ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

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July 16, 2014

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Ms. Hamburg:

The Committee on Oversight and Government Reform is conducting oversight of the Food and Drug Administration's proposed rule regarding "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products."[1] The FDA proposes to increase legal liability for generic drug manufacturers by establishing a process that gives the manufacturers limited discretion over the content of labels on the drugs that they produce.[2] We are concerned about inadequacies in the FDA rulemaking process, including the failure to include any costs associated with the resulting increase in litigation and the outsized influence of outside lobbying groups. As part of the Committee's oversight, we request that you provide information relating to the development of the proposed rule.

The proposed rule establishes a process by which drug manufacturers may change their generic drug labels prior to receiving approval for the change from FDA. Currently, labels on generic drugs must be exactly the same as the label on the corresponding brand drug.[3] Labeling for both brand and generic drugs is heavily regulated by FDA and most substantive changes to labels require prior FDA approval.[4] However, under limited circumstances, drug manufacturers may change the label on a brand drug prior to FDA approval of the change.[5] If the brand drug label change is approved, manufacturers of the generic drug are required to update their corresponding labels to match the FDA-

[1] Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67985 (proposed Nov. 13, 2013) (to be codified at 21 C.F.R. 314, 601) [hereinafter *NPRM*] *available at:* http://www.gpo.gov/fdsys/pkg/FR-2013-11-13/pdf/2013-26799.pdf.
[2] NPRM, *supra* note 1.
[3] NPRM, *supra* note 1; and *see* Allison Stoddart, *Missing After Mensing: A Remedy for Generic Drug Consumers*, 53 B.C.L. rev. 1967 (2012).
[4] *Id.*
[5] NPRM, *supra* note 1.

approved label. Because manufacturers of generic drugs are unable to change their labels without FDA approval, they do not face liability based on the content of their labels.[6]

Recently, the Supreme Court clarified legal liability for drug manufacturers in failure-to-warn lawsuits, which involve allegations of injuries resulting from inadequate or misleading drug labels. In 2009, the Court found that manufacturers of brand drugs may face liability for inadequacies in their label because they have the ability to change their label in limited circumstances without FDA approval.[7] However, in 2011, the Supreme Court found manufacturers of generic drugs are not liable for inadequacies in their labels, because they do not have discretion over their labels.[8] FDA developed the proposed rule to ensure manufacturers of generic drugs would face liability, and resulting litigation, by establishing a process for generic drug manufacturers to change their label without prior FDA approval.[9] It seems to us that the proposed rule is not designed to address a health or safety related concern; instead, it is designed to placate special interest groups and increase lawsuits.

FDA seemed content with the current method of regulating drug labeling for several decades, presumably finding it to be an effective and efficient method of ensuring health and safety.[10] Manufacturers' of generic drugs inability to unilaterally change the labels of their drugs does not affect their responsibility to play a role in ensuring health and safety. According to FDA, manufacturers of generic and brand drugs are both required to conduct vigilant surveillance of the effects of their drugs and to report any adverse information back to FDA, including suggested changes to the FDA approved label.[11]

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[6] *Pliva v. Mensing*, 131 S. Ct. 2,567 (2011).
[7] *Wyeth v. Levine*, 555 U.S. 555 (2009).
[8] *Pliva v. Mensing*, 131 S. Ct. 2,567 (2011).
[9] According to Dr. Janet Woodcock, Director of FDA Center for Drug Evaluation and Research, the rulemaking was prompted by "the court ruling that pointed out a disparity in the obligations between the generics and the innovator drugs" and "[a]fter the court decision, I sat down with the staff... and we went over options for dealing with this disparity between the two groups. And we went ahead and drafted this rule." *Examining Concerns Regarding FDA's Proposed Changes to Generic Drug Labeling Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 113th Cong. (Apr. 1, 2014) [hereinafter *Hearing*] *available at:* http://energycommerce.house.gov/hearing/examining-concerns-regarding-fdas-proposed-changes-generic-drug-labeling.
[10] NPRM, *supra* note 1 (discussing the history of labeling regulations and recent regulatory updates).
[11] NPRM, *supra* note 1 ("Accordingly, all [application] holders... are required to develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences... . Application holders must promptly review all adverse drug experience information.... Application holders also must comply with requirements for other postmarketing reports.... requirements include submission of an annual report (including a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product, and a description of actions the applicant has taken or intends to take as a result of this new information) and, if appropriate, proposed revisions to product labeling" and "All holders of marketing applications for drug products have an ongoing obligation to ensure their labeling is accurate and up-to-date.").

The FDA has failed explain how public health will improve, or how much improvement is expected, from increased liability.[12] The FDA admits that they "do not have economic data on the potential adverse health effects" of generic drug manufacturers not having discretion over the content of their generic drug labels.[13] The FDA only claims that it "may lead [generic manufacturers] to participate more actively" in identifying safety concerns.[14] Importantly, the FDA acknowledges the rule may not result in any actual improvements to communication because generic manufacturers already report health and safety concerns.[15]

The Committee is concerned with several dubious aspects of this rulemaking. First, the FDA provided the public with an inadequate Preliminary Economic Impact Analysis,[16] by disingenuously excluding the expected cost of litigation as a result of increased liability. This is especially important because the FDA readily admits the proposed rule will alter legal liability and claims that some costs are not quantified because there is "uncertainty about how the proposed rule will alter consumer and industry behavior."[17] However, a private sector analysis of the proposed rule showed that, by using liability insurance premiums as a conservative proxy for actual litigation costs, generic drug manufacturers could face billions of dollars in litigation costs.[18]

Second, the FDA readily admits that the only group it met with prior to issuance of the proposed rule was the American Association of Justice, formerly known as the Association of Trial Lawyers of America.[19] On February 15, 2013, this special interest

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[12] NPRM, *supra* note 1 ("The economic benefits to the public health from adoption of the proposed rule are not quantified.").

[13] FDA, Docket No. FDA-2013-N-0500, Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products Preliminary Regulatory Impact Analysis, 5 (2013) *available at*: http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-0500-0001.

[14] *Id.*

[15] *Id.*

[16] As mentioned above, the Preliminary Economic Impact Analysis fails to identify any benefits. It also fails to quantify the costs of more than one additional label change application despite calculating an average of 10.8 generic manufacturers per CBE-0 application. FDA asserted the costs to FDA would be only $6,500 to $13,000 to maintain the webpage created under the rule, but did not provide an explanation of that cost or an estimate to the costs to FDA regarding increased review of applications. *Id.*

[17] *Id.*

[18] Alex Brill, *FDA's Proposed Generic Drug Labeling Rule: An Economic Assessment*, (Feb. 5, 2014) *available at*: http://www.matrixglobaladvisors.com/GenericLabelingRule.pdf.

[19] Hearing, *supra* note 5 (Mr. Shimkus: All right. Before proposing the 2000 rule, the FDA held multiple focus groups and conducted a national survey of healthcare providers. Prior to issuing the proposed rule in November of 2013, did the FDA discuss these changes with physicians?
Dr. Woodcock: Yes. Well, the physicians were part of the focus groups. We had a public—
Mr. Shimkus: No, I am talking about this current rule that you are proposing.
Dr. Woodcock: Oh, this one. Oh, I am sorry. No.
Mr. Shimkus: Did the FDA meet with any pharmacists to hear their thoughts?
Dr. Woodcock: No, not to my knowledge.
Mr. Shimkus: Did you meet with any of the branded drug companies?
Dr. Woodcock: Not to my knowledge.
Mr. Shimkus: What about the generic drug companies?
Dr. Woodcock: Not to my knowledge. I did not.

group met with senior level FDA staff, including Daniel Sigelman, Senior Policy Advisor to the Commissioner and former trial lawyer. Under Executive Order 12866, "before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation."[20] Given the intent of the rule is to create an environment for increased litigation, the Committee finds it troubling that the FDA consulted only with trial lawyers, but no other major stakeholder likely to be affected.[21]

Finally, FDA has not provided the public with an analysis of regulatory alternatives considered and rejected to explain why the agency selected this method of regulation.[22] The agency elected to propose a rule which directly conflicts with the long-standing principle of sameness in generic drug labeling.[23] While FDA has asserted before Congress that multiple alternative regulatory schemes were under consideration, the notice of proposed rulemaking does not identify or analyze any alternative regulatory methods the FDA considered and rejected.[24]

To assist the Committee in its oversight, we request that FDA produce the following documents and information, in electronic format, for the time period January 1, 2010, to the present:

1. All documents and communications referring or relating to failure-to-warn liability for drug manufacturers.

2. All documents and communications referring or relating to FDA's February 15, 2013, meeting with the American Association for Justice.

3. All documents and communications to or from Daniel Sigelman and any other FDA staff that attended the February 15, 2013, meeting with the American Association for Justice referring or relating to the "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products" proposed rule.

4. All documents and communications referring or relating to the content of the Preliminary Economic Impact Analysis for the proposed rule.

Mr. Shimkus: Did the FDA meet with the trial lawyers?
Dr. Woodcock: My understanding is that this is the case. However--
Mr. Shimkus: So in 2000 you met with all these groups?
Dr. Woodcock: That is correct.)

[20] Exec. Order No. 12866, 58 Fed. Reg. 51735 (Oct. 4, 1993) and *see also* Exec. Order No. 13563, 76 Fed. Reg. 3821 (Jan. 21, 2011) (requiring agencies seek input from affected parties).

[21] Hearing, *supra* note 9.

[22] *See* NPRM, *supra* note 1.

[23] *See* Hearing, *supra* note 9, and NPRM, *supra* note 1.

[24] *See* Hearing, *supra* note 9, and NPRM, *supra* note 1.

5. All documents and communications referring or relating to *Pliva v. Mensing* or *Mutual Pharmaceutical Company v. Bartlett*.[25]

6. All documents and communications referring or relating to alternative methods of regulating generic drug labels considered by FDA during the course of the rulemaking.

In addition, the Committee requests that you designate officials within FDA to provide a briefing to the Committee staff on or before July 23, 2014.

The Committee on Oversight and Government Reform is the principal oversight committee of the House of Representatives and may at "any time" investigate "any matter" as set forth in House Rule X. An attachment to this letter provides additional information about responding to the Committee's request.

We request that you provide the requested documents and information as soon as possible, but no later than 5:00 p.m. on July 30, 2014. When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building. The Committee prefers, if possible, to receive all documents in electronic format.

Sincerely,

Darrell Issa
Chairman

Jim Jordan
Chairman, Subcommittee on
Economic Growth, Job Creation,
and Regulatory Affairs

Rob Woodall
Member of Congress

Enclosure

cc: The Honorable Elijah E. Cummings, Ranking Minority Member

The Honorable Matthew A. Cartwright, Ranking Minority Member
Subcommittee on Economic Growth, Job Creation and Regulatory Affairs

[25] *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2,466 (2013).

DARRELL E. ISSA, CALIFORNIA
CHAIRMAN

ELIJAH E. CUMMINGS, MARYLAND
RANKING MINORITY MEMBER

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Minority (202) 225–5051

Responding to Committee Document Requests

1. In complying with this request, you are required to produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. You should also produce documents that you have a legal right to obtain, that you have a right to copy or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party. Requested records, documents, data or information should not be destroyed, modified, removed, transferred or otherwise made inaccessible to the Committee.

2. In the event that any entity, organization or individual denoted in this request has been, or is also known by any other name than that herein denoted, the request shall be read also to include that alternative identification.

3. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, or thumb drive) in lieu of paper productions.

4. Documents produced in electronic format should also be organized, identified, and indexed electronically.

5. Electronic document productions should be prepared according to the following standards:

   (a) The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

   (b) Document numbers in the load file should match document Bates numbers and TIF file names.

   (c) If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

   (d) All electronic documents produced to the Committee should include the following fields of metadata specific to each document;

   BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT,CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM,

CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD, INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

6. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, box or folder is produced, each CD, hard drive, memory stick, thumb drive, box or folder should contain an index describing its contents.

7. Documents produced in response to this request shall be produced together with copies of file labels, dividers or identifying markers with which they were associated when the request was served.

8. When you produce documents, you should identify the paragraph in the Committee's schedule to which the documents respond.

9. It shall not be a basis for refusal to produce documents that any other person or entity also possesses non-identical or identical copies of the same documents.

10. If any of the requested information is only reasonably available in machine-readable form (such as on a computer server, hard drive, or computer backup tape), you should consult with the Committee staff to determine the appropriate format in which to produce the information.

11. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

12. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) the privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author and addressee; and (e) the relationship of the author and addressee to each other.

13. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (stating its date, author, subject and recipients) and explain the circumstances under which the document ceased to be in your possession, custody, or control.

14. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, you are required to produce all documents which would be responsive as if the date or other descriptive detail were correct.

15. Unless otherwise specified, the time period covered by this request is from January 1, 2009 to the present.

16. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data or information, not produced because it has not been

located or discovered by the return date, shall be produced immediately upon subsequent location or discovery.

17. All documents shall be Bates-stamped sequentially and produced sequentially.

18. Two sets of documents shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2471 of the Rayburn House Office Building.

19. Upon completion of the document production, you should submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control which reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Schedule Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, inter-office and intra-office communications, electronic mail (e-mail), contracts, cables, notations of any type of conversation, telephone call, meeting or other communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, email (desktop or mobile device), text message, instant message, MMS or SMS message, regular mail, telexes, releases, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information which might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neuter genders.

4. The terms “person” or “persons” mean natural persons, firms, partnerships, associations, corporations, subsidiaries, divisions, departments, joint ventures, proprietorships, syndicates, or other legal, business or government entities, and all subsidiaries, affiliates, divisions, departments, branches, or other units thereof.

5. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual's complete name and title; and (b) the individual's business address and phone number.

6. The term “referring or relating,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with or is pertinent to that subject in any manner whatsoever.

7. The term “employee” means agent, borrowed employee, casual employee, consultant, contractor, de facto employee, independent contractor, joint adventurer, loaned employee, part-time employee, permanent employee, provisional employee, subcontractor, or any other type of service provider.