distribution and would not need to be amended.²⁸ Additionally, FDA officials also noted that any regulatory change would likely allow the complete substitution of paper labeling with electronic labeling but not require it.

In addition to concerns about FDA’s regulations, stakeholders representing pharmacists and patients have also raised concerns that e-mailing drug labeling to patients might implicate the Health Insurance Portability and Accountability Act Security Rule.²⁹ The Security Rule defines safeguards that certain entities must implement to provide assurance that health information is protected from inappropriate uses and disclosure.³⁰ However, one official representing pharmacists said that pharmacies could email certain information to patients without raising

²⁶21 C.F.R. § 200.100(c)(1).

²⁷21 C.F.R. §§ 310.501(b), 310.515(b).

²⁸FDA regulations require that manufacturers ensure that Medication Guides are available for distribution either by providing sufficient numbers of Medication Guides to distributors or pharmacies, or by providing the means to produce sufficient Medication Guides. 21 C.F.R. § 208.24(b).

²⁹Pub. L. No. 104-191, Title II, Subtitle F, 110 Stat. 1936, 2021 (codified at 42 U.S.C. §§ 1320d–1320d-8). The Health Insurance Portability and Accountability Act Privacy and Security Rules were promulgated at 45 C.F.R. Parts 160 and 164.

³⁰This report did not assess the application of the Health Insurance Portability and Accountability Act or the Act’s Security Rule to electronic drug labeling.

Security Rule concerns, such as e-mailing patients to say that they have new information in their health record.

Stakeholders also noted that additional responsibilities would be placed on pharmacies if paper labeling was completely substituted with electronic drug labeling. For example, stakeholders representing various pharmacists and pharmacies expressed concern that if patients want to continue receiving drug labeling in paper form, it would result in a shift in responsibilities from drug manufacturers to pharmacies. Drug manufacturers currently provide pharmacies with a supply of paper labeling for patients. Stakeholders said that completely substituting electronic labeling for paper labeling would place an additional burden on pharmacies if they were asked to print drug labeling for patients because pharmacies would need to purchase additional resources, such as computer terminals, printers, and other office supplies, such as paper, ink, and toner.³¹ Drug labeling can range in length, for example, from a few pages to as many as 45 pages, in some instances. According to the Kaiser Family Foundation, in 2011, approximately 3.8 billion prescription drugs were filled in retail pharmacies.³²

In addition, stakeholders representing pharmacies said that most pharmacies, in order to protect their systems from potential threats like computer viruses, do not have Internet access. Without Internet access, pharmacists might not be able to retrieve an electronic version of drug labeling, if needed for their reference or for a patient's reference. However, one stakeholder representing drug manufacturers pointed to enhanced security protections, such as firewalls, to protect systems against such external threats. This stakeholder also said that the Internet has become more widely available in recent years and that the issue of limited Internet access in pharmacies is probably less prominent than it once was.

³¹Stakeholders also noted that if PMI were implemented electronically, it would likely not place an additional burden on pharmacies and could potentially reduce the burden because pharmacies would print a single document.

³²SDI Health, L.L.C., special data request for Henry J. Kaiser Family Foundation, 2012, accessed May 16, 2013, <http://kff.org/other/state-indicator/total-retail-rx-drugs/>.

Agency Comments

We provided a draft of this report to HHS for comment. HHS provided technical comments on the draft report, which we incorporated as appropriate.

We are sending copies of this report to the Secretary of HHS, the Commissioner of the FDA, and other interested parties. In addition, this report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have questions about this report, please contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix III.



Marcia Crosse
Director, Health Care

Appendix I: List of Entities Interviewed

1. Food and Drug Administration (FDA)
2. National Library of Medicine
3. Agency for Healthcare Research and Quality
4. Biotechnology Industry Organization
5. Generic Pharmaceutical Association
6. Pharmaceutical Research and Manufacturers of America
7. Pharmaceutical Printed Literature Association
8. American Academy of Physician Assistants
9. American Congress of Obstetricians and Gynecologists
10. American Medical Association
11. American Pharmacists Association
12. American Society for Automation on Pharmacy
13. American Society of Health-System Pharmacists
14. National Association of Chain Drug Stores
15. National Community Pharmacists Association
16. Elsevier/Gold Standard
17. Wolters Kluwer
18. AARP
19. National Council on Patient Information and Education
20. Public Citizen

Appendix II: Timeline of Key Events Related to Patient Drug Information

For more than a decade, various efforts have been initiated to improve patient drug information. Table 2 shows a timeline of key events related to these efforts.

Table 2: Patient Drug Labeling: Timeline of Key Events

Date	Event
August 1995	Food and Drug Administration (FDA) Proposed Rule: FDA proposes performance standards that would define acceptable levels of information distribution and quality. The proposed rule establishes goals for the distribution of useful drug information and also requires Medication Guides for selected drug products. ^a
August 1996	Public Law 104-180: Directs the Secretary of Health and Human Services (HHS) to request that relevant stakeholders in the private sector develop a comprehensive plan with goals consistent with FDA's rule proposed in August 1995 on the distribution and quality of patient drug information. If these goals are not met by 2001, the Secretary of HHS shall seek public comment on other initiatives that may be carried out to meet such goals. ^b
December 1996	Private-sector stakeholders submit the Action Plan for the Provision of Useful Prescription Medicine Information. ^c
December 2001	University of Wisconsin – Madison publishes its FDA-commissioned study of written prescription information: <i>Evaluation of Written Prescription Information Provided in Community Pharmacies</i> . ^d
July 2002	FDA Drug Safety and Risk Management Advisory Committee reviews the results of the University of Wisconsin – Madison study. ^e
July 2003	FDA holds a public meeting on the status of useful written consumer medication information (CMI). ^f
July 2006	FDA issues Guidance for Useful Written CMI. ^g
November 2008	University of Florida publishes the results of its FDA-commissioned study: <i>Expert and Consumer Evaluation of Consumer Medication Information</i> . ^h
February 2009	FDA Risk Communication Advisory Committee recommends that FDA adopt a single document for communicating prescription drug information to patients. ⁱ
September 2009	FDA holds public workshop to explore potential approaches to providing effective written prescription drug information for patients. ^j
May 2010	FDA announces its experimental study of patient information prototypes in the Federal Register. ^k
July 2010	Brookings Institution convenes the first of three workshops on patient medication information (PMI): The Science of Communicating Medication Information to Consumers. ^l
September 2010	FDA holds public hearing on formats for PMI: Public Hearing on the Development and Distribution of PMI for Prescription Drugs. ^m
October 2010	Brookings Institution convenes second workshop on PMI: Ensuring Access to Effective PMI. ⁿ
February 2011	Brookings Institution convenes third workshop on PMI: Designing Pilot Programs to Distribute PMI. ^o

Source: GAO analysis of federal law, federal regulations, and FDA information on improving patient drug information.

^a60 Fed. Reg. 44182 (Aug. 24, 1995).

^bPub. L. No. 104-180, § 601, 110 Stat. 1569, 1593 (1996).

^cThe Steering Committee for the Collaborative Development of a Long-Range Action Plan for the Provision of Useful Prescription Medicine Information, *Action Plan for the Provision of Useful Prescription Medicine Information* (Keystone, Colo.: December 1996).

^dBonnie L. Svarstad and Jeanine K. Mount, *Evaluation of Written Prescription Information Provided in Community Pharmacies* (Madison, Wisc.: December 2001).

**Appendix II: Timeline of Key Events Related to
Patient Drug Information**

^eTranscript of FDA Drug Safety and Risk Management Advisory Committee Meeting on Consumer Medication Information, held in Gaithersburg, Maryland., July 2002.

^fTranscript of FDA Public Meeting on the Current Status of Useful Written Prescription Drug Information for Consumers, held in Washington, D.C., July 2003.

^gFDA, *Guidance: Useful Written Consumer Medication Information (CMI)* (Rockville, Md.: July 2006).

^hCarole L. Kimberlin and Almut G. Winterstein, *Expert and Consumer Evaluation of Consumer Medication Information* (Gainesville, Fla.: November 2008).

ⁱMinutes of FDA Risk Communication Advisory Committee Meeting held in Washington, D.C., February 2009.

^jTranscript of FDA Public Workshop on Providing Effective Information to Consumers about Prescription Drug Risks and Benefits held in Gaithersburg, Maryland, September 2009.

^k75 Fed. Reg. 23775 (May 4, 2010).

^lBrookings Institution Engelberg Center for Health Care Reform, *Patient Medication Information*, accessed on April 13, 2013, <http://www.brookings.edu/about/centers/health/projects/pmi>.

^mTranscript of FDA Public Hearing on Development and Distribution of Patient Medication Information for Prescription Drugs held in Silver Spring, Maryland, September 2010.

ⁿBrookings Institution Engelberg Center for Health Care Reform, *Patient Medication Information*, accessed on April 13, 2013, <http://www.brookings.edu/about/centers/health/projects/pmi>.

^oIbid.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7114 or crossem@gao.gov

Staff Acknowledgments

In addition to the named above, Thomas Conahan, Assistant Director; Cathleen Hamann; Gay Hee Lee; Janice Llanos-Velazquez; and Monica Perez-Nelson made key contributions to this report.

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