March 17, 2015
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Proposed Rule to Require the Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products [Docket No. FDA-2007-N-0363]

Dear Sir or Madam:

We write in opposition to the Food and Drug Administration’s (“FDA”) proposed rule requiring the electronic distribution of prescribing information intended for physicians, pharmacists and other healthcare professionals. Consumers for Paper Options (“CPO”) strongly opposes this proposal on the grounds that it does not demonstrate any need to replace the current, paper-based labeling system with one that is web-based—a shift that carries with it a number of serious, if unintended, potential consequences. The paper inserts that accompany pharmaceutical products, known as Professional Inserts (“PI”), play a critical role in ensuring the safety of the public as it relates to the consumption of prescription medicine. They contain important prescribing information for pharmacists, such as drug interactions and dosage guidelines. In their paper form, these labels are the most reliable method of delivering this vital information from the pharmaceutical manufacturers who make the drugs to the pharmacists who distribute them.

The FDA’s primary purported reason for proposing a switch to electronic labeling is to “ensure that the most current prescribing information for prescription drugs will be available and readily accessible to healthcare professionals at the time of clinical decision making and dispensing.”1 However, FDA fails to show the need for the rule or account for the unintended harms it could cause.

First, FDA has not established that the rule is necessary, as it has made no attempt to demonstrate that the current system is inadequate and needs to be replaced. Under Executive Orders 12866 and 13563, “agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people.” E.O. 12866, § 1(a). FDA’s proposal does not pass this fundamental test for regulating.

FDA’s Preliminary Regulatory Impact Analysis (PRIA) does not demonstrate any systemic failure due to market imperfections or ineffective prior regulations. The PRIA fails to assess the status quo. The FDA makes bald assertions but does not determine the extent of their claim about the potential for outdated

1 79 Fed. Reg. at 75506.
paper form prescribing information to increase health risks for patients. In short, this proposal is a solution in search of a problem.

Currently, health care professionals have access to both paper prescribing information (via traditional printed prescribing information that accompanies drug packages) and electronic prescribing information (via several existing websites). FDA suggests that the existing system increases health risks for patients because, it asserts, the available information may be outdated. But FDA has done nothing to investigate – let alone demonstrate – the extent to which use of prescribing information under the existing system actually poses a risk to health. In particular, FDA offers no qualitative or quantitative evidence that prescribing errors or adverse health outcomes have actually occurred due to out-of-date label information.

Second, the PRIA fails to consider the potential negative public health effects that might occur as a result of the rule, including:

- The risk of adverse health outcomes associated with workflow interruptions, general lack of Internet access, or Internet outages. When electronic labeling is unavailable or pharmacists cannot spare the time required to search for prescribing information on the Internet, a prohibition on paper labeling may leave pharmacists without a critical tool for counseling patients on the proper use of their medications. FDA has not examined the potential adverse health outcomes that may be associated with pharmacists’ forced reliance on outdated compendia or their own memories for prescribing information.

- The potential risk to patient health should electronic prescribing information in FDA’s proposed repository be altered as a result of a cybersecurity breach.

Evidence indicating people do not absorb information as well when they use electronic media as they do when they read print, which could in turn, lead to prescribing errors that potentially cause patients to experience adverse health events. A Government Accountability Office Report analyzing the impact of the exclusive use of electronic drug labeling noted that there are “times when such technology is simply not available due to power outages or during the aftermath of natural disasters, such as Hurricanes Sandy and Katrina.” Unsurprisingly, a survey of pharmacists conducted by NERA Economic Consulting found that 82 percent of respondents with Internet access indicated that they have at some point or another experienced a loss of Internet connectivity.

Also worrisome is the FDA’s presumption that nearly all pharmacies have easy and adequate access to the Internet, in light of the Federal Communications Commission (FCC) report this year that 55 million Americans still lack advanced Internet access such a broadband.

The survey upon which the Agency relies indicates that only four percent of pharmacists responded that they did not have Internet access. However, that number does not tell the whole story. In a separate survey, 27 percent of pharmacists indicated that their pharmacy “either does not have Internet access

---

2 GAO-13-592, at 11.
or that they cannot browse the Internet.”\(^5\) Moreover, the same survey upon which the FDA is basing its claim specifically acknowledges the concern of some pharmacists that e-labeling may not be readily accessible due to connectivity issues or because of corporate policies that prohibit Internet accessibility at the store level.

CPO is particularly concerned that pharmacists in rural or economically depressed communities may disproportionately experience issues related to Internet connectivity and accessibility. Compounding this concern is the fact that by the FDA’s own estimations, the transition to an exclusively web-based labeling system could cost pharmacies anywhere from $45 to $90 million in expenses that are currently covered by drug manufacturers. It is our fear that this rule proposal is likely to most negatively impact—and endanger the health of—members of rural and economically disadvantaged communities who can least afford to make the switch from paper to digital. To ensure the safety of all Americans when it comes to matters of prescription medicine, the continued inclusion of paper PI is essential.

In addition to issues of connectivity and accessibility, numerous studies have found that reading online versus reading on paper impairs the comprehension and absorption of information.\(^6\) The information contained in PIs is extremely important. The warnings and instructions for usage that these labels provide can be a matter of life and death for some patients, especially for seniors and those taking multiple prescription drugs.

It is the expressed mission of CPO to “preserve access to important paper-based information.”\(^7\) While we recognize the trend towards a more digital world, we urge the FDA to strongly consider the negative impact of this rule on the millions of Americans who rely on paper-based options. The risks to the health and safety of those who depend on paper labeling information should not come secondary to the few, if any, potential benefits of switching to an exclusively web-based labeling system. This rule proposal is a solution in search of a problem, and it may very well create more problems than it solves.

It is therefore on behalf of our members that we submit these comments and ask that the FDA reconsider and formally withdraw this proposed rule.

Thank you for your consideration.


\(^6\) http://www.scientificamerican.com/article/reading-paper-screens/

\(^7\) http://paperoptions.org/about-us