

# **Comments at FDA Meeting to Discuss Proposed Rule that Would Allow Manufacturers of Generic Medications to Autonomously Update Their Product Label**

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## **Summary:**

On March 27, 2015, the FDA held a public meeting to discuss a proposed rule first published in the November 13, 2013 Federal Register that would allow manufacturers of generic medications to autonomously update their product label (aka Prescribing Information or “PI”) while subsequently submitting the changes for FDA approval. If the FDA approves the labeling changes, all other manufactures of the equivalent drugs (including the brand drug if still in production) would be required to update their labels within 30 days. This stands in contrast to the current conditions in which generic manufactures have **no timely mechanism** to institute a label change and are **not allowed** to update their drug PIs without FDA approval. There is also no time limit currently in existence, so if a brand drug manufacturer updates its PI, there can be a significant time lag (on the order of years) until the generic manufacturers are told to update their labeling.

The aim of this rule is two-fold: improve patient safety by creating a mechanism for timely updates to drug labels and it would allow the generic manufacturers to be liable for damages caused by their product if they fail to provide adequate warning on the labeling. Currently, patients who are injured by generic drugs have no legal recourse, a status upheld as result of two landmark Supreme Court cases.

The aim of the public meeting was to “provide a public forum for FDA to listen to comments” from stakeholders regarding the proposed rule and any alternatives. The comment period is currently open and will extend until April 27, 2015.

## **Numbers of Interest:**

A total of 40 speakers offered remarks during the meeting: 38 scheduled speakers, 2 unscheduled.

15 out of 40 speakers opposed the rule (or supported the industry crafted alternative rule). 11 of those speakers represented the pharmaceutical industry (either a specific company or a trade group), 3 represented organizations that advocated for the interests of minorities, and 1 speaker was an economist that had been hired by GPhA to conduct an analysis of the cost burden on the industry if the rule was to be implemented.

25 out of 40 speakers supported the rule or made comments that supported the rationale for the rule. 10 of those speakers (including me) represented patient advocacy organizations, 8 were patients who offered personal testimony of how they had been harmed by generic drugs, 4 were attorneys who spoke on behalf of patients who had been harmed but were unable to travel due to illness, 2 were speakers from academia whose comments supported arguments in favor of the rule, 1 was Maryland State Senator Catherine Pugh, and 1 was an economist who refuted the predictions of the industry-commissioned cost burden analysis.

### **Those Opposed to the Rule:**

The main arguments against the rule came from the pharmaceutical industry—the emerging themes were that the rule would (1) create a significant cost-burden for the industry, (2) be impracticable due to the difficulty of accessing safety data, (3) exceed the FDA’s legal authority, (4) create confusion for patients and providers.

This last theme was emphasized by the speaker from GPhA who offered the results of a telephone survey as evidence of likely physician confusion (link to the study here:

[http://www.gphaonline.org/media/cms/GPhA\\_Report\\_v2\\_4\\_FINA\\_L\\_2\\_.pdf](http://www.gphaonline.org/media/cms/GPhA_Report_v2_4_FINA_L_2_.pdf)).

The main concern from those speakers representing the interests of minority groups focused almost exclusively on the confusion the rule might cause amongst patients and providers, and also indicated that the increased costs of prescriptions (predicted by the industry-

sponsored analysis) would be prohibitive for underserved populations or patients of low socio-economic status.

The argument that the rule could cause confusion is based on the prediction that multiple labels could exist for the same drug in the market at the same time. For example generic manufacturer A updates their label for a statin, while generic manufacturer B still uses the old label for the same statin.

### **The Response from Those Supporting the Rule:**

Several speakers addressed the issue of patient/clinician confusion by reminding the room that under the **current rules**, a brand manufacturer may change their label while a generic making the same drug must wait for *an indefinite period* for the FDA to instruct them to update the labels for their generic product. They pointed out that the proposed new rule would address this issue directly by limiting that delay in labeling parity via the 30 day time limit.

Other speakers pointed out that ALL safety data for a given drug that is known to the FDA is available for free (as it is published online by the FDA) and therefore all companies have adequate access to drug safety data. One speaker in particular, an attorney for patients injured by generic medicines, brandished his laptop during his remarks and noted, “Here is my \$700 pharmacovigilance department...if you can use Google, you can monitor drug safety.”

A few of the speakers with legal background noted that the proposed rule was well within the FDA’s legal authority as described in the FD&C Act and the PHS act.

The economist who refuted the industry-sponsored analysis succinctly described the flawed assumptions that had been employed in their model, and pointed out that even if the industry cost-burden model *were* correct, the maximum *cost per prescription* that could be passed on to consumers was \$1.15, an arguably negligible sum.

The personal testimony of the patients who had been injured by generic drugs that did not contain adequate safety warnings on their label included emotional descriptions of ruptured tendons due to

quinolones, amputations due to intra-arterial promethazine, life-altering birth defects due to fluoxetine and citalopram, and sudden cardiac death due to Darvon. These individual stakeholders provided intimate details of how their lives were permanently altered by preventable injury, and while their comments may not be available on the web docket due to privacy reasons, they may be available whenever the FDA posts its webcast for re-watching.

### **FDA Panel Reaction:**

Without exception, the FDA Panel seemed to ask questions of those opposing the rule that would force concessions from those speakers regarding the fallacies of their arguments. For example, they asked the GPhA speaker to comment on the methodology of the telephone survey he had referenced to argue that the new rule would cause confusion; the speaker did not know that the same survey showed that 79% of the respondents were unaware of the proposed rule (and ostensibly, unable to offer a meaningful opinion, thus refuting the ‘study’).

Similarly, it seemed that the FDA Panel asked questions of those speaking in favor of the proposed rule in order to refute claims made by those who opposed the rule. After my testimony, for example, Dr. Egan on the FDA panel asked me how I stay abreast of changes regarding medicines. I answered that I stay current through my constant engagement with professional organizations, reading scientific journals, speaking with colleagues in the clinic, and considering my professional obligation as a healthcare provider to maintain an interest in the safety of the medicines I prescribe. I further commented that I did not understand the argument that physicians would be confused by different drug labels because if I *was* to see a discrepancy in labeling, it would motivate me to investigate any safety issues and exercise greater caution while caring for the patient.

In summary, the FDA Panel was favorable towards those supporting the proposed rule, and seemed to challenge the arguments of those who opposed it.

## **My Testimony and Lessons Learned:**

The week before the public meeting, I had the opportunity to conference with Paul Brown from the National Center for Health Research and Sarah Rooney, JD from the American Association for Justice. This was a critical opportunity for me to understand the FDA's proposed rule from a legal perspective, and appreciate how it would enhance patient safety and industry accountability.

I attended a Hill Briefing the evening prior to the public meeting, and I got to meet Dr. Carome from Public Citizen and others who would speak the next day.

Between those two experiences and my own research, I was able to become fluent on an issue of which I had little knowledge prior to my involvement. It became clear that the best strategy for my remarks would be to represent the practicing physician's perspective on how the proposed rule would improve safety in the clinic.

As I noted last time I testified before FDA, the intimidating aspects of speaking before a partially hostile audience was mitigated by the fellowship with like-minded allies. I sat next to Dr. Anna Mazzucco from NCHR during the meeting; it was helpful to have a 'support system' during 8 hours of intense dialogue.

I also have benefitted greatly from the mentorship of Lisa, John, and Rosemary who have helped me with my writing and provided a deeper understanding of FDA and its functions. I am grateful to the NPA-FDA Task Force for providing such a supportive and educational environment to help me develop my advocacy skills.

Looking ahead to future advocacy opportunities, I realize that I can improve my testimony and oration by further studying the arguments of the opposition. In other words, if I was to do this again, I would have spent more time reading the comments posted on the FDA web site by the opposition and attempted to address head-on the claim that the rule would cause "physician confusion".