

May 13, 2015

Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Room 2217
Silver Spring, MD 20993

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

Re: Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products, 79 Fed. Reg. 75506, December 18, 2014 (FDA-2007-N-0363)

Commissioner Hamburg:

On December 18, 2014, the United States Food and Drug Administration (FDA) published a proposed rule titled: *Electronic Distribution of Prescribing Information for Human Prescription Drugs, Including Biological Products*.¹ The Office of Advocacy (Advocacy) urges the FDA to improve its small business impact analysis as required under the RFA and to entertain additional regulatory alternatives designed to lessen the economic impacts of this regulation on small entities.

I. Background

Advocacy was established pursuant to Pub. L. 94-305 to represent the views of small entities before federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA), so the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),² as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA),³ gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, federal agencies are required by the RFA to assess the impact of the proposed rule on small business and to consider less burdensome alternatives. The Small

¹ 79 Fed. Reg. 75506 (December 18, 2014).

² 5 U.S.C §601 et seq.

³ Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. § 601 et. seq.).

Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.⁴ The agency must include, in any explanation or discussion accompanying the final rule's publication in the Federal Register, the agency's response to these written comments submitted by Advocacy on the proposed rule, unless the agency certifies that the public interest is not served by doing so.⁵

II. Small businesses are concerned with the potential economic impacts of this rule.

The preamble of the rule provides that the FDA is authorized under various sections of the federal Food, Drug, and Cosmetic Act, to require that prescribing information be distributed electronically and to require that paper copies of the prescribing information no longer be distributed except as provided in this regulation.⁶ This rulemaking seeks to accomplish this goal by amending existing prescription labeling to require manufacturers to distribute the prescribing information electronically, instead of in paper form. Going forward, manufacturers would be required to submit the prescribing information to FDA for posting on FDA's publicly available labeling website. FDA submits that if finalized this rule will help ensure that the most current prescribing information will be more readily available to the public and health care professionals because it will be updated in real time.⁷ The preamble also suggests that the proposed rule would generate benefits in the form of production cost savings because of the elimination of the paper forms,⁸ and public health benefits from fewer prescribing errors made due to out-of-date information.⁹

Advocacy was approached by a number of small businesses and their representatives that are concerned about many requirements contained in this regulation. They believe that if the rule is finalized it will impose a significant economic impact on their businesses. These small businesses are represented by the American Forest and Paper Association (AFPA) and the Pharmaceutical Printed Literature Association (PPLA). Other affected industries that contacted Advocacy include businesses that provide material and machinery support to the insert printing companies. Advocacy was also approached by the National Community Pharmacists Association (NCPA) that represents approximately 23,000 independent community pharmacies, the majority of which are small businesses. The small pharmacies also believe that this rule will have a negative impact on their businesses, physicians, and their customers.

The print representatives told Advocacy that this regulation's goal of modernizing prescription labeling information through the use of an electronic system will not necessarily result in improved outcomes for small pharmacies and their customers. To the contrary, the proposed rule's expected benefits may be outweighed by its potential for

⁴ Small Business Jobs Act of 2010 (Pub. L. 111-240) § 1601.

⁵ *Id.*

⁶ 79 Fed. Reg. 75507.

⁷ 79 Fed. Reg. 75506.

⁸ 79 Fed. Reg. 75524.

⁹ See: *The FDA's economic analysis*, page 5, at:

<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm>

negative public health and economic outcomes. For example, public health may not be improved by the magnitude assumed in the rule's economic analysis as interested persons will now have to access the Internet to obtain drug and drug interaction information. For certain sectors of the population this could be significantly more costly than having it "on or within the package from which the drug is dispensed," as is currently required under existing FDA prescription drug labeling regulations. Advocacy appreciates that some of these increased transaction costs can be mediated. However, any potential cost-reducing solution for consumers pushes costs onto small pharmacies which will be expressed as additional transactional costs, including but not limited to, printing, computer, and paperwork burdens.

The industry believes that it is inappropriate to rely solely on an Internet-driven system as: 1) not all persons and health providers have Internet service; 2) Internet service is subject to service interruptions; 3) many pharmacists and consumers find value in paper options; and 4) concerns exist with respect to cybersecurity. Printing companies also claim that they have invested considerable revenue to acquire improved infrastructure and machines in an effort to comply with recently promulgated FDA regulations governing the format and content of printed prescribing information, only to have the FDA propose converting to a purely electronic system.¹⁰ Consequently, these small entities may experience a greater regulatory burden resulting from the requirements of this rule. In particular, the printing industry is concerned that the FDA has failed to rationalize the costs and benefits of its proposal by entertaining an alternative that employs a combination of electronic and traditional printed prescription information designed to provide the public with drug safety information under all circumstances. Lastly, these small business representatives believe that the rule's regulatory impact analysis fails to adequately analyze the aforementioned impacts of the requirements and reasonable alternatives on their industry.

The community pharmacists indicated to Advocacy that this rule essentially shifts the costs for providing prescription information from drug manufacturers to the pharmacies, and they are not in a position to absorb the increased costs. These costs include the acquisition of additional computer terminals, printers and other office supplies such as paper, ink and toner. The NCPA suggests that the FDA's assumption that pharmacists can readily access the Internet is misplaced. They believe that the rule will also have an effect on customer service as patients will be required to wait if a customer requests that the pharmacist provide them with printed prescription information. The NCPA supports the establishment of a dual-system that employs both electronic and paper prescription information regulation.

Industry stakeholders that approached Advocacy specifically referred to two reports in support of their position that this regulation will have a detrimental effect on their businesses and on the nation's public health. A Government Accountability Office

¹⁰ See: Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products and Guidance. 71 Fed. Reg. 3922 (January 24, 2006), and Guidance for Industry on Labeling for Human Prescription Drug and Biological Products – Implementing the Physician Labeling Rule Content and Format Requirements. 78 Fed. Reg. 12760 (February 25, 2013).

(GAO) report concluded that 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.¹¹ The same small industry representatives cite to a NERA Economic Consulting report which surveyed pharmacists' business practices related to prescription inserts.¹² The report concluded that pharmacists find value in printed inserts as they are fast and easy to access, the inserts are familiar and allow pharmacists to readily search for needed information with a minimal interruption to work flow and without errors. The survey also found that 27 percent of pharmacists indicated that their pharmacy either does not have internet access or they do not have the ability to "browse the internet" during work due to a corporate policy forbidding it.

III. Advocacy encourages the FDA to improve its impact analysis and consider reasonable alternatives.

Section 603 of the RFA generally requires regulatory agencies to prepare an Initial Regulatory Flexibility Analysis (IRFA) to accompany every proposed rule. In summary, the agency must identify the number of small entities likely to be impacted by the rule, provide a description of the expected economic impacts including the projected reporting or recordkeeping requirements of the rule, and provide a description of any significant alternatives to the proposed rule which minimizes any significant economic impacts on small businesses.¹³

Pursuant to Advocacy's mandate under the RFA, my office has reviewed this rule, including the Regulatory Impact Analysis, and the Regulatory Flexibility Analysis which includes the FDA's Initial Regulatory Flexibility Analysis (IRFA).¹⁴ Advocacy is pleased that the FDA concluded that this regulation will have a significant impact on a substantial number of small entities,¹⁵ and therefore the agency's completion of the IRFA is appropriate. The FDA's IRFA indicates that the rule will impact approximately 292,834 business establishments, the vast majority of which (aside from warehouse and supercenters) are deemed small based on SBA size standards.¹⁶ Advocacy encourages the FDA to improve the transparency of the rule's RFA analysis and to entertain reasonable alternatives in light of the issues brought to our attention by affected industries.

¹¹ United States Government Accountability Office Report to Congressional Committees; Electronic Drug Labeling No Consensus on the Advantages and Disadvantages of Its Exclusive Use; GAO-13-592 (July 2013).

¹² See: :

http://www.nera.com/content/dam/nera/publications/2015/Survey%20of%20Pharmacists%20Attitudes%20Towards%20E_labeling%20Final.pdf.

¹³ 5 USC §603.

¹⁴ See: <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm> (Ref.7), hereinafter referred to as RIA.

¹⁵ See: RIA, Table 21, at page 35.

¹⁶ *Id.*

While Advocacy appreciates the data provided by the FDA, the proposed regulation's preamble and regulatory impact analysis acknowledge that it is difficult to adequately assess costs and benefits. The FDA calculates a range of savings associated with the rule of between \$5 million and \$73.5 million using a 7 percent discount rate over 10 years.¹⁷ The FDA explains the large range as being due to uncertainty associated with such a large change in practices for such a large number of manufacturers and users.¹⁸ This uncertainty manifests itself in many ways in the regulation including changes in individual pharmacy practices and policies,¹⁹ the actual health benefits realized from fewer prescribing errors,²⁰ and the extent to which the disproportionate impact and significant magnitude of costs borne by the printing industry can be measured.

The proposed rule is clear in its assumption that pharmacies will incur net costs as health care users transition from printed to electronic prescription information. The FDA estimates that at a 7 percent discount rate over 10 years, the annualized costs to pharmacies will increase from \$47 million to \$89 million.²¹ These costs are due to increased capital costs to access the information, search time and printing materials. The FDA assumes that these are one-time costs. Small pharmacy representatives suggest that the FDA has not adequately analyzed the extent to which small pharmacies can absorb these costs, that contrary to FDA's assumption many of the costs will be ongoing, and that the rule will have a negative impact on public health because of a disruption to pharmacies business practices.

Section 603(c) of the RFA requires that any IRFA must "contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities." Advocacy appreciates and commends the FDA for recognizing the likely need for a delay in the implementation date following finalization of this rule, and for asking the public to comment on whether a dual system allowing for both paper and electronic prescription information is desirable until the compliance date is reached.²² Advocacy has been told by printing and small pharmacy representatives that such a dual system is indeed desirable and they would like input on the length of time for which such a system would be maintained.

IV. Conclusion

Advocacy commends the FDA for acknowledging those sections in the rule where the agency had difficulty calculating costs and benefits. Not surprisingly, many of those areas closely parallel affected industries' concerns about the agency's assumptions about the economic impacts associated with this regulation. Given the considerable uncertainty surrounding FDA's assumptions and estimates on the costs necessary for the affected

¹⁷ 79 Fed. Reg. at 75524.

¹⁸ *Id.*

¹⁹ See: RIA page 33.

²⁰ See: RIA page 5.

²¹ 79 Fed. Reg at 75507.

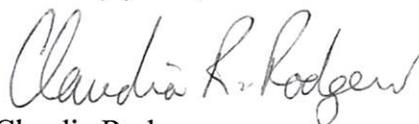
²² 79 Fed. Reg at 75525.

pharmacy and print industries to transition to an electronic prescription information system only, Advocacy encourages the FDA to give increased weight to the comments voiced by affected entities in the final rule. As part of its review of comments submitted by interested parties to this regulation, the FDA should improve its analysis on how the anticipated impacts of this rule will affect costs in the final rule. This is especially important given the FDA's responsibility to elucidate a compelling public need for this regulation under Executive Orders 12866 and 13563, as contrasted with the GAO's conclusion that relying on electronic labeling as a complete substitute for paper labeling could adversely impact public health. Hopefully this expanded analysis will result in removing some of the economic uncertainty referred to in the proposed rule.

Lastly, the FDA should entertain reasonable alternatives designed to reduce impacts on affected small entities, including analyzing the costs and benefits of using the dual-system alternative suggested by the small entities that approached Advocacy.

If you have any questions or concerns, please do not hesitate to contact me or Linwood Rayford at (202) 205-6533, or linwood.rayford@sba.gov.

Sincerely yours,



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Cc: Howard Shelanski, Administrator, Office of Information and Regulatory Affairs